# 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 June 30, 2020

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 Stock | 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 August 5, 2020 was 149,981,347.

## PART I - FINANCIAL INFORMATION

This 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 and timing to advance our product candidates into, and to successfully initiate, conduct, enroll and complete, clinical trials;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- the potential of our cell therapy platform, and our plans to apply our platform to research, develop and commercialize our product candidates;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the potential scope and value of our intellectual property rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- the 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 and Part I, Item 1A, "Risk Factors" in our most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "Commission") on March 12, 2020.

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 and Part I, Item 1A, "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Commission on March 12, 2020. 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.

On August 9, 2019, BioTime, Inc. changed its corporate name to Lineage Cell Therapeutics, Inc. Unless the context requires otherwise, references in this Report to "Lineage," "we," "us," and "our" refer to Lineage Cell Therapeutics, Inc. and its consolidated subsidiaries.

**Recent Transactions Affecting Our Corporate Organization**

*Asterias Merger*

On March 8, 2019, we acquired the outstanding shares of common stock of Asterias Biotherapeutics, Inc. ("Asterias") held by stockholders other than Lineage via merger (the "Asterias Merger"). In the Asterias Merger, the outstanding shares of Asterias common stock held by stockholders other than Lineage were converted into our common shares at an exchange ratio of 0.71 Lineage shares for each Asterias share.

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

**Item 1. Financial Statements**

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

| | June 30, 2020 (Unaudited) | December 31, 2019 (Notes 2 and 3) |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $ 12,676 | $ 9,497 |
| Marketable equity securities | 7,575 | 21,219 |
| Promissory note from Juvenescence (Note 5) | 24,372 | 23,616 |
| Trade accounts and grants receivable, net | 193 | 317 |
| Receivables from affiliates, net | 7 | 7 |
| Prepaid expenses and other current assets | 1,377 | 2,863 |
| Total current assets | 46,200 | 57,519 |
| | | |
| NONCURRENT ASSETS | | |
| Property and equipment, net (Notes 6 & 15) | 7,142 | 8,175 |
| Deposits and other long-term assets | 649 | 864 |
| Goodwill | 10,672 | 10,672 |
| Intangible assets, net | 47,417 | 48,248 |
| TOTAL ASSETS | $ 112,080 | $ 125,478 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued liabilities | $ 5,948 | $ 5,226 |
| Financing lease and right of use lease liabilities, current portion (Note 15) | 1,241 | 1,223 |
| Deferred revenues, current portion | 297 | 45 |
| Liability classified warrants, current portion | 33 | - |
| Total current liabilities | 7,519 | 6,494 |
| | | |
| LONG-TERM LIABILITIES | | |
| Deferred tax liability | 3,315 | 3,315 |
| Deferred revenues | - | 200 |
| Right-of-use lease liability, net of current portion (Note 15) | 3,276 | 3,868 |
| Financing lease, net of current portion | 62 | 77 |
| Liability classified warrants, net of current portion | 215 | 277 |
| TOTAL LIABILITIES | 14,387 | 14,231 |
| | | |
| Commitments and contingencies (Note 15) | | |
| | | |
| SHAREHOLDERS' EQUITY | | |
| Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of June 30, 2020 and December 31, 2019 | - | - |
| Common shares, no par value, 250,000 shares authorized; 149,831 shares issued and outstanding as of June 30, 2020 and 149,804 shares issued and outstanding as of December 31, 2019 | 388,271 | 387,062 |
| Accumulated other comprehensive loss | (486) | (681) |
| Accumulated deficit | (288,343) | (273,422) |
| Lineage Cell Therapeutics, Inc. shareholders' equity | 99,442 | 112,959 |
| Noncontrolling deficit | (1,749) | (1,712) |
| Total shareholders' equity | 97,693 | 111,247 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | $ 112,080 | $ 125,478 |

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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| **REVENUES:** | | | | |
| Grant revenue | $ 287 | $ 529 | $ 635 | $ 1,278 |
| Royalties from product sales and license fees | 99 | 140 | 265 | 226 |
| Sale of research products and services | - | 110 | - | 203 |
| Total revenues | 386 | 779 | 900 | 1,707 |
| Cost of sales | (75) | (107) | (169) | (175) |
| Gross profit | 311 | 672 | 731 | 1,532 |
| **OPERATING EXPENSES:** | | | | |
| Research and development | 2,805 | 5,235 | 6,144 | 10,196 |
| General and administrative | 3,908 | 6,258 | 8,427 | 14,918 |
| Total operating expenses | 6,713 | 11,493 | 14,571 | 25,114 |
| Loss from operations | (6,402) | (10,821) | (13,840) | (23,582) |
| **OTHER INCOME/(EXPENSES):** | | | | |
| Interest income, net | 380 | 437 | 785 | 879 |
| Gain on sale of marketable securities | 2,470 | - | 3,728 | - |
| Unrealized (loss) gain on marketable equity securities | (4,146) | (607) | (5,484) | 1,324 |
| (Loss) gain on equity method investment in OncoCyte Corporation (“OncoCyte”) at fair value | - | (21,425) | - | 16,288 |
| Gain on equity method investment in Asterias at fair value | - | - | - | 6,744 |
| Unrealized (loss) gain on warrant liability | (6) | 234 | 29 | 271 |
| Other income (expense), net | 1,174 | 882 | (176) | 1,688 |
| Total other (expense) income, net | (128) | (20,479) | (1,118) | 27,194 |
| **(LOSS)/INCOME BEFORE INCOME TAXES** | (6,530) | (31,300) | (14,958) | 3,612 |
| Deferred income tax benefit | - | 1,248 | - | 5,632 |
| **NET (LOSS)/INCOME** | (6,530) | (30,052) | (14,958) | 9,244 |
| Net loss attributable to noncontrolling interest | 8 | 20 | 37 | 34 |
| **NET (LOSS)/INCOME ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.** | $ (6,522) | $ (30,032) | $ (14,921) | $ 9,278 |
| NET (LOSS)/INCOME PER COMMON SHARE: | | | | |
| BASIC | $ (0.04) | $ (0.20) | $ (0.10) | $ 0.07 |
| DILUTED | $ (0.04) | $ (0.20) | $ (0.10) | $ 0.07 |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: | | | | |
| BASIC | 149,821 | 149,582 | 149,814 | 141,270 |
| DILUTED | 149,821 | 149,582 | 149,814 | 141,270 |

See accompanying notes to the condensed consolidated interim financial statements.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| **NET (LOSS)/INCOME** | $ (6,530) | $ (30,052) | $ (14,958) | $ 9,244 |
| Other comprehensive income (loss), net of tax: | | | | |
| Foreign currency translation adjustment, net of tax | (1,120) | (487) | 195 | (1,219) |
| **COMPREHENSIVE (LOSS)/INCOME** | (7,650) | (30,539) | (14,763) | 8,025 |
| Less: Comprehensive loss attributable to noncontrolling interest | 8 | 20 | 37 | 34 |
| **COMPREHENSIVE (LOSS)/INCOME ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC. COMMON SHAREHOLDERS** | $ (7,642) | $ (30,519) | $ (14,726) | $ 8,059 |

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)**

| | Six Months Ended June 30, | |
|---|---|---|
| | **2020** | **2019** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net (loss) income attributable to Lineage Cell Therapeutics, Inc. | $ (14,921) | $ 9,278 |
| Net loss allocable to noncontrolling interest | (37) | (34) |
| Adjustments to reconcile net (loss) income attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities: | | |
| Unrealized gain on equity method investment in OncoCyte at fair value | - | (16,288) |
| Unrealized gain on equity method investment in Asterias at fair value | - | (6,744) |
| Gain on sale of marketable securities | (3,728) | - |
| Unrealized loss (gain) on marketable equity securities | 5,484 | (1,324) |
| Deferred income tax benefit | - | (5,632) |
| Depreciation expense, including amortization of leasehold improvements | 423 | 513 |
| Amortization of right-of-use asset | 18 | 27 |
| Amortization of intangible assets | 831 | 992 |
| Stock-based compensation | 1,232 | 2,202 |
| Change in unrealized gain on warrant liability | (29) | (271) |
| Write-off of security deposit | 150 | - |
| Foreign currency remeasurement and other (gain) loss | 236 | (1,461) |
| Changes in operating assets and liabilities: | | |
| Accounts and grants receivable, net | 125 | (863) |
| Accrued interest receivable | (756) | (756) |
| Receivables from OncoCyte and AgeX, net of payables | - | 2,185 |
| Prepaid expenses and other current assets | 1,442 | (1) |
| Accounts payable and accrued liabilities | 214 | (804) |
| Deferred revenue and other liabilities | 51 | - |
| Net cash used in operating activities | (9,265) | (18,981) |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Proceeds from the sale of OncoCyte common shares | 10,941 | - |
| Proceeds from the sale of AgeX common shares | 985 | - |
| Cash and cash equivalents acquired in the Asterias Merger | - | 3,117 |
| Purchase of equipment and other assets | (16) | (364) |
| Security deposit paid and other | 48 | (1) |
| Net cash provided by investing activities | 11,958 | 2,752 |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Common shares received and retired for employee taxes paid | (13) | (77) |
| Reimbursement from landlord on tenant improvements | - | 744 |
| Repayment of financing lease liabilities | (17) | (14) |
| Proceeds from Paycheck Protection Program (“PPP”) Loan (Note 8) | 523 | - |
| Proceeds from sale of subsidiary warrants | - | (40) |
| Repayment of principal portion of promissory notes | - | (70) |
| Net cash provided by financing activities | 493 | 543 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (38) | 83 |
| **NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH** | 3,148 | (15,603) |
| **CASH, CASH EQUIVALENTS AND RESTRICTED CASH:** | | |
| At beginning of the period | 10,096 | 24,399 |
| At end of the period | $ 13,244 | $ 8,796 |

See accompanying notes to the condensed consolidated interim financial statements.

## 1. Organization and Business Overview

Lineage is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage's focus is to develop therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. Lineage's programs are based on its proprietary cell-based therapy platform and associated development and manufacturing capabilities. From this platform Lineage develops and manufactures specialized, terminally-differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or administered as a means of helping the body mount an effective immune response to cancer.

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

- *OpRegen*®, a retinal pigment epithelium cell replacement therapy currently in a Phase 1/2a multicenter clinical trial for the treatment of advanced dry age-related macular degeneration ("AMD") with geographic atrophy. There currently are no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry AMD, which accounts for approximately 85-90% of all AMD cases and is the leading cause of blindness in people over the age of 60.

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

- *VAC2*, a cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase 1 clinical trial in non-small cell lung cancer. This clinical trial is being funded and conducted by Cancer Research UK, the world's largest independent cancer research charity.

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

*Asterias Merger*

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

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

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

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

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

*Investment in OncoCyte*

Lineage has significant equity holdings in OncoCyte Corporation ("OncoCyte"), a publicly traded company (NYSE American: OCX), which Lineage founded and, in the past, was a majority-owned consolidated subsidiary until February 17, 2017, when Lineage deconsolidated OncoCyte's financial statements. OncoCyte is developing confirmatory diagnostic tests for lung cancer utilizing novel liquid biopsy technology. As of June 30, 2020, Lineage owned approximately 3.6 million shares of OncoCyte common stock, or 5.4% of its outstanding shares (see Note 4).

**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 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, 2019 was derived from the audited consolidated financial statements at that date, but does not include all the information and footnotes required by GAAP. 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, 2019.

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 the entire year.

*Principles of consolidation*

Lineage's condensed consolidated interim financial statements include the accounts of its subsidiaries. The following table reflects Lineage's ownership, directly or through one or more subsidiaries, of the outstanding shares of its operating subsidiaries as of June 30, 2020.

| 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") | Products to treat age-related macular degeneration | 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 | Developing bone grafting products for orthopedic diseases and injuries | 99.8% | USA |

(1) Includes shares owned by Lineage and ESI.

All material intercompany accounts and transactions have been eliminated in consolidation. As of June 30, 2020, Lineage consolidated its direct and indirect wholly owned or majority-owned subsidiaries because Lineage has the ability to control their operating and financial decisions and policies through its ownership, and the noncontrolling interest is reflected as a separate element of shareholders' equity on Lineage's consolidated balance sheets.

*Liquidity*

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

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 of common shares from time to time in at-the-market transactions under the Sales Agreement. As of June 30, 2020, no sales had been made under the Sales Agreement.

At June 30, 2020, Lineage had an accumulated deficit of approximately $288.3 million, working capital of $38.7 million and shareholders' equity of $97.7 million. Lineage has evaluated its projected cash flows and believes that its $20.3 million of cash, cash equivalents and marketable equity securities and its access to additional capital through the Sales Agreement at June 30, 2020, are sufficient to fund Lineage's planned operations for at least the next twelve months from the issuance date of the condensed consolidated financial statements included herein. If Lineage needs near term working capital or liquidity to supplement its cash and cash equivalents for its operations, Lineage may sell some, or all, of its marketable equity securities, as necessary.

If the promissory note issued by Juvenescence in favor of Lineage discussed in Note 5 is converted into equity securities of Juvenescence prior to its maturity date, the Juvenescence equity securities may be marketable securities that Lineage may use to supplement its liquidity, as needed. If such promissory note is not converted, it is payable in cash, plus accrued interest, at maturity on August 30, 2020. The value of the promissory note is $24.4 million as of June 30, 2020.

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

Lineage's projected cash flows are subject to various risks and uncertainties, and the unavailability or inadequacy of financing to meet future capital needs could force Lineage to modify, curtail, delay, or suspend some or all aspects of its planned operations. Lineage's determination as to when it will seek new financing and the amount of financing that it will need will be based on Lineage's evaluation of the progress it makes in its research and development programs, any changes to the scope and focus of those programs, any changes in grant funding for certain of those programs, and projection of future costs, revenues, and rates of expenditure. Lineage'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. In addition, Lineage has incurred and expects to continue incurring significant costs in connection with the acquisition of Asterias and with integrating its operations. Lineage may incur additional costs to maintain employee morale and to retain key employees. Lineage cannot assure that adequate financing will be available on favorable terms, if at all. Sales of additional equity securities by Lineage or its subsidiaries and affiliates could result in the dilution of the interests of current shareholders.

*Business Combinations*

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

*Marketable Equity Securities*

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

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

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

*Revenue Recognition*

During the first quarter of 2018, Lineage adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) *ASU 2014-09, Revenues from Contracts with Customers (Topic 606)*, which created a single, principle-based revenue recognition model that supersedes and replaces nearly all existing U.S. GAAP revenue recognition guidance. Lineage adopted ASU 2014-09 using the modified retrospective transition method applied to those contracts which were not completed as of the adoption date. Results for reporting periods beginning on January 1, 2018 and thereafter are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with Lineage’s historical revenue recognition accounting under Topic 605.

Lineage recognizes revenue 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.

Lineage’s largest source of revenue is currently related to government grants. 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 good or services to the government entities funding the grant. Lineage has, and will continue to, account for grants received to perform research and development services in accordance with ASC 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development services for others. If Lineage or a subsidiary receiving the grant is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then Lineage is required to estimate and recognize that liability. Alternatively, if Lineage or a subsidiary receiving the grant is not required to repay, or if it is required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development services for others, in which case, grant revenue is recognized when the related research and development expenses are incurred (see Note 15).

Deferred grant revenues represent grant funds received from the governmental funding agencies for which the allowable expenses have not yet been incurred as of the balance sheet date reported. As of June 30, 2020, deferred grant revenue was $97,000.

*Basic and diluted net income (loss) per share attributable to common shareholders*

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

For the three and six months ended June 30, 2020 and for the three months ended June 30, 2019, Lineage reported a net loss attributable to common shareholders, and therefore, all potentially dilutive common shares were considered antidilutive for that period. For the six months ended June 30, 2019, Lineage reported net income attributable to common shareholders, and therefore, performed an analysis of common share equivalents to determine their impact on diluted net income, and determined that none of the common share equivalents were dilutive.

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

| | Three Months Ended June 30, (unaudited) | | Six Months Ended June 30, (unaudited) | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Stock options | 17,692 | 15,374 | 16,054 | 15,103 |
| Lineage Warrants (1) (Note 3) | 1,090 | 1,296 | 1,090 | 917 |
| Restricted stock units | 139 | 271 | 150 | 275 |

(1)Although the Lineage Warrants are classified as liabilities, these warrants are considered for dilutive earnings per share calculations in accordance with ASC 260, *Earnings Per Share*, and determined to be anti-dilutive 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):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (unaudited) | |
| Cash and cash equivalents | $ 12,676 | $ 9,497 |
| Restricted cash included in deposits and other long-term assets (see Note 15) | 568 | 599 |
| Total cash, cash equivalents, and restricted cash as shown in the condensed consolidated statements of cash flows | $ 13,244 | $ 10,096 |

*Lease accounting and impact of adoption of the new lease standard*

On January 1, 2019, Lineage adopted ASU 2016-02, *Leases* (Topic 842, "ASC 842") and its subsequent amendments affecting Lineage: (i) ASU 2018-10, *Codification Improvements to Topic 842, Leases*; and (ii) ASU 2018-11, *Leases (Topic 842): Targeted improvements*, using the modified retrospective method.

Lineage management determines if an arrangement is a lease at inception. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. When determining whether a lease is a finance lease or an operating lease, ASC 842 does not specifically define criteria to determine "major part of remaining economic life of the underlying asset" and "substantially all of the fair value of the underlying asset." For lease classification determination, Lineage continues to use (i) greater to or equal to 75% to determine whether the lease term is a major part of the remaining economic life of the underlying asset and (ii) greater to or equal to 90% to determine whether the present value of the sum of lease payments is substantially all of the fair value of the underlying asset. Under the available practical expedients, Lineage accounts for the lease and non-lease components as a single lease component. Lineage recognizes right-of-use ("ROU") assets and lease liabilities for leases with terms greater than twelve months in the condensed consolidated balance sheet.

ROU assets represent Lineage's right to use an underlying asset during the lease term and lease liabilities represent Lineage's 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 Lineage's leases do not provide an implicit rate, Lineage uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lineage uses the implicit rate when readily determinable. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Lineage's lease terms may include options to extend or terminate the lease when it is reasonably certain that Lineage will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Operating leases are included as right-of-use assets in property and equipment (see Note 6), 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 Lineage's condensed consolidated balance sheets.

In connection with the adoption on ASC 842 on January 1, 2019, Lineage derecognized net book value of leasehold improvements and corresponding lease liabilities of $1.9 million and $2.0 million, respectively, which was the carrying value of certain operating leases as of December 31, 2018, included in property and equipment and lease liabilities, respectively, recorded pursuant to build to suit lease accounting under the previous ASC 840 lease standard. The derecognition of these amounts from the superseded ASC 840 lease standard was offset by a cumulative effect adjustment of $0.1 million as a reduction of Lineage's accumulated deficit on January 1, 2019. These build to suit leases were primarily related to the Alameda and the Cell Cure Leases described in Note 15. ASC 842 requires build to suit leases recognized on Lineage's consolidated balance sheets as of December 31, 2018 to be derecognized upon the adoption of the new lease standard and be recognized in accordance with the new standard on January 1, 2019.

The adoption of ASC 842 had a material impact in Lineage's consolidated balance sheets, with the most significant impact resulting from the recognition of ROU assets and lease liabilities for operating leases with remaining terms greater than twelve months on the adoption date. Lineage's accounting for financing leases (previously referred to as "capital leases") remained substantially unchanged (see Note 15).

*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 our 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, 2019.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740 and removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. This ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years with early adoption permitted. Lineage is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

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

**3. Asterias Merger**

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

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

As of March 8, 2019, the assets and liabilities of Asterias have been included in the condensed consolidated balance sheet of Lineage. The results of operations of Asterias from March 8, 2019 through December 31, 2019 have been included in the condensed consolidated statement of operations of Lineage for the year ended December 31, 2019, as well as for the three and six months ended June 30, 2020.

*Calculation of the purchase price*

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

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

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

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

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

*Purchase price allocation*

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

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

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

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

| | Asset Fair Value | Useful Life (Years) |
|---|---|---|
| | (in thousands, except for useful life) | |
| In process research and development ("IPR&D") | $ 46,540 | n/a |
| Royalty contracts | 650 | 5 |
| | $ 47,190 | |

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

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

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

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

These IPR&D assets are indefinite-lived intangible assets until the completion or abandonment of the associated research and development ("R&D") efforts. Once the R&D efforts are completed or abandoned, the IPR&D will either be amortized over the asset life as a finite-lived intangible asset or be impaired, respectively, in accordance with ASC 350, *Intangibles - Goodwill and Other*. In accordance with ASC 350, goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment at least annually and between annual tests if Lineage becomes aware of an event or a change in circumstances that would indicate the asset may be impaired.

Because the IPR&D (prior to completion or abandonment of the R&D) is considered an indefinite-lived asset for accounting purposes, the fair value of the IPR&D on the acquisition date creates a deferred income tax liability ("DTL") in accordance with ASC 740, *Income Taxes* (see Note 13). This DTL is computed using the fair value of the IPR&D assets on the acquisition date multiplied by Lineage's federal and state income tax rates. While this DTL would reverse on impairment or sale or commencement of amortization of the related intangible assets, those events are not anticipated under ASC 740 for purposes of predicting reversal of a temporary difference to support the realization of deferred tax assets, except for certain deferred tax assets and credit carryforwards that are also indefinite in nature as of the closing of the Asterias Merger, which may be considered for reversal under ASC 740 as further discussed in Note 13.

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

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

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

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

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

As of June 30, 2020, the total number of common shares of Lineage subject to warrants that were assumed by Lineage in connection with the Asterias Merger was 1,089,900, with similar terms and conditions retained under the Lineage Warrants as per the original Warrant Agreements. The Lineage Warrants have an exercise price of $6.15 per warrant share and expire on May 13, 2021.

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

*Goodwill* - Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at least annually, or more frequently if circumstances indicate potential impairment.

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

Acquisition related costs recorded in general and administrative expenses were $0.2 million and $0.9 million for the three months ended June 30, 2020 and 2019, and $0.7 million and $4.4 million for the six months ended June 30, 2020 and 2019, respectively.

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

*Asterias Merger Related Litigation* - See Note 15 Commitments and Contingencies for discussion regarding litigation related to the Asterias Merger.

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

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

In the six months ended June 30, 2020, Lineage sold approximately 4.8 million shares of OncoCyte common stock for net proceeds of $10.9 million. Lineage's ownership in OncoCyte was reduced to approximately 5.4% as of June 30, 2020.

As of June 30, 2020, Lineage owned 3.6 million shares of OncoCyte common stock. These shares had a fair value of $6.9 million, based on the closing price of OncoCyte of $1.91 per share on June 30, 2020. As of December 31, 2019, Lineage had 8.4 million shares of OncoCyte common stock. These shares had a fair value of $19.0 million, based on the closing price of OncoCyte of $2.25 per share on December 31, 2019.

For the three months ended June 30, 2020, Lineage recorded a realized gain of $2.1 million due to sales of OncoCyte shares in the period. In the same period, Lineage also recorded an unrealized loss of $4.0 million related to its OncoCyte shares. The unrealized loss is comprised of $2.2 million related to the difference between the book cost basis of OncoCyte shares sold in the period versus the applicable prior month's ending OncoCyte stock price and an additional $1.8 million related to the shares remaining at June 30, 2020 and the decrease in OncoCyte's stock price from $2.45 at March 31, 2020 to $1.91 at June 30, 2020. For the three months ended June 30, 2019, Lineage recorded an unrealized loss of $21.4 million due to the decrease in OncoCyte's stock price from $3.95 per share at March 31, 2019 to $2.49 per share at June 30, 2019.

For the six months ended June 30, 2020, Lineage recorded a realized gain of $3.1 million due to sales of OncoCyte shares in the period. In the same period, Lineage also recorded an unrealized loss of $4.2 million related to its OncoCyte shares. The unrealized loss is comprised of $3.7 million related to the difference between the book cost basis of OncoCyte shares sold in the period versus the applicable prior month's ending OncoCyte stock price and an additional $0.5 million related to the shares remaining at June 30, 2020 and the decrease in OncoCyte's stock price from $2.25 at December 31, 2019 to $1.91 at June 30, 2020. For the six months ended June 30, 2019, Lineage recorded an unrealized gain of $16.3 million due to the increase in OncoCyte's stock price from $1.38 per share at December 31, 2018 to $2.49 per share at June 30, 2019.

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

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

On August 30, 2018, Lineage entered into a Stock Purchase Agreement with Juvenescence Limited and AgeX, 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. The transactions contemplated by the Stock Purchase Agreement are referred to as the Juvenescence Transaction in this Report.

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

For the three and six months ended June 30, 2020, Lineage recognized $378,000 and $756,000, respectively, in interest income on the Promissory Note. As of June 30, 2020, the principal and accrued interest balance of the Promissory Note was $24.4 million.

*Shared Services*

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

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

**6. Property and Equipment, Net**

At June 30, 2020 and December 31, 2019, property and equipment was comprised of the following (in thousands):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (unaudited) | |
| Equipment, furniture and fixtures | $ 4,128 | $ 4,148 |
| Leasehold improvements | 2,841 | 2,862 |
| Right-of-use assets (1) | 5,780 | 5,756 |
| Accumulated depreciation and amortization | (5,607) | (4,591) |
| Property and equipment, net | $ 7,142 | $ 8,175 |

(1) Lineage adopted ASC 842 on January 1, 2019. For additional information on this standard and right-of-use assets and liabilities (see Notes 2 and 15).

Property and equipment at both June 30, 2020 and December 31, 2019 includes $96,000 in financing leases. Depreciation and amortization expense amounted to $210,000 and $244,000 for the three months ended June 30, 2020 and 2019, and $423,000 and $513,000 for the six months ended June 30, 2020 and 2019, respectively. During the three and six months ended June 30, 2020, Lineage sold equipment with a net book value of $13,000 and recognized a loss of $2,000. Additionally, Lineage sold non-capitalized assets for a gain of $46,000. Both the gain and loss are included in research and development expenses on the statement of operations.

**7. Goodwill and Intangible Assets, Net**

At June 30, 2020 and December 31, 2019, goodwill and intangible assets, net consisted of the following (in thousands):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (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[2] | 650 | 650 |
| Total intangible assets | 66,143 | 66,143 |
| Accumulated amortization | (18,726) | (17,895) |
| Intangible assets, net | $ 47,417 | $ 48,248 |

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

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

Amortization recognized in research and development expenses was $0.3 million and $0.5 million for the three months ended June 30, 2020 and 2019, and $0.8 million and $0.9 million for the six months ended June 30, 2020 and 2019, respectively.

**8. Accounts Payable and Accrued Liabilities**

At June 30, 2020 and December 31, 2019, accounts payable and accrued liabilities consisted of the following (in thousands):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (unaudited) | |
| Accounts payable | $ 3,424 | $ 2,427 |
| Accrued compensation | 1,177 | 1,549 |
| Accrued liabilities | 763 | 1,246 |
| PPP loan payable | 523 | - |
| Other current liabilities | 61 | 4 |
| Total | $ 5,948 | $ 5,226 |

*PPP Loan Payable*

In April 2020, Lineage received a loan for $523,000 from Axos Bank under the PPP contained within the new Coronavirus Aid, Relief and Economic Security ("CARES") Act. The PPP loan has a term of two years, is unsecured, and is guaranteed by the U.S. Small Business Administration ("SBA"). The loan carries a fixed interest rate of one percent per annum, with the first six months of interest deferred. Under the CARES Act, Lineage will be 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 are adhered to by Lineage, all or part of such loan could be forgiven. Lineage believes that all or a substantial portion of the PPP loan is eligible for forgiveness within one year and classifies the loan as a short-term liability. However, Lineage cannot provide any assurance regarding eligibility or whether the PPP loan will ultimately be forgiven by the SBA. Any forgiven amounts will not be included in Lineage's taxable income.

*2019 Separation Payments*

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

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

In connection with the relocation of Lineage's corporate headquarters to Carlsbad, California, discussed in Note 15, Lineage entered into a plan of termination with certain Lineage employees with potential separation payments in the aggregate of $0.7 million. Termination dates for these individuals range from August 9, 2019 to September 30, 2019. These employees had to provide services related to the transition of services and activities in connection with the relocation and be an employee of Lineage as of their date of termination in order to receive separation benefits. Lineage recorded the aggregate liability ratably over their respective service periods from June 2019 through the above termination dates, in accordance with ASC 420. As of December 31, 2019, all separation payments had been made.

**9. Fair Value Measurements**

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

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

We measure cash, cash equivalents, marketable securities and our liability classified warrants at fair value on a recurring basis. The fair values of such assets were as follows for June 30, 2020 and December 31, 2019 (in thousands):

| | | Fair Value Measurements Using | | |
|---|---|---|---|---|
| | **Balance at June 30, 2020** | **Quoted Prices in Active Markets for Identical Assets (Level 1)** | **Significant Other Observable Inputs (Level 2)** | **Significant Unobservable Inputs (Level 3)** |
| Assets: | | | | |
| Cash and cash equivalents | $ 12,676 | $ 12,676 | $ - | $ - |
| Marketable securities | 7,575 | 7,575 | - | - |
| | | | | |
| Liabilities: | | | | |
| Lineage Warrants | 15 | - | - | 15 |
| Cell Cure Warrants | 233 | - | - | 233 |

| | | Fair Value Measurements Using | | |
|---|---|---|---|---|
| | **Balance at December 31, 2019** | **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 | $ 9,497 | $ 9,497 | $ - | $ - |
| Marketable securities | 21,219 | 21,219 | - | - |
| | | | | |
| Liabilities: | | | | |
| Lineage Warrants | 20 | - | - | 20 |
| Cell Cure Warrants | 257 | - | - | 257 |

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

In determining fair value, Lineage utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and also considers counterparty credit risk in its assessment of fair value.

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

The fair value of the Lineage Warrants is determined by using Black-Scholes option pricing models which take into consideration the probability of a fundamental transaction, as defined in the warrant agreement, the exercise price of the warrants and the contractual remaining term of the warrants. The Lineage Warrants have an expiration date of May 13, 2021. The Lineage Warrants are included in current liabilities on the condensed consolidated balance sheets. Changes in the fair value of the Lineage Warrants at each reporting period are included in the condensed consolidated statements of operations under unrealized gain/(loss) on warrant liability. For the three and six months ended June 30, 2020, Lineage recognized an unrealized loss of $3,000 and an unrealized gain of $4,000 on the Lineage Warrants, respectively, which was primarily related to the reduction in the remaining life of the warrants.

The fair value of the Cell Cure Warrants (defined below) is determined by using Black-Scholes option pricing models which take into consideration the fair value of the Cell Cure ordinary shares, adjusted for lack of marketability, as appropriate, the contractual remaining term of the warrants and the expected stock price volatility over the term. The Cell Cure Warrants are included in current (portion with terms expiring within the next twelve months) and long-term liabilities on the condensed consolidated balance sheets. Changes in the fair value of the Cell Cure Warrants at each reporting period are included in the condensed consolidated statements of operations under unrealized gain/(loss) on warrant liability. For the three and six months ended June 30, 2020, Lineage recognized an unrealized loss of $2,000 and an unrealized gain of $25,000 on the Cell Cure Warrants, respectively, primarily related to the reduction in the remaining life of the warrants.

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**

*Shared Facilities and Service Agreements with Affiliates*

Under the terms of Shared Facilities Agreements, Lineage allowed OncoCyte and AgeX to use Lineage’s premises and equipment located at Lineage’s headquarters in Alameda, California for the purpose of conducting business. Lineage also provided accounting, billing, bookkeeping, payroll, treasury, payment of accounts payable, and other similar administrative services to OncoCyte and AgeX. The Shared Facilities Agreements also allowed Lineage to provide the services of attorneys, accountants, and other professionals who may provide professional services to Lineage. Lineage also provided OncoCyte and AgeX with the services of laboratory and research personnel, including Lineage employees and contractors, for the performance of research and development work for OncoCyte and AgeX at the premises. Shared services with AgeX were terminated on July 31, 2019 with respect to the use of Lineage’s office and laboratory facilities and September 30, 2019 with respect to all other remaining shared services. Shared services with OncoCyte were terminated on September 30, 2019, and December 31, 2019 with respect to all other remaining shared services.

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

The Use Fee was determined and invoiced to OncoCyte and AgeX on a regular basis, generally monthly or quarterly. Each invoice was payable in full within 30 days after receipt. Any invoice, or portion thereof, not paid in full when due bore interest at the rate of 15% per annum until paid, unless the failure to make a payment was due to any inaction or delay in making a payment by Lineage. Lineage did not charge OncoCyte or AgeX any interest.

In addition to the Use Fee, OncoCyte and AgeX reimbursed Lineage for any out of pocket costs incurred by Lineage for the purchase of office supplies, laboratory supplies, and other goods and materials and services for the account or use of OncoCyte or AgeX. Lineage was not obligated to purchase or acquire any office supplies or other goods and materials or any services for OncoCyte or AgeX, and if any such supplies, goods, materials or services were obtained, Lineage could arrange for the suppliers to invoice OncoCyte or AgeX directly.

The Use Fees charged to OncoCyte and AgeX were not reflected in revenues, but instead Lineage's general and administrative expenses and research and development expenses were shown net of those charges in the condensed consolidated statements of operations.

For the three months ended June 30, 2019, Lineage charged Use Fees of $670,000 to OncoCyte and AgeX; $179,000 was offset against general and administrative expenses and $491,000 was offset against research and development expenses.

For the six months ended June 30, 2019, Lineage charged Use Fees of $1,395,000 to OncoCyte and AgeX; $411,000 was offset against general and administrative expenses and $984,000 was offset against research and development expenses.

Even though shared services have been terminated, there are still a small number of vendors that are paid by Lineage on behalf of AgeX or OncoCyte. These are typically repaid on a quarterly basis. As of June 30, 2020, receivables for these items total $7,000.

*Other related party transactions*

Lineage currently pays $5,050 per month for the use of approximately 900 square feet of office space in New York City, which is made available to Lineage on a month-by-month basis by one of its directors at an amount that approximates his cost (see Note 15). These payments are expected to cease in March 2021 when the office space lease expires.

In April 2019, Lineage issued 251,835 common shares of Lineage to Broadwood Partners, L.P., an Asterias and Lineage shareholder, in exchange for the settlement of Asterias Warrants in connection with the Asterias Merger (see Note 3).

In connection with the putative shareholder class action lawsuits filed in February 2019 and October 2019 challenging the Asterias Merger (see Note 15), Lineage has agreed to pay for the legal defense of Neal Bradsher, director, and Broadwood Partners, L.P., a shareholder of Lineage, and Broadwood Capital, Inc., which manages Broadwood Partners, L.P., all of which were named in the lawsuits. Through June 30, 2020, Lineage has incurred a total of $350,000 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 1,000,000 shares, 2,000,000 shares and 623,090 shares of OncoCyte common stock from Lineage in July 2019, September 2019 and January 2020, respectively.

**11. Shareholders' Equity**

*Preferred Shares*

Lineage is authorized to issue 2,000,000 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 June 30, 2020, Lineage was authorized to issue 250,000,000 common shares, no par value. As of June 30, 2020, and December 31, 2019, Lineage had 149,831,347 and 149,804,284 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 $25,000,000. Lineage is not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of the NYSE American, to sell the shares from time to time based upon Lineage's instructions, including any price, time or size limits specified by Lineage. Under the Sales Agreement, Cantor Fitzgerald may sell the shares by any method deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or by any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald's obligations to sell the shares under the Sales Agreement are subject to satisfaction of certain conditions, including the continued effectiveness of Lineage's Registration Statement on Form S-3 (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. As of June 30, 2020, no sales had been made 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 six months ended June 30, 2020 and 2019 (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 | 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 loss | - | - | - | - | - | - | 1,315 | 1,315 |
| NET INCOME/(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 INCOME/(LOSS) | - | - | - | - | (6,522) | (8) | - | (6,530) |
| **BALANCE AT JUNE 30, 2020** | - | $ - | 149,831 | $ 388,271 | $ (288,343) | $ (1,749) | $ (486) | $ 97,693 |

| | Preferred Shares | | Common Shares | | | | Accumulated Other | Total |
|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Amount | Number of Shares | Amount | Accumulated Deficit | Noncontrolling Interest/ (Deficit) | Comprehensive Income | Shareholders' Equity |
| **BALANCE AT DECEMBER 31, 2018** | - | $ - | 127,136 | $ 354,270 | $ (261,856) | $ (1,594) | $ 1,426 | $ 92,246 |
| Shares issued in connection with the Asterias Merger | - | - | 24,696 | 32,353 | - | - | - | 32,353 |
| Shares retired in connection with the Asterias Merger | - | - | (2,622) | (3,435) | - | - | - | (3,435) |
| Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes | - | - | 118 | (75) | - | - | - | (75) |
| Stock-based compensation | - | - | - | 1,361 | - | - | - | 1,361 |
| Stock-based compensation for shares issued upon vesting of Asterias restricted stock units attributable to post combination services | - | - | 60 | 79 | - | - | - | 79 |
| Adjustment upon adoption of leasing standard | - | - | - | - | 143 | - | - | 143 |
| Foreign currency translation loss | - | - | - | - | - | - | (732) | (732) |
| NET INCOME/(LOSS) | - | - | - | - | 39,310 | (14) | - | 39,296 |
| **BALANCE AT MARCH 31, 2019** | - | $ - | 149,388 | $ 384,553 | $ (222,403) | $ (1,608) | $ 694 | $ 161,236 |
| Shares issued for settlement of BioTime Warrants | - | - | 252 | 302 | - | - | - | 302 |
| Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes | - | - | 3 | (2) | - | - | - | (2) |
| Stock-based compensation | - | - | - | 762 | - | - | - | 762 |
| Foreign currency translation loss | - | - | - | - | - | - | (487) | (487 |
| NET INCOME/(LOSS) | - | - | - | - | (30,032) | (20) | - | (30,052) |
| **BALANCE AT JUNE 30, 2019** | - | $ - | 149,643 | $ 385,615 | $ (252,435) | $ (1,628) | $ 207 | $ 131,759 |

*Warrants*

*Lineage (previously Asterias) Warrants - Liability Classified*

In March 2019, in connection with the closing of the Asterias Merger, Lineage assumed outstanding Asterias Warrants. As of June 30, 2020, the total number of common shares of Lineage subject to warrants that were assumed by Lineage in connection with the Asterias Merger was 1,089,900, which were converted to Lineage Warrants 30 days after the closing of the Asterias Merger, with similar terms and conditions retained under the Lineage Warrants as per the original Warrant Agreements. The Lineage Warrants have an exercise price of $6.15 per warrant share and expire on May 13, 2021.

*Cell Cure Warrants - Liability Classified*

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

**12. Stock-Based Awards**

*Equity Incentive Plan Awards*

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

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

| | Shares Available for Grant | Number of Options Outstanding | Number of RSUs Outstanding | Weighted Average Exercise Price |
|---|---|---|---|---|
| December 31, 2019 | 9,157 | 14,710 | 166 | $ 2.17 |
| Restricted stock units vested | - | - | (42) | - |
| Options granted | (4,946) | 4,946 | - | 0.70 |
| Options exercised | - | - | - | - |
| Options expired/forfeited/cancelled | 3,211 | (3,211) | - | 2.67 |
| June 30, 2020 | 7,422 | 16,445 | 124 | $ 1.63 |
| Options exercisable at June 30, 2020 | | 8,090 | | $ 2.31 |

At the effective time of the Asterias Merger, Lineage assumed sponsorship of the Asterias 2013 Equity Incentive Plan (the "Asterias Equity Plan"), with references to Asterias and Asterias common stock therein to be deemed references to Lineage and Lineage common shares. There were 7,309,184 shares available under the Asterias Equity Plan immediately before the closing of the Asterias Merger, which became 5,189,520 shares immediately following the Asterias Merger. The shares available under the Asterias Equity Plan will be for awards granted to those former Asterias employees who continued as Lineage employees upon consummation of the Asterias Merger.

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

| | Shares Available for Grant | Number of Options Outstanding | Weighted Average Exercise Price |
|---|---|---|---|
| December 31, 2019 | 4,840 | 350 | $ 1.57 |
| Options granted | - | - | - |
| Options exercised | - | - | - |
| Options forfeited | - | | - |
| June 30, 2020 | 4,840 | 350 | $ 1.57 |
| Options exercisable at June 30, 2020 | | 109 | $ 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:

| | Six Months Ended June 30, (unaudited) | |
|---|---|---|
| | 2020 | 2019 |
| Expected life (in years) | 6.25 | 6.1 |
| Risk-free interest rates | 0.8% | 2.5% |
| Volatility | 67.5% | 60.2% |
| Dividend yield | 0% | 0% |

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

| | Three Months Ended June 30, (unaudited) | | Six Months Ended June 30, (unaudited) | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Research and development | $ 121 | $ 161 | $ 217 | $ 283 |
| General and administrative | 485 | 601 | 1,015 | 1,919 |
| Total stock-based compensation expense | $ 606 | $ 762 | $ 1,232 | $ 2,202 |

The expense related to 84,940 shares of Asterias restricted stock unit awards that immediately vested on the closing of the Asterias Merger and converted into the right to receive common shares of Lineage based on the Merger Exchange Ratio, resulting in 60,304 common shares of Lineage issued on March 8, 2019, was included in stock-based compensation expense for the six months ended June 30, 2019. The expense was not included as part of the purchase price of the Asterias Merger because these awards were principally attributable to post-combination services.

**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 the OncoCyte, and AgeX shares of common stock Lineage holds, and prior to March 8, 2019, Asterias shares Lineage held), 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 June 30, 2020, is a source of future taxable income to Lineage, as prescribed by ASC 740-10-30-17, that will more likely than not result in the realization of its deferred tax assets to the extent of the deferred tax liability. This deferred tax liability is determined based on the closing prices of the OncoCyte shares as of June 30, 2020. 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.

Prior to the Asterias Merger discussed in Note 3, the Asterias shares of common stock Lineage held generated similar deferred tax liabilities to Lineage as the OncoCyte shares discussed above. As of the Asterias Merger date and due to Asterias becoming a wholly owned subsidiary of Lineage, the Asterias deferred tax liabilities were eliminated with a corresponding adjustment to Lineage's valuation allowance, resulting in no tax provision or benefit from this adjustment.

In connection with the Asterias Merger, a deferred tax liability of $10.8 million was recorded as part of the acquisition accounting (see Note 3). 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.

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, 2019, a portion of the valuation allowance was released as it relates to Lineage's indefinite lived assets that can be used against the indefinite lived liabilities. The amount of the valuation allowance released was $7.4 million; 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 six months ended June 30, 2020, Lineage did not record any provision or benefit for income taxes, as Lineage had taxable income related to a gain on the sale of OncoCyte shares in the applicable periods. This taxable income was offset by net operating loss carryforwards.

For the three and six months ended June 30, 2019, Lineage recorded a $1.2 million and $5.6 million valuation allowance release and corresponding tax benefit, respectively, that were primarily related to state research and development credits, including federal net operating losses generated for the three and six months ended June 30, 2019, both of which are available and indefinite in nature.

**14. Supplemental Cash Flow Information**

Supplemental disclosure of cash flow information for the six months ended June 30, 2020 and 2019 is as follows (in thousands):

| | Six Months Ended June 30, (unaudited) | |
|---|---|---|
| | **2020** | **2019** |
| Cash paid during period for interest | $ 13 | $ 17 |
| | | |
| Supplemental disclosures of non-cash investing and financing activities: | | |
| Issuance of common shares for the Asterias Merger (Note 3) | $ - | $ 32,353 |
| Assumption of liabilities in the Asterias Merger (Note 3) | - | 1,136 |
| Assumptions of warrants in the Asterias Merger (Note 3) | - | 867 |

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

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

*Alameda Lease*

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

Base rent under the Alameda Lease beginning on February 1, 2020 is $72,676 per month and will increase by approximately 3% annually on every February 1 thereafter during the lease term.

In addition to base rent, Lineage will pay a pro rata portion of increases in certain expenses, including real property taxes, utilities (to the extent not separately metered to the leased space) and the landlord's operating expenses, over the amounts of those expenses incurred by the landlord. As security for the performance of its obligations under the Alameda Lease, Lineage provided the landlord with a security deposit of approximately $424,000, which was reduced to $78,000 on January 24, 2019 in accordance with the terms of the lease. The security deposit amount is considered restricted cash and $78,000 is included in deposits and other long-term assets as of June 30, 2020 (see Note 2).

*Alameda Sublease*

In April 2020, Lineage entered into a sublease with Industrial Microbes, Inc. for the usage of 10,000 square feet in one of its leased Alameda buildings. The lease commenced on April 24, 2020 and expires on January 31, 2023.

Base rent under the sublease is $28,000 per month and will increase by 3% annually on every February 1 during the lease term. Base rent for the first month was abated. In addition to base rent and utilities, Industrial Microbes will pay a pro-rata portion of increases in operating expenses, after an abatement period of one year.

As security for the performance of its obligations under the sublease, Industrial Microbes provided Lineage with a security deposit of $56,000.

*New York Leased Office Space*

Lineage currently pays $5,050 per month for the use of approximately 900 square feet of office space in New York City, which is made available to Lineage for use in conducting meetings and other business affairs, on a month-by-month basis, by one of its directors at an amount that approximates his cost. This lease is not in the scope of ASC 842 because it is a month to month lease (see Note 2).

*Cell Cure Leases*

Cell Cure leases 728.5 square meters (approximately 7,842 square feet) of office and laboratory space in Jerusalem, Israel under a lease that expires December 31, 2020, with two options to extend the lease for five years each (the "Original Cell Cure Lease"). Base monthly rent is NIS 37,882 (approximately US $11,000 per month using the December 31, 2018 exchange rate). In addition to base rent, Cell Cure pays a pro-rata share of real property taxes and certain costs related to the operation and maintenance of the building in which the leased premises are located.

On January 28, 2018, Cell Cure entered into another lease agreement for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with two options to extend the lease for 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 $388,000 deposit required under the January 2018 Lease, which amount is included in deposits and other long-term assets on the consolidated balance sheet as of December 31, 2018, to be held as restricted cash during the term of the January 2018 Lease.

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| **Cash paid for amounts included in the measurement of lease liabilities:** | | |
| Operating cash flows from operating leases | $ 797 | $ 670 |
| Operating cash flows from financing leases | 13 | 17 |
| Financing cash flows from financing leases | 17 | 14 |
| | | |
| **Right-of-use assets obtained in exchange for lease obligations:** | | |
| Operating leases | 29 | 89 |
| Financing leases | - | - |

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

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| **Operating leases** | | |
| Right-of-use assets, net | $ 4,077 | $ 4,666 |
| | | |
| Right-of-use lease liabilities, current | 1,210 | 1,190 |
| Right-of-use lease liabilities, noncurrent | 3,276 | 3,868 |
| Total operating lease liabilities | $ 4,486 | $ 5,058 |
| | | |
| **Financing leases** | | |
| Property and equipment, gross | $ 96 | $ 96 |
| Accumulated depreciation | (57) | (48) |
| Property and equipment, net | $ 39 | $ 48 |
| | | |
| Current liabilities | 31 | 33 |
| Long-term liabilities | 62 | 77 |
| Total finance lease liabilities | $ 93 | $ 110 |
| | | |
| **Weighted average remaining lease term** | | |
| Operating leases | 3.7 years | 4.1 years |
| Finance leases | 2.9 years | 3.4 years |
| **Weighted average discount rate** | | |
| Operating leases | 9.1% | 9.1% |
| Finance leases | 10.2% | 10.0% |

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

| | Operating Leases | Finance Leases |
|---|---|---|
| **Year Ending December 31,** | | |
| 2020 | $ 800 | $ 21 |
| 2021 | 1,539 | 36 |
| 2022 | 1,518 | 36 |
| 2023 | 400 | 15 |
| 2024 | 308 | - |
| Thereafter | 790 | - |
| | | |
| Total lease payments | $ 5,355 | $ 108 |
| Less imputed interest | (869) | (15) |
| Total | $ 4,486 | $ 93 |

*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 January 30, 2020 and May 1, 2020 (the "Gyroscope Agreement"). As amended, the Gyroscope Agreement provides Lineage access to Gyroscope's vitrectomy-free subretinal injection device as a means of delivering OpRegen in Lineage's ongoing Phase 1/2a clinical trial through September 10, 2020 (the "Access Period"). 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 on January 30, 2020 and $0.3 million of which is payable upon the maturity of the Juvenescence promissory note. In May 2020, due to the COVID-19 pandemic and the impact on clinical trial enrollment, the parties agreed to a no-cost extension to the Access Period through September 10, 2020.

Lineage has exclusive rights to the Gyroscope technology and its injection device for the treatment of dry AMD during the term of the Gyroscope Agreement.

*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 disclosing to the court the parties' agreement to resolve, for $200,000, Plaintiffs' claim for an award of attorneys' fees and expenses in connection with the purported benefit conferred on Asterias stockholders by the Supplemental Disclosures. The court granted the stipulation and dismissed the action August 14, 2019. Lineage continues to believe that the claims and allegations in the action lack merit, but believed that it was in Lineage's shareholders' best interest for the action to be dismissed and to resolve the fee claim in a timely manner without additional costly litigation expenses.

On October 14, 2019, another putative class action lawsuit was filed challenging the Asterias Merger. This action (captioned *Ross v. Lineage Cell Therapeutics, Inc., et al.*, C.A. No. 2019-0822) was filed in Delaware Chancery Court and names Lineage, the Asterias board of directors, one member of Lineage's board of directors, and certain stockholders of both Lineage and Asterias as defendants. The action was brought by a purported stockholder of Asterias, on behalf of a putative class of Asterias stockholders, and asserts breach of fiduciary duty and aiding and abetting claims under Delaware law. The complaint alleges, among other things, that the process leading up to the Asterias Merger was conflicted, that the Asterias Merger consideration was inadequate, and that the proxy statement filed by Asterias with the Commission omitted certain material information, which allegedly rendered the information disclosed materially misleading. The complaint seeks, among other things, that a class be certified, the recovery of monetary damages, and attorneys' fees and costs. 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.

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 June 30, 2020 and December 31, 2019.

*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 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. 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 January 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 June 30, 2020, 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. License fees and related expenses under these agreements were $5,000 and $33,000 for the six months ended June 30, 2020 and 2019, respectively.

*Grants*

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

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

**16. Subsequent Events**

*Termination of Services and Related Return of Project Funds*

On August 4, 2020, Lineage agreed to terminate a services agreement with a former service provider that Asterias had not used since 2018. The service provider returned unspent project funds of approximately $0.8 million and is in the process of returning Asterias materials in its possession. The unspent project funds will be recorded as an offset to research and development expenses in the third quarter of 2020.

**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, 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 and in Part I, Item 1A, "Risk Factors" in our most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "Commission") on March 12, 2020.*

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**

Lineage 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 aiding the body in detecting and combating cancer. Lineage's programs are based on our proprietary cell-based therapy platform and associated development and manufacturing capabilities. From this platform, Lineage develops and manufactures specialized, terminally or partially differentiated human cells from established and well-characterized pluripotent cell lines. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or are administered as a means of helping the body mount an effective immune response to cancer.

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

- *OpRegen®*, a retinal pigment epithelium cell replacement therapy currently in a Phase 1/2a multicenter clinical trial for the treatment of advanced dry age-related macular degeneration ("AMD") with geographic atrophy. There currently are no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry AMD, which accounts for approximately 85-90% of all AMD cases and is the leading cause of blindness in people over the age of 60. We and our subsidiary, Cell Cure, have rights to issued U.S. and international patents and pending patent applications covering OpRegen. The expiration dates of the issued patents, and the estimated expiration dates of the pending patent applications, range from 2025 to 2038.

- *OPC1*, an oligodendrocyte progenitor cell therapy currently in a Phase 1/2a multicenter clinical trial for acute spinal cord injuries. This clinical trial has been partially funded by the California Institute for Regenerative Medicine. We have numerous U.S. and international issued patents and pending patent applications that are relevant to neural cells, such as oligodendrocyte progenitor cells, including patent families acquired from Geron Corporation ("Geron") that are directed to the differentiation of pluripotent stem cells, including human embryonic stem ("hES") cells, into various neural cell types, as well as various culture and purification methods. These U.S. and international issued patents and pending patent applications also include those in-licensed from the Regents of the University of California. The expiration dates of the issued patents, and the estimated expiration dates of the pending patent applications, range from 2020 to 2040.

- *VAC2*, an allogeneic (non-patient-specific or "off-the-shelf") cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase 1 clinical trial in non-small cell lung cancer. This clinical trial is being funded and conducted by Cancer Research UK, the world's largest independent cancer research charity. We have numerous U.S. and international issued patents and pending patent applications that are relevant to dendritic cells, including patent families acquired from Geron or in-licensed from third parties that are directed to the differentiation of pluripotent stem cells, including hES cells, into hematopoietic progenitor cells and immature and mature dendritic cells. The expiration dates of the issued patents, and the estimated expiration dates of the pending patent applications, range from 2020 to 2041.

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

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

In addition to seeking to create value for shareholders by developing product candidates and other technologies through our clinical development programs, we also seek to create value from our technologies through partnering and strategic transactions. We founded two companies that later became publicly traded companies: OncoCyte Corporation ("OncoCyte") and AgeX Therapeutics, Inc. ("AgeX"). The combined value of these holdings as of August 4, 2020, was approximately $6.9 million, based on the closing price of their common stock on that date. We also hold a convertible promissory note from Juvenescence Limited ("Juvenescence") in connection with our sale of AgeX stock to Juvenescence in August 2018. The value of the Juvenescence note of $24.4 million at June 30, 2020 is based on the principal amount of $21.6 million plus accrued interest. In this Report, see Part II, Item 1A, "Risk Factors—Risks Related to Our Business Operations and Capital Requirements—The value of our investments in public companies fluctuates based on their respective stock prices and could be negatively affected by poor business performance".

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

**Critical Accounting Policies**

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 GAAP. 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, 2019, except as follows:

*Business Combinations*

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

*Goodwill and IPR&D*

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at least annually, or more frequently if circumstances indicate potential impairment.

IPR&D assets are indefinite-lived intangible assets until the completion or abandonment of the associated research and development ("R&D") efforts. Once the R&D efforts are completed or abandoned, the IPR&D will either be amortized over the asset life as a finite-lived intangible asset or be impaired, respectively, in accordance with ASC 350, *Intangibles - Goodwill and Other*. In accordance with ASC 350, goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment at least annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the asset may be impaired.

*Leases*

We account for leases in accordance with ASC 842, *Leases*. We determine if an arrangement is a lease at inception. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. Under the available practical expedients for the adoption of ASC 842, we account for the lease and non-lease components as a single lease component. We recognize right-of-use ("ROU") assets and lease liabilities for leases with terms greater than twelve months in the 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 right-of-use 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.

**Results of Operations**

*Comparison of Three and Six Months Ended June 30, 2020 and 2019*

*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 June 30, (unaudited) | | $ Increase/ (Decrease) | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2020 | 2019 | | |
| Grant revenue | $ 287 | $ 529 | $ (242) | (46)% |
| Royalties from product sales and license fees | 99 | 140 | (41) | (29)% |
| Sale of research products and services | - | 110 | (110) | (100)% |
| Total revenues | 386 | 779 | (393) | (50)% |
| Cost of sales | (75) | (107) | (32) | (30)% |
| Gross profit | $ 311 | $ 672 | $ (361) | (54)% |

| | Six Months Ended June 30, (unaudited) | | $ Increase/ (Decrease) | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2020 | 2019 | | |
| Grant revenue | $ 635 | $ 1,278 | $ (643) | (50)% |
| Royalties from product sales and license fees | 265 | 226 | 39 | 17% |
| Sale of research products and services | - | 203 | (203) | (100)% |
| Total revenues | 900 | 1,707 | (807) | (47)% |
| Cost of sales | (169) | (175) | (6) | (3)% |
| Gross profit | $ 731 | $ 1,532 | $ (801) | (52)% |

Our total revenues decreased by $393,000 for the three months ended June 30, 2020 as compared to the same period in the prior year, primarily reflecting a $242,000 decrease in grant revenues due to less grant-related activities and a $110,000 decrease in the sale of research products and services due to the cessation of such sales.

Our total revenues decreased by $807,000 for the six months ended June 30, 2020 as compared to the same period in the prior year, primarily reflecting a $643,000 decrease in grant revenues due to less grant-related activities and a $203,000 decrease in the sale of research products and services due to the cessation of such sales.

Our grant revenues are generated primarily by Cell Cure from the IIA for the development of OpRegen® and from a Small Business Innovation Research grant from the National Institutes of Health for our vision restoration program (the “NIH grant”). NIH grant related activities are scheduled to be completed in the third quarter of 2020.

Grant revenues generated by Cell Cure from the IIA for the development of OpRegen amounted to $130,000 and $261,000 for the three and six months ended June 30, 2020 and $486,000 and $916,000 for the three and six months ended June 30, 2019, respectively.

Grant revenues generated by the NIH grant amounted to $157,000 and $374,000 for the three and six months ended June 30, 2020 and $43,000 and $362,000 for the three and six months ended June 30, 2019, respectively.

*Operating expenses*

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

| | Three Months Ended June 30 (unaudited) | | $ | % |
|---|---|---|---|---|
| | 2020 | 2019 | (Decrease) | (Decrease) |
| Research and development expenses | $ 2,805 | $ 5,235 | $ (2,430) | (46)% |
| General and administrative expenses | 3,908 | 6,258 | (2,350) | (38)% |

| | Six Months Ended June 30 (unaudited) | | $ | % |
|---|---|---|---|---|
| | 2020 | 2019 | (Decrease) | (Decrease) |
| Research and development expenses | $ 6,144 | $ 10,196 | $ (4,052) | (40)% |
| General and administrative expenses | 8,427 | 14,918 | (6,491) | (44)% |

*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 June 30, (unaudited) | | | |
|---|---|---|---|---|
| | Amount | | Percent of Total | |
| Program | 2020 | 2019 | 2020 | 2019 |
| OpRegen® and other ophthalmic applications | $ 1,400 | $ 3,092 | 50% | 59% |
| OPC1 | 1,132 | 1,818 | 40% | 35% |
| VAC platform | 185 | 142 | 7% | 3% |
| Renevia and all other | 88 | 183 | 3% | 3% |
| Total research and development expenses | $ 2,805 | $ 5,235 | 100% | 100% |

| | Six Months Ended June 30, (unaudited) | | | |
|---|---|---|---|---|
| | Amount | | Percent of Total | |
| Program | 2020 | 2019 | 2020 | 2019 |
| OpRegen® and other ophthalmic applications | $ 3,262 | $ 6,738 | 53% | 66% |
| OPC1 | 2,361 | 2,509 | 38% | 25% |
| VAC platform | 301 | 245 | 5% | 2% |
| Renevia and all other | 220 | 704 | 4% | 7% |
| Total research and development expenses | $ 6,144 | $ 10,196 | 100% | 100% |

The decrease of $2.4 million in total research and development expenses for the three months ended June 30, 2020 as compared to the same period in the prior year is mainly attributable to the following:

- a decrease of $1.7 million in OpRegen and other ophthalmic application expenses, attributable primarily to a decrease in manufacturing activities in 2020 as compared to 2019, and
- a decrease of $0.7 million in OPC1 related expenses, primarily related to a decrease in development activities in 2020 as compared to 2019 when technology transfer was a focus upon OPC1 coming in-house with the acquisition of Asterias.

The decrease of $4.1 million in total research and development expenses for the six months ended June 30, 2020 as compared to the same period in the prior year is mainly attributable to the following:

- a decrease of $3.5 million in OpRegen and other ophthalmic application expenses, attributable primarily to a decrease in manufacturing activities in 2020 as compared to 2019,
- a decrease of $0.5 million in Renevia and other related expenses as Renevia received a CE Mark in September 2019 and we are spending less on research activities as we are actively looking for a commercialization partner in Europe, offset by
- a decrease of $0.1 million in OPC1 related expenses, primarily related to a decrease in development activities in 2020 as compared to 2019 when technology transfer was a focus upon OPC1 coming in-house with the acquisition of Asterias.

*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 decrease of $2.4 million in general and administrative expenses for the three months ended June 30, 2020 compared to the same period in 2019, was primarily attributable to a $1.6 million reduction in Asterias Merger related expenses, a $0.2 million reduction in compensation expenses, a $0.2 million reduction in investor and public relations expenses, a $0.2 million reduction in accounting expenses, a $0.1 million reduction in rent expenses, a $0.1 million reduction in travel expenses and a $0.1 million reduction in consulting expenses, offset by a $0.2 million increase related to the cessation of shared services reimbursements.

The total net decrease of $6.5 million in general and administrative expenses for the six months ended June 30, 2020 compared to the same period in 2019, was primarily attributable to a $5.0 million reduction in Asterias Merger related expenses, a $1.1 million reduction in compensation costs, a $0.6 million reduction in accounting expenses, a $0.2 million reduction in investor and public relations expenses, a $0.2 million reduction in consulting expenses, a $0.2 million reduction in travel expenses and a $0.1 million reduction in rent expenses, offset by a $0.5 million increase in legal and patent expenses and a $0.4 million increase related to the cessation of shared services reimbursements.

*Other income and expenses, net*

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

| | Three Months Ended June 30, (unaudited) | |
|---|---|---|
| | **2020** | **2019** |
| **Other income and expenses, net** | | |
| Interest income, net | $ 380 | $ 437 |
| Loss on equity method investment in OncoCyte at fair value | - | (21,425) |
| Gain on sale of marketable securities | 2,470 | - |
| Unrealized loss on marketable equity securities | (4,146) | (607) |
| Unrealized (loss) gain on warrant liability | (6) | 234 |
| Other income, net | 1,174 | 882 |
| Total other expense, net | $ (128) | $ (20,479) |

| | Six Months Ended June 30, (unaudited) | |
|---|---|---|
| | 2020 | 2019 |
| **Other income and expenses, net** | | |
| Interest income, net | $ 785 | $ 879 |
| Gain on equity method investment in Asterias at fair value | - | 6,744 |
| Gain on equity method investment in OncoCyte at fair value | - | 16,288 |
| Gain on sale of marketable securities | 3,728 | - |
| Unrealized (loss) gain on marketable equity securities | (5,484) | 1,324 |
| Unrealized gain on warrant liability | 29 | 271 |
| Other income (expense), net | (176) | 1,688 |
| Total other income (expense), net | $ (1,118) | $ 27,194 |

*Interest income, net* – During the three and six months ended June 30, 2020 and the three and six months ended June 30, 2019, we earned $0.4 million and $0.8 million and $0.4 million and $0.8 million of interest income, respectively, from our Juvenescence promissory note.

*Gain on equity method investment in Asterias* – Prior to the closing of the Asterias Merger on March 8, 2019, we owned 21.7 million shares of common stock of Asterias, which we accounted for at fair value using the equity method of accounting. The fair value of our Asterias shares was approximately $20.2 million as of March 8, 2019, the closing date of the Asterias Merger, based on $0.93 per share, which was calculated by multiplying: (i) $1.31, the closing price of our common shares on such date; by (ii) the Merger Exchange Ratio. The fair value of our Asterias shares was approximately $13.5 million as of December 31, 2018, based on the closing price of Asterias common stock of $0.62 per share on such date. Accordingly, we recorded an unrealized gain of $6.7 million for the year ended December 31, 2019, representing the change in fair value of Asterias common stock from December 31, 2018 to March 8, 2019.

*Gain on equity method investment in OncoCyte* – Prior to September 11, 2019, Lineage elected to account for its shares of OncoCyte common stock at fair value using the equity method of accounting. Lineage sold 2.25 million shares of OncoCyte common stock for net proceeds of $4.2 million in July 2019. Accordingly, Lineage's ownership in OncoCyte was reduced from 28% to 24%. Lineage sold an additional 4.0 million shares of OncoCyte common stock for net proceeds of $6.5 million on September 11, 2019. Lineage's ownership in OncoCyte was further reduced to 16% at this time. Effective September 11, 2019, Lineage began accounting for its shares of OncoCyte common stock as marketable equity securities.

As of June 30, 2020, Lineage owned 3.6 million shares of OncoCyte common stock. These shares had a fair value of $6.9 million, based on the closing price of OncoCyte common stock of $1.91 per share on June 30, 2020. As of December 31, 2019, Lineage had 8.4 million shares of OncoCyte common stock. These shares had a fair value of $19.0 million, based on the closing price of OncoCyte common stock of $2.25 per share on December 31, 2019.

For the three months ended June 30, 2020, Lineage recorded a realized gain of $2.1 million due to sales of OncoCyte shares in the period. In the same period, Lineage also recorded an unrealized loss of $4.0 million related to its OncoCyte shares. The unrealized loss is comprised of $2.2 million related to the difference between the book cost basis of OncoCyte shares sold in the period versus the applicable prior month's ending OncoCyte stock price and an additional $1.8 million related to the shares remaining at June 30, 2020 and the decrease in OncoCyte's stock price from $2.45 at March 31, 2020 to $1.91 at June 30, 2020. For the three months ended June 30, 2019, Lineage recorded an unrealized loss of $21.4 million due to the decrease in OncoCyte's stock price from $3.95 per share at March 31, 2019 to $2.49 per share at June 30, 2019.

For the six months ended June 30, 2020, Lineage recorded a realized gain of $3.1 million due to sales of OncoCyte shares in the period. In the same period, Lineage also recorded an unrealized loss of $4.2 million related to its OncoCyte shares. The unrealized loss is comprised of $3.7 million related to the difference between the book cost basis of OncoCyte shares sold in the period versus the applicable prior month's ending OncoCyte share price and an additional $0.5 million related to the shares remaining at June 30, 2020 and the decrease in OncoCyte's stock price from $2.25 at December 31, 2019 to $1.91 at June 30, 2020. For the six months ended June 30, 2019, Lineage recorded an unrealized gain of $16.3 million due to the increase in OncoCyte's stock price from $1.38 per share at December 31, 2018 to $2.49 per share at June 30, 2019.

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.

*Marketable equity securities* - We also account for the shares we hold in HBL and AgeX as marketable equity securities, carried at fair market value on our consolidated balance sheets. For the three and six months ended June 30, 2020, Lineage recorded realized gains of $0.4 million and $0.6 million, respectively, due to sales of AgeX shares in the period. Sales of HBL securities were negligible. For the three and six months ended June 30, 2019, there were no significant sales of HBL or AgeX shares.

For the three and six months ended June 30, 2020, we recorded unrealized losses of $0.2 million and $1.2 million, respectively. For the three months ended June 30, 2020, a majority of the unrealized loss was related to the difference between the book cost basis of AgeX shares sold in the period versus the applicable prior month's ending AgeX stock price. For the six months ended June 30, 2020, $0.4 million of the unrealized loss was related to the difference between the book cost basis of AgeX shares sold in the period versus the applicable prior month's ending AgeX share price and an additional $0.8 million was related to the AgeX shares remaining at June 30, 2020 and the decrease in AgeX's stock price from $1.82 at December 31, 2019 to $0.95 at June 30, 2020.

For the three and six months ended June 30, 2019, we recorded an unrealized loss of $0.6 million and a gain of $1.3 million, respectively, due to changes in fair market value of the marketable equity securities from March 31, 2019 to June 30, 2019 and December 31, 2018 to June 30, 2019.

*Other income (expense), net* - Other income (expense), net, in 2020 and 2019 consist primarily of net foreign currency transaction gains and losses recognized by Cell Cure and ESI, changes in the fair value of the Cell Cure Warrants, dividend income and interest income, net. Foreign currency transaction gains and losses for the periods presented are principally related to the remeasurement of the US 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 June 30, 2020, 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 June 30, 2020. 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 (see Note 3). 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.

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, 2019, a portion of the valuation allowance was released as it relates to Lineage's indefinite lived assets that can be used against the indefinite lived liabilities. The amount of the valuation allowance released was $7.4 million; 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 six months ended June 30, 2020, Lineage did not record any provision or benefit for income taxes, as Lineage had taxable income related to a gain on the sale of OncoCyte shares in the period. This taxable income was offset by net operating loss carryforwards.

For the three and six months ended June 30, 2019, Lineage recorded a $1.2 million and $5.6 million valuation allowance release and corresponding tax benefit, respectively, that were primarily related to state research and development credits, including federal net operating losses generated for the three and six months ended June 30, 2019, both of which are available and indefinite in nature.

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

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

**Liquidity and Capital Resources**

At June 30, 2020, we had $20.3 million of cash, cash equivalents and marketable equity securities on hand, which includes our investments in HBL, AgeX and OncoCyte. We may use our marketable equity securities for liquidity, as necessary, and as market conditions allow. The market value may not represent the amount that could be realized in a sale of investment shares due to various market and regulatory factors, including trading volume or market depth factors and volume and manner of sale restrictions under Federal securities laws, prevailing market conditions and prices at the time of any sale, and subsequent sales of securities by the entities. In addition, the value of our marketable equity securities may be significantly and adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Since inception, we have incurred significant operating losses and have funded our operations primarily through the issuance of equity securities, the sale of common stock of our former subsidiaries, AgeX and OncoCyte, payments from research grants, royalties from product sales and sales of research products and services. At June 30, 2020, we had an accumulated deficit of $288.3 million, working capital of $38.7 million and shareholders' equity of $97.7 million. We evaluated the projected cash flows for Lineage and our subsidiaries, and we believe that our $20.3 million in cash, cash equivalents and marketable equity securities and our access to additional capital through the Sales Agreement at June 30, 2020, 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.

If the promissory note issued by Juvenescence in favor of Lineage discussed in Note 5 to our consolidated financial statements included elsewhere in this Report is converted into equity securities of Juvenescence prior to its maturity date, the Juvenescence equity securities may be marketable securities that Lineage may use to supplement its liquidity, as needed. If such promissory note is not converted, it is payable in cash, plus accrued interest, at maturity on August 30, 2020. The value of the promissory note is $24.4 million as of June 30, 2020.

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

The COVID-19 pandemic has impacted patient enrollment in our OpRegen Phase 1/2a multicenter clinical trial and the VAC2 Phase 1 multicenter clinical trial. In particular, we have seen sites pause enrollment to focus on, and direct resources to, the COVID-19 pandemic. Additionally, patients may choose not to enroll or continue participating in clinical trials as a result of the pandemic. We are unable to predict with confidence the duration of such patient enrollment delays and difficulties. If patient enrollment is delayed for an extended period of time, such clinical trials could be delayed or otherwise adversely affected. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials could result in significant delays.

We may be inclined to increase spending later in the year to accelerate clinical trial activities and try to mitigate the impact of the COVID-19 related enrollment 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 $9.3 million for the six months ended June 30, 2020 primarily reflects the loss from operations of $13.8 million less the changes in assets and liabilities of $1.1 million. These items were offset primarily by non-cash expenses of $1.3 million of depreciation and amortization and $1.2 million for stock-based compensation. The unrealized loss on marketable securities is a non-cash item that had no effect on cash flows.

Net cash used in operating activities of $19.0 million for the six months ended June 30, 2019 primarily reflects the loss from operations of $23.6 million, offset primarily by non-cash expenses of $2.2 million for stock-based compensation and $1.5 million of depreciation and amortization. The unrealized gains on equity method investments and marketable securities and deferred tax benefit are non-cash items that had no effect on cash flows.

***Cash flows provided by investing activities***

Cash provided by investing activities of $12.0 million for the six months ended June 30, 2020 was associated primarily with receipts of $10.9 million from sales of a portion of our OncoCyte holdings and $1.0 million in sales of a portion of our AgeX holdings.

Cash provided by investing activities of $2.8 million for the six months ended June 30, 2019 was associated primarily with the receipt of $3.1 million of cash that Asterias had on the closing date of the Asterias Merger, offset by $0.4 million in purchases of equipment and other assets.

***Cash flows provided by financing activities***

Cash provided by financing activities of $0.5 million for the six months ended June 30, 2020 was associated primarily with proceeds of $0.5 million from a PPP loan.

Cash provided by financing activities of $0.5 million for the six months ended June 30, 2019 was associated primarily with $0.7 million in landlord reimbursements for tenant improvements, offset by $0.1 million in common shares received and retired for employee taxes paid.

**Off-Balance Sheet Arrangements**

As of June 30, 2020 and December 31, 2019, 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 Securities Exchange Act of 1934 ("Exchange Act"). Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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, 2019, as filed with the Commission on March 12, 2020.

**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, 2019 were $38.9 million and our total operating losses for the six months ended June 30, 2020 were $13.8 million and we had an accumulated deficit of $288.3 million as of June 30, 2020. 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 $6.1 million during the six months ended June 30, 2020, and $17.9 million during the fiscal year ended December 31, 2019. 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 June 30, 2020, we had $20.3 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 and our access to additional capital through the Sales Agreement as of June 30, 2020 will be sufficient to fund our planned operations for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we may use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Any equity capital raise could result in the dilution of the interests of shareholders or may otherwise limit our ability to finance further in the future, which may negatively impact our business and operations. Any debt capital financing may involve covenants that restrict our operations, including limitations on additional borrowing and on the use of our assets. If we raise capital through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to us. There can be no assurance that we will be able to raise capital on favorable terms, or at all, or at times and in amounts needed to successfully finance product development, clinical trials, and general operations.

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

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

The defendants specifically deny all allegations in the litigation and intend to defend it vigorously. However, any adverse ruling in this case could result in additional payments. Additional lawsuits arising out of or relating to the merger agreement and/or the merger may be filed in the future.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally known as the Tax Cuts and Jobs Act (the "2017 Tax Act"), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act could be repealed or modified in future legislation. 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 to offset future taxable income may be subject to limitations.***

As of December 31, 2019, we had net operating loss ("NOL") carryforwards for U.S. federal and state tax purposes of approximately $164.0 million and $121.1 million, respectively. A portion of the federal and state NOL carryforwards will begin to expire, if not utilized, in varying amounts between 2027 and 2039. NOLs that expire unused will be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited. It is uncertain if and to what extent various states will conform to the federal tax law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

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

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

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

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

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

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

We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third-party vendors who may have, or could gain, access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

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

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

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

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

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

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

We have equity investments in two publicly traded companies, OncoCyte and AgeX. As of June 30, 2020, the value of our investments in OncoCyte and AgeX was approximately $6.9 million and $0.2 million, respectively, based on their closing stock prices as of that date. If these companies were to have delays in clinical trials or commercialization activities or otherwise realize the specific business, regulatory and other risks applicable to them, the value of their common stock and the valuation of our investment could be negatively affected. If these companies were to fail and ultimately cease operations, we may lose the entire value of our investments. 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.

**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.

**We received a loan under the Paycheck Protection Program of the CARES Act, and all or a portion of the loan may not be forgivable.***

In April 2020, we received a loan for $523,000 from Axos Bank under the PPP contained within the new CARES Act. The PPP loan has a term of two years, is unsecured, and is guaranteed by the U.S. Small Business Administration (SBA). The loan carries a fixed interest rate of one percent per annum, with the first six months of interest deferred. Under the CARES Act, we will be 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 we maintain our number of employees 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 are adhered to by us, all or part of such loan could be forgiven. However, we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP loan will ultimately be forgiven by the SBA. Any forgiven amounts will not be included in our taxable income.

## Risks Related to Government Regulation

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

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, (“HITECH”) and their implementing regulations, which imposes certain requirements on covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, relating to the privacy, security, and transmission of individually identifiable health information;

- The Physician Payments Sunshine Act which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

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

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

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

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

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

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

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

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

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

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

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

- We will face similar regulatory issues in foreign countries.

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

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

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

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

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

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

**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, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. 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;
- created new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the Public Health program;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Centers for Medicare & Medicaid Services ("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 remain judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, and eliminating the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the 2017 Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020.This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding 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, advertising and promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that may prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place greater restrictions on the marketing practices of health care companies. Health care companies are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. Risks relating to compliance with laws and regulations may be heightened as we bring products to the market globally.

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

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

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

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

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

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

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

Even after initial FDA or foreign regulatory agency approval has been obtained, further studies may be required to provide additional data on safety or to gain approval for the use of a product as a treatment for clinical indications other than those initially targeted. Use of a product during testing and after marketing could reveal side effects that could delay, impede, or prevent marketing approval, result in a regulatory agency-ordered product recall, or in regulatory agency-imposed limitations on permissible uses or in withdrawal of approval. For example, if the FDA or foreign regulatory agency becomes aware of new safety information after approval of a product, it may require us to conduct further clinical trials to assess a known or potential serious risk and to assure that the benefit of the product 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 particular, data presented from the Phase 1/2a open-label trial showed that both the surgical procedure and the OpRegen cells were generally well tolerated, with no treatment-related systemic serious adverse events reported to date in the first nine patients. The best corrected visual acuity of these patients remained relatively stable. In addition, the imaging of patients 8 and 9 suggested early signs of structural improvement within the retina. However, we do not know how OpRegen will perform in future clinical trials.

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

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 acute spinal cord injuries, and VAC2 is in a Phase 1 clinical trial in non-small cell lung cancer. As a result of these and other future clinical trials for these product candidates or any of our future product candidates may make our decision as to which product candidates to focus on more difficult and we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential or likelihood of success.

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

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

**The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, other health care providers and others in the medical community.**

Even if a product candidate obtains regulatory approval, its commercial success will depend in part on physicians, patients, third-party payors, other health care providers and others in the medical community accepting our product candidates as medically useful, cost-effective, and safe. Any product we bring to the market may not gain market acceptance by such parties. The degree of market acceptance of any of our products will depend on several factors, including without limitation:

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;

- the cost of treatment, 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. We do not currently have nor do we plan to acquire the infrastructure or capability to internally manufacture Renevia or our other HyStem products on a clinical or commercial scale. Although we have manufacturing capability through Cell Cure for OpRegen in Israel, we will need greater manufacturing capacity if we are to successfully commercialize our products. Unless we can raise the capital required to construct our own commercial scale manufacturing facilities and can develop the expertise to manage and operate a manufacturing facility of our own, we may need to rely on third-party manufacturers to manufacture any products we develop. There is no assurance that we will be able to identify manufacturers on acceptable terms or at all. Regardless of whether we do our own manufacturing or rely on third parties to manufacture products for us, we will face risks related to the manufacture of our products including these risks:

- We or any third-party manufacturers might not timely formulate and manufacture our products or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- We or any third-party manufacturers may not execute our manufacturing procedures appropriately.
- Any third-party manufacturers we engage may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products on a commercial scale.
- We or any third-party manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices (“cGMP”), and other government regulations and corresponding foreign standards. We will not have control over third-party manufacturers’ compliance with applicable regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.
- We may not obtain licenses for third-party intellectual property rights needed by manufacturers to produce our products.
- Third-party manufacturers could breach or terminate their agreements with us.
- We or third-party manufacturers may experience manufacturing difficulties as a result of resource constraints, labor disputes, unstable political environments, natural disasters, public health crises such as pandemics and epidemics, political crises such as terrorism, war, political insecurity or other conflict, or other events outside of our or our third-party manufacturers control (including as a result of actual or threatened public health emergencies and outbreaks of disease such as the current COVID-19 pandemic). This may result in business closures that affect us and our third-party manufacturers.

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

If we or any third-party manufacturers we may engage were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials or to the medical market place would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require us to either commence new clinical trials at additional expense or terminate clinical trials completely. Each risk could delay our clinical trials, any approval of our product candidates by the FDA, or the commercialization of our product candidates, and could result in higher costs or deprive us of potential product revenue.

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

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

**We may not secure a commercialization partner for Renevia.**

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

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

**The ongoing COVID-19 pandemic 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 spread in 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 has impacted patient enrollment in our OpRegen Phase 1/2a multicenter clinical trial and the VAC2 Phase 1 multicenter clinical trial. In particular, some sites have paused enrollment to focus on, and direct resources to, the COVID-19 pandemic, while at other sites, patients are choosing not to enroll or continue participating in the clinical trial as a result of the pandemic. We are unable to predict with confidence the duration of such patient enrollment delays and difficulties. If patient enrollment is delayed for an extended period of time, such clinical trials could be delayed or otherwise adversely affected. Our inability to enroll 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. As a result, we may experience new or additional delays and difficulties in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

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

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted for the U.K. to leave the EU. The U.K. formally left the EU on January 31, 2020, which is commonly referred to as Brexit. The U.K. is subject to a transition period until December 31, 2020 (the “Transition Period”), during which EU rules continue to apply. During the Transition Period, negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period. Due to the COVID-19 global pandemic, negotiations between the U.K. and the EU that were scheduled for March and April were either being postponed or occurring in a reduced forum via video conference. There is, therefore, an increased likelihood that the Transition Period may need to be extended beyond December 31, 2020 (although it remains the position of the UK government that it will not be extended).

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the European Medicines Agency (the “EMA”) relocated to Amsterdam from London. Following the Transition Period, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the U.K., the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the affected nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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

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

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

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

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

**Cell Cure has received Israeli government grants for certain of its research and development activities. The terms of these grants may require Cell Cure to seek approvals and to satisfy specified conditions to manufacture products and transfer or license grant-supported technologies outside of Israel. In the context of such approvals, Cell Cure will be required to pay penalties in addition to the repayment of the grants. Such grants are applied for on a yearly basis and may not be available or only partially granted in the future, which would increase our costs.**

Cell Cure has received Israeli government grants for certain of its research and development activities. The terms of these grants require prior approval and the satisfaction of specified conditions to manufacture products and transfer or license technologies outside of Israel.

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), and the regulations, guidelines, rules, procedures and benefit tracks thereunder (collectively, the "Innovation Law"), annual research and development programs that meet specified criteria and are approved by a committee of the Israel Innovation Authority ("IIA") are eligible for grants. The grants awarded are typically up to 50% of the project's expenditures, as determined by the IIA committee and subject to the benefit track under which the grant was awarded. A company that receives a grant from the IIA ( a "Grant Recipient"), is typically required to pay royalties to the IIA on income generated from products incorporating know-how developed using such grants (including income derived from services associated with such products) or on all revenues of the Grant Recipient (depending upon the terms of the approval letters issued by the IIA), until 100% of the U.S. dollar-linked grant plus annual LIBOR interest is repaid. In general, the rate of such royalties varies between 3% to 5%.

The obligation to pay royalties is contingent on actual revenues being generated from such products and services or actual revenues being generated by the Grant Recipient in general (as the case may be). In the absence of such revenues, no payment of royalties is required. It should be noted that the restrictions under the Innovation Law will continue to apply even after the repayment of such royalties in full by the Grant Recipient including restrictions on the sale, transfer or licensing to a foreign entity of know-how developed as part of the programs under which the grants were given.

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

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

Part of Cell Cure's research and development efforts have been financed, partially, through grants that it has received from the IIA and when we acquired our holdings in Cell Cure, we undertook in writing, vis-à-vis the IIA, to abide by, and to ensure the abidance of Cell Cure to, the Innovation Law. We therefore must comply with the requirements of the Innovation Law and related regulations. As of December 31, 2019, we received approximately $14.5 million of such grants.

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

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

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

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

**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 the 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 $14.0 million of funding from CIRM to support clinical development of OPC1. We intend to apply for additional CIRM grants, if available; however, we cannot provide any assurance that such grants will be awarded. If we are unable to obtain another CIRM grant, we will need to raise funds through other mechanisms to support future clinical studies of OPC1, which may take additional time and effort. If capital is not immediately available, this may force us to amend, delay, or discontinue the clinical trial and development work for OPC1 until funding is secured.

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

If we are able to develop our product candidates and obtain necessary regulatory approvals, we may need to rely on marketing, selling or distributing 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 able to negotiate distribution or sales agreements with third parties on favorable terms to justify our investment in our products or achieve sufficient revenues to support our operations.

## Risks Pertaining to Our Common Shares

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

The market price of our common shares, like that of the shares of many biotechnology companies, has been highly volatile. The price of our common shares may rise rapidly in response to certain events, such as the commencement of clinical trials of an experimental new therapy, even though the outcome of those trials and the likelihood of ultimate FDA approval of a therapeutic product remain uncertain. Similarly, prices of our common shares may fall rapidly in response to certain events such as unfavorable results of clinical trials or a delay or failure to obtain FDA approval. The failure of our earnings to meet analysts' expectations could result in a significant rapid decline in the market price of our common shares.

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

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

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

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

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

Our directors, executive officers and their affiliates, in the aggregate, owned approximately 28% of our outstanding common shares as of December 31, 2019. As a result, these shareholders, if acting together, will be able to heavily influence or control matters requiring approval by our shareholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be averse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deter certain public investors from purchasing our common shares and might ultimately affect the market price of our common shares.

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

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

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

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

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

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

We are currently authorized to issue an aggregate of 252,000,000 shares of capital stock consisting of 250,000,000 common shares and 2,000,000 "blank check" preferred shares, which means we may issue, without stockholder approval, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common shares respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common shares. Any preferred shares may also be convertible into common shares on terms that would be dilutive to holders of common shares. Our subsidiaries may also issue their own preferred shares with a similar impact on our ownership of the subsidiaries.

As of June 30, 2020, Lineage had 149,831,347 common shares outstanding, 16,795,105 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans, 123,600 common shares reserved for issuance upon the vesting and settlement of restricted stock units under our equity incentive plan, and 1,089,900 common shares subject to warrants.

In addition, in May 2020 we entered into a Controlled Equity Offering$^{SM}$ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which we may, but are not obligated to, raise up to $25.0 million of common shares from time to time in at-the-market transactions under the Sales Agreement. As of June 30, 2020, no sales had been made 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.

**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*† | Second Amendment to Clinical Trial and Option Agreement dated May 6, 2020 between Cancer Research UK, Cancer Research Technology Limited ("CRT"), Asterias Biotherapeutics, Inc. and Registrant. | | | | |
| 10.2*† | Agreement dated May 6, 2020 between CRT and Registrant | | | | |
| 31.1* | Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002 | | | | |
| 31.2* | Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002 | | | | |
| 32.1# | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | |
| 101* | Interactive Data File | | | | |
| 101.INS* | XBRL Instance Document | | | | |
| 101.SCH* | XBRL Taxonomy Extension Schema | | | | |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase | | | | |
| 101.DEF* | XBRL Taxonomy Extension Definition Document | | | | |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase | | | | |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase | | | | |

* Filed herewith

# Furnished herewith

† Portions of this exhibit have been omitted because the omitted information is: (i) not material; and (ii) would likely cause competitive harm to the registrant if publicly disclosed

**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: August 6, 2020

*/s/ Brian M. Culley*

Brian M. Culley
Chief Executive Officer

Date: August 6, 2020

*/s/ Brandi L. Roberts*

Brandi L. Roberts
Chief Financial Officer

**Exhibit 10.1**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE LINEAGE CELL THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION: (A) IS NOT MATERIAL AND (B) WOULD LIKELY CAUSE COMPETITIVE HARM TO LINEAGE CELL THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.**

# SECOND AMENDMENT TO CLINICAL TRIAL AND OPTION AGREEMENT

**THIS SECOND AMENDMENT** (this "**Amendment**") is made the 6th day of May, 2020 ("**Amendment Effective Date**")

**BETWEEN**:

**CANCER RESEARCH UK** a company limited by guarantee registered under number 4325234 and a charity registered under number 1089464 of 2 Redman Place, Stratford, London, E20 1JQ, England (the **"Charity"**);

**CANCER RESEARCH TECHNOLOGY LIMITED** a company registered in England and Wales with number 1626049 and registered office at 2 Redman Place, Stratford, London, E20 1JQ, England (**"CRT"**);

**ASTERIAS BIOTHERAPEUTICS, INC.**, a Delaware corporation and subsidiary of Lineage Cell Therapeutics, Inc., a California corporation, with its principal place of business at 2173 Salk Avenue, Suite 200, Carlsbad, CA 92008, USA ("**Asterias**"); and

**LINEAGE CELL THERAPEUTICS, INC.**, a California corporation with its principal place of business at 2173 Salk Avenue, Suite 200, Carlsbad, CA 92008, USA ("**Lineage Cell**" and the "**Company**," and, together with Asterias, the Charity and CRT, the "**Parties**").

**WHEREAS:**

**(A)** The Parties entered into that certain Clinical Trial and Option Agreement dated September 8, 2014, as amended by an amendment agreement made between the Charity, CRT and Asterias dated September 8, 2014 (the "**Agreement**")..

**(B)** The Parties desire to amend the Agreement to provide for the Company's early exercise of the Option (as defined in the Agreement) and the Charity's continued conduct of the Clinical Trial.

**NOW IT IS HEREBY AGREED** as follows:

## 1. DEFINITIONS AND INTERPRETATION

1.1 In this Amendment, capitalized terms used but not defined shall have the meaning attributed to them in the Agreement.

1.2 In this Amendment:

1.2.1 unless the context requires otherwise, all references to a particular Clause, paragraph or Schedule shall be references to that clause, paragraph or schedule, of or to this Amendment;

1.2.2 unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;

1.2.3 unless the contrary intention appears, words denoting persons shall include any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality;

1.2.4 reference to any statute or regulation includes any modification or re-enactment of that statute or regulation, provided that the modification or re-enactment does not diminish the rights or extend the obligations of any Party; and

1.2.5 references to the words "include" or "including" shall be construed without limitation to the generality of the preceding words.

**2. AMENDMENTS**

2.1 Clause 1.1 of the Agreement is hereby revised to delete in its entirety the definition of "Signature Period."

2.2 The following two clauses are hereby added to the Agreement as Clauses 3.14 and 3.15 respectively:

3.14 Promptly following the Amendment Effective Date, the Charity and the Company acting reasonably and in good faith shall agree a plan ("**3.14 Plan**") under which the Charity shall provide to the Company:

3.14.1 all manufacturing Know-How, information, and regulatory information in the Charity's Control that is related to the Product Manufacturing Process, including batch records (collectively, the "**Product Manufacturing Process Information**");

3.14.2 reasonable access to personnel responsible for the conduct and control of the Clinical Trial and the generation and implementation of the Product Manufacturing Process Information;

3.14.3 all Clinical Trial Results existing as of the Amendment Effective Date;

3.14.4 copies of all material regulatory filings (including clinical trial authorisations) and correspondence with any Regulatory Authority regarding the Product; and

3.14.5 the 3.14 Plan shall include a methodology for the periodic identification and provision to the Company of all data and information that are generated as a result of the Charity continuing to conduct the Clinical Trial under the Agreement and Controlled by the Charity.

3.14.6 The 3.14 Plan shall be reviewed and amended as the Parties acting reasonably may from time to time agree so as to facilitate the implementation of this clause 3.14. The Charity shall at all times during the Clinical Trial use its Commercially Reasonable Efforts to faithfully adhere to the 3.14 Plan.

3.14.7 The Company acknowledges and agrees that save in respect of Data Listings, the Final Report, and data arising from the Clinical Trial that are provided by the Charity to the Company after the Clinical Trial Database Lock Date, the Clinical Trial Results that are provided to the Company under the 3.14 Plan will not be cleaned or validated and therefore should not be relied upon and the Company uses those Clinical Trial Results at its own risk.

3.15 The Company hereby elects pursuant to clause 3.11 of the Agreement to receive a Full Clinical Study Report instead of a Report Synopsis. For the avoidance of doubt, the Charity will provide a Full Clinical Study Report within [***] after the Clinical Trial Database Lock Date and the Company's payment of the Option Fee pursuant to clause 4.1.2 of that certain License Agreement entered into by CRT and the Company on even date herewith shall be credited against the Full CS Report Fee.

2.3 Clauses 7.4 and 7.5 of the Agreement are hereby deleted in their entirety and replaced with the following:

7.4. Effective on the Amendment Effective Date: (i) the Company hereby submits its Exercise Notice to CRT to exercise the Option to enter into the License; and (ii) the Parties agree to execute and enter into the License on the Amendment Effective Date (the **"License Agreement**").

2.4 Clause 11.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

11.1 Unless terminated earlier pursuant to the provisions hereunder, and except as otherwise provided hereunder, this Agreement shall remain in full force and effect from the Commencement Date until the date that the Company receives the Final Report or, if later, the Full Clinical Study Report.

2.5 The following is hereby added to the end of Clause 11.5:

11.5 Upon either Party's reasonable request, and without affecting the Charity's rights and powers under this Agreement the Parties shall discuss in good faith the merits of continuing versus winding down the Clinical Trial, taking into consideration, without limitation, the results of the trial data generated to date, trial recruitment, and resource allocation.

2.6 The address of the Company in Clause 16.1 is hereby deleted in its entirety and replaced with the following:

Lineage Cell Therapeutics, Inc.
2173 Salk Avenue, Suite 200
Carlsbad, CA 92008
Contact: Legal
Email: legal@lineagecell.com

**3. ASSIGNMENT**

3.1 For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Asterias hereby assigns to Lineage Cell, and Lineage Cell hereby accepts and assumes, all of Asterias' rights and obligations under the Agreement, including all rights, claims, and causes of action of Asterias under the Agreement existing as of the Amendment Effective Date. All such assigned rights shall inure to the benefit of and be enforceable by Lineage Cell, and all such obligations shall be binding on and be enforceable against Lineage Cell by the Charity and CRT, in each case in accordance with the terms of the Agreement. All references in the Agreement to "the Company" shall, as of the Amendment Effective Date, be references to Lineage Cell.

3.2 CRT and the Charity hereby agree and consent to the assignment and transfer set forth in clause 3.1.

**4. ENTIRE AGREEMENT**

4.1 Except as expressly modified herein, all terms and conditions set forth in the Agreement, as in effect on the Amendment Effective Date, shall remain in full force and effect. The Agreement as modified by this Amendment, together with the License Agreement, embodies and sets forth the entire agreement and understanding of the Parties and supersedes all prior oral or written agreements, understandings or arrangements relating to the subject matter of this Amendment. No party has relied on any statement in deciding to enter into this Amendment that is not expressly set out in this Amendment.

**5. SEVERABILITY**

5.1 If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Amendment, or the application hereof to any circumstances, to be invalid or to be unenforceable in a final non-appealable order, the remainder of this Amendment and the application of such term, provision or condition or part thereof to circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each of the other terms, provisions and conditions of this Amendment shall be valid and enforceable to the fullest extent permissible by law.

**6. EXECUTION**

6.1 This Amendment may be executed in any one or more number of counterpart agreements, and as scanned email attachments, and all signatures and counterparts so exchanged shall be considered as original and shall be deemed to form part of and together constitute this Agreement.

**7. GOVERNING LAW AND JURISDICTION**

7.1 This Amendment is governed by and construed in accordance with English Law and each Party hereby agrees to submit to the exclusive jurisdiction of the English Courts in respect of any claim or dispute arising out of this Amendment or its subject matter.

**IN WITNESS** whereof this Agreement has been executed by duly authorised officers of the Parties on the day first above written.

Signed by: */s/ Tony Hickson*
Name: Tony Hickson
Title: Chief Business Officer

For and on behalf of
**CANCER RESEARCH TECHNOLOGY LIMITED**

Signed by: */s/ Dr Nigel A Blackburn*
Name: Dr Nigel A Blackburn
Title: Director of Drug Development

For and on behalf of
**CANCER RESEARCH UK**

Signed by: */s/ Brandi Roberts*
Name: Brandi Roberts
Title: Chief Financial Officer

For and on behalf of
**ASTERIAS BIOTHERAPEUTICS, INC.**

Signed by: */s/ Brian M. Culley*
Name: Brian M. Culley
Title: Chief Executive Officer

For and on behalf of
**LINEAGE CELL THERAPEUTICS, INC.**

**Exhibit 10.2**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE LINEAGE CELL THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION: (A) IS NOT MATERIAL AND (B) WOULD LIKELY CAUSE COMPETITIVE HARM TO LINEAGE CELL THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.**

**THIS AGREEMENT is made the 6th day of May 2020**

**BETWEEN:**

**(1)** **CANCER RESEARCH TECHNOLOGY LIMITED**, a company registered in England and Wales under number 1626049 with registered office at 2 Redman Place, Stratford, London, E20 1JQ (**"CRT"**);

**(2)** **LINEAGE CELL THERAPEUTICS, INC.**, a California company with principal place of business at 2173 Salk Avenue, Suite 200, Carlsbad, CA 92008, USA (the **"Company"**).

**RECITALS**

**(A)** CRT is a wholly owned subsidiary of Cancer Research UK (the "**Charity**") and is, by arrangement with the Charity, responsible for the management, exploitation and commercialisation of intellectual property generated by the Charity or using funding from the Charity.

**(B)** Pursuant to a Clinical Trial and Option Agreement between CRT, the Charity and the Company dated September 8, 2014, as amended on even date hereof, attached at Appendix 2 (the "**CTOA**") the Charity is conducting the Clinical Trial (as defined below) and has assigned (and agrees to and will assign if the assignment of future rights in prohibited by applicable law) the results of such Clinical Trial and all intellectual property therein to CRT.

**(C)** CRT has agreed to grant the Company a licence under the Licensed Intellectual Property (as defined below) upon the terms and conditions set out in this Agreement.

**(D)** CRT and the Company have agreed to enter into this Agreement prior to the Option Period (as defined in the CTOA) and Signature Period (as defined in the CTOA).

**OPERATIVE PROVISIONS**

**1. INTERPRETATION**

1.1 In this Agreement except where the context requires otherwise, the following words and expressions shall have the following meanings:

| | |
|---|---|
| "**Accountancy Opinion"** | means the opinion of an independent United Kingdom chartered accountant appointed by agreement between the Parties or in default of such agreement within twenty one (21) days of either Party seeking in writing to the other to appoint such accountant, at the request of either Party, by the President for the time being of the Institute of Chartered Accountants in England and Wales, referred to in Clauses 1, 6.3 and 24.1. |

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| **“Affiliate”** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **“Affordable Price”** | means in relation to a Licensed Product: (i) a determination by the UK Pricing Authority that such Licensed Product should be used within the NHS; and/or (ii) approval by the UK Pricing Authority of the price proposed by the Company or its Sub-Licensee in relation to sales of that Licensed Product in the United Kingdom (or one or more constituent countries thereof). |
| **“Agreement”** | means this agreement and each of the Appendices as amended from time to time in accordance with Clause 21. |
| **“BLA”** | means, in relation to any Licensed Product, a biologics licence application, supplementary biologics licence application or any of their equivalents filed with the United States Food and Drugs Administration (FDA) or any successor to it, a marketing authorisation application or its equivalent filed with the European Medicines Agency (EMEA) or any successor to it, or a marketing authorisation application or a product licence application or equivalent filed with the relevant Regulatory Authority in any one or more countries or regions within the Territory. |
| **“Clinical Trial”** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **“Clinical Trial Results”** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **“Commencement”** | means the first dosing of a human subject in a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial (as context requires). |
| **“Company Combination Patent Rights”** | has the same meaning as that ascribed to that phrase in the CTOA. |
| “**Company Foreground Patent Rights**” | Means those of the Company Patent Rights with applications solely or primarily related to the Product and Related Products. |
| **“Company Intellectual Property”** | has the same meaning as that ascribed to that phrase in the CTOA. |

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| **“Company Patent Rights”** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **“Competing Programme”** | means a research and development programme, other than one conducted by the Charity or CRT or any of their Affiliates under the CTOA, under which human subjects in a clinical trial have or are to be administered a cell based therapy that incorporates the hTERT Antigen . |
| **“Confidential Information”** | means all information relating to the manufacturing methods, product specifications, customers, suppliers, business partners, clients, finances, operating budgets and forecasts, business plans and products, and the Development Plan, as revised or amended from time to time (in each case actual or prospective) of a Party which is not in the public domain and which is acquired by the other Party pursuant to this Agreement. |
| “**Contributors**” | has the same meaning as that ascribed to that phrase in the CTOA. |
| “**Control**” | means the possession (directly or indirectly) of fifty per cent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions of such entity through the ownership of securities or by contract or otherwise and “**Controls**” and “**Controlled by**” shall be construed accordingly. |
| **“Coronavirus Related Product”** | means a Related Product that is modified to express one or more antigens specifically intended to treat COVID-19 or other diseases caused by coronaviruses. |
| **“Coronavirus Related Licensed Product”** | means a Related Licensed Product which contains a Coronavirus Related Product, whether or not as the sole active ingredient. |
| **“Currency”** | means pounds sterling or such other currency as CRT may reasonably specify from time to time. |
| **“Data Exclusivity Period”** | means any period of clinical trial data or other regulatory exclusivity, together with any such periods under national implementations in the European Union of Article 10.1 of Directive 2001/EC/83 and all equivalents elsewhere in the Territory. |

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| **"Data Listings"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"Development Plan"** | means the development plan at Appendix 1 (as the same shall be updated in accordance with Clause 3.1) which describes: (i) the steps to be taken to develop Licensed Products (including at least one Primary Licensed Product) within the Field and the Territory; (ii) the relevant timescales within which such steps will be taken; and (iii) the estimated costs associated with each step. |
| **"Effective Date"** | means the date this Agreement is made. |
| **"Exclusive Results"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"Expert Opinion"** | means the opinion of an independent expert appointed by agreement between the Parties or in default of such agreement within twenty one (21) days of either Party seeking in writing to the other to appoint such expert, by the President for the time being of the Association of the British Pharmaceutical Industry referred to in Clauses 12.3 and 24.1. |
| **"Field"** | means the use of the Product and/or any Related Product(s) in immunotherapy applications using [***] for the treatment, prophylaxis, prevention and/or cure of human disease and conditions. |
| **"Final Report"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"First Commercial Sale"** | means, with respect to a Licensed Product, the first transfer or disposition for value of such Licensed Product by or on behalf of the Company or a Sub-Licensee or an Affiliate of either of them, after all relevant Regulatory Authorisations for the transfer or disposition of such Licensed Product have been obtained in respect of the relevant region or country. |
| **"FTO Royalties"** | means, on a Licensed Product by Licensed Product basis, any royalties on the sale of a Licensed Product payable by the Company under a license from a third party (after the application of any royalty stacking provisions contained therein) to the extent that: (i) but for such license the manufacture, sale, use or distribution of such Licensed Product would infringe the Intellectual Property Rights of such third party licensor, and (ii) such royalty payable is reasonably attributable to the grant of rights used in respect of a Licensed Product and not to unrelated rights also granted pursuant to the same agreement and/or by the same third party licensor. |

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| **"hTERT Antigen"** | has the same meaning as that ascribed to that phrase in the CTOA |
| **"Indication"** | means a disease classification block as defined within the 'International Statistical Classification of Diseases and Related Health Problems' as published from time to time by the World Health Organization (e.g. "C50 Malignant neoplasm of Breast", "C92 Myeloid leukaemia", "B20 Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases", "M34 Systemic sclerosis"). |
| **"Investigational Medicinal Product"** or **"IMP"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"Intellectual Property Rights"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"Know-How"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"Licensed Intellectual Property"** | means the Clinical Trial Results and all Intellectual Property Rights therein. |
| **"Licensed Product"** | means any Primary Licensed Product and any Related Licensed Product |
| **"Major Markets"** | means United States of America, [***]. |
| **"Milestone Event"** | has the meaning specified in Clause 4.2. |
| **"Milestone Payments"** | has the meaning specified in Clause 4.2. |
| **"Net Sales Value"** | means, in relation to Licensed Product:<br><br>the gross amount invoiced by the Company or Sub-Licensee or Affiliate of the Company or a Sub-licensee less any value added tax or other sales tax, transport charges (including transport insurance) and costs of packaging to the extent that any of those items are included as separate items in the amount so invoiced, and after deducting any allowances for lost or damaged items or permitted returns, and discounts allowed and rebates given in the normal course of trade, and in the event of more than one such sale, the first such sale; |

| | |
|---|---|
| **"New Company IP"** | means any Intellectual Property Rights developed by or on behalf of the Company on or after the Effective Date that directly relate to a Licensed Product and its use. |
| **"Non-Exclusive Results"** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **"Oncology Indication"** | means an Indication in the range C00 – D48 (e.g. "C50 Malignant neoplasm of Breast", "C92 Myeloid leukaemia"). |
| **"Party"** | means either party to this Agreement and "**Parties**" means both of them. |
| **"Patent Rights"** | has the same meaning as ascribed to that phrase in the CTOA. |
| **"Phase II Clinical Trial"** | means a clinical trial of a Licensed Product (or in the adaptation of an existing clinical trial) in any country that would satisfy the requirements of 21 CFR §312.21(b) and is intended to establish dose response and/or preliminary data on the efficacy of Licensed Product and/or route of administration of the Licensed Product. |
| **"Phase III Clinical Trial"** | means a clinical trial of a Licensed Product (or the adaptation of an existing clinical trial) to be a larger scale (than Phase I or Phase II), usually multi-centered trial in any country that would satisfy the requirements of 21 CFR §312.21(c) and is intended to establish the efficacy and safety of the Licensed Product or any other human clinical trial of the Licensed Product intended as a pivotal trial for regulatory approval purposes whether or not such trial is a traditional Phase III trial. |
| **"Phase III Clinical Trial Completion"** | means the date of the last treatment visit of the last human subject under the relevant Phase III Clinical Trial. |
| **"pound"** and **"£"** | means British pound sterling or if England changes its currency during the Term, then a sum equivalent in the new currency based on the spot exchange rate at the date of adoption of the new currency. |
| **"Price Approval"** | means, in those countries in the Territory where Regulatory Authorities may approve or determine pricing and/or pricing reimbursement for pharmaceutical products, such approval or determination. |

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| **"Primary Licensed Product"** | means any product that contains the Product, whether or not as the sole active ingredient; provided that if the Company discontinues development of the Product, "Primary Licensed Product" shall be deemed to mean any product that contains the Related Product, whether or not as the sole active ingredient, as designated by the Company in accordance with Clause 4.8. |
| **"Product"** | has the same meaning as ascribed to that phrase in the CTOA. |
| **"Product Manufacturing Process"** | has the same meaning as ascribed to that phrase in the CTOA. |
| **"Quarter"** | means any of the three-monthly periods commencing on the first day of any of the months of January, April, July, and October in any year and **"Quarterly"** has a corresponding meaning. |
| **"Regulatory Authorisations"** | means all marketing authorisations, approvals, clearances and authorisations that may be required by a Regulatory Authority in any country or region within the Territory prior to Phase II Clinical Trial Commencement and/or Phase III Clinical Trial Commencement and/or commercial sale of the Licensed Product, including any necessary variations thereto, but excluding always any Price Approvals. |
| **"Regulatory Authority"** | means any local or national agency, court, authority, department, inspectorate, minister, ministry official or public or statutory person (whether autonomous or not) of, or of any government of, any country having jurisdiction over this Agreement or either of the Parties or over the development or marketing of medicinal products including, the European Medicines Agency and the European Court of Justice. |
| **"Related Licensed Product"** | means any product that is not a Primary Licensed Product and:<br>(a) which contains a Related Product, whether or not as the sole active ingredient; and/or<br>(b) whose application for a Regulatory Authorisation from a Regulatory Authority in any jurisdiction included the Clinical Trial Results and/or the Final Report and/or the Data Listings or any part of any of them. |

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| **“Related Product”** | has the same meaning as that ascribed to that phrase in the CTOA. |
| **“Signature Fee”** | means the sum of one million, two hundred and fifty thousand pounds (£1,250,000). |
| **“Sub-Licence Revenue”** | means any monies or non-monetary consideration (including securities) receivable from time to time by the Company or an Affiliate in respect of: (i) any sub-licence granted by the Company or an Affiliate under this Agreement; (ii) any licence granted by the Company or an Affiliate (whether under the Company Intellectual Property or otherwise) to sell Licensed Products anywhere in the Territory; and/or (iii) the grant of the right to acquire such a sub-licence or licence, including, in each case, option fees, licence issue fees or other up-front payments, annual licence fees, or other lump sum payments which are attributable to the grant of the rights in question, but excluding: (i) any milestone payments due on the achievement of specific development or sales milestones that are additional to those listed in Clause 4.2; (ii) royalties as referred to in Clause 4.5; (iii) sales to distributors or wholesalers for resale, and sales made by sales agents, where in any such case the sales have already been or will be accounted for to CRT in determining Net Sales Value; and (iv) any money or non-monetary consideration (including securities or licences of patents, know-how, or other intellectual property) received by the Company from an Affiliate, provided that such money or non-monetary consideration shall not reduce the Net Sales Value of any Licensed Product sold by the Company or any Affiliate. In the case of non-monetary Sub-Licence Revenue, the value shall be assessed at the date of receipt of the same by the Company or, at the option of CRT, at the date the non-monetary consideration is realised as monetary and in the absence of agreement by the Parties, the value shall be determined by Accountancy Opinion. |

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| **“Sub-Licensee”** | means any person who is granted: (i) a sub-licence in accordance with Clause 2.3 in respect of the rights granted under this Agreement (and any further tiers of sub-licence there under); and/or (ii) a licence by the Company (whether under the Company Intellectual Property or otherwise) to sell Licensed Products anywhere in the Territory, but shall not mean distributors, wholesalers, and sales agents. |
| **“Term”** | means the term of this Agreement as determined under Clause 12.1. |
| **“Territory”** | means worldwide. |
| **“Tobacco Party”** | means: (i) any entity who develops, sells or manufactures tobacco products; and/ or (ii) any entity which makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products. Furthermore, Tobacco Party shall include any entity that is an Affiliate of any entity referred to in (i) or (ii). |
| **“UK Pricing Authority”** | means any supra-national, national or regional government department, authority, agency or entity (including a non-departmental public body or similar entity) with responsibility for evaluating the cost effectiveness of medicinal products in the United Kingdom (or one or more constituent countries thereof) or otherwise determining whether the NHS (or constituent parts thereof) should purchase medicinal products. |
| **“Year”** | means a calendar year. |

1.2 In this Agreement:

1.1.1 unless the context requires otherwise, all references to a particular Clause, paragraph or Appendix shall be references to that clause, paragraph or appendix, in or to this Agreement;

1.1.2 the headings are inserted for convenience only and shall be ignored in construing this Agreement;

1.1.3 unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;

1.1.4 unless the contrary intention appears, words denoting persons shall include any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality; and

1.1.5 references to the words 'include' or 'including' shall be construed without limitation to the generality of the preceding words.

**2. GRANT OF LICENCE**

2.1 Subject to the provisions of this Agreement and the surviving provisions of the CTOA, CRT hereby grants to the Company:

2.1.1 an exclusive licence under the Exclusive Results; and

2.1.2 a non-exclusive licence under the Non-Exclusive Results,

in each case to research, develop, make, have made, import, use and sell Licensed Products in the Field in the Territory and to apply for Regulatory Authorisation for such Licensed Products in any jurisdiction.

2.2 CRT hereby reserves and excepts from the exclusive licence under Clause 2.1.1:

2.2.1 the worldwide, perpetual and irrevocable right for the Contributors and the Charity (including use by scientists funded and/or employed by the Charity) to:

(a) use the Licensed Intellectual Property for the purpose of non-commercial scientific research carried out by or for or under their respective direction in accordance with their respective charitable and/or academic status, whether alone or in collaboration with a third party or third parties and whether sponsored or funded, in whole or in part, by any third party including any commercial entity; and

(b) make publications in relation to the Licensed Intellectual Property and any results of research using the same in accordance with generally accepted academic practice; and

2.2.2 the worldwide, limited right for the Charity to continue its conduct of the Clinical Trial in accordance with the terms of the CTOA until the completion or termination of such Clinical Trial as provided in the CTOA.

2.3 The Company shall be entitled to grant sub-licences in respect of the rights granted under this Agreement, provided that:

2.3.1 any sub-licence granted by the Company shall be expressed to terminate automatically on the termination of this Agreement for any reason;

2.3.2 the Company shall ensure that there are included in the terms of any sub-licence like obligations and undertakings on the part of the Sub-Licensee for the benefit of the Charity as are contained in this Agreement (including Clause 9 (indemnity) and Clause 14 (confidentiality) and, if further tiers of sub-licensing is allowed, this Clause 2.3) and shall further ensure that all Sub-Licensees duly comply with the same;

2.3.3 no sub-licence shall be granted to a Tobacco Party;

2.3.4 the sub-licence (other than a sublicence with an Affiliate) shall be entered into on an arms-length basis reflecting the market value of the rights granted; and

2.3.5 the Company shall provide CRT with a copy of such sub-licence within thirty (30) days of entering into it.

2.4 Any breach of Clause 2.3 shall be deemed to be a material breach.

2.5 The grant of any sub-licence shall be without prejudice to the Company's obligations under this Agreement. Any act or omission of any such Sub-Licensee which, if it were the act or omission of the Company would be a breach of any of the provisions of this Agreement, will be deemed to be a breach of this Agreement by the Company who will be liable to CRT accordingly.

2.5.1 CRT will provide the Company with any Long Term Survival Data (as defined in the CTOA) as and when the Charity has completed collection of the same and/or as otherwise provided in the CTOA.

2.6 Subject to the restrictions, pre-approvals and limitations as outlined in Clause 6.1 and Schedule 7A of the CTOA, the Company hereby grants to the Charity a non-exclusive, royalty free licence under the Company Intellectual Property (including the right to use Company Materials) for the Charity and scientists funded by the Charity to adapt and use the Product Manufacturing Process and make and have made Products and Related Products for non-commercial research purposes, provided that such research will not include clinical research (other than the Clinical Trial) without the prior written consent of the Company which shall be in Company's sole control, on a case-by-case basis, and subject to establishment of a clinical trial agreement providing Company with appropriate safeguards and indemnities for such trial.

2.7 If, within one year of the Effective Date of this Agreement (or the Clinical Trial Database Lock Date, if later), Company wishes to publish or publicly disclose the Clinical Trial Results, it will first provide a copy of such intended disclosure to the Charity for its review at least thirty (30) days prior to the intended date of submission for publication or public disclosure. Charity will complete its review of such intended disclosure within thirty (30) days of receipt. If, during its thirty (30) day review period, Charity reasonably determines that information contained within such intended disclosure will materially impact the ability of Charity, CRT, or a Contributor to publish results of, or to protect any Intellectual Property Rights arising from, the Clinical Trial, Company will, at its discretion, either remove such information prior to disclosure or delay disclosure for up to ninety (90) days to allow for protection or publication. If Charity does not respond within thirty (30) days of receipt, it shall be deemed to have consented to the intended disclosure. The foregoing provisions of this Clause 2.8 shall not apply to disclosure of Clinical Trial Results, or any portion thereof, by the Company to the extent required for (a) satisfying mandatory reporting and disclosure obligations under United States and other securities laws; or (b) to existing licensors or sublicensors of the Company in order to comply with reporting obligations in existence as at the date of this agreement under Third Party Licences, provided that in the case of (b) the disclosure shall be limited to only information as may be reasonably required by the Third Party Licence and subject to the third party that is receiving the information being bound by confidentiality obligations that are no less restrictive than those that the Company is bound by under this Agreement in respect of confidential information disclosed to it by the Charity .

**3. PERFORMANCE**

3.1 The Company shall provide an updated Development Plan to CRT on at least a six-monthly basis throughout the Term. The Company shall provide the first such Development Plan to CRT within ninety (90) days after the Effective Date. As of the date of this Agreement, the Company has provided the scope of work attached hereto as Appendix 3.

3.2 The Company shall use its commercially reasonable endeavours to procure the achievement of Phase II Clinical Trial Commencement for the Primary Licensed Product within [***]months of the Effective Date.

3.3 The Company shall use its commercially reasonable endeavours at all times during the Term to:

3.3.1 comply with the most up-to-date version of the Development Plan; provided that and without affecting the Company's obligations under clause 3.2 above the Company may at any time cease activities under a Development Plan that pertain to the development of any Coronavirus Related Licensed Product(s) if the Company determines in its sole discretion that such activities are no longer commercially or scientifically reasonable;

3.3.2 develop and pursue Regulatory Authorisation for a Licensed Product for use in one or more Oncology Indications in each of the Major Markets;

3.3.3 introduce a Licensed Product for use in one or more Oncology Indications into each of the Major Markets as soon as reasonably and commercially practical following receipt of the corresponding Regulatory Authorisations and subsequently use commercially reasonable efforts to market the Licensed Product and pursue maximum market penetration in the Major Markets;

3.3.4 launch each Licensed Product in the United Kingdom as soon as practicable and in any event no later than [***]months after the date the first Regulatory Authorisation is granted by the European Medicines Agency; and

3.3.5 make Licensed Products that are launched in the United Kingdom available at an Affordable Price if required by a Regulatory Authority having jurisdiction over pricing in the United Kingdom.

3.4 Subject to Clause 3.5.2, at least once every six (6) months the Company shall provide CRT with a report as to the progress of the development of each Licensed Product, the progress of any applications for Regulatory Authorisation and Price Approval, and the progress of and plans for the marketing and sale of the Licensed Product and its compliance with the Development Plan, in such form and detail as CRT may reasonably require.

3.5 If, prior to the First Commercial Sale in the United Kingdom and two (2) other Major Markets, the Company undergoes a change of Control, or acquires or begins (whether independently or with a third party) a Competing Programme:

3.5.1 it shall notify CRT in writing within thirty (30) days after the change of Control occurring, or its commencement or acquisition of the Competing Programme; and

3.5.2 for the [***] period following the change of Control, or commencement or acquisition of the Competing Programme, it shall provide CRT with a report described in Clause 3.4 at least once every three (3) months.

3.6 The Company shall give CRT prompt notice upon the occurrence of any Milestone Event.

3.7 The Company shall submit to CRT:

3.7.1 a copy of its detailed operating budget (including a quarterly cash flow and expenditure forecast) for the Product in respect of each Financial Year as adopted by the Company's board (the "**Annual Budget**"), at least thirty (30) days prior to the commencement of the Financial Year to which the Annual Budget relates;

3.7.2 quarterly management accounts of the Company (to include, inter alia, a (consolidated) profit and loss account, balance sheet and cash flow statement and shall indicate where such management accounts differ to any material extent from the Annual Budget for such period), within five (5) business days after the date by which such financial statements are filed with the United States Securities and Exchange Commission for such period, but in no event later than fifty (50) days after quarter close for the first three financial quarters and ninety five (95) days after close of the financial year. Such quarterly management accounts shall be prepared in accordance with United States generally accepted accounting principles consistently applied.

3.8 Any breach of Clause 3 shall be deemed to be a material breach of this Agreement.

3.9 The Company may perform its obligations under Clause 3 in whole or in part through the efforts of its Affiliates, contractors, subcontractors, licensees and sublicensees.

**4. CONSIDERATION**

4.1 The Company shall pay:

4.1.1 the Signature Fee to CRT as follows: £500,000 on or before September 30, 2020; £500,000 on or before January 31, 2021; and £250,000 on or before April 30, 2021; and

4.1.2 the Option Fee on the date of this Agreement.

4.2 The Company shall pay the following payments ("Milestone Payments") to CRT after the first occurrence of each of the following events ("Milestone Events") in accordance with this Clause 4.2 and Clause 5.2:

4.2.1 Development Milestone Events in relation to [***]:

(a) [***];

(b) [***];

4.2.2 Development Milestone Events in relation to [***]:

(a) [***];

(b) [***];

4.2.3 Sales Milestone Events in relation to [***]

(a) [***];

(b) [***]; and

(c) [***].

4.2.4 Sales Milestone Events in relation to [***]

(a) [***];

(b) [***]; and

(c) [***].

Upon the occurrence of each [***] in respect of a Licensed Product [***], if not already triggered, the corresponding [***] for that same Licensed Product shall be deemed to have occurred. For the avoidance of doubt a Milestone Event may be triggered by the actions of the Company, a Sub-Licensee or any third party acting on behalf of the Company or any Sub-Licensee.

4.3 Subject to Clause 4.4, the Company shall pay to CRT:

4.3.1 Forty per cent (40%) of all Sub-Licence Revenue if the relevant sub-licence is granted by the Company prior to Commencement of a Phase II Trial for the relevant Primary Licensed Product;

4.3.2 [***] of all Sub-Licence Revenue if the relevant sub-licence is granted by the Company after [***] but prior to [***] for the relevant Primary Licensed Product;

4.3.3 [***] of all Sub-Licence Revenue if the relevant sub-licence is granted by the Company after [***] but prior to [***] for the relevant Primary Licensed Product; and

4.3.4 Seven and a half per cent (7.5%) of all Sub-Licence Revenue if the relevant sub-licence is granted by the Company after Phase III Clinical Trial Completion for the relevant Primary Licensed Product.

4.4 In the event that any Milestone Event is triggered by any Sub-Licensee, the Company shall pay to CRT the greater of: (i) [***]; and (ii) [***].

4.5 Subject to Clauses 4.6 and 4.7, the Company will pay to CRT royalties on Licensed Products at the following royalty rates based on the Net Sales Value of Licensed Products in the applicable Year:

(a) for that portion of the Net Sales Value of all Primary Licensed Products that is less than or equal to [***], a royalty rate of [***]; and

(b) for that portion of the Net Sales Value of all Primary Licensed Products greater than [***], a royalty rate of [***]; and

(c) for that portion of the Net Sales Value of all Related Licensed Products that is less than or equal to [***], a royalty rate of [***]; and

(d) for that portion of the Net Sales Value of all Related Licensed Products greater than [***], a royalty rate of [***].

4.6 The Company shall pay royalties to CRT in accordance with Clause 4.5 on a Licensed Product by Licensed Product, and country by country basis until the later of:

4.6.1 the expiry of any Data Exclusivity Period in respect of the data submitted for the BLA for such Licensed Product in such country; and

4.6.2 the expiry of ten (10) years from the First Commercial Sale; and.

4.6.3 the date when unauthorised manufacture, sale or use of the Licensed Product would no longer infringe a valid claim of the Company Patent Rights in the country of sale or manufacture.

4.7 In the event that the Company incurs FTO Royalties with respect to a Licensed Product in a country in a Quarter the following provisions shall take effect with respect to that Licensed Product in that country in that Quarter:

4.7.1 [***];

4.7.2 [***];

4.7.3 [***].

4.8 Subject to clause 4.9 below, if at any time the Company discontinues development of the Product, the Company shall promptly notify CRT of such discontinuation and of the Related Product that will replace such discontinued Primary Licensed Product. Upon such notification, such replacement Related Product shall be deemed the Primary Licensed Product for the purposes of this Agreement.

4.9 If at the time that the Company gives notice to CRT pursuant to clause 4.8 above the Company has more than one Related Product in development that qualifies for substituting for the Primary Licensed Product that is being discontinued, ("Alternatives") then it shall give notice of this to CRT and provide information regarding the details of each Alternative to CRT as reasonably requested by CRT, including [***] (the "**Alternative Summary**"). The Company shall also identify in the Alternative Summary its preference for the Alternative that it wishes to substitute as the Primary Licensed Product and the reasons for that choice. All information provided in the Alternative Summary shall be the Confidential Information of the Company. It is presumed that [***] will be the preferred choice of the Parties. CRT shall have [***] to consider the Alternative Summary and to obtain clarification from the Company regarding the information included therein and then, if applicable, within [***] of receiving any outstanding clarification that has been requested by CRT give notice to the Company of whether it:

4.9.1 accepts the Company's preferred Alternative; or

4.9.2 wishes to elect a different Alternative to substitute as the Primary Licensed Product.

4.9.3 In the case where CRT makes an election pursuant to clause 4.9.2, the Company may within [***] of receiving the election notice raise an objection to the choice of Alternative made by CRT. The objection may be made only on the ground that [***]. In the event of the Company raising such objection the Parties shall review all of the circumstances and acting reasonably and fairly together resolve the matter, provided always that CRT may at any time abandon its election made pursuant to clause 4.9.2 thereby defaulting to the Company's preferred Alternative.

4.10 For clarity, Milestone Payments under Clause 4.2 are payable one-time only and any Milestone Payment paid in respect of a discontinued Primary Licensed Product shall not be payable in respect of any replacement Primary Licensed Product.

**5. PAYMENT AND STATEMENT**

5.1 All payments due to CRT under this Agreement shall be made in the Currency in cleared funds to the following bank account:

[***]

5.2 The Company shall pay to CRT:

5.2.1 the Signature Fee on the date specified in Clause 4.1;

5.2.2 each of the Milestone Payments within thirty (30) days after the relevant Milestone Event occurring;

5.2.3 CRT's share of Sub-Licence Revenue due under Clause 4.3 Quarterly within thirty (30) days after the end of the Quarter in which the consideration upon which Sub-Licence Revenue is based is received by the Company from Sub-Licensee ; and

5.2.4 the royalties due pursuant to Clause 4.5 Quarterly within thirty (30) days after the end of each Quarter in which the relevant Net Sales Value is invoiced by the Company or a Sub-Licensee.

5.3 Where Licensed Products are sold or Sub-Licence Revenue is received by the Company (or a Sub-Licensee) in a currency other than the Currency, the rate of exchange to be used for converting such other currency into the Currency shall be the relevant mid-spot rate for the currency quoted by the Financial Times on the last day of the Quarter to which they relate.

5.4 All costs of transmission and currency conversion shall be borne by the Company.

5.5 All payments to CRT under this Agreement are expressed to be exclusive of value added tax howsoever arising, and the Company shall pay to CRT in addition to those payments or, if earlier, on receipt of a tax invoice or invoices from CRT, all value added tax for which CRT is liable to account in relation to any supply made or deemed to be made for value added tax purposes pursuant to this Agreement.

5.6 All sums payable under this Agreement shall be paid without deduction or deferment in respect of any claims whatsoever and of any taxes except any tax which the Company is required by law to deduct or withhold. If the Company is required by law to make any such tax deduction or withholding, the Company shall pay to CRT such amount as shall, after deduction, amount to the sum referred to in this Agreement give reasonable assistance to CRT to claim exemption from or (if that is not possible) a credit for the deduction or withholding under any applicable double taxation or similar agreement from time to time in force, and shall promptly give CRT proper evidence as to the deduction or withholding and payment over of the tax deducted or withheld.

5.7 Where CRT does not receive payment of any sums due to it by the due date, interest shall accrue both before and after any judgment on the sum due and owing to CRT at the rate equivalent to an annual rate of four percent (4%) over the then current base rate of the Bank of England, calculated on a daily basis, until the full amount is paid to CRT, without prejudice to CRT's right to receive payment on the due date.

5.8 Within thirty (30) days after the end of each Quarter, the Company shall send to CRT a written statement detailing in respect of that Quarter (including a nil report if appropriate):

5.8.1 any Milestone Payments which became due to CRT;

5.8.2 for each sub-licence, details of each item of Sub-Licence Revenue received by the Company during that Quarter and the Sub-Licence Revenue payable to CRT thereon;

5.8.3 the quantity of each type of Licensed Product sold or otherwise disposed of by the Company or any Sub-Licensees in each country in the Territory;

5.8.4 the Net Sales Value in respect of each such type of Licensed Product in each country of the Territory;

5.8.5 the aggregate Net Sales Value in respect of that Quarter for Licensed Product;

5.8.6 the type and value of deductions made in the calculation of Net Sales Value by type of Licensed Product and country;

5.8.7 any currency conversions, showing the rates used;

5.8.8 any further information necessary for the calculation of Sub-Licence Revenue and Net Sales Value of Licensed Products and/or the royalties due to CRT; and

5.8.9 the amount of the royalties due to CRT in respect of that Quarter.

**6. ACCOUNTS**

6.1 The Company shall:

6.1.1 keep and notwithstanding termination of this Agreement, maintain and shall procure that each Sub-Licensee keeps and maintains, for at least six (6) years, true and accurate accounts and records (including any underlying documents supporting such accounts and records) in sufficient detail to enable the amount of all sums payable under this Agreement to be determined; and

6.1.2 during the Term and thereafter until the said period of three (3) years relevant to the accounts and records has expired, at the reasonable request of CRT and (subject to Clause 6.2) at the expense of CRT from time to time, permit [or procure permission for] a qualified accountant nominated by CRT to inspect and audit those accounts and records and, to the extent that they relate to the calculation of those sums, to take copies of them. Subject to receiving not less than thirty (30) days written notice, the Company shall at the request of CRT assemble in one location each that is respectively convenient to the Company and Sub-Licensee(s) all such relevant accounts and records of the Company and Sub-Licensee(s).

6.2 If, following any inspection pursuant to Clause 6.1.2, CRT's nominated accountant certifies to CRT that the payments in respect of any Quarter or Year fall short of the sums which were properly payable in respect of that Quarter or Year under this Agreement, CRT shall send a copy of the certificate to the Company and the Company shall (subject to Clause 6.3) within seven (7) days of the date of receipt of the certificate pay the shortfall to CRT and, if the shortfall exceeds two per cent (2%) of the sum properly payable, the Company shall also reimburse to CRT the reasonable costs and expenses of CRT in making the inspection.

6.3 If within seven (7) days of the date of receipt by the Company any certificate produced pursuant to Clause 6.2 the Company notifies CRT in writing that it disputes the certificate, the dispute shall be referred for resolution by Accountancy Opinion in accordance with Clause 24.1.

**7. INTELLECTUAL PROPERTY PROTECTION, PROCEEDINGS AND COSTS**

7.1 The Company shall throughout the Term continue to prosecute and maintain the Company Patent Rights at its own cost and shall use commercially reasonable endeavours to maximise the scope of such Company Patent Rights, or where prosecution and maintenance of such Patent Rights is controlled by a licensor of the Company, the Company will use commercially reasonable efforts to procure that the licensor continues to prosecute and maintain such Patent Rights where the licensor has such obligation under its Third Party Licence agreement; provided that the Company shall not be obligated to commence litigation for such purpose. Notwithstanding the foregoing, if the Company elects not to prosecute or maintain any part of the Company Patent Rights it controls in any part of the Territory, the Company shall notify CRT in writing at least ninety (90) days prior to the expiration of any applicable time bars. After receipt of such notice, CRT may elect, before the expiry of any such time bars, by written notice to the Company, to take an assignment of the relevant Company Patent Rights such that CRT may continue to prosecute and/or maintain the Company Patent Rights at CRT's sole discretion and expense.

7.2 If the Company becomes aware that a Company Patent Right being prosecuted or maintained by one of its licensors is due to expire or the licensor has elected not to prosecute or maintain any such Company Patent Rights the Company will promptly notify CRT in writing. In the case of a licensor electing not to prosecute or maintain any Company Patent Rights (as opposed to expiration), where reasonably possible, the Company will take assignment of such Patent Rights or request the right for CRT to take assignment of such Patent Rights.

**8. WARRANTY**

8.1 Each Party warrants that it has the legal capacity to enter into this Agreement.

8.2 Each Party acknowledges that, in entering into this Agreement, it does not do so in reliance on any warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded to the fullest extent permitted by law.

8.3 Without limiting the scope of Clause 8.2, CRT does not give any warranty, representation or undertaking:

8.3.1 as to the efficacy or usefulness or accuracy of the Clinical Trial Results; or

8.3.2 that the exercise of rights granted under this Agreement will not infringe the intellectual property or other rights of any other person.

**9. INDEMNITY**

9.1 The Company shall indemnify and hold harmless CRT, the Contributors and the Charity and their respective officers, employees and agents (the "Indemnified Parties") from and against any and all third party claims, demands, losses, damages and expenses (including, without limitation, legal fees) arising from or in connection with the exercise of the rights granted in Clause 2 by the Company or any Affiliate of the Company or a Sub-Licensee or or any affiliate of a Sub-Licensee in relation to the Licensed Product. This Clause 9 shall not limit the rights of the Company and the liabilities of CRT under Clause 9.1 of the CTOA.

9.2 Promptly after receipt by CRT of any claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation to which the indemnity provided for in this Clause 9 may apply, CRT shall give written notice to the Company of such fact and specifying that the Company shall have the option to assume the defence thereof by election in writing within seven (7) days of receipt of such notice. If the Company fails to make such election, the Indemnified Party may assume such defence and the Company will be liable for the legal and other expenses consequently incurred in connection with such defence. The Parties will co-operate in good faith in the conduct of any defence, provide such reasonable assistance as may be required to enable any claim properly to be defended and the Party with conduct of the action shall provide promptly to the other Party copies of all correspondence and documents and notice in writing of the substance of all oral communications relating to such action.

9.3 Should the Company assume conduct of the defence:

9.3.1 the Indemnified Party may retain separate legal advisers, at its sole cost and expense, save that if the Company denies the applicability of the indemnity or reserves its position in relation to the same, the indemnity in this Clause 9 shall extend to the Indemnified Party's costs and expenses so incurred if it is subsequently resolved between the Parties or determined by a court of competent jurisdiction (after exhaustion or expiration of all rights of appeal) that the indemnity under this Clause 9 was available to the Indemnified Party in the terms claimed by the Indemnified Party; and

9.3.2 the Company will not, except with the written consent of the Indemnified Party consent to the entry of any judgment or enter into any settlement provided always, that if the Indemnified Party unreasonably refuses to consent to such entry of judgment or settlement and the matter proceeds to trial at which a greater amount is ordered by the Court then the amount which the Indemnified Party shall be entitled to recover from the Company pursuant to this Clause 9 shall be limited to the amount for which the action would otherwise have been settled or compromised and the Indemnified Party shall assume all costs of defending the claim or proceeding from the date of the Indemnified Party's refusal; and

9.3.3 CRT shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed; and

9.3.4 the Company shall not be responsible for or bound by any settlement made by CRT in breach of Clause 9.3.3.

**10. INSURANCE**

10.1 The Company shall maintain, at its own cost, comprehensive product liability insurance and general commercial liability insurance. Within thirty (30) days of the Effective Date and of the beginning of each policy period, the Company shall provide CRT with a certificate evidencing the coverage required hereby, and the amount thereof. Such insurance shall be with a reputable insurance company and shall be maintained for not less than six (6) years following the expiration/termination of this Agreement for any reason or if such coverage is of the 'claims made' type, for ten (10) years following the expiration or termination of this Agreement for any reason.

**11. LIMITATION OF LIABILITY**

11.1 Neither Party nor the Charity, nor their respective officers, employees and agents shall have liability whether under statute or in tort (including negligence), contract or otherwise to the other Party in respect of any consequential, indirect or pure economic loss nor in any event for loss of goodwill, opportunity, profit or contract.

11.2 Nothing in this Agreement shall be construed as excluding or limiting the liability of either Party or the Charity or any of their respective officers, employees and agents to the other Party for death or personal injury of any person resulting from the negligence of such persons.

**12. TERM AND TERMINATION**

12.1 This Agreement will become effective on the Effective Date and, subject to the provisions of this Clause 12, will remain effective in each country of the Territory until expiry of the obligation of the Company under Clauses 4.5 and 4.6 to pay royalties in relation to that country pursuant to this Agreement.

12.2 Without prejudice to any other rights of the Parties this Agreement may be terminated by notice in writing:

12.2.1 by either Party forthwith if the other Party shall be in material breach of any of its obligations under this Agreement and in the case of a remediable breach fails to remedy the breach within sixty (60) days of written notice containing full particulars of the breach and requiring it to be remedied;

12.2.2 by CRT if a voluntary arrangement is proposed or approved or an administration order is made, or a receiver or administrative receiver is appointed of any of the Company's assets or undertakings or a winding-up resolution or petition is passed (otherwise than for the purpose of solvent reconstruction or amalgamation) or if any circumstances arise which entitle the Court or a creditor to appoint a receiver, administrative receiver or administrator or make a winding-up order or similar or equivalent action is taken against or by the Company by reason of its insolvency;

12.2.3 by CRT forthwith in the event that, by way of merger, acquisition or otherwise, the Company becomes a Tobacco Party; or

12.2.4 by CRT upon forty five (45) days written notice to the Company if the Company:

(a) discontinues the development (including prosecuting application for Regulatory Authorisation) of all Licensed Products; or

(b) after the filing of the IND, discontinues the development (including prosecuting application for Regulatory Authorisation) of one or more Licensed Product(s) in all disease indications (in which case termination shall not apply to the whole Agreement but shall be limited to such Licensed Product(s)); or

(c) after the filing of the IND, discontinues the development (including prosecuting application for Regulatory Authorisation) of one or more Licensed Product(s) in oncology (in which case termination shall not apply to the whole Agreement but shall be limited to such Licensed Product(s) in oncology); or

(d) fails to use its commercially reasonable efforts to obtain Regulatory Authorisation in a timely manner in all of the Major Markets, taking into account the unique aspects of the development and regulatory path for a Licensed Product, indication and market (in which case termination shall be effective only in respect of that Licensed Product in that Major Market); or

(e) having obtained Regulatory Authorisation for a Licensed Product in a Major Market, ceases to actively market and sell such Licensed Product in such Major Market (in which case termination shall be effective only in respect of that Licensed Product in that Major Market); or

(f) ceases to carry on business in the Field; or

(g) without reasonable cause fails to commence sale of a Licensed Product in a Major Market within two (2) years of obtaining Regulatory Authorization to market the Licensed Product in such market; or

(h) without CRT's prior written consent, abandons or fails to prosecute any of the Company Patent Rights in any Major Market.

12.3 In the event of disagreement between the Parties as to whether entitlement to terminate has arisen under Clause 12.2.1 or 12.2.4, the Parties at their joint cost and expense shall obtain an Expert Opinion which shall be final as to whether it has arisen.

12.4 For the purpose of Clause 12.2.4, the efforts and actions of the Company shall be deemed to include the efforts and actions of its Affiliates, contractors, subcontractors, licensees and sublicensees.

**13. EFFECTS OF TERMINATION**

13.1 Subject to Clause 13.2, upon the termination of this Agreement for any reason:

13.1.1 other than termination by CRT pursuant to Clause 12.2.1 ,12.2.2 or 12.2.3 subject to all the terms of this Agreement (including without limitation payment of royalties), the Company shall be entitled for a period not exceeding [***] following such termination to:

(a) manufacture any of the Licensed Products to the extent necessary to satisfy orders accepted before termination; and

(b) sell, use or otherwise dispose of any unsold stocks of the Licensed Products.

13.1.2 subject to Clause 13.1.1, the Company shall, and shall procure that all Sub-Licensees shall, cease to exploit the Licensed Intellectual Property in any way, either directly or indirectly;

13.1.3 subject to Clause 13.1.1, the Company shall, at the request and option of CRT, return or destroy CRT's Confidential Information;

13.1.4 notwithstanding any provision of this Agreement allowing the Company credit, payment of royalties and all other sums to CRT shall become due and payable to CRT immediately upon notice of termination of this Agreement;

13.1.5 the Company shall, within fourteen (14) days of notice of termination of this Agreement provide CRT with a final written statement detailing, in respect of the time elapsed since the last statement under Clause 5.8, the matters set out in Clause 5.8;

13.1.6 other than termination by the Company pursuant to Clause 12.2.1, the Company:

(a) subject to 13.1.6(b), shall execute with CRT an exclusive, perpetual, worldwide, sub-licensable licence under the Company Intellectual Property, Company Combination Patent Rights and New Company IP to research, develop, make, have made, market, use and sell Licensed Products, on revenue share terms to be agreed;

and in the case of Company Intellectual Property licensed to the Company under a Third Party Licence, such licence shall include a grant to CRT of a sub-licence reasonably similar to those provided for by Schedule 6 (CRT Licence) of the CTOA, and provide CRT with such assistance as CRT may reasonably request in liaising with the licensors under the Third Party Licences for the purpose of obtaining direct contractual rights with such licensors should they be so required;

(b) at CRT's request, upon completion of such licence, shall promptly transfer to CRT (or any person nominated by CRT) any and all documents and information in the Company's control or possession relating to the Company Foreground Patent Rights and CRT may assume responsibility for the prosecution, maintenance and enforcement of the same; and

(c) at CRT's request, upon completion of such licence, shall transfer to CRT (or its nominee) any Regulatory Authorisations, Price Approvals and other permits and applications relating to Licensed Products.

13.2 This Clause 13.2 shall not apply in the case of termination of this Agreement under Clause 12.1. In the event that this Agreement is terminated solely in respect of particular Licensed Product and/or Indication and/or Major Market, the provisions of Clause 13.1 shall apply, but solely in respect of the relevant Licensed Product, Indication and/or Major Market.

13.3 The termination of this Agreement howsoever arising will be without prejudice to the rights and duties of either Party accrued prior to termination. The following Clauses will continue to be enforceable notwithstanding termination: Clauses 1 (Definitions), 6 (Accounts), 9 (Indemnity), 10 (Insurance), 11 (Limitation of Liability), 12 (Termination), 13 (Effects of Termination), 14 (Confidentiality), 19 (Severability), 24 (Dispute Resolution) and 25 (Law and Jurisdiction).

**14. CONFIDENTIALITY**

14.1 Each Party undertakes with the other that it shall keep and it shall procure that its respective directors and employees keep secret and confidential all Confidential Information belonging to or controlled by the other Party and shall not disclose the same or any part of the same to any person whatsoever other than:

14.1.1 in the case of the Company: (i) to Sub-Licensees subject to compliance with Clause 2.3.4, (ii) to potential development partners, sublicensees, and investors bound by terms of confidentiality at least as strict as those herein, and (iii) as necessary in communications with Regulatory Authorities in the Territory relating to the Licensed Products.

14.1.2 in the case of CRT to the Charity; and

14.1.3 in the case of each Party, to its directors or employees directly or indirectly concerned in the exercise of the rights granted under this Agreement.

14.2 The provisions of Clause 14.1 shall not apply to Confidential Information which CRT or the Company (as the case may be):

14.2.1 can prove to have been in its possession (other than under an obligation of confidence to the other or to a third party) at the date of receipt or which enters the public domain otherwise than through a breach of any obligation of confidentiality owed to the Party communicating such information to the other;

14.2.2 can prove it has independently developed; or

14.2.3 is required to disclose by law or by the order of a competent court, solely to the extent of such disclosure.

14.3 The provisions of this Clause 14 shall remain in force for a period of five (5) years from the expiry or termination of this Agreement

**15. ASSIGNMENT**

15.1 The Company shall not without CRT’s consent assign its rights under this Agreement except in conjunction with a merger or consolidation of the Company with another business entity or the sale of all or substantially all or a substantial part of its business and related assets that includes its business in relation to the Licensed Products other than a merger or consolidation with, or a sale of assets to, a Tobacco Party and provided that Company obtains a direct covenant from the acquiring party to CRT undertaking to be bound by the terms of this Agreement.

**16. NOTICES**

16.1 Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been given:

16.1.1 upon delivery if given in person; or

16.1.2 upon confirmation of receipt if sent by facsimile (or other similar means of electronic communication such as email); or

16.1.3 (if posted to an inland destination) three (3) business days after deposit into First Class post; or

16.1.4 (If posted to an overseas destination)five (5) days after deposit into airmail post,

16.1.5 upon delivery by air delivery service;

to a Party at the address set out below for such Party or such other address as the Party may from time to time designate by written notice to the other Party.

Address of the Company

Lineage Cell Therapeutics, Inc.
2173 Salk Avenue, Suite 200
Carlsbad, CA 92008 USA
Contact: Legal/contracts
Email: legal@lineagecell.com

Address of CRT

2 Redman Place
London E20 1JQ
United Kingdom
Contact: Chief Executive Officer
Fax: +44 (0) 20 3014 8633

**17. WAIVER**

17.1 No failure or delay on the part of either Party hereto to exercise any right or remedy under this Agreement shall be construed as or operate as a waiver thereof nor shall any single or partial exercise of any right or remedy under this Agreement preclude the exercise of any other right or remedy or preclude the further exercise of such right or remedy as the case may be.

**18. FORCE MAJEURE**

18.1 Except in relation to obligations pursuant to Clauses 4 and/or 5, neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance (a "Delay") and where they cease to do so. In the event of a Delay lasting for twenty six (26) weeks or more the non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the affected Party.

**19. SEVERABILITY**

19.1 If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Agreement, or the application hereof to any circumstances, to be invalid or to be unenforceable in a final non-appealable order, the remainder of this Agreement and the application of such term, provision or condition or part thereof to circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each of the other terms, provisions and conditions of this Agreement shall be valid and enforceable to the fullest extent permissible by law.

**20. ENTIRE AGREEMENT**

20.1 This Agreement together with the CTOA (as amended), embodies and sets forth the entire agreement and understanding of the Parties and supersedes all prior oral or written agreements, understandings or arrangements relating to the subject matter of this Agreement. Without prejudice to any liability for fraudulent misrepresentation or fraudulent misstatement neither Party shall be entitled to rely on any agreement, understanding or arrangement which is not expressly set forth in this Agreement unless otherwise agreed between the Parties and recorded in writing.

**21. AMENDMENT**

21.1 This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the Parties.

**22. PUBLIC ANNOUNCEMENTS**

22.1 The text of any press release, shareholders' report or other communication to be published or disclosed to the public in any way by or in the media concerning CRT or the Charity, the subject matter of this Agreement or concerning this Agreement itself, other than as required by law or by any Regulatory Authority or the rules of any securities exchange, shall be submitted to CRT at least five (5) business days in advance of publication for approval, such approval not to be unreasonably withheld; provided, that disclosure that repeats or restates prior public disclosure permitted by this Agreement need not be submitted to the Charity or CRT for approval.

**23. FURTHER ASSURANCE**

23.1 The Parties hereby undertake to do all such other acts and things, and execute and provide all such documents at the requesting Party's cost as may be necessary or desirable to give effect to the purposes of this Agreement.

**24. DISPUTE RESOLUTION**

24.1 Insofar as this Agreement provides that a matter shall be resolved by Accountancy Opinion or Expert Opinion the opinion of such expert (who shall act as an expert and not as an arbitrator) shall be final and binding on the Parties. In the event of a Party seeking an Accountancy Opinion or Expert Opinion under this Agreement, each Party shall make written submissions to the expert so appointed and to the other Party within fourteen (14) days of the appointment. Each Party shall have seven (7) days to respond to the other's submissions. The expert shall be requested to deliver his Accountancy Opinion or Expert Opinion within a further thirty (30) days. The costs of any Accountancy Opinion or Expert Opinion shall be borne in such proportions as the expert may determine in his opinion to be fair and reasonable in all the circumstances or, if no such determination is made in the opinion, by the Parties in equal proportions.

24.2 It shall be a condition precedent to the commencement of any action in court or other tribunal (save an action for an interim injunction or an Expert Opinion sought under Clause 12.1) in respect of any dispute relating to this Agreement that the Parties have sought to resolve the dispute by either Party notifying the other Party in writing for resolution to the Chief Executive Officer (in the case of CRT) and the Chief Executive Officer (in the case of the Company) (or their express delegates) (the "Senior Executives") who shall meet (whether in person or via teleconference) within twenty one (21) days of such notice to seek resolution in good faith. If the Senior Executives are unable to resolve the dispute at such meeting, either Party may pursue any remedy available to such Party at law or in equity, subject to the terms and conditions of this Agreement and the other agreements expressly contemplated hereunder.

**25. LAW AND JURISDICTION**

25.1 This Agreement shall be governed by and construed in accordance with English Law and, subject to the provisions of Clauses 24.1 and 24.2, each Party agrees to submit to the exclusive jurisdiction of the English Courts (except in respect of disputes under Clause 14 where jurisdiction is non-exclusive).

**26. EXECUTION**

26.1 This Agreement may be executed in any one or more number of counterpart agreements , and as scanned email attachments, and all signatures and counterparts so exchanged shall be considered as original and shall be deemed to form part of and together constitute this Agreement.

**27. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999**

27.1 Save that the Charity, the Contributors and their and CRT's respective officers, employees and agents in respect of Clauses 9 and 11 may enforce those respective terms, no term of this Agreement is enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a Party to this Agreement. Notwithstanding the provisions of this Clause, the Parties shall be entitled to amend, suspend, cancel or terminate this Agreement or any part of it in accordance with Clause 21, without the consent of any third party including those referred to in this Clause.

{Signature Page Follows}

The Parties hereby execute this Agreement by their duly authorised representatives:

Signed by: */s/ Tony Hickson*
Name: Tony Hickson
Title: Chief Business Officer

For and on behalf of
**CANCER RESEARCH TECHNOLOGY LIMITED**

Signed by: */s/ Brian Culley*
Name: Brian Culley
Title: Chief Executive Officer

For and on behalf of
**LINEAGE CELL THERAPEUTICS, INC**

**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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: August 6, 2020

*/s/ Brian M. Culley*

Brian M. Culley
Chief Executive Officer

**Exhibit 31.2**

**CERTIFICATIONS**

I, Brandi L. Roberts, 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: August 6, 2020

*/s/ Brandi L. Roberts*

Brandi L. Roberts
Chief 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 June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Brian M. Culley, Chief Executive Officer of the Company, and Brandi L. Roberts, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 6, 2020

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

*/s/ Brandi L. Roberts*
Brandi L. Roberts
Chief Financial Officer