

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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission file number **001-12830**

Lineage Cell Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of
incorporation or organization)

94-3127919
(IRS Employer
Identification No.)

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

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

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common shares no par value	LCTX	NYSE American

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

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

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

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

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

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

The number of common shares outstanding as of November 3, 2023 was 174,986,671.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are subject to substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report, but are also contained elsewhere in this report. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements in this report include, but are not limited to, statements about:

- the potential to receive developmental, regulatory, and commercialization milestone and royalty payments under our Collaboration and License Agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc.;
- our plans to research, develop and commercialize our product candidates;
- the initiation, progress, success, cost and timing of our clinical trials and other product development activities;
- the therapeutic potential of our product candidates, and the indications for which we intend to develop our product candidates;
- our ability to successfully manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- the potential of our cell therapy platform;
- our expectations and plans regarding existing and potential future collaborations with third parties such as pharmaceutical and biotechnology companies, government agencies, academic laboratories, and research institutes for the discovery, development, and/or commercialization of novel cell therapy products;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the potential scope and value of our intellectual property rights; and
- the effects on our operations of pandemics, including the recent COVID-19 pandemic, geopolitical conflicts, political and economic instability, and rising inflation and interest rates.

Forward-looking statements reflect our views and expectations as of the date of this report about future events and our future performance and condition, and involve known and unknown risks, uncertainties and other factors that may cause our actual activities, performance, results or condition to be materially different from those expressed or implied by the forward-looking statements. You should refer to “Item 1A. Risk Factors” in Part II of this report and “Item 1A. Risk Factors” in Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the “2022 10-K”) as filed with the Securities and Exchange Commission on March 9, 2023, for a discussion of important factors that may cause our actual activities, performance, results and condition to differ materially from those expressed or implied by our forward-looking statements. As a result of a variety of factors, including those discussed in Part II, Item 1A of this report and Part I, Item 1A of the 2022 10-K, our forward-looking statements may prove to be inaccurate, and the inaccuracy may be material. Accordingly, you should not place undue reliance on any forward-looking statement. We anticipate that subsequent events and developments may cause our current views and expectations to change. However, while we may elect to update the forward-looking statements in this report at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date after the date of this report.

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

MARKET DATA AND TRADEMARKS

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

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

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

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 31,474	\$ 11,355
Marketable securities	9,858	46,520
Accounts receivable, net (Note 3)	432	297
Prepaid expenses and other current assets	1,717	1,828
Total current assets	43,481	60,000
NONCURRENT ASSETS		
Property and equipment, net (Notes 6 and 14)	4,854	5,673
Deposits and other long-term assets	552	627
Goodwill	10,672	10,672
Intangible assets, net	46,594	46,692
TOTAL ASSETS	\$ 106,153	\$ 123,664
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,030	\$ 8,608
Lease liabilities, current portion (Note 14)	881	916
Financing lease, current portion (Note 14)	55	36
Deferred revenues (Note 3)	9,915	9,421
Total current liabilities	15,881	18,981
LONG-TERM LIABILITIES		
Deferred tax liability	273	2,076
Deferred revenues, net of current portion (Note 3)	21,195	27,725
Lease liability, net of current portion (Note 14)	2,047	2,860
Financing lease, net of current portion (Note 14)	97	84
Other long-term liabilities	-	2
TOTAL LIABILITIES	39,493	51,728
Commitments and contingencies (Note 14)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common shares, no par value, 450,000 and 250,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 174,987 and 170,093 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	450,282	440,280
Accumulated other comprehensive loss	(2,084)	(3,571)
Accumulated deficit	(380,081)	(363,370)
Lineage Cell Therapeutics, Inc. shareholders' equity	68,117	73,339
Noncontrolling deficit	(1,457)	(1,403)
Total shareholders' equity	66,660	71,936
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 106,153	\$ 123,664

See accompanying notes to the condensed consolidated interim financial statements.

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
REVENUES:				
Collaboration revenues	\$ 957	\$ 2,592	\$ 5,949	\$ 11,605
Royalties and license fees	289	406	908	1,183
Total revenues	<u>1,246</u>	<u>2,998</u>	<u>6,857</u>	<u>12,788</u>
Cost of sales	<u>(169)</u>	<u>(235)</u>	<u>(415)</u>	<u>(626)</u>
Gross profit	<u>1,077</u>	<u>2,763</u>	<u>6,442</u>	<u>12,162</u>
OPERATING EXPENSES:				
Research and development	3,741	3,592	11,799	9,883
General and administrative	4,041	4,422	13,014	18,160
Total operating expenses	<u>7,782</u>	<u>8,014</u>	<u>24,813</u>	<u>28,043</u>
Loss from operations	<u>(6,705)</u>	<u>(5,251)</u>	<u>(18,371)</u>	<u>(15,881)</u>
OTHER INCOME (EXPENSES):				
Interest income, net	433	384	1,225	435
Loss on marketable equity securities, net	(60)	(233)	(170)	(1,677)
Gain on revaluation of warrant liability	-	-	1	223
Other expenses, net	<u>(826)</u>	<u>(475)</u>	<u>(1,253)</u>	<u>(2,550)</u>
Total other income (expenses), net	<u>(453)</u>	<u>(324)</u>	<u>(197)</u>	<u>(3,569)</u>
LOSS BEFORE INCOME TAXES	<u>(7,158)</u>	<u>(5,575)</u>	<u>(18,568)</u>	<u>(19,450)</u>
Provision for income tax benefit (expense)	<u>-</u>	<u>(541)</u>	<u>1,803</u>	<u>(541)</u>
NET LOSS	<u>(7,158)</u>	<u>(6,116)</u>	<u>(16,765)</u>	<u>(19,991)</u>
Net loss attributable to noncontrolling interest	<u>48</u>	<u>47</u>	<u>54</u>	<u>72</u>
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	<u>\$ (7,110)</u>	<u>\$ (6,069)</u>	<u>\$ (16,711)</u>	<u>\$ (19,919)</u>
NET LOSS PER COMMON SHARE:				
Basic and Diluted	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ (0.10)</u>	<u>\$ (0.12)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic and Diluted	<u>174,868</u>	<u>169,786</u>	<u>171,880</u>	<u>169,722</u>

See accompanying notes to the condensed consolidated interim financial statements.

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
NET LOSS	\$ (7,158)	\$ (6,116)	\$ (16,765)	\$ (19,991)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustment	518	323	1,337	2,177
Unrealized gain (loss) on marketable debt securities	9	(150)	150	(150)
COMPREHENSIVE LOSS	<u>(6,631)</u>	<u>(5,943)</u>	<u>(15,278)</u>	<u>(17,964)</u>
Less: Comprehensive loss attributable to noncontrolling interest	48	47	54	72
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	<u>\$ (6,583)</u>	<u>\$ (5,896)</u>	<u>\$ (15,224)</u>	<u>\$ (17,892)</u>

See accompanying notes to the condensed consolidated interim financial statements.

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

	Nine Months ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	\$ (16,711)	\$ (19,919)
Net loss allocable to noncontrolling interest	(54)	(72)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash (used in) provided by operating activities:		
Loss on marketable equity securities, net	170	1,677
Accretion of income on marketable debt securities	(647)	(186)
Depreciation expense, including amortization of leasehold improvements	419	441
Change in right-of-use assets and liabilities	86	(24)
Amortization of intangible assets	98	113
Stock-based compensation	3,580	3,328
Gain on revaluation of warrant liability	(1)	(223)
Deferred income tax benefit	(1,803)	-
Foreign currency remeasurement and other loss	1,893	2,668
Changes in operating assets and liabilities:		
Accounts receivable, net (Note 3)	(141)	50,206
Prepaid expenses and other current assets	56	517
Accounts payable and accrued liabilities (Note 7)	(3,456)	(17,573)
Deferred revenue and other liabilities (Note 3)	(6,036)	(11,591)
Net cash (used in) provided by operating activities	(22,547)	9,362
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	196	-
Purchases of marketable debt securities	(16,403)	(40,628)
Maturities of marketable debt securities	53,497	-
Purchase of equipment	(583)	(429)
Net cash provided by (used in) investing activities	36,707	(41,057)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	88	506
Common shares received and retired for employee taxes paid	(37)	(17)
Proceeds from exercise of subsidiary warrants, net	-	991
Proceeds from sale of common shares	6,625	148
Payments for offering costs	(199)	(95)
Repayment of financing lease liability	(41)	(23)
Net cash provided by financing activities	6,436	1,510
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(532)	(795)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	20,064	(30,980)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	11,936	56,277
At end of the period	<u>\$ 32,000</u>	<u>\$ 25,297</u>
Reconciliation of cash, cash equivalents and restricted cash, end of period:		
Cash and cash equivalents	\$ 31,474	\$ 24,752
Restricted cash included in deposits and other long-term assets (see Note 14 (Commitments and Contingencies))	526	545
Total cash, cash equivalents, and restricted cash	\$ 32,000	\$ 25,297

See accompanying notes to the condensed consolidated interim financial statements.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)

1. Organization and Business Overview

We are a clinical-stage biotechnology company developing novel allogeneic, or “off-the-shelf”, cell therapies to address unmet medical needs. Our programs are based on our proprietary, cell-based technology platform, and its associated development and manufacturing capabilities. From this platform, we design, develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. The cells we manufacture are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages which are relevant to the underlying condition are transplanted into patients in an effort to (a) *replace* or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) *restore* or augment the patient’s functional activity.

Our business strategy is to efficiently leverage our technology platform and our development, formulation, delivery, and manufacturing capabilities to advance our programs internally or in conjunction with strategic partners to further enhance their value and probability of success.

A significant area of focus is a partnership we entered into with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively or individually, “Roche” or “Genentech”), under which we are developing our lead cell therapy program known as OpRegen[®], for the treatment of ocular disorders, including geographic atrophy (“GA”) secondary to age-related macular degeneration (“AMD”). OpRegen is a suspension of human allogeneic retinal pigmented epithelial (“RPE”) cells and is currently being evaluated in a Phase 2a multicenter clinical trial in patients with GA secondary to AMD. OpRegen subretinal delivery has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. Under the terms of the Collaboration and License Agreement we entered into with Roche in December 2021 (the “Roche Agreement”), we received a \$50.0 million upfront payment and are eligible to receive up to \$620.0 million in certain developmental, regulatory, and commercialization milestone payments. We also are eligible to receive tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets.

Our most advanced unpartnered product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury (“SCI”). OPC1 has been tested in two clinical trials to date; a five patient Phase 1 clinical trial in acute thoracic SCI, where all subjects are followed for at least 10 years, and a 25 patient Phase 1/2a multicenter clinical trial in subacute cervical SCI, where all subjects were evaluated for at least two years. Results from both studies have been published in the Journal of Neurosurgery Spine. OPC1 clinical development has been supported in part by a \$14.3 million grant from the California Institute for Regenerative Medicine. The next planned clinical trial for the OPC1 program is the DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, which will evaluate the safety and utility of a novel spinal cord delivery device in both subacute and chronic SCI patients.

Our pipeline of allogeneic, or “off-the-shelf”, cell therapy programs currently includes:

- *OpRegen*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter clinical trial, being conducted by Roche, for the treatment of GA secondary to AMD, also known as atrophic or dry AMD.
- *OPC1*, an allogeneic oligodendrocyte progenitor cell therapy currently in long-term follow-up from a Phase 1/2a multicenter clinical trial for cervical spinal cord injuries.
- *ANP1*, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating hearing loss.
- *PNC1*, an allogeneic photoreceptor cell transplant currently in preclinical development for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *VAC*, an allogeneic cancer immunotherapy comprised of antigen-presenting dendritic cells. A Phase 1 clinical trial in non-small cell lung cancer (“NSCLC”) of a VAC product candidate, VAC2, was recently completed. This clinical trial was funded and conducted by Cancer Research UK (“CRUK”).

Other Programs

We have additional undisclosed product candidates being considered for development and which cover a range of therapeutic areas and unmet medical needs. Generally, these product candidates are based on the same platform technology and employ a similar, guided cell differentiation and transplant approach as the product candidates described above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety profiles.

Our efforts to broaden the application of our cell therapy platform and support long-term growth include a strategic collaboration we entered into with Eterna Therapeutics. This reflected a portion of our corporate strategy to capitalize on our process development capabilities by combining them with cell engineering and/or editing technologies, to create novel and potentially superior product profiles.

In addition to seeking to create value for shareholders by developing product candidates and advancing those candidates through clinical development, we also may seek to create value from licensing non-core intellectual property or related technologies, through partnering and/or strategic transactions.

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

The accompanying unaudited condensed consolidated interim financial statements were prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. In accordance with those rules and regulations, certain information and footnote disclosures normally included in comprehensive consolidated financial statements have been condensed or omitted. The condensed consolidated balance sheet as of December 31, 2022 was derived from the audited consolidated financial statements at that date but does not include all the information and footnotes required by GAAP. These unaudited condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the 2022 10-K.

The accompanying unaudited 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 our 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

The accompanying unaudited condensed consolidated interim financial statements include the accounts of our subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. The following table sets out Lineage’s ownership, directly or indirectly, of the outstanding shares of its subsidiaries as of September 30, 2023.

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

(1) Includes shares owned by Lineage and ES Cell International Pte. Ltd.

As of September 30, 2023, 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 condensed consolidated balance sheets.

Liquidity

At September 30, 2023, we had \$41.3 million of cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities, together with our projected cash flows, will be sufficient to enable us to carry out our planned operations through at least twelve months from the issuance date of the accompanying condensed consolidated interim financial statements.

Capital Resources

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

As of September 30, 2023, \$57.2 million remained available for sale under our at-the-market offering program (“ATM”). See Note 11 (Shareholders’ Equity) for additional information.

As of September 30, 2023, we had \$9.9 million of marketable securities. We may use our marketable securities for liquidity as necessary and as market conditions allow. The market value of our marketable securities may not represent the amount that could be realized in a sale of such securities due to various market and regulatory factors, including trading volume, prevailing market conditions and prices at the time of any sale and subsequent sales of securities by the entities. In addition, the value of our marketable securities may be significantly and adversely impacted by deteriorating global economic conditions and the recent disruptions to and the volatility in the credit and financial markets in the United States and worldwide resulting from the recent pandemics, including the COVID-19 pandemic, geopolitical conflicts, political and economic instability, rising inflation and interest rates, and other macroeconomic factors.

Additional Capital Requirements

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

Our obligations to licensors under license agreements and our obligations related to grants received from government entities require us to make future payments, such as sublicense fees, milestone payments, redemption fees, royalties and patent maintenance costs. Sublicense fees are payable to licensors or government entities when we sublicense the applicable intellectual property to third parties; the fees are based on a percentage of the license fees we receive from sublicensees. Milestone payments, including those related to the Roche Agreement, are due to licensors or government entities upon achievement of commercial, development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of milestone payments and royalties received under the Roche Agreement. See Note 14 (Commitment and Contingencies) for additional information. Royalties, including those related to royalties we may receive under the Roche Agreement, are payable to licensors or government entities based on a percentage of net sales of licensed products. Patent maintenance costs are payable to licensors as reimbursement for the cost of maintaining license patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements are uncertain and may fluctuate significantly from period to period. As of September 30, 2023, we have not included these commitments on our condensed consolidated balance sheet because the achievement of events that would trigger our payment obligations and the timing thereof are not fixed and determinable.

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

Significant Accounting Policies

We describe our significant accounting policies in Note 2 to the consolidated financial statements in Item 8 of the 2022 10-K. There have been no changes to our significant accounting policies during the nine months ended September 30, 2023.

Recently Issued and Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that are adopted by the Company as of the specified effective date. The Company has evaluated recently issued accounting pronouncements and does not believe any will have a material impact on the Company’s condensed consolidated financial statements or related financial statement disclosures.

3. Revenue

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
Revenues under collaborative agreements				
Upfront license fees	\$ 957	\$ 2,592	\$ 5,949	\$ 11,605
Total revenues under collaborative agreements	957	2,592	5,949	11,605
Royalties and license fees	289	406	908	1,183
Total revenue	\$ 1,246	\$ 2,998	\$ 6,857	\$ 12,788

We are recognizing the upfront payment of \$50.0 million under the Roche Agreement utilizing an input method of costs incurred over total estimated costs to be incurred. At each reporting period, we update our total estimated collaboration costs, and any resulting adjustments are recorded on a cumulative basis which would affect revenue and net income (loss) and deferred revenue in the period of adjustment. We believe the input methodology represents the most appropriate measure of progress towards satisfaction of the identified performance obligations.

During the three and nine months ended September 30, 2023, we recognized \$1.2 million and \$6.9 million in total revenue, respectively, of which \$1.0 million and \$5.9 million, respectively, was recognized in revenues under collaborative agreements related to the upfront payment from Roche, which was included in deferred revenues at December 31, 2022.

During the three and nine months ended September 30, 2022, we recognized \$3.0 million and \$12.8 million in total revenue, respectively, of which \$2.6 million and \$11.6 million, respectively, was recognized in revenues under collaborative agreements related to the upfront payment from Roche, which was included in deferred revenues at December 31, 2021.

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

	September 30, 2023	December 31, 2022
Accounts receivable, net (1)	\$ 325	\$ 297
Deferred revenues	\$ 31,110	\$ 37,146

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

As of September 30, 2023, the amounts included in the transaction price of our contracts with customers (ASU 2014-09 – *Revenue from Contracts with Customers* (Topic 606)), including collaboration partners, and allocated goods and services not yet provided were \$32.8 million, of which \$31.1 million has been collected and is reported as deferred revenues, and \$1.6 million relates to unfulfilled commitments related to the ITI collaboration (see Note 14 (Commitments and Contingencies) for additional information), the latter is currently estimated to be delivered by the end of the third quarter of 2024. Of the total deferred revenues of \$31.1 million, approximately \$9.9 million is expected to be recognized within the next 12 months.

4. Marketable Debt Securities

Marketable securities on the Company's condensed consolidated balance sheet consists of \$9.8 million in marketable debt securities and \$0.1 million in marketable equity securities (note 5) as of September 30, 2023 and \$46.1 million in marketable debt securities and \$0.4 in marketable equity securities (note 5) at December 31, 2022.

The following tables are a summary of available-for-sale debt securities included within marketable securities in the Company's condensed consolidated balance sheet as of September 30, 2023 and December 31, 2022 (in thousands):

		September 30, 2023 (Unaudited)			
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial Assets:					
	U.S. Treasury securities	\$ 9,800	\$ 1	\$ -	\$ 9,801
	Total	\$ 9,800	\$ 1	\$ -	\$ 9,801

		December 31, 2022			
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial Assets:					
	U.S. Treasury securities	\$ 46,247	\$ 2	\$ (152)	\$ 46,097
	Total	\$ 46,247	\$ 2	\$ (152)	\$ 46,097

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of September 30, 2023. We believe that the individual unrealized losses represent temporary declines resulting from changes in interest rates, and we intend to hold these marketable debt securities to their maturity. The Company currently does not intend to sell these securities prior to maturity and does not consider these investments to be other-than-temporarily impaired at September 30, 2023.

As of September 30, 2023, the amortized cost and estimated fair value of the Company's available-for-sale debt securities by contractual maturity are shown below (in thousands):

Available-for-sale debt securities maturing:	Amortized Cost	Estimated Fair Value
In one year or less	\$ 9,800	\$ 9,801
Total available-for-sale debt securities	\$ 9,800	\$ 9,801

We did not have any marketable debt securities classified as cash equivalents on the condensed consolidated balance sheets as of September 30, 2023 or December 31, 2022.

5. Marketable Equity Securities

Lineage's marketable equity securities includes the shares of stock of OncoCyte Corporation and Hadasit Bio-Holdings Ltd ("HBL"). All share prices are determined based on the closing price of OncoCyte and HBL common stock on the last day of the applicable quarter, or the last trading day of the applicable quarter, if the last day of a quarter fell on a day that was not a trading day.

As of September 30, 2023, Lineage owned approximately 7,500 shares of OncoCyte common stock, which had a fair value of \$24,000 based on the closing price of OncoCyte common stock of \$3.12 per share on that date. As of December 31, 2022, Lineage owned approximately 56,000 shares of OncoCyte common stock, which had a fair value of \$0.4 million based on the closing price of OncoCyte common stock of \$6.42 per share on that date. The fair market value of the HBL shares were not material as of September 30, 2023 and December 31, 2022.

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

	Three Months ended		Nine Months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Loss on marketable equity securities, net	\$ (60)	\$ (233)	\$ (170)	\$ (1,677)
Less: Loss recognized in earnings on marketable equity securities sold	23	-	23	-
Unrealized loss recognized on marketable equity securities held at end of period, net	<u>\$ (37)</u>	<u>\$ (233)</u>	<u>\$ (147)</u>	<u>\$ (1,677)</u>

6. Property and Equipment, Net

At September 30, 2023 and December 31, 2022 property and equipment, net was comprised of the following (in thousands):

	September 30, 2023	December 31, 2022
	(Unaudited)	
Equipment, furniture and fixtures	\$ 3,363	\$ 3,264
Leasehold improvements	2,195	2,150
Right-of-use assets	5,890	6,109
Accumulated depreciation and amortization	(6,594)	(5,850)
Property and equipment, net	<u>\$ 4,854</u>	<u>\$ 5,673</u>

Property and equipment for financing leases was \$193,000 and \$121,000 on September 30, 2023 and December 31, 2022, respectively.

Depreciation and amortization expense was \$143,000 and \$145,000 for the three months ended September 30, 2023 and 2022, respectively, and \$419,000 and \$441,000 for the nine months ended September 30, 2023 and 2022, respectively.

7. Goodwill and Intangible Assets, Net

At September 30, 2023 and December 31, 2022 goodwill and intangible assets, net consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
	(Unaudited)	
Goodwill ⁽¹⁾	<u>\$ 10,672</u>	<u>\$ 10,672</u>
Intangible assets:		
Acquired IPR&D – OPC1 (from the Asterias Merger) ⁽²⁾	\$ 31,700	\$ 31,700
Acquired IPR&D – VAC (from the Asterias Merger) ⁽²⁾	14,840	14,840
Intangible assets subject to amortization:		
Acquired patents	18,953	18,953
Acquired royalty contracts ⁽³⁾	650	650
Total intangible assets	<u>66,143</u>	<u>66,143</u>
Accumulated amortization ⁽⁴⁾	(19,549)	(19,451)
Intangible assets, net	<u>\$ 46,594</u>	<u>\$ 46,692</u>

(1) Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in the Asterias Merger, see Note 14 (Commitment and Contingencies) for further discussion on the Asterias Merger.

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

- (3) Asterias had royalty cash flows under patent families it acquired from Geron Corporation (“Geron”). Such patent families are expected to continue to generate revenue, are not used in the OPC1 or the VAC platform, and are considered to be separate long-lived intangible assets under Accounting Standards Codifications (“ASC”) Topic 805, *Business Combinations*.
- (4) As of September 30, 2023 acquired patents were fully amortized and the acquired royalty contracts had a remaining unamortized balance of approximately \$54,000.

Lineage amortizes its intangible assets over an estimated period of 5 to 10 years on a straight-line basis. Lineage recognized approximately \$33,000 in amortization expense of intangible assets during each of the three months ended September 30, 2023 and 2022, and \$98,000 during each of the nine months ended September 30, 2023 and 2022.

Amortization of intangible assets for periods subsequent to September 30, 2023 is as follows (in thousands):

Year Ending December 31,	Amortization Expense
2023	\$ 32
2024	22
Total	<u>\$ 54</u>

8. Accounts Payable and Accrued Liabilities

At September 30, 2023 and December 31, 2022 accounts payable and accrued liabilities consisted of the following (in thousands):

	September 30, 2023 (Unaudited)	December 31, 2022
Accounts payable	\$ 2,430	\$ 2,393
Accrued compensation	2,251	2,382
Accrued liabilities ⁽¹⁾	349	3,833
Total	<u>\$ 5,030</u>	<u>\$ 8,608</u>

- (1) The decrease in accrued liabilities was due to a payment made in connection with the settlement of litigation in February 2023 related to the Asterias Merger. See Note 14 (Commitment and Contingencies) for additional information.

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

We measure our money market fund, marketable securities and our liability classified warrants at fair value on a recurring basis. The fair values of such assets and liabilities were as follows as of September 30, 2023 and December 31, 2022 (in thousands):

	Balance at September 30, 2023	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund ⁽¹⁾	\$ 19,782	\$ 19,782	\$ -	\$ -
Marketable debt securities	9,801	9,801	-	-
Marketable equity securities	57	57	-	-
Total assets measured at fair value	<u>\$ 29,640</u>	<u>\$ 29,640</u>	<u>\$ -</u>	<u>\$ -</u>

	Balance at December 31, 2022	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund ⁽¹⁾	\$ 4,102	\$ 4,102	\$ -	\$ -
Marketable debt securities	46,097	46,097	-	-
Marketable equity securities	423	423	-	-
Total assets measured at fair value	<u>\$ 50,622</u>	<u>\$ 50,622</u>	<u>\$ -</u>	<u>\$ -</u>
Liabilities:				
Warrants to purchase Cell Cure ordinary shares ⁽²⁾	\$ 2	\$ -	\$ -	\$ 2
Total liabilities measured at fair value	<u>\$ 2</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2</u>

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheet.

(2) Included in other long-term liabilities in the accompanying condensed consolidated balance sheet. As of September 30, 2023, the fair value of our liability classified warrants was zero.

Lineage's marketable equity securities includes the shares of stock of OncoCyte and HBL. Both securities have readily determinable fair values and are measured at fair value and reported as current assets on the accompanying condensed consolidated balance sheets based on the closing trading price of the security as of the date being presented.

The carrying value of cash, restricted cash, accounts receivable, accounts payable, and accrued liabilities approximate their respective fair values due to their relative short maturities.

10. Related Party Transactions

In connection with the putative shareholder class action lawsuits filed in February 2019 and October 2019 challenging the Asterias Merger (see Note 14), Lineage agreed to pay the expenses for the legal defense of Neal Bradsher, a member of the Lineage board of directors, Broadwood Partners, L.P., a shareholder of Lineage, and Broadwood Capital, Inc., which serves as the general partner of Broadwood Partners, L.P., all of whom were named defendants in the lawsuits, prior to being dismissed. Through September 30, 2023, Lineage has incurred approximately \$626,000 in legal expenses on behalf of the foregoing parties.

11. Shareholders' Equity

Preferred Shares

Lineage is authorized to issue 2,000,000 preferred shares, no par value. The preferred shares may be issued in one or more series as the Lineage board of directors may determine by resolution. The Lineage board of directors is authorized to fix the number of shares of any series of preferred shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed on the preferred shares as a class, or upon any wholly unissued series of any preferred shares. The Lineage board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of preferred shares subsequent to the issue of shares of that series. As of September 30, 2023 and December 31, 2022, there were no preferred shares issued or outstanding.

Common Shares

At December 31, 2022, Lineage was authorized to issue 250,000,000 common shares, no par value. In September 2023, our shareholders approved an increase in the number of authorized common shares, no par value, from 250,000,000 to 450,000,000. As of September 30, 2023 and December 31, 2022, there were 174,986,671 and 170,093,114 common shares issued and outstanding, respectively.

At-The-Market Offering Program

In May 2020, Lineage entered into a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which Lineage may sell its common shares from time to time through an "at-the-market offering" program under the Sales Agreement.

In March 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of \$25.0 million of common shares through the ATM program under the Sales Agreement ("March 2021 Prospectus Supplement").

In December 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of up to \$64.1 million of common shares (which included \$14.1 million of its common shares which then remained unsold under the March 2021 Prospectus Supplement) through the ATM program under the Sales Agreement. Following the filing of the prospectus supplement in December 2021, no further sales were made or will be made under the March 2021 Prospectus Supplement. The prospectus supplement filed in December 2021 was updated, amended and supplemented by a prospectus supplement filed with the SEC on May 18, 2023 (the prospectus supplement filed in December 2021, as updated, amended and supplemented by the prospectus supplement filed in May 2023, the "Current Prospectus Supplement").

As of September 30, 2023, Lineage had sold 4,882,803 common shares under the Current Prospectus Supplement at a weighted average price per share of \$1.41 for gross proceeds of \$6.9 million. As of September 30, 2023, \$57.2 million remained available for sale under the Current Prospectus Supplement. During the nine months ended September 30, 2023, 4,774,603 shares were sold under the Current Prospectus Supplement for gross proceeds of \$6.6 million and net proceeds of \$6.4 million.

The shares offered under the Current Prospectus Supplement are registered pursuant to Lineage's effective shelf registration statement on Form S-3 (File No. 333-254167), which was filed with the SEC on March 5, 2021 and declared effective on March 19, 2021.

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

Reconciliation of Changes in Shareholders' Equity

The following tables document the changes in shareholders' equity for the three and nine months ended September 30, 2023 and 2022 (unaudited and in thousands):

	Preferred Shares		Common Shares		Accumulated Deficit	Noncontrolling Deficit	Accumulated Other Comprehensive Income / (Loss)	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
BALANCE - December 31, 2022	-	\$ -	170,093	\$ 440,280	\$ (363,370)	\$ (1,403)	\$ (3,571)	\$ 71,936
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	53	(37)	-	-	-	(37)
Shares issued upon exercise of stock options	-	-	28	25	-	-	-	25
Stock-based compensation	-	-	-	1,031	-	-	-	1,031
Unrealized gain on marketable debt securities	-	-	-	-	-	-	91	91
Foreign currency translation gain	-	-	-	-	-	-	373	373
Net loss	-	-	-	-	(4,372)	(32)	-	(4,404)
BALANCE - March 31, 2023	-	-	170,174	441,299	(367,742)	(1,435)	(3,107)	69,015
Shares issued through ATM	-	-	4,237	5,841	-	-	-	5,841
Financing related fees	-	-	-	(193)	-	-	-	(193)
Shares issued upon exercise of stock options	-	-	28	22	-	-	-	22
Stock-based compensation	-	-	-	1,280	-	-	-	1,280
Unrealized gain on marketable debt securities	-	-	-	-	-	-	50	50
Foreign currency translation gain	-	-	-	-	-	-	446	446
Net income (loss)	-	-	-	-	(5,229)	26	-	(5,203)
BALANCE - June 30, 2023	-	-	174,439	448,249	(372,971)	(1,409)	(2,611)	71,258
Shares issued through ATM	-	-	538	784	-	-	-	784
Financing related fees	-	-	-	(28)	-	-	-	(28)
Shares issued upon exercise of stock options	-	-	10	8	-	-	-	8
Stock-based compensation	-	-	-	1,269	-	-	-	1,269
Unrealized gain on marketable debt securities	-	-	-	-	-	-	9	9
Foreign currency translation gain	-	-	-	-	-	-	518	518
Net income (loss)	-	-	-	-	(7,110)	(48)	-	(7,158)
BALANCE - September 30, 2023	-	\$ -	174,987	\$ 450,282	\$ (380,081)	\$ (1,457)	\$ (2,084)	\$ 66,660

	Preferred Shares		Common Shares		Accumulated Deficit	Noncontrolling Deficit	Accumulated Other Comprehensive Income / (Loss)	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
BALANCE - December 31, 2021	-	\$ -	169,477	\$ 434,529	\$ (337,097)	\$ (1,323)	\$ (5,211)	\$ 90,898
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	10	(8)	-	-	-	(8)
Shares issued upon exercise of stock options	-	-	240	189	-	-	-	189
Subsidiary warrant exercise	-	-	-	2	-	-	-	2
Stock-based compensation	-	-	-	1,106	-	-	-	1,106
Foreign currency translation gain	-	-	-	-	-	-	124	124
Net loss	-	-	-	-	(7,087)	(6)	-	(7,093)
BALANCE - March 31, 2022	-	-	169,727	435,818	(344,184)	(1,329)	(5,087)	85,218
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	10	(9)	-	-	-	(9)
Shares issued upon exercise of stock options	-	-	11	10	-	-	-	10
Subsidiary warrant exercise, net	-	-	-	97	-	-	-	97
Stock-based compensation	-	-	-	1,235	-	-	-	1,235
Foreign currency translation gain	-	-	-	-	-	-	1,730	1,730
Net loss	-	-	-	-	(6,763)	(19)	-	(6,782)
BALANCE - June 30, 2022	-	-	169,748	437,151	(350,947)	(1,348)	(3,357)	81,499
Shares issued upon exercise of stock options	-	-	138	118	-	-	-	118
Subsidiary warrant exercise, net	-	-	-	892	-	-	-	892
Stock-based compensation	-	-	-	987	-	-	-	987
Unrealized loss on marketable debt securities	-	-	-	-	-	-	(150)	(150)
Foreign currency translation gain	-	-	-	-	-	-	323	323
Net loss	-	-	-	-	(6,069)	(47)	-	(6,116)
BALANCE - September 30, 2022	-	\$ -	169,886	\$ 439,148	\$ (357,016)	\$ (1,395)	\$ (3,184)	\$ 77,553

12. Stock-Based Awards

Equity Incentive Plan Awards

In September 2021, our shareholders approved the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan (the "2021 Plan"), which became effective upon such approval. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs"), and other stock awards. All of our employees (including those of our affiliates), non-employee directors and consultants are eligible to participate in the 2021 Plan. In September 2023, our shareholders approved an amendment to the 2021 Plan to increase the number of common shares that may be issued under the 2021 Plan by 19,500,000.

Subject to adjustment for certain changes in our capitalization, the aggregate number of our common shares that may be issued under the 2021 Plan will not exceed the sum of (i) 34,500,000 shares and (ii) the number of shares subject to awards granted under the Lineage Cell Therapeutics Inc. 2012 Equity Incentive Plan (the "2012 Plan") that were outstanding when the 2021 Plan became effective and are not issued because such awards expire or otherwise terminate. As of September 30, 2023, there were 25,436,929 shares available for grant under the 2021 Plan.

As a result of the approval of the 2021 Plan by our shareholders, no additional awards will be granted under the 2012 Plan.

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

	Number of Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2022	6,001	\$ 1.40
Options granted	5,720	\$ 1.45
Options expired/forfeited/cancelled	(239)	\$ 1.42
Balance at September 30, 2023	<u>11,482</u>	<u>\$ 1.42</u>
Options exercisable at September 30, 2023	<u>2,054</u>	<u>\$ 1.43</u>

	Number of RSUs Outstanding
Balance at December 31, 2022	939
RSUs forfeited	(100)
RSUs vested	(80)
Balance at September 30, 2023	<u>759</u>

A summary of activity of the 2012 Plan, and the 2018 inducement option (which was issued to a Lineage executive outside of all equity plans), is as follows (in thousands, except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2022	12,172	\$ 1.83
Options exercised	(66)	\$ 0.84
Options expired/forfeited/cancelled	(420)	\$ 1.89
Balance at September 30, 2023	<u>11,686</u>	<u>\$ 1.83</u>
Options exercisable at September 30, 2023	<u>9,846</u>	<u>\$ 1.69</u>

Stock-based compensation expense

The fair value of each option award is estimated on the date of grant using a Black-Scholes option pricing model applying the weighted-average assumptions noted in the following table:

	Nine Months ended September 30, (unaudited)	
	2023	2022
Expected life (in years)	6.20	6.20
Risk-free interest rates	4.1%	2.1%
Volatility	74.7%	73.6%
Dividend yield	-	-

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

	Three Months ended September 30, (unaudited)		Nine Months ended September 30, (unaudited)	
	2023	2022	2023	2022
Research and development	\$ 260	\$ 204	\$ 729	\$ 559
General and administrative	1,009	783	2,851	2,769
Total stock-based compensation expense	<u>\$ 1,269</u>	<u>\$ 987</u>	<u>\$ 3,580</u>	<u>\$ 3,328</u>

As of September 30, 2023, total unrecognized compensation costs related to unvested stock options and unvested RSUs under all equity plans (including the 2018 inducement option), were \$10.6 million, which is expected to be recognized as expense over a weighted average period of approximately 2.6 years.

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

For the three and nine months ended September 30, 2023 and 2022, respectively, Lineage reported a net loss attributable to common shareholders, and therefore, all potentially dilutive common shares were considered antidilutive for those periods.

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
Stock options	23,168	17,972	23,168	17,972
Restricted stock units	759	939	759	939

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, 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.

Under ASC 740, a valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Lineage established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries.

For the tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 (“TCJA”) eliminated the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to IRC Section 174. Although Congress is considering legislation that would repeal or defer this capitalization and amortization requirement, it is not certain that this provision will be repealed or otherwise modified. If the requirement is not repealed or replaced, it will decrease our tax deduction for research and development expenses in future years.

The 2017 Tax Act subjects a U.S. stockholder to Global Intangible Low-Taxed Income (“GILTI”) earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. stockholder’s total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50% of GILTI; however, this deduction is limited to the company’s pre-GILTI U.S. income. Lineage incurred GILTI income during the years 2021 and 2022. For the three and nine months ended September 30, 2023, no GILTI income was included in the Company’s tax provision.

Lineage recorded a \$1.8 million deferred tax benefit for the nine months ended September 30, 2023, due to the ability to offset certain deferred tax assets against the deferred tax liability associated with IPR&D, and the related release of the valuation allowance. It was determined that a portion of the deferred tax liability related to the indefinite lived assets may be realized prior to the expiration of certain pre 2018 net operating losses. Lineage did not record a deferred tax benefit for the second and third quarters of 2023, and did not record a deferred tax benefit for the three and nine months ended September 30, 2022.

For the three and nine months ended September 30, 2022, Lineage recorded a withholding tax for the amount of \$0.5 million on interest expense deemed paid to Lineage from Cell Cure on the purchase of intellectual property pursuant to the US Israeli tax treaty. There was no comparable tax expense recorded for the three and nine months ended September 30, 2023.

14. Commitments and Contingencies

Real Property Leases

Carlsbad Lease

In May 2019, Lineage entered into a lease for approximately 8,841 square feet of rentable space in an office park in Carlsbad, California. The lease was amended in December 2022 and the term was extended for a period of thirty-seven months (the “Extended Term”) commencing on March 1, 2023 (the “Extended Term Commencement Date”). The lease expires on March 31, 2026, and rent was abated for months two through four of the Extended Term. The monthly base rent was \$24,666 through the Extended Term Commencement Date, after which it increased to \$25,197. As security for the performance of its obligations under the lease, Lineage provided the landlord a security deposit of \$17,850, which is included in deposits and other long-term assets on the condensed consolidated balance sheet as of September 30, 2023.

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

Carlsbad Sublease

In September 2022, Lineage entered into a sublease for approximately 4,500 square feet of rentable industrial space in Carlsbad, California for a term that commenced on October 1, 2022 and expires on March 31, 2024. As security for the performance of its obligations under the sublease, Lineage provided the landlord with a security deposit of \$22,500, which is included in prepaid expense and other current assets on the condensed consolidated balance sheet as of September 30, 2023. Base rent is \$22,500 per month until the sublease expires.

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, 2027, with an option to extend the lease for five years. Base monthly rent is NIS 39,776 (approximately \$12,200 per month). 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. These pro-rata charges are expensed as incurred and excluded from the calculation of the ROU assets and lease liabilities.

In January 2018, Cell Cure entered into a lease for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility that expires on December 31, 2027, with an option to extend the lease for five years. Base rent and construction allowance payments are NIS 93,827 per month (approximately \$26,000 per month). Cell Cure has a security deposit denominated in NIS with the landlord held as restricted cash during the term of its facility lease. The value of this security deposit in USD fluctuates based upon currency exchange rates and was \$426,000 as of September 30, 2023, which is included in deposits and other long-term assets on the condensed consolidated balance sheet.

In November 2021, Cell Cure entered into a lease for an additional 133 square meters (approximately 1,432 square feet) of office space in the same facility that commenced on December 1, 2021, and expires on December 31, 2027, with an option to extend the lease for five years. The base monthly rent was NIS 11,880 (approximately US \$3,757) through October 31, 2022 and increased to NIS 12,494 (approximately US \$3,951) on November 1, 2022.

In August 2022, Cell Cure entered into a lease for 300 square meters (approximately 3,229 square feet) of office and laboratory space in Jerusalem, Israel that expires on December 31, 2027, with an option to extend the lease for five years. Base monthly rent is 16,350 NIS (approximately \$4,800 per month). When executing this lease, Cell Cure modified the expiration dates and options terms for the leases identified above to align with this lease.

Supplemental Information – Leases

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

	Nine Months ended September 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 833	\$ 727
Operating cash flows from financing leases	\$ 8	\$ 14
Financing cash flows from financing leases	\$ 41	\$ 23
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	\$ -	\$ 1,028
Finance leases	\$ 79	\$ -

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

	September 30,	December 31,
	2023	2022
	(Unaudited)	
Operating leases		
Right-of-use assets, net	\$ 2,652	\$ 3,517
Right-of-use lease liabilities, current	\$ 881	\$ 916
Right-of-use lease liabilities, noncurrent	2,047	2,860
Total operating lease liabilities	\$ 2,928	\$ 3,776
Financing leases		
Right-of-use assets, net	\$ 141	\$ 105
Lease liabilities, current	\$ 55	\$ 29
Lease liabilities, noncurrent	97	84
Total finance lease liabilities	152	113
Other current liabilities	-	7
Total finance lease liabilities	\$ 152	\$ 120
Weighted average remaining lease term		
Operating leases	3.7 years	4.3 years
Finance leases	3.2 years	4.1 years
Weighted average discount rate		
Operating leases	6.4%	6.3%
Finance leases	6.8%	6.9%

Future minimum lease commitments are as follows as of September 30, 2023 (in thousands):

Year Ending December 31,	(Unaudited)	
	Operating Leases	Finance Leases
2023	\$ 275	\$ 16
2024	921	60
2025	852	50
2026	623	26
2027	658	18
Total lease payments	3,329	170
Less imputed interest	(401)	(18)
Total	\$ 2,928	\$ 152

Collaborations

Roche Agreement

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

Under the terms of the Roche Agreement, Roche paid Lineage a \$50.0 million upfront payment and Lineage is eligible to receive up to an additional \$620.0 million in certain developmental, regulatory and commercialization milestone payments. Lineage also is eligible for tiered double-digit percentage royalties on net sales of OpRegen in the U.S and other major markets. All regulatory and commercial milestone payments and royalty payments are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalty payments on net sales of OpRegen are subject to financial offsets based on the existence of competing products. Roche assumed responsibility for further clinical development and commercialization of OpRegen. Lineage is responsible for completing activities related to the ongoing clinical study, for which enrollment is complete, and performing certain manufacturing and process development activities.

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

In January 2022, Lineage received the \$50.0 million upfront payment from Roche. Subsequently, Lineage, via Cell Cure, paid \$12.1 million to the IIA, and \$8.9 million to Hadasit Medical Research Services and Development Ltd. ("Hadasit"). Such payments were made in accordance with obligations under the Innovation Law (as discussed below) and under the terms of Cell Cure's agreements with Hadasit (as discussed below). The payment to Hadasit was reduced by \$1.9 million in accordance with the provisions of such agreements discussed below that reduce the sublicensing fee payable to Hadasit for costs related to Lineage's performance obligations under the Roche Agreement. To the extent such costs are not incurred within five years after the execution of the Roche Agreement, Cell Cure will be required to pay Hadasit 21.5% of the amount of costs not incurred.

ITI Collaboration Agreement

In April 2021, Lineage entered into a collaborative agreement with Immunomic Therapeutics, Inc. ("ITI") whereby Lineage agreed to perform up to approximately \$2.2 million worth of certain research, development, manufacturing, and oversight activities related to the development of an allogeneic VAC-CMV product candidate. ITI will reimburse Lineage for these costs and full-time employee costs for the manufacturing of the VAC-CMV product candidate. As of September 30, 2023, Lineage has a remaining performance obligation of approximately \$1.6 million for the aforementioned activities. Upon execution of the agreement in April 2021, \$0.5 million was paid by ITI to Lineage. Upon delivery of research-grade VAC-CMV product generated by Lineage, ITI paid an additional \$0.5 million in August 2021. ITI is currently evaluating its next step under the agreement.

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

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

The terms of the grants under the Innovation Law generally require that the products developed as part of the programs under which the grants were given be manufactured in Israel. The know-how developed thereunder may not be transferred outside of Israel unless prior written approval is received from the IIA. Transfer of IIA-funded know-how outside of Israel is subject to approval and payment of a redemption fee to the IIA calculated according to formulas provided under the Innovation Law. In November 2021, the IIA research committee approved an application made by Cell Cure with respect to the grant of an exclusive license and transfer of the technological know-how for OpRegen to Roche. Under the provisions for the redemption fee, Lineage is obligated to pay the IIA approximately 24.1% of the upfront, milestone, and royalty payments which may be received under the Roche Agreement, up to an aggregate cap on all payments, such cap growing over time via interest accrual until paid in full. As of September 30, 2023, the aggregate cap amount was approximately \$92.7 million.

Pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, between Cell Cure and Hadasit, and a certain letter agreement entered into on December 17, 2021, Hadasit was entitled to, and was paid, a sublicensing fee of 21.5% of the \$50.0 million upfront payment under the Roche Agreement (subject to certain reductions, including for costs related to Lineage’s performance obligations under the Roche Agreement) and of any milestone payments, and up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives under the Roche Agreement. The letter agreement generally terminates upon the termination of the Roche Agreement.

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

In May 2020, Lineage and Asterias entered into a Second Amendment to the Clinical Trial and Option Agreement (the “Second CTOA Amendment”) with CRUK and Cancer Research Technology (“CRT”). The Second CTOA Amendment amended the initial agreement and the first amendment to the Clinical Trial and Option Agreement, each of which is dated September 8, 2014, between Asterias, CRUK and CRT. Pursuant to the Second CTOA Amendment, Lineage assumed all obligations of Asterias and exercised early its option to acquire data generated in the Phase 1 clinical trial of VAC2 in non-small cell lung cancer being conducted by CRUK.

Lineage and CRT effectuated the option by simultaneously entering into a license agreement (the “CRT License Agreement”) pursuant to which Lineage paid a signature fee of £1,250,000 (approximately \$1.6 million). For the primary licensed product for the first indication, the CRT 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 milestone 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 CRT License Agreement for the uncured material breach of the other party. CRT may terminate the CRT License Agreement in the case of Lineage’s insolvency or if Lineage ceases all development and commercialization of all products under the CRT License Agreement.

Other Contingent Obligations

We have obligations under license agreements and grants received from government entities to make future payments to third parties, which become due and payable on the achievement of certain development, regulatory and commercial milestones or on the sublicense of our rights to another party. These commitments include sublicense fees, milestone payments, redemption fees and royalties. Sublicense fees are payable to licensors or government entities when we sublicense underlying intellectual property to third parties; the fees are based on a percentage of the license fees we receive from sublicensees. Milestone payments are due to licensors or government entities upon the future achievement of certain development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone and royalties received under the Roche Agreement. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products. As of September 30, 2023, we have not included these commitments on our condensed consolidated balance sheet because the achievement and timing of these events are not fixed and determinable.

Litigation – General

From time to time, we are subject to legal proceedings and claims in the ordinary course of business. While management presently believes that the ultimate outcome of these proceedings, individually and in the aggregate, will not materially harm our financial position, cash flows, or overall trends in results of operations, legal proceedings are subject to inherent uncertainties, and unfavorable rulings or outcomes could occur that have individually or in aggregate, a material adverse effect on our business, financial condition or operating results. We are not currently subject to any pending material litigation, other than ordinary routine litigation incidental to our business.

Asterias Merger

In November 2018, Lineage, Asterias Biotherapeutics, Inc. (“Asterias”), and Patrick Merger Sub, Inc., a wholly owned subsidiary of Lineage, entered into an Agreement and Plan of Merger pursuant to which Lineage agreed to acquire all of the outstanding common stock of Asterias in a stock-for-stock transaction (the “Asterias Merger”). The Asterias Merger closed in March 2019. In October 2019, a putative class action lawsuit was filed against the company and certain other named defendants challenging the Asterias Merger.

In February 2023, the court approved a Stipulation and Agreement of Compromise and Settlement pursuant to which, Lineage and certain insurers of the defendants paid \$10.65 million (the “Settlement Amount”) into a fund created for the benefit of the purported class and in consideration for the full and final release, settlement and discharge of all claims. Approximately \$7.12 million of the Settlement Amount was funded by certain insurers and approximately \$3.53 million was paid by Lineage in cash.

Lineage and all defendants have denied, and continue to deny, the claims alleged in the lawsuit and the settlement does not reflect or constitute any admission, concession, presumption, proof, evidence or finding of any liability, fault, wrongdoing or injury or damages, or of any wrongful conduct, acts or omissions on the part any defendant.

Premvia Litigation Settlement

In July 2019, the Company, along with other named defendants, was sued in the Superior Court of the State of California in a matter captioned *Gonzalez v. Aronowitz, M.D., et al.* The plaintiff asserted medical negligence and product liability causes of action relating to the 2017 and 2018 use in a clinical trial of a product candidate, Premvia, that the Company is no longer developing and has no plans to pursue, and that is not related to the cell therapy candidates the Company currently is developing. In February 2023, the Company and the other defendants each entered into settlement agreements with the plaintiff pursuant to which the defendants without admitting any liability, which the defendants expressly denied, each agreed to pay specified amounts to the plaintiff in exchange for a full settlement and release and discharge of claims. The Company’s insurance covered the full amount paid by the Company excluding the \$25,000 insurance deductible.

HBL Books and Records Request

On April 17, 2023, Cell Cure Neurosciences Ltd. (“Cell Cure”), Lineage’s subsidiary, received a motion for disclosure of documents pursuant to Section 198A of the Israeli Companies Law 5759-1999. The motion was filed in the district court in Tel Aviv-Yafo (the “Court”) by HBL Hadasit Bio-Holdings Ltd. (“HBL”), currently an approximately 5% shareholder of Cell Cure. According to the motion, the requested production of documents is intended to allow HBL to examine the possibility of pursuing a derivative action related to, among other things, the validity of an intercompany Collaboration and License Agreement (the “Intercompany Agreement”) entered into between Lineage and Cell Cure pursuant to which Cell Cure conveyed certain rights and other assets to Lineage, and Lineage agreed to undertake certain liabilities and obligations of Cell Cure relating to the OpRegen® program. In its motion, HBL alleges, among other things, that Lineage, in its capacity as Cell Cure’s controlling shareholder, and members of Cell Cure’s board of directors caused damage to Cell Cure because the Intercompany Agreement was an interested party transaction that was not fairly priced and exploits Cell Cure’s resources for the benefit of Lineage. The motion seeks an order to compel Cell Cure to disclose and deliver to HBL the documents described in the motion, such additional, cumulative, or alternative relief as the court deems appropriate, and reimbursement of HBL’s expenses, including attorneys’ fees. Cell Cure filed an opposition to the motion on July 9, 2023. The Court has set a hearing date for the motion of December 3, 2023. 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 employment agreements with all of its executive officers. Under the provisions of the agreements, Lineage may be required to incur severance obligations for matters relating to changes in control, as defined in the agreements, and involuntary terminations.

Indemnification

In the normal course of business, Lineage may agree to indemnify and reimburse other parties, typically Lineage's clinical research organizations, investigators, clinical sites, and suppliers, for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of Lineage's products and services. Indemnification could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to Lineage products and services. The term of these indemnification agreements generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. The potential future payments Lineage could be required to make under these indemnification agreements will generally not be subject to any specified maximum amount. Generally, Lineage has not been subject to any material claims or demands for indemnification. Lineage maintains liability insurance policies that limit its financial exposure under the indemnification agreements. Accordingly, Lineage has not recorded any liabilities for these agreements as of September 30, 2023 or December 31, 2022.

Royalty Obligations and License Fees

We have licensing agreements with research institutions, universities and other parties providing us with certain rights to use intellectual property in conducting research and development activities in exchange for the payment of royalties on future product sales, if any. In addition, in order to maintain these licenses and other rights, we must comply with various conditions including the payment of patent related costs and annual minimum maintenance fees.

As part of the Asterias Merger, Lineage acquired certain royalty revenues for cash flows generated under patent families that Asterias acquired from Geron Corporation. Lineage continues to make royalty payments to Geron from royalties generated from these patents. Royalty revenues and royalty payments are included withing Royalties and license fees and Cost of sales, respectively, in our condensed consolidated statements of operations.

15. Subsequent Events

Israel-Hamas War

All of our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, Cell Cure, at its facility in Jerusalem, Israel, and more than two-thirds of our employees are Cell Cure employees who are based in the same facility. As of the date of this report, our operations have not been materially or adversely impacted as a result of the Israel-Hamas war that began in October 2023. It is currently not possible to predict the scope, duration or severity of the ongoing war or its effects on our operations, financial condition or operating results. The ongoing war is rapidly evolving, and could materially adversely impact our business and operations, including our ability to raise capital, as well as the overall economy in Israel and the value of the New Israeli Shekel.

Item 2. Management’s Discussion and Analysis of Financial Condition and Result of Operations

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated interim financial statements and notes thereto included in this report and our audited financial statements and notes thereto for the year ended December 31, 2022 included in the 2022 10-K. Past operating results are not necessarily indicative of results that may occur in future periods.

The following discussion includes forward-looking statements. See “Special Note Regarding Forward-Looking Statements,” above. Forward-looking statements are not guarantees of future performance and our actual results may differ materially from those currently anticipated and from historical results depending upon a variety of factors, including, but not limited to, those discussed in Part I, Item 1A. Risk Factors of our 2022 10-K, and in our subsequent filings with the SEC, including any discussed in Part II, Item 1A of this report under the heading “Risk Factors.”

All information presented in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

Company and Business Overview

We are a clinical-stage biotechnology company developing novel allogeneic, or “off-the-shelf”, cell therapies to address unmet medical needs. Our programs are based on our proprietary, cell-based technology platform, and its associated development and manufacturing capabilities. From this platform, we design, develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. The cells we manufacture are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages which are relevant to the underlying condition are transplanted into patients in an effort to (a) *replace* or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) *restore* or augment the patient’s functional activity.

Our business strategy is to efficiently leverage our technology platform and our development, formulation, delivery, and manufacturing capabilities to advance our programs internally or in conjunction with strategic partners to further enhance their value and probability of success.

A significant area of focus is a partnership we entered into with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively or individually, “Roche” or “Genentech”), under which we are developing our lead cell therapy program known as OpRegen[®], for the treatment of ocular disorders, including geographic atrophy (“GA”) secondary to age-related macular degeneration (“AMD”). OpRegen is a suspension of human allogeneic retinal pigmented epithelial (“RPE”) cells and is currently being evaluated in a Phase 2a multicenter clinical trial in patients with GA secondary to AMD. OpRegen subretinal delivery has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. Under the terms of the Collaboration and License Agreement we entered into with Roche in December 2021 (the “Roche Agreement”), we received a \$50.0 million upfront payment and are eligible to receive up to \$620.0 million in certain developmental, regulatory, and commercialization milestone payments. We also are eligible to receive tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets.

Our most advanced unpartnered product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury (“SCI”). OPC1 has been tested in two clinical trials to date; a five patient Phase 1 clinical trial in acute thoracic SCI, where all subjects are followed for at least 10 years, and a 25 patient Phase 1/2a multicenter clinical trial in subacute cervical SCI, where all subjects were evaluated for at least two years. Results from both studies have been published in the Journal of Neurosurgery Spine. OPC1 clinical development has been supported in part by a \$14.3 million grant from the California Institute for Regenerative Medicine. The next planned clinical trial for the OPC1 program is the DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, which will evaluate the safety and utility of a novel spinal cord delivery device in both subacute and chronic SCI patients.

Our pipeline of allogeneic, or “off-the-shelf”, cell therapy programs currently includes:

- *OpRegen*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter clinical trial, being conducted by Roche, for the treatment of GA secondary to AMD, also known as atrophic or dry AMD.
- *OPC1*, an allogeneic oligodendrocyte progenitor cell therapy currently in long-term follow-up from a Phase 1/2a multicenter clinical trial for cervical spinal cord injuries.
- *ANP1*, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating hearing loss.
- *PNC1*, an allogeneic photoreceptor cell transplant currently in preclinical development for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *VAC*, an allogeneic cancer immunotherapy comprised of antigen-presenting dendritic cells. A Phase 1 clinical trial in non-small cell lung cancer (“NSCLC”) of a VAC product candidate, VAC2, was recently completed. This clinical trial was funded and conducted by Cancer Research UK (“CRUK”).

Other Programs

We have additional undisclosed product candidates being considered for development and which cover a range of therapeutic areas and unmet medical needs. Generally, these product candidates are based on the same platform technology and employ a similar, guided cell differentiation and transplant approach as the product candidates described above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety profiles.

Our efforts to broaden the application of our cell therapy platform and support long-term growth include a strategic collaboration we entered into with Eterna Therapeutics. This reflected a portion of our corporate strategy to capitalize on our process development capabilities by combining them with cell engineering and/or editing technologies, to create novel and potentially superior product profiles.

In addition to seeking to create value for shareholders by developing product candidates and advancing those candidates through clinical development, we also may seek to create value from licensing non-core intellectual property or related technologies, through partnering and/or strategic transactions.

Israel-Hamas War

All of our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, Cell Cure, at its facility in Jerusalem, Israel, and more than two-thirds of our employees are Cell Cure employees who are based in the same facility. As of the date of this report, our operations have not been materially or adversely impacted as a result of the Israel-Hamas war that began in October 2023.

As a result of safety concerns and in response to government-imposed restrictions on movement and travel and other precautions taken to address the ongoing war, our operations at our facilities in Israel were temporarily impacted. Further, a number of our employees in Israel are members of the military reserves and subject to immediate call-up in response to the war in Israel. A number of our employees in Israel have been activated for military duty and we expect additional employees will also be activated. In addition, the general impact on employees operating in a region at war could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from the war, any long-term closure of our facilities in Israel, or if those facilities were damaged, or if hostilities otherwise disrupt the ongoing operation of our facilities, our operations would be materially and adversely impacted.

It is currently not possible to predict the scope, duration or severity of the ongoing war or its effects on our operations, financial condition or operating results. The ongoing war is rapidly evolving, and could materially adversely impact our business and operations, including our ability to raise capital, as well as the overall economy in Israel and the value of the New Israeli Shekel. See the risk factor titled, “All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel. Accordingly, political, economic and military conditions in Israel could directly affect our business. Any event or condition that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results,” in our 2022 10-K.

Our commercial insurance may not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business.

Critical Accounting 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. See Part II, Item 7 – Critical Accounting Estimates and our consolidated financial statements and related notes in Part II, Item 8 of our 2022 10-K for accounting policies and related estimates we believe are the most critical to understanding our condensed consolidated interim financial statements, financial condition and results of operations and which require complex management judgment and assumptions or involve uncertainties. There have not been any changes to our significant accounting policies or their application since we filed our 2022 10-K.

Results of Operations

Comparison of Three and Nine months Ended September 30, 2023 and 2022

Revenues and Cost of Sales

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

	Three Months ended September 30, (unaudited)				Nine Months ended September 30, (unaudited)			
	2023	2022	\$ change	% change	2023	2022	\$ change	% change
Collaboration revenues	\$ 957	\$ 2,592	\$ (1,635)	(63)%	\$ 5,949	\$ 11,605	\$ (5,656)	(49)%
Royalties and license fees	289	406	(117)	(29)%	908	1,183	(275)	(23)%
Total revenues	1,246	2,998	(1,752)	(58)%	6,857	12,788	(5,931)	(46)%
Cost of sales	(169)	(235)	66	(28)%	(415)	(626)	211	(34)%
Gross profit	\$ 1,077	\$ 2,763	\$ (1,686)	(61)%	\$ 6,442	\$ 12,162	\$ (5,720)	(47)%

For the three and nine months ended September 30, 2023, the \$1.8 million and \$5.9 million year-over-year decrease in total revenues, respectively, was primarily due to a \$1.6 million and \$5.7 million decrease, respectively, in collaboration revenues related to lower current period recognition of the \$50.0 million upfront licensing payment from Roche, resulting from an updated collaboration forecast. The collaboration revenue was included in deferred revenues at December 31, 2022 (see Note 3 for further discussion).

Operating expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

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

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

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

	Three Months ended September 30, (unaudited)				Nine Months ended September 30, (unaudited)			
	2023		2022		2023		2022	
			\$ change	% change			\$ change	% change
Research and development	\$ 3,741	\$ 3,592	\$ 149	4%	\$ 11,799	\$ 9,883	\$ 1,916	19%
General and administrative	4,041	4,422	(381)	(9)%	13,014	18,160	(5,146)	(28)%
Total	\$ 7,782	\$ 8,014	\$ (232)	(3)%	\$ 24,813	\$ 28,043	\$ (3,230)	(12)%

The following table shows the amount of our total research and development expenses by program for the periods presented (in thousands).

	Three Months ended September 30, (unaudited)				Nine Months ended September 30, (unaudited)			
	Amount		Percent of Total		Amount		Percent of Total	
	2023	2022	2023	2022	2023	2022	2023	2022
OpRegen®	\$ 1,284	\$ 1,387	34%	39%	\$ 4,381	\$ 3,675	37%	37%
OPC1	1,402	1,172	38%	33%	4,236	3,238	36%	33%
ANP1	415	271	11%	7%	1,556	506	13%	5%
PNC1	115	161	3%	4%	348	406	3%	4%
VAC platform	26	496	1%	14%	332	1,927	3%	20%
All other programs	499	105	13%	3%	946	131	8%	1%
Total research and development expenses	\$ 3,741	\$ 3,592	100%	100%	\$ 11,799	\$ 9,883	100%	100%

Research and development expenses. For the three months ended September 30, 2023, the \$0.1 million year-over-year increase in total research and development expenses is primarily attributable to a \$0.2 million increase for our OPC1 program and a \$0.5 million increase for preclinical and other research and development programs. These increases were partially offset by a \$0.5 million decrease for our VAC program, primarily related to reduced manufacturing activities.

For the nine months ended September 30, 2023, the \$1.9 million year-over-year increase in total research and development expenses is mainly attributable to a \$0.7 million increase in our OpRegen program, a \$1.0 million increase in our OPC1 program and a \$1.8 million increase in preclinical and other research and development programs. These increases were partially offset by a \$1.6 million decrease in our VAC program, primarily related to reduced manufacturing activities.

General and administrative expenses. For the three months ended September 30, 2023, the \$0.4 million year-over-year decrease in general and administrative expenses was primarily attributable to overall reduction in costs incurred for services provided by third parties, consulting costs, legal cost and recruiting related expenses.

For the nine months ended September 30, 2023, the \$5.1 million year-over-year decrease in general and administrative expenses was primarily attributable to (i) a \$4.2 million decrease in legal and litigation expense, primarily due to the settlement of the Asterias litigation, and (ii) an overall reduction in costs incurred for services provided by third parties, consulting costs and compensation related expenses.

Other income and (expenses), net

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

	Three Months ended September 30, (unaudited)				Nine Months ended September 30, (unaudited)			
	2023	2022	\$ change	% change	2023	2022	\$ change	% change
Other income (expenses), net								
Interest income, net	\$ 433	\$ 384	\$ 49	13%	\$ 1,225	\$ 435	\$ 790	182%
Loss on marketable equity securities, net	(60)	(233)	173	(74)%	(170)	(1,677)	1,507	(90)%
Gain on revaluation of warrant liability	-	-	-	-	1	223	(222)	(100)%
Other expenses, net	(826)	(475)	(351)	74%	(1,253)	(2,550)	1,297	(51)%
Total	\$ (453)	\$ (324)	\$ (129)	40%	\$ (197)	\$ (3,569)	\$ 3,372	(94)%

Interest income, net. During the third quarter of 2022, we began to invest our excess cash in short-term U.S. Treasury securities resulting in an increase in interest income. See Note 4 (Marketable Debt Securities) to our condensed consolidated interim financial statements included in this report for additional information regarding our marketable debt securities.

Marketable equity securities. We expect our total other income (expenses), net, to fluctuate each reporting period based on the changes in the market price of the common stock of OncoCyte Corporation (“OncoCyte”) and Hadasit Bio-Holdings Ltd (“HBL”) which could impact our net income or loss reported in our condensed consolidated statements of operations for a particular reporting period. These shares are carried at fair market value on our consolidated balance sheet. See Note 5 (Marketable Equity Securities) to our condensed consolidated interim financial statements included in this report for additional information regarding our marketable equity securities.

For the three and nine months ended September 30, 2023, Lineage recognized a net loss on marketable equity securities of \$0.1 million and \$0.2 million, respectively, primarily related to changes in the fair market value during the respective periods.

For the three and nine months ended September 30, 2022, Lineage recognized a net loss on marketable equity securities of \$0.2 million and \$1.7 million, respectively, related to changes in the fair market value during the respective periods.

Other expenses, net. Other expenses, net, for each of the three and nine months ended September 30, 2023 and 2022 consisted of net foreign currency transaction gains and losses recognized by our subsidiaries Cell Cure and ES Cell International Pte. Ltd and an employee retention credit payroll tax refund (discussed below). The employee retention credit payroll tax refund was recorded in the quarter ended June 30, 2023. Foreign currency transaction gains and losses for the periods presented are principally related to the remeasurement of the U.S. dollar denominated notes payable and notes receivable between Cell Cure and Lineage.

Under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), the Company is eligible for an employee retention credit subject to certain criteria. The employee retention credit is a payroll tax refund per employee, which was designed by the U.S. Treasury Department to assist businesses that retained employees during the COVID pandemic. For the nine months ended September 30, 2023, we recorded an employee retention credit of \$0.5 million, due to a decline in the quarterly revenue during 2020 and 2021 as compared to the same quarterly period in 2019.

Income Taxes

Under ASC 740, *Income Taxes*, a valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. We established a full valuation allowance as of December 31, 2018, due to the uncertainty of realizing future tax benefits from the net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries.

For the nine months ended September 30, 2023, Lineage recorded a \$1.8 million deferred tax benefit due to the ability to offset certain deferred tax assets against the deferred tax liability associated with IPR&D, and the related release of the valuation allowance. It was determined that a portion of the deferred tax liability related to the indefinite lived assets may be realized prior to the expiration of certain pre 2018 net operating losses. Lineage did not record a deferred tax benefit for the second and third quarters of 2023, and did not record a deferred tax benefit for the three and nine months ended September 30, 2022.

For the three and nine months ended September 30, 2022, Lineage recorded a withholding tax for the amount of \$0.5 million on interest expense deemed paid to Lineage from Cell Cure on the purchase of intellectual property pursuant to the US Israeli tax treaty. There was no comparable tax expense recorded for the three and nine months ended September 30, 2023. See Note 13 (Income Taxes) to our condensed consolidated interim financial statements included in this report for additional information.

Liquidity and Capital Resources

Sources of Liquidity

We have historically funded our operations primarily through proceeds from the sale of shares of our common stock, the sale of common stock of our former subsidiaries, research grants, revenues from collaborations, and royalties from product sales that are unrelated to our current cell therapy product candidates.

As of September 30, 2023, \$57.2 million remained available for sale under our at-the-market offering program and we owned marketable securities with a fair value of \$9.9 million based on the closing price of such securities on that date. See Note 4 (Marketable Debt Securities), Note 5 (Marketable Equity Securities) and Note 11 (Shareholders' Equity) to our condensed consolidated interim financial statements included in this report for additional information regarding the marketable securities we own and our at-the-market offering program, respectively. We may sell shares of our common stock and the marketable securities we own for liquidity. However, when we can effect such sales and the amount of shares we can sell depends on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price and volume of our common stock and of the marketable securities we own. The market value of marketable securities we own may not represent the amount that could be realized in a sale of such securities due to various market factors, including prevailing market conditions and prices at the time of any sale. In addition, the market value of marketable securities we own 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 recent pandemics, including the COVID-19 pandemic, geopolitical conflicts, political and economic instability, rising inflation and interest rates, and other macroeconomic factors.

Cash Flows

Cash flows (used in) provided by operating activities

Net cash used in operating activities was \$22.5 million for the nine months ended September 30, 2023, which primarily reflects the loss from operations of \$18.4 million plus the changes in operating assets and liabilities of \$9.6 million. These items were offset by the non-cash expenses of \$3.6 million for stock-based compensation and \$0.6 million for depreciation and amortization. The foreign currency remeasurement and deferred tax benefit had no effect on cash flows.

Net cash provided by operating activities was \$9.4 million for the nine months ended September 30, 2022, which primarily reflects the net changes in assets and liabilities of \$21.4 million, plus the \$3.8 million in non-cash expenses for stock-based compensation and depreciation and amortization, less the loss from operations of \$15.9 million. The change in assets and liabilities was impacted by the receipt of the \$50.0 million upfront payment under the Roche Agreement, and subsequent related payments to the IIA and Hadasit (see Note 14 (Commitments and Contingencies) to the condensed consolidated interim financial statements included in this report for additional information), partially offset by the accrual of the litigation settlement described in Note 14 (Commitments and Contingencies) to the condensed consolidated interim financial statements included in this report. The unrealized loss on marketable equity securities and foreign currency remeasurement had no effect on the cash flows.

Cash flows provided by (used in) investing activities

Cash provided by investing activities for the nine months ended September 30, 2023 was \$36.7 million and consisted of \$53.5 million in U.S. Treasury securities which matured during the period and \$0.2 million in proceeds from the sale of marketable equity securities, partially offset by \$16.4 million used to purchase U.S. Treasury securities and \$0.6 million used to purchase equipment.

Cash used by investing activities for the nine months ended September 30, 2022 was \$41.1 million and consisted of \$40.6 million related to the purchase of U.S. Treasury securities and \$0.4 million for the purchase of equipment.

Cash flows provided by financing activities

Cash provided by financing activities for the nine months ended September 30, 2023 was \$6.4 million and primarily consisted of net proceeds from the sale of our common shares under our at-the-market offering program.

Cash provided by financing activities for the nine months ended September 30, 2022 was \$1.5 million and consisted of \$1.0 million of proceeds from the exercise of warrants to purchase shares of Cell Cure and \$0.5 million of proceeds from the exercise of employee stock options.

Financial Obligations

Our financial obligations primarily consist of obligations to our licensors under license agreements, obligations related to grants received from government entities, including the IIA, obligations under vendor contracts to provide research services and other purchase commitments with suppliers.

Our obligations to licensors under license agreements and related to grants received from government entities require us to make future payments relating to sublicense fees, milestone payments, redemption fees, royalties and patent maintenance costs. Sublicense fees are payable to licensors or government entities when we sublicense underlying intellectual property to third parties; the fees are based on a percentage of the license fees we receive from sublicensees. Milestone payments, including those related to the Roche Agreement, are due to licensors or government entities upon future achievement of certain commercial, development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone and royalties received under the Roche Agreement, see Note 14 (Commitment and Contingencies) for additional information. Royalties, including those related to royalties we may receive under the Roche Agreement, are payable to licensors or government entities based on a percentage of net sales of licensed products. Patent maintenance costs are payable to licensors as reimbursement for the cost of maintaining license patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements are uncertain and may fluctuate significantly from period to period. As of September 30, 2023, we have not included these commitments on our consolidated balance sheet because the achievement and timing of these events are not fixed and determinable.

As discussed above, we have received grants under the Innovation Law and are required to pay royalties to the IIA from the revenues generated from the sale of product candidates and related services developed, in whole or in part pursuant to, or as a result of, a research and development program funded by the IIA. Under the Innovation Law, we are also required to pay redemption fees to the IIA. To date, through a series of separate grants beginning in 2007, Cell Cure has received a total of \$15.4 million from the IIA to support the OpRegen program. We are obligated to pay approximately 24.1% of any future payments received under the Roche Agreement to the IIA, up to an aggregate cap on all payments to IIA, such cap growing over time via interest accrual until paid in full, which was approximately \$92.7 million as of September 30, 2023. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone payments and royalties received under the Roche Agreement. As of September 30, 2023, we have not included any future financial obligations due to the IIA under the Innovation Law in our consolidated balance sheet because the achievement and timing of the events that would require future payments to the IIA under the Innovation Law is not fixed and determinable. See Note 14 (Commitments and Contingencies) to our condensed consolidated interim financial statements included in this report for additional information.

Under the terms of the leases for the facilities from which Cell Cure and Lineage operate, a total of \$3.5 million of rent payments will become due, of which \$0.3 million will become due in 2023.

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

Future Funding Requirements

At September 30, 2023, we had an accumulated deficit of approximately \$380.1 million. We expect to continue to incur losses for at least the next several years. We expect that our operating expenses will continue to increase for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates. As a result, we will need significant additional capital to fund our operations. Our determination as to when we will seek additional capital and the amount of additional capital that we will need will be based on our evaluation of the progress we make in our research and development programs, changes to the scope and focus of those programs, changes in grant funding for certain of those programs, and projection of future costs, revenues, and rates of expenditure. If we are unable to raise additional capital when and as needed, we may be required to delay, postpone, or cancel our clinical trials or limit the number of clinical trial sites.

We may seek to obtain the additional capital we may need through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration agreements. We cannot assure that adequate additional capital will be available on favorable terms, if at all. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common shares to decline, and the issuance of additional equity securities could result in the dilution of the interests of our current shareholders. If we obtain additional capital through strategic alliances and licensing or collaboration agreements, we may be required to relinquish rights to our intellectual property, our product candidates or otherwise agree to terms unfavorable to us. The unavailability or inadequacy of additional capital to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our current planned operations. Our ability to raise additional capital may be adversely impacted 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 recent pandemics, including the COVID-19 pandemic, geopolitical conflicts, political and economic instability, rising inflation and interest rates, and other macroeconomic factors.

We believe that our \$41.3 million in cash, cash equivalents and marketable securities at September 30, 2023, provide sufficient 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. We believe we will meet our longer-term expected future cash requirements and obligations with our current cash and cash equivalents, milestone and other payments we expect to receive under our collaboration agreements, and proceeds we receive from sales of our common shares under our at-the-market offering program.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our Chief Executive Officer and our Chief Financial Officer, 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 were effective as of the end of the period covered by this report to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act: (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (ii) is accumulated and communicated to management, including 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

We are not currently a party to any material legal proceedings. From time-to-time we may be involved in a variety of legal proceedings. Such proceedings may initially be viewed as immaterial but could later prove to be material. Legal proceedings are inherently unpredictable and excessive verdicts do occur. Given the inherent uncertainties in litigation, even when we can reasonably estimate the amount of possible loss or range of loss and reasonably estimable loss contingencies, the actual outcome may change in the future due to new developments or changes in approach. In addition, legal proceedings could involve significant expense and diversion of management's attention and resources from other matters. For a discussion of legal proceedings in which we are involved, see Note 14 (Commitments and Contingencies) in the Notes to the Condensed Consolidated Financial Statements in Part I, Item 1 of this report.

Item 1A. Risk Factors

An investment in our common shares involves a high degree of risk. You should carefully consider the risks and uncertainties described in the 2022 10-K, in addition to other information in this report, when evaluating our business and before deciding whether to purchase, hold or sell our common shares. Each of these risks and uncertainties, as well as additional risks and uncertainties not presently known to us or that we currently consider immaterial, could harm our business, financial condition, results of operations and/or growth prospects, as well as adversely affect the market price of our common shares, in which case you may lose all or part of your investment. There have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in the 2022 10-K, except as described below.

An extended curtailment or halt of operations at the FDA, SEC and other government agencies, including due to a U.S. federal government shutdown, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and our ability to raise additional capital.

Twice in the past decade, the previous appropriations legislation deadline was reached and Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U.S. government shutdowns that caused federal agencies to halt non-essential operations. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. If lawmakers cannot pass a continuing resolution or a new federal budget by November 17, 2023, another federal government shutdown would begin. A federal government shutdown could prevent staff at federal agencies from performing key functions that may adversely affect our business. For example, disruptions at the FDA may delay meetings and other communications with agency staff necessary to progress development of our product candidates and may slow the time necessary for acceptance, review and approval of applications to commence clinical studies or to market a new product in the U.S. In addition, a government shutdown could prevent SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. While we currently have an effective shelf registration statement on Form S-3, if a federal government shutdown halts non-essential SEC operations for an extended period, it may negatively impact our ability to raise additional capital through registered offerings of our securities in the future. If a prolonged U.S. government shutdown or other event or condition occurs that prevents the FDA, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, which could have a material adverse effect on our business.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

Not applicable.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.

(b) None.

(c) Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item in this report.

Item 6. Exhibits

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
3.1*	Restated Articles of Incorporation, as amended				
3.2	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^	Amendment to the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan	10.1	8-K	September 7, 2023	001-12830
31.1*	Certification of Chief Executive Officer and 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				
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith

Furnished herewith

^ Management contract or compensatory plan or arrangement

SIGNATURES

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

LINEAGE CELL THERAPEUTICS, INC.

Date: November 9, 2023

/s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer

Date: November 9, 2023

/s/ Jill Ann Howe

Jill Ann Howe
Chief Financial Officer

RESTATED ARTICLES OF INCORPORATION
OF
BIOTIME, INC.

Michael D. West, Ph.D., Aditya Mohanty, and Judith Segall certify that:

1. They are the Co-Chief Executive Officers and the Secretary, respectively, of BioTime, Inc., a California Corporation.

2. The Articles of Incorporation of this corporation, as amended to date (the “*Articles of Incorporation*”), without alterations or amendments (other than omissions required by Section 910 of the California Corporations Code), are restated to read in full as follows:

“ONE: The name of this corporation is BioTime, Inc.

TWO: The purpose of the corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of California other than the banking business, the trust company business, or the practice of a profession permitted to be incorporated by the California Corporations Code.

THREE: The corporation is authorized to issue two classes of shares, which shall be designated “Common Shares” and “Preferred Shares”. The number of Common Shares which the corporation is authorized to issue is 150,000,000, and the number of Preferred Shares which the corporation is authorized to issue is 2,000,000. The Preferred Shares may be issued in one or more series as the board of directors may by resolution designate. The board of directors is authorized to fix the number of shares of any series of Preferred Shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon the Preferred Shares as a class, or upon any wholly unissued series of Preferred Shares. The board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of Preferred Shares subsequent to the issue of shares of that series.

FOUR: The liability of the directors of the corporation for monetary damages shall be eliminated to the fullest extent permissible under California law. The corporation is authorized to indemnify “agents”, as such term is defined in Section 317 of the California Corporations Code, to the fullest extent permissible under California law.”

3. The foregoing restatement of the Articles of Incorporation has been duly approved by the board of directors.

4. The foregoing restatement of the Articles of Incorporation has been duly approved by the required vote of shareholders in accordance with Section 902, California Corporations Code. The total number of outstanding shares of the corporation entitled to vote is 106,658,109. The number of shares voting in favor of the amendment equaled or exceeded the vote required. The percentage vote required was more than 50%. There are no Preferred Shares of the corporation issued and outstanding.

We further declare under penalty of perjury under the laws of the State of California that the matters set forth in this certificate are true and correct of our own knowledge.

Date: August 10, 2017

/s/ Michael D. West

Michael D. West, Ph.D.
Co-Chief Executive Officer

/s/ Aditya Mohanty

Aditya Mohanty
Co-Chief Executive Officer

/s/ Judith Segall

Judith Segall, Secretary

CERTIFICATE OF AMENDMENT
OF ARTICLES OF INCORPORATION
BIOTIME, INC.

The undersigned, Michael D. West, Ph.D., Aditya Mohanty, and Stephana Patton, certify that:

1. They are the Co-Chief Executive Officers and the Secretary, respectively, of BioTime, Inc., a California corporation (the "**Corporation**").
2. Article THREE of the Corporation's Restated Articles of Incorporation is amended to read as follows:

"THREE: The corporation is authorized to issue two classes of shares, which shall be designated "Common Shares" and "Preferred Shares". The number of Common Shares which the corporation is authorized to issue is 250,000,000, and the number of Preferred Shares which the corporation is authorized to issue is 2,000,000. The Preferred Shares may be issued in one or more series as the board of directors may by resolution designate. The board of directors is authorized to fix the number of shares of any series of Preferred Shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon the Preferred Shares as a class, or upon any wholly unissued series of Preferred Shares. The board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of Preferred Shares subsequent to the issue of shares of that series."

3. The foregoing amendment of Articles of Incorporation has been duly approved by the board of directors.

4. The foregoing amendment of the Articles of Incorporation has been duly approved by the required vote of shareholders in accordance with Section 902 of the California Corporations Code. The total number of outstanding Common Shares of the Corporation entitled to vote with respect to this amendment was 106,658,109. The number of Common Shares voting in favor of the amendment equaled or exceeded the vote required. The percentage vote required was more than 50% of the outstanding Common Shares entitled to vote. There are no Preferred Shares of the Corporation issued and outstanding.

We further declare under penalty of perjury under the laws of the State of California that the matters set forth in this certificate are true and correct of our own knowledge.

Date: May 1, 2018.

/s/ Michael D. West

Michael D. West
Co-Chief Executive Officer

/s/ Aditya Mohanty

Aditya Mohanty
Co-Chief Executive Officer

/s/ Stephana Patton

Stephana Patton, Secretary

**CERTIFICATE OF AMENDMENT
OF ARTICLES OF INCORPORATION
LINEAGE CELL THERAPEUTICS, INC.**

The undersigned, Brian M. Culley and George A. Samuel III, certify that:

1. They are the President and Chief Executive Officer and the Secretary, respectively, of Lineage Cell Therapeutics, Inc., a California corporation (the "Corporation").
2. Article THREE of the Corporation's Restated Articles of Incorporation is amended to read as follows:

"THREE: The corporation is authorized to issue two classes of shares, which shall be designated "Common Shares" and "Preferred Shares". The number of Common Shares which the corporation is authorized to issue is 450,000,000, and the number of Preferred Shares which the corporation is authorized to issue is 2,000,000. The Preferred Shares may be issued in one or more series as the board of directors may by resolution designate. The board of directors is authorized to fix the number of shares of any series of Preferred Shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon the Preferred Shares as a class, or upon any wholly unissued series of Preferred Shares. The board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of Preferred Shares subsequent to the issue of shares of that series."
3. The foregoing amendment to the Corporation's Restated Articles of Incorporation has been duly approved by the board of directors of the Corporation.
4. The foregoing amendment to the Corporation's Restated Articles of Incorporation has been duly approved by the required vote of shareholders in accordance with Section 902 of the California Corporations Code. The total number of outstanding Common Shares of the Corporation entitled to vote with respect to this amendment was 174,752,271. The number of Common Shares voting in favor of the amendment equaled or exceeded the vote required. The percentage vote required was more than 50% of the outstanding Common Shares entitled to vote. There are no Preferred Shares of the Corporation issued and outstanding.

We further declare under penalty of perjury under the laws of the State of California that the matters set forth in this certificate are true and correct of our own knowledge.

DATE: September 6, 2023.

/s/ Brian M. Culley

Brian M. Culley
President and Chief Executive Officer

/s/ George A. Samuel III

George A. Samuel III
Secretary

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 the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ Brian M. Culley

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

CERTIFICATIONS

I, Jill Ann Howe, 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 the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ Jill Ann Howe

Jill Ann Howe
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the quarterly report on Form 10-Q of Lineage Cell Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2023 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 Jill Ann Howe, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 9, 2023

/s/ Brian M. Culley

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

/s/ Jill Ann Howe

Jill Ann Howe
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Lineage Cell Therapeutics, Inc. and will be retained by Lineage Cell Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
