

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

FORM 10-Q

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

For the quarterly period ended June 30, 2024

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	LCTX	NYSE American LLC

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 August 2, 2024 was 188,837,375.

Lineage Cell Therapeutics, Inc.

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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 involve 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 ability to obtain additional capital to fund our operations;
- 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 the Israel-Hamas war, other geopolitical conflicts, political and economic instability, public health emergencies and macroeconomic conditions.

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 I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the “2023 10-K”) as filed with the Securities and Exchange Commission (the “SEC”) on March 7, 2024, 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 I, Item 1A of the 2023 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)
(UNAUDITED)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 29,622	\$ 35,442
Marketable securities	8,874	50
Accounts receivable, net	235	745
Prepaid expenses and other current assets	1,659	2,204
Total current assets	40,390	38,441
NONCURRENT ASSETS		
Property and equipment, net	2,018	2,245
Operating lease right-of-use assets	2,584	2,522
Deposits and other long-term assets	598	577
Goodwill	10,672	10,672
Intangible assets, net	46,540	46,562
TOTAL ASSETS	\$ 102,802	\$ 101,019
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,018	\$ 6,270
Operating lease liabilities, current portion	1,069	830
Finance lease liabilities, current portion	46	52
Deferred revenues, current portion	9,142	10,808
Total current liabilities	15,275	17,960
LONG-TERM LIABILITIES		
Deferred tax liability	273	273
Deferred revenues, net of current portion	18,543	18,693
Operating lease liabilities, net of current portion	1,768	1,979
Finance lease liabilities, net of current portion	68	91
TOTAL LIABILITIES	35,927	38,996
Commitments and contingencies (Note 13)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common shares, no par value, 450,000 shares authorized as of June 30, 2024 and December 31, 2023; 188,824 and 174,987 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	467,928	451,343
Accumulated other comprehensive loss	(2,470)	(3,068)
Accumulated deficit	(397,158)	(384,856)
Lineage's shareholders' equity	68,300	63,419
Noncontrolling deficit	(1,425)	(1,396)
Total shareholders' equity	66,875	62,023
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 102,802	\$ 101,019

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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
REVENUES:				
Collaboration revenues	\$ 1,098	\$ 2,871	\$ 2,285	\$ 4,992
Royalties, license and other revenues	310	354	567	619
Total revenues	<u>1,408</u>	<u>3,225</u>	<u>2,852</u>	<u>5,611</u>
OPERATING EXPENSES:				
Cost of sales	44	127	142	246
Research and development	2,868	3,873	5,878	8,058
General and administrative	4,363	4,249	9,360	8,973
Total operating expenses	<u>7,275</u>	<u>8,249</u>	<u>15,380</u>	<u>17,277</u>
Loss from operations	<u>(5,867)</u>	<u>(5,024)</u>	<u>(12,528)</u>	<u>(11,666)</u>
OTHER INCOME (EXPENSES):				
Interest income	463	382	925	792
Loss on marketable equity securities, net	(10)	(150)	(15)	(110)
Foreign currency transaction loss, net	(378)	(497)	(732)	(969)
Other income	19	86	19	543
Total other income (expenses)	<u>94</u>	<u>(179)</u>	<u>197</u>	<u>256</u>
LOSS BEFORE INCOME TAXES	<u>(5,773)</u>	<u>(5,203)</u>	<u>(12,331)</u>	<u>(11,410)</u>
Provision for income tax benefit	<u>—</u>	<u>—</u>	<u>—</u>	<u>1,803</u>
NET LOSS	<u>(5,773)</u>	<u>(5,203)</u>	<u>(12,331)</u>	<u>(9,607)</u>
Net (income) loss attributable to noncontrolling interest	<u>13</u>	<u>(26)</u>	<u>29</u>	<u>6</u>
NET LOSS ATTRIBUTABLE TO LINEAGE	<u>\$ (5,760)</u>	<u>\$ (5,229)</u>	<u>\$ (12,302)</u>	<u>\$ (9,601)</u>
Net loss per common share attributable to Lineage basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>
Weighted-average common shares used to compute basic and diluted net loss per common share	<u>188,813</u>	<u>170,592</u>	<u>185,861</u>	<u>170,361</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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
NET LOSS	\$ (5,773)	\$ (5,203)	\$ (12,331)	\$ (9,607)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustment	307	446	605	819
Unrealized gain (loss) on marketable debt securities	(6)	50	(7)	141
COMPREHENSIVE LOSS	<u>(5,472)</u>	<u>(4,707)</u>	<u>(11,733)</u>	<u>(8,647)</u>
Less: Comprehensive (income) loss attributable to noncontrolling interest	13	(26)	29	6
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	<u>\$ (5,459)</u>	<u>\$ (4,733)</u>	<u>\$ (11,704)</u>	<u>\$ (8,641)</u>

See accompanying notes to the condensed consolidated interim financial statements.

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

Three Months Ended June 30, 2024

	Common		Accumulated Deficit	Noncontrolling Deficit	Accumulated Other Comprehensiv e Income / (Loss)	Total Shareholders' Equity
	Shares					
	Shares	Amount				
BALANCE - March 31, 2024	188,754	\$ 466,571	\$ (391,398)	\$ (1,412)	\$ (2,771)	\$ 70,990
Shares issued through ATM	26	33	—	—	—	33
Financing related fees	—	(1)	—	—	—	(1)
Shares issued upon exercise of stock options	44	56	—	—	—	56
Stock-based compensation	—	1,269	—	—	—	1,269
Unrealized loss on marketable debt securities	—	—	—	—	(6)	(6)
Foreign currency translation adjustment	—	—	—	—	307	307
Net loss	—	—	(5,760)	(13)	—	(5,773)
BALANCE - June 30, 2024	188,824	\$ 467,928	\$ (397,158)	\$ (1,425)	\$ (2,470)	\$ 66,875

Three Months Ended June 30, 2023

	Common		Accumulated Deficit	Noncontrolling Deficit	Accumulated Other Comprehensiv e Income / (Loss)	Total Shareholders' Equity
	Shares					
	Shares	Amount				
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 adjustment	—	—	—	—	446	446
Net loss	—	—	(5,229)	26	—	(5,203)
BALANCE - June 30, 2023	174,439	\$ 448,249	\$ (372,971)	\$ (1,409)	\$ (2,611)	\$ 71,258

See accompanying notes to the condensed consolidated interim financial statements.

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

Six Months Ended June 30, 2024						
	Common		Accumulated Deficit	Noncontrolling Deficit	Accumulated Other Comprehensiv e Income / (Loss)	Total Shareholders' Equity
	Shares					
	Shares	Amount				
BALANCE - December 31, 2023	174,987	\$ 451,343	\$ (384,856)	\$ (1,396)	\$ (3,068)	\$ 62,023
Shares issued through registered direct financing	13,462	14,000	—	—	—	14,000
Shares issued through ATM	56	70	—	—	—	70
Financing related fees	—	(113)	—	—	—	(113)
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	45	(23)	—	—	—	(23)
Shares issued upon exercise of stock options	274	219	—	—	—	219
Stock-based compensation	—	2,432	—	—	—	2,432
Unrealized loss on marketable debt securities	—	—	—	—	(7)	(7)
Foreign currency translation adjustment	—	—	—	—	605	605
Net loss	—	—	(12,302)	(29)	—	(12,331)
BALANCE - June 30, 2024	188,824	\$ 467,928	\$ (397,158)	\$ (1,425)	\$ (2,470)	\$ 66,875

Six Months Ended June 30, 2023						
	Common		Accumulated Deficit	Noncontrolling Deficit	Accumulated Other Comprehensiv e Income / (Loss)	Total Shareholders' Equity
	Shares					
	Shares	Amount				
BALANCE - December 31, 2022	170,093	\$ 440,280	\$ (363,370)	\$ (1,403)	\$ (3,571)	\$ 71,936
Shares issued through ATM	4,237	5,841	—	—	—	5,841
Financing related fees	—	(193)	—	—	—	(193)
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	56	47	—	—	—	47
Stock-based compensation	—	2,311	—	—	—	2,311
Unrealized gain on marketable debt securities	—	—	—	—	141	141
Foreign currency translation adjustment	—	—	—	—	819	819
Net loss	—	—	(9,601)	(6)	—	(9,607)
BALANCE - June 30, 2023	174,439	\$ 448,249	\$ (372,971)	\$ (1,409)	\$ (2,611)	\$ 71,258

See accompanying notes to the condensed consolidated interim financial statements.

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

	Six Months Ended June 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	\$ (12,302)	\$ (9,601)
Net loss attributable to noncontrolling interest	(29)	(6)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Loss on marketable equity securities, net	15	110
Accretion of income on marketable debt securities	(102)	(516)
Depreciation and amortization expense	295	276
Change in right-of-use assets and liabilities	(20)	81
Amortization of intangible assets	22	65
Stock-based compensation	2,432	2,311
Deferred income tax benefit	—	(1,803)
Foreign currency remeasurement and other loss	767	1,011
Changes in operating assets and liabilities:		
Accounts receivable	508	(147)
Prepaid expenses and other current assets	516	(270)
Accounts payable and accrued liabilities	(1,245)	(3,941)
Deferred revenue	(1,816)	(5,080)
Net cash used in operating activities	<u>(10,959)</u>	<u>(17,510)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	18	—
Purchases of marketable debt securities	(8,761)	(12,635)
Maturities of marketable debt securities	—	47,664
Purchase of equipment	(88)	(444)
Net cash (used in) provided by investing activities	<u>(8,831)</u>	<u>34,585</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	219	80
Common shares received and retired for employee taxes paid	(23)	(37)
Proceeds from sale of common shares	14,070	5,789
Payments for offering costs	(113)	(174)
Repayment of finance lease liabilities	(27)	(29)
Net cash provided by financing activities	<u>14,126</u>	<u>5,629</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(158)	(192)
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,822)	22,512
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	35,992	11,936
At end of the period	<u>\$ 30,170</u>	<u>\$ 34,448</u>
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	\$ 4	\$ 5
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Property and equipment expenditures in accounts payable	\$ 58	\$ 93
Reconciliation of cash, cash equivalents and restricted cash, end of period:		
Cash and cash equivalents	\$ 29,622	\$ 33,886
Restricted cash included in deposits and other long-term assets (see Note 13 (Commitments and Contingencies))	548	562
Total cash, cash equivalents, and restricted cash	<u>\$ 30,170</u>	<u>\$ 34,448</u>

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 associated development, formulation, delivery 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 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 collaboration 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 our lead cell therapy program known as OpRegen[®], is being developed for the treatment of ocular disorders, including geographic atrophy (“GA”) secondary to age-related macular degeneration (“AMD”). OpRegen (also known as RG6501) 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 in January 2022 and are eligible to receive up to an additional \$620.0 million in 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. On May 7, 2024, we entered into a service agreement with Genentech pursuant to which we will provide supplemental clinical, technical, training, manufacturing, and procurement services to support the ongoing advancement and optimization of the OpRegen program.

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 (“CIRM”). We plan to apply for additional funding from CIRM for continued clinical development of OPC1 for the treatment of SCI. In January 2024, we filed an Investigational New Drug (“IND”) amendment for OPC1 as it relates to our proposed DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, to evaluate the safety and utility of a novel spinal cord delivery device to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. As previously reported in March 2024, we received written correspondence from the FDA, advising us that due to significant workload and conflicting PDUFA priorities at the agency, its review of our IND amendment and the DOSED study protocol is still ongoing. We continue to focus on customary trial preparations and related activities to support opening our first clinical study site for the DOSED study and we intend to open our first clinical study site as soon as feasible following confirmation that the FDA has no further feedback or additional information requests relating to our IND amendment.

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

- *RG6501 (OpRegen)*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm 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 which we plan to evaluate in the DOSED clinical study, to test the safety and utility of a novel spinal cord delivery device in both subacute and chronic spinal cord injuries and continues to be evaluated in long-term follow-up from a Phase 1/2a multicenter clinical trial for subacute cervical spinal cord injuries.
- *ANPI*, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating hearing loss.

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

- *PNCL*, an allogeneic photoreceptor cell transplant currently being developed for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *RND1*, a novel hypimmune induced pluripotent stem cell (“iPSC”) line being developed in collaboration with Eterna Therapeutics Inc., which will be evaluated for differentiation into cell transplant product candidates for central nervous system diseases and other neurology indications.

Other Programs

We have additional undisclosed product candidates being considered for development and we may consider others, 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 most of the product candidates described above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety 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 our non-core intellectual property or related technologies and capabilities, through licensing collaborations and/or strategic transactions, such as our business development approach to our VAC dendritic cell therapy platform.

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, 2023 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 2023 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. Certain prior period amounts in the condensed consolidated interim financial statements and accompanying notes have been reclassified to conform to the current period presentation. The reclassification of these items had no impact on net loss, net loss per share, financial position or cash flows in the current or prior periods. Specifically, our reclassifications are (i) operating lease right-of-use assets are now presented separately from property and equipment, net, on the condensed consolidated balance sheets, (ii) cost of sales are now included in operating expenses on the condensed consolidated statements of operations, and (iii) foreign currency transaction gains (losses) are now presented separately from other income (expenses) on the condensed consolidated statements of operations.

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 June 30, 2024:

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.

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As of June 30, 2024, 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 June 30, 2024, we had \$38.5 million of cash, cash equivalents and marketable securities. At June 30, 2024 and 2023, the Company had restricted cash of \$0.1 million required to be set aside for its corporate credit card facility. Additionally, Cell Cure has restricted cash related to its lease. See Note 13 (Commitments and contingencies). 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 June 30, 2024, \$39.97 million remained available for sale under our at-the-market offering program ("ATM"). See Note 10 (Shareholders' Equity) for additional information.

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, royalty fees and patent maintenance fees. 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-related revenue 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 13 (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 June 30, 2024, 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 2023 10-K. There have been no changes to our significant accounting policies during the six months ended June 30, 2024.

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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 interim financial statements or related financial statement disclosures.

3. Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues under collaborative agreements				
Upfront license fees ⁽¹⁾	\$ 1,098	\$ 2,871	\$ 2,285	\$ 4,992
Total revenues under collaborative agreements	1,098	2,871	2,285	4,992
Royalties, license and other revenues ⁽²⁾	310	354	567	619
Total revenue	<u>\$ 1,408</u>	<u>\$ 3,225</u>	<u>\$ 2,852</u>	<u>\$ 5,611</u>

⁽¹⁾ All of the upfront license fee revenue recognized each period was included within deferred revenue as contract liabilities at the beginning of the period. This revenue originated from the \$50.0 million upfront payment under the Roche Agreement.

⁽²⁾ Included within royalties, license and other revenues recognized for the six months ended June 30, 2024 and 2023, was \$30,000 and \$87,000, respectively, that was included within deferred revenues as contract liabilities as of January 1, 2024 and 2023, respectively.

We are recognizing the \$50.0 million upfront payment 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 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.

For contracts with customers including collaboration partners which are within the scope of Accounting Standards Update (“ASU”) 2014-09 – *Revenue from Contracts with Customers* (Topic 606), the aggregate amount of the transaction price allocated to remaining performance obligations as of June 30, 2024 was \$31.6 million, of which \$27.7 million is reported as deferred revenues. The \$31.6 million is primarily expected to be converted to revenue by December 2026.

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

	June 30, 2024	December 31, 2023
Accounts receivable, net - beginning of the year ⁽¹⁾	\$ 676	\$ 297
Accounts receivable, net - end of the period ⁽¹⁾	\$ 223	\$ 676
Contract liabilities ⁽¹⁾		
Deferred revenues - beginning of the year	\$ 29,501	\$ 37,146
Deferred revenues - end of the period	\$ 27,685	\$ 29,501

⁽¹⁾ Excludes grants receivable which are outside the scope of ASU 2014-09.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (CONTINUED)
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4. Marketable Securities

The following table summarizes the fair value of marketable securities held by the Company and their location in the Company's condensed consolidated balance sheet (in thousands):

	June 30, 2024	December 31, 2023
Marketable debt securities		
Included within cash and cash equivalents ⁽¹⁾	\$ 5,031	\$ 8,856
Included within marketable securities	\$ 8,857	\$ —
Marketable equity securities		
Included within marketable securities	\$ 17	\$ 50

⁽¹⁾ Cash equivalents have an original maturity of three months or less when purchased.

Marketable Debt Securities

The following table summarizes the available-for-sale debt securities classified within cash and cash equivalents and within marketable securities in the Company's condensed consolidated balance sheet as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial Assets:				
U.S. Treasury securities	\$ 13,894	\$ —	\$ (6)	\$ 13,888
Total	\$ 13,894	\$ —	\$ (6)	\$ 13,888
	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial Assets:				
U.S. Treasury securities	\$ 8,855	\$ 1	\$ —	\$ 8,856
Total	\$ 8,855	\$ 1	\$ —	\$ 8,856

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of June 30, 2024 or December 31, 2023. The Company believes 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.

As of June 30, 2024, 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	\$ 13,894	\$ 13,888
Total available-for-sale debt securities	\$ 13,894	\$ 13,888

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Marketable Equity Securities

Marketable equity securities are reported at fair value with unrealized gains and losses related to mark-to-market adjustments included in income. Lineage's marketable equity securities consist of shares of common stock of OncoCyte Corporation ("OCX") and of Hadasit Bio-Holdings Ltd. ("HBL"). All share prices are determined based on the closing price of OCX and HBL common stock on the last trading day of the applicable quarter.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
(Loss) gain on marketable equity securities, net	\$ (10)	\$ (150)	\$ (15)	\$ (110)
Less: Loss recognized in earnings on marketable equity securities sold	4	—	4	—
Unrealized (loss) gain recognized on marketable equity securities held at end of period, net	\$ (6)	\$ (150)	\$ (11)	\$ (110)

5. Property and Equipment, Net

Property and equipment, including finance leases, are stated at cost, net of accumulated depreciation and amortization. The cost of property and equipment is depreciated or amortized using the straight-line method over the estimated useful life of the asset, ranging from 3 to 10 years. Finance lease right-of-use assets are amortized over the lease term. Leasehold improvements are amortized over the shorter of the useful life or the lease term.

At June 30, 2024 and December 31, 2023, property and equipment, net was comprised of the following (in thousands):

	June 30, 2024	December 31, 2023
Equipment, furniture and fixtures	\$ 3,628	\$ 3,614
Leasehold improvements	2,232	2,313
Right-of-use assets - finance lease	194	198
Accumulated depreciation and amortization	(4,036)	(3,880)
Property and equipment, net	\$ 2,018	\$ 2,245

Depreciation and amortization expense was \$142,000 and \$138,000 for the three months ended June 30, 2024 and 2023, respectively, and \$295,000 and \$276,000 for the six months ended June 30, 2024 and 2023, respectively. These amounts include amortization expense for right-of-use finance lease assets of \$14,000 and \$13,000 for the three months ended June 30, 2024 and 2023, respectively, and \$28,000 and \$23,000 for the six months ended June 30, 2024 and 2023, respectively.

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6. Goodwill and Intangible Assets, Net

At June 30, 2024 and December 31, 2023, goodwill and intangible assets, net consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Goodwill ⁽¹⁾	\$ 10,672	\$ 10,672
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	66,143	66,143
Accumulated amortization ⁽⁴⁾	(19,603)	(19,581)
Intangible assets, net	\$ 46,540	\$ 46,562

⁽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 13 (Commitments and Contingencies) for further discussion on the Asterias Merger. To date, we have not recognized any goodwill impairment.

⁽²⁾ Asterias had two in-process research and development ("IPR&D") intangible assets that were valued at \$46.5 million as part of the purchase price allocation that was performed in connection with the Asterias Merger. The fair value of these assets 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. 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 ASC Topic 805, *Business Combinations*.

⁽⁴⁾ The acquired patents and acquired royalty contracts were fully amortized as of the end of the first quarter of 2024.

Lineage amortizes its intangible assets over an estimated period of 5 to 10 years on a straight-line basis. Lineage recognized \$0 and \$32,000 in amortization expense of intangible assets during the three months ended June 30, 2024 and 2023, respectively, and \$22,000 and \$65,000 during the six months ended June 30, 2024 and 2023, respectively.

7. Accounts Payable and Accrued Liabilities

At June 30, 2024 and December 31, 2023, accounts payable and accrued liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accounts payable	\$ 2,388	\$ 2,050
Accrued compensation	2,216	3,123
Accrued liabilities	414	1,097
Total	\$ 5,018	\$ 6,270

8. 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 in accordance with 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.

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- Level 3 – Inputs to the valuation methodology that are unobservable. Unobservable inputs are those in which little or no market data exists, reflect those that a market participant would use, and are therefore determined using estimates and assumptions developed by the Company.

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

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. We measure our cash equivalents and marketable securities at fair value on a recurring basis. The fair values of such assets were as follows as of June 30, 2024 and December 31, 2023 (in thousands):

	Balance at June 30, 2024	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⁾	\$ 17,853	\$ 17,853	\$ —	\$ —
Marketable debt securities ⁽¹⁾	5,031	5,031	—	—
Marketable debt securities	8,857	8,857	—	—
Marketable equity securities ⁽²⁾	17	17	—	—
Total assets measured at fair value	\$ 31,758	\$ 31,758	\$ —	\$ —

	Balance at December 31, 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⁾	\$ 21,029	\$ 21,029	\$ —	\$ —
Marketable debt securities ⁽¹⁾	8,856	8,856	—	—
Marketable equity securities ⁽²⁾	50	50	—	—
Total assets measured at fair value	\$ 29,935	\$ 29,935	\$ —	\$ —

⁽¹⁾ Included in cash and cash equivalents in the accompanying condensed consolidated balance sheet. Marketable debt securities purchased with an original maturity of three months or less have been classified as cash equivalents.

⁽²⁾ Lineage's marketable equity securities include the shares of stock of OCX and HBL. Both securities have readily determinable fair values quoted on the NASDAQ or TASE (Level 1). These securities 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.

9. 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 13 (Commitments and Contingencies)), 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. From inception of the matter through July 2023, Lineage incurred approximately \$626,000 in legal expenses on behalf of the foregoing parties, and since then Lineage has not incurred any additional expenses.

On February 6, 2024, we entered into a stock purchase agreement with certain investors relating to the purchase and sale in a registered direct offering of an aggregate of 13,461,540 of our common shares. The offering price was \$1.04 per common share. The offering closed on February 8, 2024. Broadwood Partners, L.P., which is affiliated with Neal Bradsher, a member of our board of directors, purchased 6,730,770 common shares in the offering, and Don Bailey, a member of our board of directors, purchased 96,155 shares in the offering.

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10. 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 June 30, 2024 and December 31, 2023, 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 June 30, 2024 and December 31, 2023, there were 188,823,975 and 174,986,671 common shares issued and outstanding, respectively.

At-The-Market Offering Program

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

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 through the ATM program under the Prior Sales Agreement, which 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 "Prior Prospectus Supplement").

In March 2024, Lineage terminated the Prior Sales Agreement and entered into a sales agreement (the "ATM Sales Agreement") with B. Riley Securities, Inc., as sales agent ("Sales Agent"), under which Lineage may offer and sell its common shares from time to time through an ATM program.

In March 2024, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of \$40.00 million of common shares through the ATM program under the ATM Sales Agreement which was updated, amended and supplemented by a prospectus supplement filed with the SEC on May 14, 2024 in connection with the offer and sale of \$39.97 million of common shares through the ATM program under the ATM Sales Agreement (the prospectus supplement filed in March 2024, as updated, amended and supplemented by the prospectus supplement filed in May 2024, the "2024 Prospectus Supplement").

Prior to its termination in March 2024, Lineage had sold 4,912,803 common shares under the Prior Prospectus Supplement at a weighted average price per share of \$1.41 for gross proceeds of \$6.9 million. During the three months ended March 31, 2024, Lineage sold 30,000 common shares under the Prior Prospectus Supplement at a weighted average price per share of \$1.23 for gross proceeds of \$37,000 and Lineage had not sold any common shares under the 2024 Prospectus Supplement. During the three months ended June 30, 2024, Lineage sold 25,830 common shares under the 2024 Prospectus Supplement at a weighted average price per share of \$1.30 for gross proceeds of \$33,000. As of June 30, 2024, \$39.97 million remained available for sale under the 2024 Prospectus Supplement.

The shares offered under the 2024 Prospectus Supplement are registered pursuant to Lineage's effective shelf registration statement on Form S-3 (File No. 333-277758), which was filed with the SEC on March 7, 2024 and declared effective on May 14, 2024.

Lineage agreed to pay Sales Agent a commission of up to 3.0% of the aggregate gross proceeds from the sale of shares under the ATM Sales Agreement, reimburse its legal fees and disbursements, and provide Sales Agent with customary indemnification and contribution rights. The Sales Agreement may be terminated by Sales Agent or Lineage at any time upon notice to the other party, or by Sales Agent 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.

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11. Stock-Based Awards

Equity Incentive Plan Awards

In September 2021, our shareholders approved the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan, and in September 2023, our shareholders approved an amendment to increase the number of common shares that may be issued thereunder by 19,500,000 (as amended to date, the “2021 Plan”). The 2021 Plan provides for the grant of incentive stock options, non-statutory 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.

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 a result of the approval of the 2021 Plan by our shareholders, no additional awards will be granted under the 2012 Plan. As of June 30, 2024, there were 22,238,337 shares available for grant under the 2021 Plan.

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

	Number of Options Outstanding (in thousands)	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	10,824	\$ 1.42	8.63	\$ 4
Options granted	6,028	\$ 1.12		
Options exercised	(20)	\$ 1.40		
Options expired/forfeited/cancelled	(542)	\$ 1.37		
Balance at June 30, 2024	<u>16,290</u>	\$ 1.31	8.65	\$ 26
Options exercisable at June 30, 2024	<u>4,528</u>	\$ 1.42	7.7	\$ —
Options exercisable and expected to vest at June 30, 2024	<u>16,290</u>	\$ 1.31	8.65	\$ 26

	Number of RSUs Outstanding	Weighted Average Grant Date Fair Value per Share
Balance at December 31, 2023	668	\$ 1.11
RSUs forfeited	(100)	\$ 0.21
RSUs vested	(67)	\$ 1.50
Balance at June 30, 2024	<u>501</u>	\$ 1.24

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 (in thousands)	Weighted Average Exercise Price (per share)
Balance at December 31, 2023	10,839	\$ 1.83
Options exercised	(254)	\$ 0.75
Options expired/forfeited/cancelled	(496)	\$ 2.15
Balance at June 30, 2024	<u>10,089</u>	\$ 1.84
Options exercisable at June 30, 2024	<u>9,415</u>	\$ 1.80

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Stock-Based Compensation Expense

Operating expenses within the condensed consolidated statements of operations include stock-based compensation expense as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	\$ 160	\$ 264	\$ 304	\$ 469
General and administrative	1,109	1,016	2,128	1,842
Total stock-based compensation expense	\$ 1,269	\$ 1,280	\$ 2,432	\$ 2,311

As of June 30, 2024, total unrecognized compensation costs related to unvested stock options and unvested RSUs under all equity plans, was \$10.5 million, which is expected to be recognized as expense over a weighted average period of approximately 2.9 years for stock options and 1.6 years for RSUs.

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 stock options and 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 any outstanding stock options, RSUs, warrants (using the treasury-stock method), or convertible preferred stock (using the if-converted method).

For the three and six months ended June 30, 2024 and 2023, 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 and Six Months Ended June 30,	
	2024	2023
Stock options	26,378	22,846
Restricted stock units	501	759

12. 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.

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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 for research activities performed in the United States, 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. For the three and six months ended June 30, 2024, no GILTI was included in the Company’s tax provision. For the three and six months ended June 30, 2023, Lineage incurred GILTI which was fully offset by net operating loss carryforwards.

Lineage did not record a deferred tax benefit or provision expense for the three or six months ended June 30, 2024 or for the three months ended June 30, 2023. For the six months ended June 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.

13. 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 June 30, 2024.

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 right-of-use (“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 expired on March 31, 2024. In February 2024, Lineage extended the term of the sublease for 24 months through March 31, 2026 on similar terms. During the extension period, the base rent is \$23,000 per month for the first twelve months and will increase to \$23,500 for the remaining twelve months. 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 deposits and other long-term assets on the condensed consolidated balance sheet as of June 30, 2024.

Cell Cure Lease

As of June 30, 2024, Cell Cure leases approximately 2,096 square meters (approximately 22,600 square feet) of combined office and laboratory space in Jerusalem, Israel under a master lease, as amended, that expires December 31, 2027. Cumulative base rent and construction allowance payments are approximately 165,000 Israeli New Shekels (“ILS”) per month (approximately \$44,000 as of June 30, 2024), excluding any future rent escalations, and includes options to extend the lease term for five years. The U.S. dollar value of the ILS denominated base rent and construction allowance payments fluctuates based upon currency exchange rates. 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

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which the leased premises are located, including parking usage fees. These pro-rata charges are expensed as incurred and excluded from the calculation of the ROU assets and lease liabilities.

Cell Cure has security deposits denominated in ILS with the landlord for this master lease held as restricted cash during the term the lease. The U.S. dollars value of the ILS denominated security deposits fluctuates based upon currency exchange rates and was \$448,000 as of June 30, 2024, which is included in deposits and other long-term assets on the condensed consolidated balance sheet.

Supplemental Information – Leases

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

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 607	\$ 538
Operating cash flows from finance leases	\$ 4	\$ 5
Financing cash flows from finance leases	\$ 27	\$ 29
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	\$ 597	\$ —
Finance leases	\$ —	\$ 79

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

	June 30, 2024	December 31, 2023
Operating leases		
Right-of-use assets	\$ 2,584	\$ 2,522
Right-of-use lease liabilities, current	\$ 1,069	\$ 830
Right-of-use lease liabilities, noncurrent	1,768	1,979
Total operating lease liabilities	\$ 2,837	\$ 2,809
Finance leases		
Right-of-use assets	\$ 194	\$ 198
Accumulated amortization	(93)	(67)
Right-of-use assets, net	\$ 101	\$ 131
Right-of-use lease liabilities, current	\$ 46	\$ 52
Right-of-use lease liabilities, noncurrent	68	91
Total finance lease liabilities	\$ 114	\$ 143
Weighted average remaining lease term		
Operating leases	2.9 years	3.5 years
Finance leases	2.7 years	3.0 years
Weighted average discount rate		
Operating leases	6.3 %	6.5 %
Finance leases	7.1 %	6.9 %

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Future minimum lease commitments are as follows as of June 30, 2024 (in thousands):

Year Ending December 31,	Operating Leases	Finance Leases
2024	\$ 579	\$ 28
2025	1,156	51
2026	724	26
2027	671	20
Total lease payments	3,130	125
Less imputed interest	(293)	(11)
Total	\$ 2,837	\$ 114

Operating lease expense was \$0.3 million and \$0.6 million for each of the three and six months ended June 30, 2024 and 2023, respectively.

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 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 obligation 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 June 30, 2024, 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.

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Agreements with Hadasit and IIA

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 paid the IIA approximately 24.1% of the upfront payment it received under the Roche Agreement, or \$12.1 million, and is obligated to pay the IIA approximately 24.1% of any 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 June 30, 2024, the aggregate cap amount was approximately \$94.3 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, Cell Cure paid a sublicensing fee to Hadasit of \$8.9 million or 21.5% of the \$50.0 million upfront payment under the Roche Agreement (subject to certain reductions), and Cell Cure is obligated to pay Hadasit (i) a maximum of 21.5% of all milestone payments Lineage receives under the Roche Agreement (subject to certain reductions, including for costs related to Lineage’s performance obligations under the Roche Agreement), and (ii) 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 based upon exchange rates in effect when the fee was paid). 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

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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-related revenue 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 or royalty payment received in respect of IIA-funded programs. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products. As of June 30, 2024, 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 during the first quarter of 2023.

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 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

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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. The Court held a hearing on the motion on March 14, 2024 at which the Court proposed, and the parties agreed, to retain a third-party valuation firm to assess the fairness of the valuation that was performed in support of the Intercompany Agreement. 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 June 30, 2024 or December 31, 2023.

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 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 within royalties, license and other revenues and cost of sales, respectively, in our condensed consolidated statements of operations.

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, 2023 included in the 2023 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 2023 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.

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 associated development, formulation, delivery 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 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 collaboration 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 our lead cell therapy program known as OpRegen[®], is being developed for the treatment of ocular disorders, including geographic atrophy (“GA”) secondary to age-related macular degeneration (“AMD”). OpRegen (also known as RG6501) 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 in January 2022 and are eligible to receive up to an additional \$620.0 million in 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. On May 7, 2024, we entered into a service agreement with Genentech pursuant to which we will provide supplemental clinical, technical, training, manufacturing, and procurement services to support the ongoing advancement and optimization of the OpRegen program.

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 (“CIRM”). We plan to apply for additional funding from CIRM for continued clinical development of OPC1 for the treatment of SCI. In January 2024, we filed an Investigational New Drug (“IND”) amendment for OPC1 as it relates to our proposed DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, to evaluate the safety and utility of a novel spinal cord delivery device to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. As previously reported in March 2024, we received written correspondence from the FDA, advising us that due to significant workload and conflicting PDUFA priorities at the agency, its review of our IND amendment and the DOSED study protocol is still ongoing. We continue to focus on customary trial preparations and related activities to support opening our first clinical study site for the DOSED study and we intend to open our first clinical study site as soon as feasible following confirmation that the FDA has no further feedback or additional information requests relating to our IND amendment.

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

- *RG6501 (OpRegen)*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, being conducted by Roche, for the treatment of GA secondary to AMD, also known as atrophic or dry AMD.
- *OPCI*, an allogeneic oligodendrocyte progenitor cell therapy which we plan to evaluate in the DOSED clinical study, to test the safety and utility of a novel spinal cord delivery device in both subacute and chronic spinal cord injuries and continues to be evaluated in long-term follow-up from a Phase 1/2a multicenter clinical trial for subacute cervical spinal cord injuries.
- *ANPI*, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating hearing loss.
- *PNCI*, an allogeneic photoreceptor cell transplant currently being developed for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *RND1*, a novel hypimmune induced pluripotent stem cell (“iPSC”) line being developed in collaboration with Eterna Therapeutics Inc., which will be evaluated for differentiation into cell transplant product candidates for central nervous system diseases and other neurology indications.

Other Programs

We have additional undisclosed product candidates being considered for development, and we may consider others 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 most of the product candidates described above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety 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 our non-core intellectual property or related technologies and capabilities, through licensing collaborations and/or strategic transactions, such as our business development approach to our VAC dendritic cell therapy platform.

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 workforce are Cell Cure employees who are based in the same facility. As of the date of the filing 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 at the outset of the war, our operations at our facilities in Israel were temporarily impacted. Further, a number of the employees in Israel are members of the military reserves and subject to immediate call-up in response to the ongoing war in Israel. A number of the employees in Israel have been activated for military duty and additional employees may 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, or if a meaningful number of employees are unable to work for significant portions of time, 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 and economic conditions in Israel and war, terrorist attacks or other armed conflicts involving Israel, such as the Israel-Hamas war that began in October 2023, 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 2023 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 2023 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. The estimates and judgments involved in our accounting policies as described in Part II, Item 8 on Form 10-K for the year ended December 31, 2023, continue to be our critical accounting policies and there have been no other material changes to our critical accounting policies during the six months ended June 30, 2024.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2024 and 2023

Revenues

The amounts in the table below show our consolidated revenues, by source, for the periods presented (in thousands except percentages).

	Three Months ended June 30,		Dollar Increase (Decrease)	Percent Increase (Decrease)	Six Months ended June 30,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2024	2023			2024	2023		
Collaboration revenues	\$ 1,098	\$ 2,871	\$ (1,773)	(62)%	\$ 2,285	\$ 4,992	\$ (2,707)	(54)%
Royalties, license and other revenues	310	354	(44)	(12)%	567	619	(52)	(8)%
Total revenues	<u>\$ 1,408</u>	<u>\$ 3,225</u>	<u>\$ (1,817)</u>	<u>(56)%</u>	<u>\$ 2,852</u>	<u>\$ 5,611</u>	<u>\$ (2,759)</u>	<u>(49)%</u>

For the three months and six months ended June 30, 2024, the \$1.8 million and \$2.8 million year over year decrease in total revenues, respectively, was primarily related to lower collaboration revenues recognized under the Roche Agreement, resulting from an overall increase in total estimated costs to be incurred under this collaboration agreement.

Collaboration revenues may fluctuate from period to period based on changes in estimated costs to support performance obligations. The collaboration revenue was included in deferred revenues at December 31, 2023 (see Note 3 (Revenue) to our condensed consolidated financial statements included in this report for additional information).

Operating expenses

Our operating expenses consist of cost of sales, research and development expenses, and general and administrative expenses.

Cost of sales. These expenses consist of costs associated with royalty revenue which has resulted from product sales by our sublicensees.

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 which have an alternative future use will be capitalized as intangible assets, and research and development 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 consist of 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 expenses.

The following table shows our operating expenses for the periods presented (in thousands, except percentages).

	Three Months ended June 30,		Dollar Increase (Decrease)	Percent Increase (Decrease)	Six Months ended June 30,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2024	2023			2024	2023		
Cost of sales	\$ 44	\$ 127	\$ (83)	(65)%	\$ 142	\$ 246	\$ (104)	(42)%
Research and development	\$ 2,868	\$ 3,873	\$ (1,005)	(26)%	\$ 5,878	\$ 8,058	\$ (2,180)	(27)%
General and administrative	4,363	4,249	114	3%	9,360	8,973	387	4%
Total	<u>\$ 7,275</u>	<u>\$ 8,249</u>	<u>\$ (974)</u>	<u>(12)%</u>	<u>\$ 15,380</u>	<u>\$ 17,277</u>	<u>\$ (1,897)</u>	<u>(11)%</u>

Research and development expenses. For the three months ended June 30, 2024, the \$1.0 million quarter-over-quarter decrease in total research and development expenses was mainly attributable to: (i) a \$0.1 million net decrease for our OpRegen program; (ii) a \$0.6 million net decrease related to our OPC1 program; and (iii) a \$0.3 million decrease for our preclinical programs.

For the six months ended June 30, 2024, the \$2.2 million year-over-year decrease in total research and development expenses was mainly attributable to: (i) a \$0.3 million net decrease for our OpRegen program; (ii) a \$1.0 million net decrease related to our OPC1 program; (iii) a \$0.6 million decrease for our preclinical programs; and (iv) a \$0.3 million decrease for our other research and development programs.

The below table shows the amount of our total research and development expenses allocated by program for the periods presented (in thousands, except percentages).

	Three Months ended June 30,				Six Months ended June 30,			
	Amount		Percent of Total		Amount		Percent of Total	
	2024	2023	2024	2023	2024	2023	2024	2023
OpRegen®	\$ 1,499	\$ 1,580	52%	41%	\$ 2,814	\$ 3,100	48%	38%
OPC1	788	1,432	28%	36%	1,817	2,833	31%	35%
ANP1	501	697	17%	18%	944	1,140	16%	14%
PNC1	16	75	1%	2%	156	233	3%	3%
RND1	3	3	0%	0%	8	306	0%	4%
Other programs and non-program expenses	61	86	2%	3%	139	446	2%	6%
Total research and development expenses	<u>\$ 2,868</u>	<u>\$ 3,873</u>	<u>100%</u>	<u>100%</u>	<u>\$ 5,878</u>	<u>\$ 8,058</u>	<u>100%</u>	<u>100%</u>

General and administrative expenses. For the three months ended June 30, 2024, the \$0.1 million quarter-over-quarter increase in general and administrative expenses was primarily attributable to (i) a \$0.1 million increase in stock-based compensation and (ii) \$0.1 million increase in personnel costs, partially offset by lower legal expense.

For the six months ended June 30, 2024, the \$0.4 million year-over-year increase in general and administrative expenses was primarily attributable to: (i) a \$0.3 million increase in stock-based compensation; (ii) \$0.1 million increase in personnel costs; and (iii) an overall net decrease in costs incurred for services provided by third parties.

Other income and (expenses)

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

Other income (expenses)	Three Months ended June 30,		Dollar Increase (Decrease)	Percent Increase (Decrease)	Six Months ended June 30,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2024	2023			2024	2023		
Interest income	\$ 463	\$ 382	\$ 81	21%	\$ 925	\$ 792	\$ 133	17%
Loss on marketable equity securities, net	(10)	(150)	140	(93)%	(15)	(110)	95	(86)%
Foreign currency transaction loss, net	(378)	(497)	119	(24)%	(732)	(969)	237	(24)%
Other income	19	86	(67)	(78)%	19	543	(524)	(97)%
Total	\$ 94	\$ (179)	\$ 273	(153)%	\$ 197	\$ 256	\$ (59)	(23)%

Interest income. Interest income was greater for the three and six months ended June 30, 2024 as compared to the same periods in the prior year primarily due to a nominal increase in interest rates within our marketable debt securities holdings and our money market funds in 2024 as compared to 2023.

Marketable equity securities, net. We expect our net gain or loss on marketable equitable securities to fluctuate each reporting period based on the changes in the market price of the common stock held by us 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 4 (Marketable Securities) to our condensed consolidated interim financial statements included in this report for additional information regarding our marketable equity securities. For the three and six months ended June 30, 2024 and 2023, Lineage recognized a net loss on marketable equity securities primarily related to changes in the fair market value of the securities during the respective periods.

Foreign currency transaction gain (loss), net. Foreign currency transaction gain (loss), net, for each of the three and six months ended June 30, 2024 and 2023 consisted of net foreign currency transaction gains and losses recognized by our subsidiaries Cell Cure and ES Cell International Pte. Ltd. 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.

Other income. For the six months ended June 30, 2023, the Company recorded an employee retention credit of \$0.5 million, and no comparable credit was recorded in 2024. The employee retention credit is a payroll tax refund per employee, under the Coronavirus Aid, Relief, and Economic Security Act which was designed by the U.S. Treasury Department to assist businesses that retained employees during the COVID pandemic. The company qualified for this credit 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 our subsidiaries.

For the six months ended June 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 in-process research and development ("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 three months ended June 30, 2023, and did not record a deferred tax benefit for the three and six months ended June 30, 2024.

Liquidity and Capital Resources

Overview

During the six months ended June 30, 2024, we incurred a loss from operations of \$12.5 million and had negative cash flow from operations of \$11.0 million. As of June 30, 2024, our accumulated deficit was \$397.2 million. Since inception, we have incurred significant operating losses and we expect to continue to incur significant operating losses for the foreseeable future.

As of June 30, 2024, we had \$38.5 million in cash, cash equivalents and marketable securities. In February 2024, we raised approximately \$13.8 million in net proceeds through a registered direct offering of our common shares. We have historically funded our

operations primarily through proceeds from the sale of our common shares and securities exercisable for or convertible into our common shares, 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. We do not expect sales of shares of our former subsidiaries that we own to be a significant source of additional funds. See Note 4 (Marketable Securities) to our condensed consolidated financial statements included in this report for additional information regarding those marketable equity securities.

During the six months ended June 30, 2024, we issued and sold 55,830 common shares under our at-the-market offering program for gross proceeds of \$70,000. As of June 30, 2024, \$39.97 million remained available for sale under our at-the-market offering program. See Note 10 (Shareholders' Equity) to our condensed consolidated financial statements included in this report for additional information regarding our at-the-market offering program.

Cash Flows

(in thousands)	Six Months Ended June 30,	
	2024	2023
Cash provided by (used in):		
Operating activities	\$ (10,959)	\$ (17,510)
Investing activities	(8,831)	34,585
Financing activities	14,126	5,629
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(158)	(192)
Net (decrease) increase in cash, cash equivalents, and restricted cash	\$ (5,822)	\$ 22,512

Cash used in operating activities

Net cash used in operating activities was \$11.0 million for the six months ended June 30, 2024, which primarily reflects the loss from operations of \$12.5 million plus the changes in operating assets and liabilities of \$2.0 million. These items were partially offset by the non-cash expenses of \$2.4 million for stock-based compensation and \$0.3 million for depreciation and amortization. The foreign currency remeasurement had no effect on cash flows.

Net cash used in operating activities was \$17.5 million for the six months ended June 30, 2023, which primarily reflects the loss from operations of \$11.7 million plus the changes in operating assets and liabilities of \$9.4 million. These items were partially offset by the non-cash expenses of \$2.3 million for stock-based compensation and \$0.3 million for depreciation and amortization. The unrealized loss on marketable securities, foreign currency remeasurement and deferred tax benefit had no effect on cash flows.

Cash (used in) provided by investing activities

Cash used in investing activities for the six months ended June 30, 2024 was \$8.8 million which was primarily from the purchase of U.S. Treasury securities.

Cash provided by investing activities for the six months ended June 30, 2023 was \$34.6 million and consisted of \$47.7 million in U.S. Treasury securities which matured during the period, partially offset by \$12.6 million used to purchase U.S. Treasury securities and \$0.4 million used to purchase equipment.

Cash provided by financing activities

Cash provided by financing activities for the six months ended June 30, 2024 was \$14.1 million and primarily consisted of net proceeds from the sale of our common shares in our registered direct offering and from the sale of our common shares under our at-the-market offering program.

Cash provided by financing activities for the six months ended June 30, 2023 was \$5.6 million and primarily consisted of net proceeds from the sale of our common shares under our at-the-market offering program.

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 for research services and other purchase commitments with suppliers.

Our obligations to licensors under license agreements and to government entities under the terms of grants we have received 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-related revenue we receive from sublicensees. Milestone payments are due to licensors or government entities upon future achievement of certain commercial, development and regulatory milestones, including those related to the Roche Agreement. 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, see Note 13 (Commitments and Contingencies) to the condensed consolidated financial statements included in this report for additional information. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products, including those related to the Roche Agreement. Patent maintenance costs are payable to licensors as reimbursement for the cost of maintaining licensed patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements and to government entities under the terms of grants we have received are uncertain and may fluctuate significantly from period to period. As of June 30, 2024, 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 we may receive 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. As of June 30, 2024, the aggregate cap amount was approximately \$94.3 million. 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 June 30, 2024, 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 13 (Commitments and Contingencies) to our condensed consolidated interim financial statements included in this report for additional information.

As of June 30, 2024, under the terms of the leases for the facilities from which Cell Cure and Lineage operate, a total of \$3.2 million of rent payments will become due, of which \$0.6 million will become due in the remainder of 2024.

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

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, government or other grant funding, or other third-party funding transactions, including potential strategic alliances and licensing or collaboration agreements, or structured financings such as royalty monetization transactions. We cannot provide any assurance 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 or structured financing, we may be required to relinquish rights to our intellectual property, our product candidates or rights to future revenue streams 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 due to external factors beyond our control, such as unfavorable global economic conditions, disruptions to and volatility in the credit and financial markets in the United States and worldwide, public health emergencies such as the COVID-19 pandemic, geopolitical conflicts, political and economic instability, inflation and relatively high interest rates, and other macroeconomic factors.

We believe that our \$38.5 million in cash, cash equivalents and marketable securities at June 30, 2024, will be sufficient to fund our 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 13 (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 2023 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 2023 10-K.

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) During the quarter covered by this report, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

Item 6. Exhibits

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
3.1	Restated Articles of Incorporation, as amended	3.1	10-Q	November 9, 2023	001-12830
3.2	Certificate of Ownership	3.1	8-K	August 12, 2019	001-12830
3.3	Second Amended and Restated Bylaws	3.1(a)	8-K	June 13, 2024	001-12830
10.1*†	Second Amended and Restated License Agreement dated June 15, 2017, between Cell Cure Neurosciences, Ltd. and Hadasit Medical Research Services and Development Ltd.				
31.1*	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
32.1#	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data as its XBRL tags are embedded within the Inline XBRL document				
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase documents				
104*	Cover page formatted as Inline XBRL and contained in Exhibit 101				

* Filed herewith

Furnished herewith

^ Management contract or compensatory plan or arrangement

† This exhibit previously was filed as Exhibit 10.2 to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2017 with certain information omitted pursuant to an order issued by the SEC on September 12, 2017 granting confidential treatment under the Securities Exchange Act of 1934 for such omitted information through August 9, 2024. In accordance with CF Disclosure Guidance: Topic No. 7, the Company is electing to transition to compliance with the requirements set out in Regulation S-K Item 601(b)(10), and, accordingly is refiling this exhibit with portions of it redacted in compliance with Regulation S-K Item 601(b)(10) as indicated therein.

SIGNATURES

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

LINEAGE CELL THERAPEUTICS, INC.

Date: August 8, 2024

/s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer

Date: August 8, 2024

/s/ Jill Ann Howe

Jill Ann Howe
Chief Financial Officer

CERTAIN INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT (AND ITS ANNEXES) BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT (AND ITS ANNEXES), “[*]” INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

SECOND AMENDED AND RESTATED LICENSE AGREEMENT

This Second Amended and Restated License Agreement (this “Second Amendment”) is made and entered into as of June 15, 2017 and will become effective as of the Date of the Second Amendment as defined below, as an amendment of the Research and License Agreement signed between the Parties on the Effective Date (the “Original Agreement”), as amended by the Amended and Restated Research and License Agreement signed on October 7, 2010 (the “First Amendment”) and the letter agreement of May 13, 2014 as supplemented by a letter agreement dated August 3, 2016 (the “Letter Agreement” and the Original Agreement, as amended by the First Amendment, the Letter Agreement and this Second Amendment, the “Agreement”), by and between: HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD., a company duly incorporated under the laws of Israel (“Hadasit”) and CELL CURE NEUROSCIENCES LTD., a company duly incorporated under the laws of Israel (the “Company”) (each a “Party” and jointly the “Parties”).

WHEREAS, in the course of research conducted at Hadassah Medical Organization (“HMO”), by [*] and his other HMO colleagues (collectively the “Researchers”) prior to the execution of the Original Agreement, the Researchers arrived at certain inventions, being the subject of and more fully described in the patents and patent applications listed in Part I of Annex A hereto, and created and/or generated the technology described therein and related Know-How (defined below); and

WHEREAS additional Licensed Technology (defined below) was developed in the course of the collaboration between the Parties under the Product Development Agreement (defined below); and

WHEREAS, Hadasit is the commercial arm and a wholly-owned subsidiary of HMO; and

WHEREAS, Hadasit is the owner of certain rights, title and interest in and to the Licensed Technology; and

WHEREAS, the Company is engaged in the development and commercialization of cell therapy applications for retinal degenerative diseases; and

WHEREAS, the Company wishes to receive, and Hadasit is willing to grant to the Company, an exclusive, worldwide, royalty bearing license (with the right to grant sublicenses subject to the terms of Section 2.4 below), to use, commercialize and/or exploit the Licensed Technology or any part thereof, in any manner whatsoever and for any purpose or indication whatsoever in the Field (as defined hereafter), all subject to and in accordance with the terms and conditions of this Agreement,

WHEREAS, Hadasit has procured and will procure the provision of certain Licensed Materials (as defined below) to the Company by HMO for use under the license granted hereby, all subject to and accordance with the terms and conditions of this Agreement; and

WHEREAS, Contemporaneously with or as soon as practical following execution of this Agreement, the Parties hereto will execute the New Product Development Agreement and the Parties, and each of [*], will execute the New Consulting Agreements, as defined herein.

NOW THEREFORE IT IS AGREED BETWEEN THE PARTIES AS FOLLOWS:

1. Definitions and Interpretation

1.1. The Preamble and Annexes hereto form an integral part of this Agreement.

- 1.2. In this Agreement the following terms shall bear the meanings assigned to them below, unless the context shall indicate a contrary intention:
- 1.2.1. "Affiliate" shall mean any person who, directly or indirectly, controls or is controlled by, or is under direct or indirect common control with the Company. For the purposes of this definition, "control" shall mean the holding, directly or indirectly, of more than 50% (fifty percent) of the issued share capital or the voting power of the Company, or the holding, directly or indirectly, of a right to appoint more than 50% (fifty percent) of the directors of the Company or of the right to appoint the chief executive officer of the Company.
 - 1.2.2. "Company IP" shall have the meaning ascribed to such term in Section 8.5 below.
 - 1.2.3. "Confidential Information" shall have the meaning ascribed to such term in Section 11.1 below.
 - 1.2.4. "Controlled IP" shall mean, with respect to Intellectual Property (other than the Licensed Technology and the Licensed Materials) developed at HMO in the laboratory of [*] without the use of the Company's manpower, resources or Intellectual Property, the possession, as will be determined at any relevant time for the purposes of Sections 6.4 and 7.5 as applicable, by HMO and/or Hadasit of the ability to grant a license or sublicense of such Intellectual Property without violating the terms of any agreement or arrangement between HMO and/or Hadasit and any third party. For the avoidance of doubt, no portion of the Controlled IP shall be considered incorporated into, or to form a part of, the Licensed Technology or the Licensed Materials, unless such Controlled IP is specifically so included in a separate agreement executed by the Parties.
 - 1.2.5. "Consulting Agreement" shall mean any Consulting Agreement between the Company and Hadasit, whereby the Company has retained or may retain, through Hadasit, the services of [*] and/or [*] and/or any other person who is employed by HMO or by the Research Fund of the Hadassah Medical Organization (the "HMO Scientists"), from time to time, including, without limitation, the New Consulting Agreements.
 - 1.2.6. "Date of the First Amendment" shall mean October 7, 2010.
 - 1.2.7. "Date of the Second Amendment" shall mean the date upon which this Agreement, the New Consulting Agreements, and the New Product Development Agreements have been duly executed and delivered by the Parties thereto, including all of the annexes and schedules to be attached to such agreements.
 - 1.2.8. "Development Programs" shall mean (i) the research and development carried out by HMO for the Company from January 1, 2009 to June 14 2016 pursuant to the Product Development Agreement, and (ii) the research and development that has been carried out since June 15, 2016 and that will continue to be carried out following the Second Amendment Date, pursuant to the New Product Development Agreement. The Development Program for the period commencing from June 15, 2016 is attached as Appendix A to the New Product Development Agreement (the "Current Development Program"), as may be amended from time to time pursuant to the provisions thereof.
 - 1.2.9. "Distributor" shall mean an independent third party with whom there is a bona fide distribution, reseller or similar agreement pursuant to which such third party does not have any rights under or to the Licensed Technology other than the right to register Licensed Products and who purchases Licensed Products in consideration for the purchase price therefor, solely for resale and/or distribution of the Licensed Products to end-users.

- 1.2.10. "Effective Date" shall mean the date on which the Original Agreement went into force, i.e. August 30, 2009.
- 1.2.11. "Field" shall mean the RPE Field and the Photoreceptor Field.
- 1.2.12. "Hadasit IP" shall have the meaning ascribed to such term in Section 8.2 below. Hadasit IP existing as of the Date of the Second Amendment is listed in Part II of Annex A hereto.
- 1.2.13. "hESC" shall mean human embryonic stem cells.
- 1.2.14. "IIA" shall mean the Israel Innovation Authority, f/k/a the office of the Chief Scientist of the Israeli Ministry of Economy.
- 1.2.15. "Indemnitees" shall have the meaning ascribed to such term in Section 12 below.
- 1.2.16. "Intellectual Property" shall mean patents, trademarks, trade names, domain names, copyright, trade secrets, know-how, rights in respect of technical information and any other intellectual property whatsoever, registrable or otherwise, and all applications (including, patent applications) for any of the foregoing.
- 1.2.17. "iPS" shall mean human induced pluripotent stem cells.
- 1.2.18. "Joint IP" shall have the meaning ascribed to such term in Section 8.1 below. Joint IP existing as of the Date of the Second Amendment is listed in Part III of Annex A hereto.
- 1.2.19. "Know-How" shall mean discoveries and inventions (whether patented or not) and any information, data, designs, formulae, ideas, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development) processes (including manufacturing processes, specifications and techniques), laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports or summaries and information contained in submissions to, and information from, ethical committees and regulatory authorities. For the avoidance of doubt, Know-How does not include any materials, such as cells.
- 1.2.20. "License" shall mean the rights and licenses granted pursuant to Section 2.1 below.
- 1.2.21. "Licensed Materials" shall mean the HAD-C-102 cell line (the "Licensed Cell Line") and the CRD008 cord feeder cell line (the "Licensed Feeder Cell Line"), including any progeny, modified or unmodified derivatives, genetically modified hESC's or clones thereof as produced or derived by or on behalf of HMO or the Company, and (ii) the related documents and materials listed in Annex B, that have been provided by Hadasit or are to be provided by Hadasit in accordance with the provisions of this Agreement and/or the Current Development Plan.
- 1.2.22. "Licensed Patents" shall mean the patents and patent applications listed in Part I of Annex A, and all corresponding patent applications in all jurisdictions, as well as all patents which may be granted on any of the foregoing patent applications; as well as all substitutions, registrations, revalidations, confirmations, reissues, reexaminations, continuations, continuations-in-part, patents of addition, divisions, renewals, reissues and extensions (including any patent term extension such as but not limited to supplementary protection certificates pursuant to Council Regulation (EEC) No. 1768/92, any Pediatric Exclusivity Extension, and foreign equivalents of any of the foregoing relating to such patents) of any of the foregoing patents. Licensed Patents shall also be construed as

including the patent applications and patents listed in Part II and Part III covering existing Hadasit IP and Hadasit's rights in the Joint IP, as well as future Hadasit IP and Hadasit's rights in future Joint IP as to which patent applications are filed and patents are granted.

- 1.2.23. "Licensed Products" shall mean (i) all products, the development, production and/or sale of which is based on, or involves, in whole or in part, the use of Licensed Technology (or any part thereof) or which is produced and/or manufactured in whole or in part, using a process, method or system covered by, or falling within the Licensed Patents or the Licensed Technology (or any part thereof) including any other use, commercialization and/or exploitation of the Licensed Technology in any manner whatsoever and for any purpose or indication whatsoever in the Field and (ii) any tangible products or materials that are produced using the Licensed Materials and/or originating from the Licensed Materials or that wholly or partially incorporate Licensed Materials, in any manner whatsoever and for any purpose or indication whatsoever in the Field.
- 1.2.24. "Licensed Technology" shall mean (i) the Licensed Patents and the inventions described therein, (ii) the Know-How related to the technology described in the Licensed Patents, and (iii) the Hadasit IP and Hadasit's rights in the Joint IP.
- 1.2.25. "Loss" shall have the meaning ascribed to such term in Section 12 below.
- 1.2.26. "Magnet Consent" shall mean the consent of the Magnet authority of the Ministry of Industry, Trade & Labor to the scope of the license granted hereunder to the Licensed Materials.
- 1.2.27. "Materials" shall mean any hESC lines and mitotically active human fibroblast feeder cell lines including any progeny, modified or unmodified derivatives, genetically modified hESC's or clones of such cells or cell line and fibroblast feeder line as produced or derived by or on behalf of HMO, other than the Licensed Materials.
- 1.2.28. "Net Sales" shall mean the gross amount billed or invoiced by or on behalf of the Company and/or its Affiliates and/or Sublicensees (the "Invoicing Entity") on Sales of Licensed Products, less the following: (i) sales taxes (including value added taxes) to the extent applicable to such sale and included in the invoice in respect of such Sale; (ii) discounts, credits or allowances, if any, actually granted on account of price adjustments, recalls, rejections or returns of Licensed Products previously sold; (iii) bad debts, provided that they are recorded as such in the Invoicing Entity's books, in accordance with acceptable accountancy practices; and (iv) packaging, freight, shipping and insurance charges, to the extent that such items are separately itemized and invoiced and actually paid as evidenced by invoices, receipts or other appropriate documents; provided however, that in any transfers of Licensed Products between the Invoicing Entity and an Affiliate of the Invoicing Entity, Net Sales shall be payable only once and shall be equal to the total amount invoiced by such Affiliate on resale to an independent third party purchaser, in each case, after deducting the amounts referred to in clauses (i) through (iv) above, to the extent applicable. In case the Affiliate uses the Licensed Products internally without resale within [*] months from such invoice, other than for the purpose of testing or conducting clinical trials, the Company shall pay royalties as if such resale occurred at market price.
- 1.2.29. "New Consulting Agreements" shall mean the new Consulting Agreements to be entered into between the Parties and each of [*] individually, contemporaneously with this Agreement, in the forms attached hereto as Annex C, to supersede the Consulting Agreement between them which was signed on the Date of the First Amendment (as defined below).

- 1.2.30. “New Product Development Agreement” shall mean the new product development agreement to be entered into by the Parties contemporaneously with this Agreement, in the form attached hereto as Annex D.
- 1.2.31. “New Research Agreement” shall mean an agreement, in a form to be agreed in good faith by the Parties following the Execution Date, and that will be attached hereto as Annex E, pursuant to which the Company shall fund the performance of additional research at HMO in the field of stem cell applications for neurodegenerative diseases following completion of the Current Development Program, in an amount of US[*] per year for a total amount of US[*], less an amount of US[*] which has already been paid by the Company, all in accordance with the detailed research plan(s) to be mutually agreed upon thereunder. At the election of the Company, the New Research Agreement may be executed by the Company’s parent, Biotime Inc., rather than the Company.
- 1.2.32. “Photoreceptor Field” shall mean the development and exploitation of human stem cell derived (such as hESC derived and iPS derived) photoreceptor cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders.
- 1.2.33. “Product Development Agreement” shall mean the Product Development Agreement entered into on the Effective Date which governed the conduct of the Development Programs prior to the execution of this Second Amendment, it being acknowledged that upon the execution of this Second Amendment the New Product Development Agreement will be deemed to have entered into effect on June 15 2016 and to have replaced the Product Development Agreement as of such date.
- 1.2.34. “R & D Law” shall mean the Law for Encouragement of Research and Development in Industry – 1984, as amended from time to time.
- 1.2.35. “RPE Field” shall mean the development and exploitation of human stem cell derived (such as hESC derived and iPS derived) retinal pigment epithelial cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders.
- 1.2.36. “Royalty Period” means, on a country-by-country basis and a Licensed Product-by-Licensed Product basis, the period commencing on the Effective Date and ending on [*] from the date of the first Sale of such Licensed Product in such country.
- 1.2.37. “Royalties” shall have the meaning ascribed to such term in Section 3.1.3 below.
- 1.2.38. “Sale” or “Sold” shall mean the transfer or disposition of a Licensed Product by the Company, an Affiliate or a Sublicensee, to a party other than a transfer (i) by the Company to an Affiliate of the Company or (ii) by a Sublicensee to an Affiliate of such Sublicensee, or (iii) without charge or [*]. For the avoidance of doubt, the term “Sale” shall include any use, commercialization or exploitation of the Licensed Technology or Licensed Products, such as but not limited to lease, rent, subscription or provision of services.
- 1.2.39. “Sublicense” shall mean any right granted, option or license given, or agreement entered into by the Company or its Affiliate under the License, to or with any other person or entity, permitting use of the Licensed Technology or Licensed Material (or any part thereof) for the manufacture and/or marketing and/or distribution (except to a Distributor) and/or Sale of Licensed Products in the Field; and the term “Sublicensee” shall be construed accordingly. Notwithstanding the foregoing, and for the avoidance of doubt, an agreement with a subcontractor whereby the Company grants the subcontractor the right to make use of the Licensed Technology or Licensed Material for the purpose of performing research and development work on behalf of the Company, or for the purpose

of manufacturing Licensed Products which are to be sold by the Company pursuant to this Agreement, and for which use the Company is required to pay or otherwise compensate the subcontractor, shall not be considered a Sublicense, provided that (i) any act or omission by such subcontractor shall be deemed an act or omission of the Company, as applicable, for the purposes of this Agreement, (ii) such subcontractor shall not be entitled to exercise any of the rights granted to the Company, its Affiliates, or Sublicensees under this Agreement for its own account, or to grant any such rights to any third person or entity, and (iii) such subcontractor shall be subject to confidentiality and non-use obligations no less restrictive than those set out in this Agreement.

1.2.40. "Sublicensing Receipts" shall mean consideration of any kind, whether monetary or otherwise, received by the Company for or in connection with the grant of Sublicenses and/or options for Sublicenses and further sublicenses, including one-time, lump sum or other payments except for: (i) amounts received by the Company which constitute royalties based on Sales of Licensed Products by Sublicensees in respect of which the Company has paid royalties to Hadasit based on Net Sales of such Sublicensee; (ii) amounts received in reimbursement of expenses incurred by the Company in filing, prosecuting, maintaining or defending Licensed Patents provided that such amounts are incurred after the grant of the Sublicense as evidenced by appropriate documentation; (iii) amounts received by the Company from a Sublicensee, and actually expended by the Company in respect of Licensed Product-related research and/or development activities to be performed by the Company for such Sublicensee, plus [*], provided that

1.2.41. any such amounts constitute research and/or development funding only and not payment for Licensed Products;

- (a) such research and/or development activities are performed pursuant to a defined research and development program and research and development budget agreed with the relevant Sublicensee, a copy of which is provided to Hadasit; and
- (b) the Company submits to Hadasit a written expense report, confirmed by the Company's chief financial officer, demonstrating that such amounts have actually been expended and/or incurred by the Company in the conduct of such research and/or development activities in accordance with such work program and budget, and that the expenses actually incurred by the Company as aforesaid include [*];

it being agreed, for the removal of doubt, that any amounts received by the Company as aforesaid, but not expended and/or incurred as set out above [*], shall be deemed to be Sublicensing Receipts. For the avoidance of doubt, Sublicensing Receipts do not include amounts received by the Company from a Sublicensee as loan or equity capital at fair market value.

Lump sum payments received by the Company or its Affiliates from Distributors in return for distribution rights and not in respect of Sales of Licensed Products shall be treated as Sublicensing Receipts hereunder.

1.2.42. "Term" shall have the meaning ascribed to such term in Section 13.1 below

1.2.43. "Third Party Royalties" shall mean royalties calculated on any amount invoiced by the Company, an Affiliate or a Sublicensee for the sale of a Licensed Product and actually paid by the Company, an Affiliate, or a Sublicensee to a third party (that is not an Affiliate of the Company or such Affiliate or such Sublicensee) for the right to use patents of such third party, without which right of use the Company, its Affiliate or Sublicensee would not be entitled to use the Licensed Technology in the development, manufacture and sale of the Licensed Product; provided, that the duty to pay the royalty

to such third party has been established in an arm's-length transaction and in good faith and is set out in a written agreement.

1.2.44. "Valid Claim" shall mean: (a) a claim of an issued and unexpired patent within the Licensed Technology that has not been (i) held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (ii) rendered unenforceable through disclaimer or otherwise, (iii) abandoned or (iv) lost through an interference proceeding; and (b) a pending claim of a pending patent application within the Licensed Technology, that has not been abandoned or finally rejected without the possibility of appeal or refiling.

1.3. In this Agreement, the terms "Amendment", "Original Agreement", "Agreement", "Hadasit", "Company", a "Party", the "Parties", "HMO", [*], and "Researchers" shall bear the definitions assigned to them respectively in the heading or in the preamble hereto, as the case may be.

1.4. In this Agreement, (including the Annexes hereto), unless the context otherwise requires:

1.4.1. "including", "includes" means including, without limiting the generality of any description preceding such terms;

1.4.2. any reference to "persons" includes partnerships, corporations, and unincorporated associations;

1.4.3. use of the singular includes the plural and vice versa and the use of any gender includes the other genders;

2. License

2.1. Hadasit hereby grants to the Company and the Company hereby accepts, as of the Effective Date, subject to the terms and conditions set out in this Agreement: an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses (subject to the terms set out in Section 2.4), to use, commercialize and/or exploit the Licensed Technology and (subject to the requirements of the Magnet Program) the Licensed Materials for use in accordance with the applicable ethical guidelines, in any manner whatsoever and for any purpose or indication whatsoever, solely in the Field. For avoidance of doubt, the License does not include any license in any materials produced at HMO other than the Licensed Materials.

2.2. For the removal of doubt, the term "exclusive", in the context of the Licensed Technology and the Licensed Materials in the Field, means that HMO shall not grant such licenses or rights to any third party in the Licensed Technology or to any Licensed Materials in the Field in order to research, develop, make, have made, register, import, manufacture, use, sell, offer for sale, produce, commercialize and distribute Licensed Products or exercise any of such rights itself in the Field, subject, however, to the right of HMO, Hadasit, and their respective researchers, employees, students and other researchers at collaborating research institutions to practice the Licensed Technology and to use the Licensed Materials (A) within the Field, to: (i) practice the Licensed Technology and to use the Licensed Materials solely for HMO's own internal academic and non-commercial research and instruction, and (ii) license or otherwise convey to other academic and not-for-profit research organizations such Licensed Technology and Licensed Materials (for no charge other than customary expense coverage and the like, in accordance with the MTA mentioned below) for use in non-commercial research, provided that such Licensed Technology and Licensed Materials will be transferred pursuant to an MTA substantially in the form attached hereto as Annex F and subject to the prior written consent of Cell Cure, which consent will not be unreasonably withheld, and (B) utilize and license/commercialize the Licensed

Technology and the Licensed Materials for any purpose outside of the Field, without restriction, provided that no Company or Sublicensee Confidential Information are used or disclosed.

- 2.3. For the further removal of doubt, the Company shall not be entitled to use the Licensed Technology or the Licensed Materials for any purpose outside of the Field.
- 2.4. For the further removal of doubt, and without derogating from any other provision hereunder, neither HMO nor Hadasit nor any of their licensees shall be restricted or prevented from using the Licensed Technology or the Licensed Materials for any purposes whatsoever outside the Field.
- 2.5. The Company shall be entitled to grant Sublicenses under the License provided that in each case (i) Hadasit approves the identity of the Sublicensee, which consent shall not be unreasonably withheld or delayed; (ii) each Sublicense agreement shall contain inter alia, provisions necessary to ensure the Company's ability to perform its obligations under this Agreement, including with respect to reporting requirements and Hadasit's audit rights as well as a provision that specifies that the Sublicense automatically expires upon termination of the License; (iii) the Company remains responsible to Hadasit for its adherence to the terms and obligations of this Agreement; (iv) the Company shall not grant any right or license in the Licensed Technology or the Licensed Materials outside of the Field; (v) each Sublicensee commits to at least the same level of insurance coverage, liability and indemnification obligations towards the Company and Hadasit/HMO as set forth herein; (vi) the Sublicense is at bona fide arms-length conditions; (vii) the material commercial terms of the Sublicense agreement and all other related agreements are provided to Hadasit at least 21 (twenty one) business days prior to the signature of the Sublicense agreement by the parties thereto to the extent practicable, and the full final versions at least 24 (twenty four) hours prior to signature, so that Hadasit can ascertain that the Sublicense agreement does not derogate from its rights under, or is otherwise inconsistent with, this Agreement, provided that nothing in this provision shall be construed as exempting the Company from any of its obligations under this Agreement; (viii) the Company and each Sublicensee commits in writing (A) to report to HMO, in advance, in accordance with the guidelines of the Institution Review Board of HMO (Helsinki Committee), regarding any potential and/or planned use of the Licensed Materials and (B) to comply with all applicable ethical guidelines; (ix) the approval of the IIA to the transfer of Licensed Technology and Licensed Materials to the Sublicensee is obtained by the Company, to the extent applicable; (x) the approval of the Israeli Ministry of Health (the "MOH") to the transfer of the Licensed Materials to the Sublicensee is obtained by the Company; in this respect, Hadasit agrees to use its reasonable efforts to assist the Company in obtaining such approval, to the extent that such approval requires action by Hadasit or HMO; and (xi) the Company shall provide to Hadasit a copy of the signed agreement and all amendments thereto (any which proposed amendment shall again be subject to the provisions of this Section 2.4 before being signed and coming into force), forthwith upon the signature thereof.

For the avoidance of any doubt, it is hereby acknowledged and agreed that (A) nothing contained in any sublicense agreement under the License shall be interpreted or applied as (i) diminishing or derogating from the rights of Hadasit hereunder for any purpose, (ii) increasing or extending the liability, obligation or commitment of Hadasit to the Company or any Sublicensee on any account, (iii) expanding or extending the rights granted hereunder by Hadasit to the Company for such Sublicense or any other purpose, or (iv) diminishing or derogating from the liability, obligation or commitment of the Company to Hadasit hereunder for any purpose; and (B) the foregoing provision shall apply notwithstanding the application or otherwise of Section 2.4(vii) above.

- 2.6. Hadasit shall procure the provision of the Licensed Materials that have not yet been provided to the Company by HMO in a timely manner pursuant to Annex B and the New Product Development Agreement.
- 2.7. Hadasit shall procure that HMO: (i) keeps on record data characterising the Licensed Materials in accordance with the parameters set out in Annex B hereto; (ii) transfers all documentation related to the Licensed Materials that have not yet been provided to the Company (as set out in Annex B

hereto) and pursuant to the Current Development Program in a timely manner; (iii) makes reasonable efforts to provide additional documentation that may be required from time to time, in order to obtain regulatory approval of Licensed Products, or make the documentation available for inspection by regulatory authorities, if not transferable.

- 2.8. Hadasit shall procure that HMO shall be solely responsible for the proper storage of the Licensed Materials while in the possession of Hadasit and/or HMO or stored on the premises of HMO and shall make them available to the Company in accordance with the procedure detailed in Annex B. The Company shall be solely responsible for the proper storage of the Licensed Materials at all times following its receipt thereof.
- 2.9. For the removal of doubt, the Company shall not be restricted or prevented from developing, producing, marketing, distributing and/or selling (whether by itself or by third parties) any materials or products for any application in the Field and/or any other types of material or product for any purpose whatsoever, on the basis of cells manufactured by the Company and/or procured from third parties, provided, however, that such cells and other cells derived, developed or produced therefrom are maintained, stored and documented separately from the Licensed Materials, and that such cells were not directly produced using or with reference to Hadasit or HMO's Confidential Information, the Licensed Patents or the Licensed Materials or any other Materials, or any other patent of Hadasit or HMO and did not originate from such Confidential Information or from any Licensed Patents or Licensed Materials or any other Materials, or any other patent of Hadasit or HMO, and do not incorporate the Confidential Information, Licensed Patents or Licensed Materials or any other Materials, or any other patent of Hadasit or HMO wholly or partially. For the avoidance of doubt, any tangible products or materials that are produced using such third party cells and/or originating from such third party cells or that wholly or partially incorporate third party cells, to the exclusion of the Licensed Materials, shall not be "Licensed Products" for the purposes hereof, unless they fall within the definition set forth in Section 1.2.23(i) hereto.
- 2.10. All amounts which the Company is committed to bear and which may be charged by Hadasit to the Company pursuant to this Section 2 and otherwise under this Agreement, shall be at quoted to the Company in advance for its approval, at reasonable current market rates or at rates charged by HMO to other companies, in Hadasit's discretion.

3. Consideration; Royalties; Additional Understandings

- 3.1. In consideration for the grant of the License, Company agrees to pay Hadasit the following:
 - 3.1.1. a one time lump sum payment of [*] on account of the reimbursement of all patent expenses incurred and paid for by Hadasit in respect to the Licensed Technology prior to the Effective Date, the receipt of which Hadasit hereby confirms;
 - 3.1.2. throughout the Royalty Period, a royalty of [*] of Net Sales from Sales of Licensed Products by any Invoicing Entity ("Royalties") provided, however, that if no Valid Claim exists with respect to a Licensed Product and the Licensed Product was not derived from the Licensed Materials, then the royalty payable to Licensor for such Licensed Product shall be reduced to [*] of the royalty set forth above; and
 - 3.1.3. [*] of Sublicensing Receipts.
- 3.2. The Company shall pay Hadasit an annual minimal non-refundable royalty ("Minimum Royalty") of US[*], which shall become due and payable only as from the first January 1 falling after the completion of the provision of services to the Company or its Affiliates by the laboratory of the [*] or any HMO researcher who may succeed him funded pursuant to the New Product Development Agreement and the New Research Agreement. The Minimum Royalty shall be

creditable against future Royalties and Sublicensing Receipts collected by the Company during the same calendar year. The Minimum Royalty shall be payable until the end of [*] years from the First Commercial Sale of a Licensed Product in the USA.

- 3.3. In the event that the Company or its Affiliates are required to pay, and actually pay, Third Party Royalties on Net Sales of a Licensed Product in a particular country, the Company shall be entitled to offset [*] of such Third-Party Royalties against royalties payable to Hadasit on the same Net Sales, provided that Hadasit's royalty shall not be reduced on account of such deductions (together with the deduction permitted pursuant to Section 3.1.2) to [*] of the royalty that would have otherwise been payable to Hadasit.
- 3.4. In addition to the Royalties, the Company agrees to pay Hadasit the non-refundable milestone payments set forth below no later than [*] days following achievement of the relevant milestone, it being agreed, however, that the milestone payments are creditable by the Company against Sublicensing Receipts which, for the avoidance of doubt, are paid either prior to or following the relevant milestone being reached:
 - (a) US[*] upon the recruitment of the first patient for the first Phase IIB clinical trial;
 - (b) US[*] upon the enrollment of the first patient in the first Phase III clinical trials.
 - (c) US[*] upon delivery of the report for the first Phase III clinical trials;
 - (d) US[*] upon the receipt of an NDA or marketing approval in the EU, whichever is the first to occur;
 - (e) US[*] upon the First Commercial Sale in the US or EU, whichever is the first to occur.
- 3.5. Unless otherwise agreed in writing, all amounts payable to Hadasit pursuant to this Section 3 shall be paid to Hadasit in US Dollars as follows: (i) in the case of Royalties, on a quarterly basis within [*] calendar days after March 31, June 30, September 30, and December 31 of each calendar year during the Term; and (ii) in the case of Sublicensing Receipts, no later than [*] days after any such Sublicensing Receipts are received by the Company from Sublicensees.
- 3.6. In the event that the Sublicensing Receipts comprise, in whole or in part, of non-cash consideration (including shares or other securities of the Sublicensee or other entity) which cannot be transferred to Hadasit in the same form as received, or which Hadasit has not consented to accept (which consent shall not be unreasonably withheld or delayed), then the fair market value thereof for the purposes of calculating Sublicensing Receipts, will be determined by mutual agreement of the Parties, and failing agreement between the Parties as aforesaid, the fair market value shall be determined by an expert appointed by mutual agreement of the Parties, who shall act as an expert and not an arbitrator and whose decision shall be final and binding on the Parties. Hadasit will notify the Company within [*] days from the Company's notice of such non-cash consideration whether it wishes to receive a non-cash consideration or pecuniary equivalent consideration (for which the Company shall be obliged from its own sources or otherwise to redeem the non-cash consideration for cash). The Company's notice should include all relevant documents and will provide Hadasit with the option to instruct the Company to transfer Hadasit's non-cash share to a trustee or other third party designated by Hadasit, without the Company incurring any liability or expense. If the Parties fail to appoint such expert within [*] days of either Party's written request to do so, then the expert shall be designated at the request of either Party by the President of the Israeli CPA Association.
- 3.7. All payments made hereunder to Hadasit shall be made by wire transfer to the following bank account or to any other bank account designated by Hadasit during the Term: [*]

- 3.8. All payments due under this Agreement shall be payable in US dollars, except in the event of Net Sales or Sublicense Receipts which are invoiced, billed or received in New Israeli Shekels, Euro, or Pounds Sterling, with respect to which payments to Hadasit will be made in New Israeli Shekels, Euro, or Pounds Sterling respectively. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the US (as reported in the Wall Street Journal) last published prior to the actual date of payment.
- 3.9. Any amount payable hereunder, which has not been made upon its due date of payment, shall bear interest from the date such payment is due until the date of its actual payment at an interest rate charged by [*] for a loan of the said amount in the said currency plus an annual compounded interest at a rate of [*].
- 3.10. The Company shall pay to Hadasit all amounts of [*] imposed on Hadasit in connection with the transactions under this Agreement. All amounts referred to in this Agreement are exclusive of Value Added Tax. For the removal of doubt, in calculating amounts received by the Company, whether by way of Net Sales, Sublicensing Receipts or Royalties, any amount deducted or withheld in connection with any such payment on account of taxes on net income (including income taxes, capital gains tax, taxes on profits or taxes of a similar nature) payable by the Company in any jurisdiction, shall be deemed, notwithstanding such deduction or withholding, to have been received by the Company.
- 3.11. Save for the deduction of withholding tax as required under applicable law, all payments to be made to Hadasit hereunder shall be made free and clear of, and without any deduction for or on account of, any set-off, counterclaim or tax.
- 3.12. If the Company or its Affiliates, if incorporated outside of Israel, elect to make payments net of any withholding tax that they may be required to deduct at source under law other than the law of Israel, then in addition to the mechanism detailed in Section 18.3 below the Company, its Affiliates or Sublicensees will provide Hadasit with reasonable assistance with Hadasit's efforts to claim an exemption from or reduction in any applicable tax withholdings and (if applicable) a refund of tax withheld, or to obtain a credit with respect to the tax paid. Each party will promptly notify the other if it becomes aware of a change in withholding tax rates.

4. Development Efforts

- 4.1. The Company undertakes, at its own expense, to make commercially reasonable efforts to commercialize Licensed Products in the RPE Field and in the Photoreceptor Field, including bio-testing of the Licensed Materials and the Licensed Products, clinical trials and other steps required for obtaining regulatory approvals from the relevant authorities as are consistent with the commercial efforts generally applied to similar products of similar potential throughout the Term.
- 4.2. Without derogating from the generality of the foregoing, in order to maintain its license in the Photoreceptor Field the Company shall be required to meet the development milestones listed in Annex G within the time frames specified therein (the "Development Milestones"). If the Company believes that it will not achieve a Development Milestone, it may notify Hadasit in writing in advance of the relevant deadline. The Company will include with such notice (a) reasonable explanations of the reasons for such failure ("Legitimate Reasons", and lack of funding shall not constitute a Legitimate Reason) and (b) a reasonable detailed written plan for achieving a reasonable extended and/or amended milestone (the "Plan"). If Hadasit in its reasonable discretion accepts the Plan, then Annex G shall be deemed as having been automatically amended accordingly. Hadasit's failure to accept or reject the Plan within [*] business days shall be deemed as approval. If there is a dispute between the parties in relation to the Plan, then they shall collaborate to develop a mutually acceptable Plan within [*] days of Hadasit's notice. Should the Company not provide a Legitimate Reason and/or a Plan accepted by Hadasit within the respective timeframes mentioned above, then Hadasit shall be entitled, by written notice to the Company, to restrict the Field to the RPE Field, and all rights and licenses granted hereunder in

the Photoreceptor Field shall revert to Hadasit. Such restriction shall be the only remedy available to Hadasit for the Company failing to reach a Development Milestone. It is understood and agreed that Hadasit shall not unreasonably exercise such right.

4.3. The Company shall be entitled to remove the Photoreceptor Field from the scope of the License at any time by providing [*] days prior written notice to Hadasit, in which case the provisions of the preceding Section 4.2 shall not longer have any effect.

5. MAGNET Program; Approvals; Applicable Laws

5.1. The Company hereby acknowledges that it is aware that the [*] supplied to the Company as provided herein were developed by [*] at HMO in part within the framework of a MAGNET program funded by the IIA within the framework of the Bereshith Consortium (in which the Company was also a member) and that Hadasit and the Company's rights therein, are subject to the terms and conditions that apply to all of the members thereof under the regulations of the Bereshith Consortium (the "Bereshith Regulations").

5.2. Hadasit represents and warrants that as of the Date of the First Amendment it was not aware of any use of the Licensed Materials by the industrial members of the Bereshith Consortium which was contradictory to the rights of the Company hereunder; and (ii) it has not received any request by the industrial members of the Bereshith Consortium to receive and/or use the Materials or the Licensed Materials in the Field. Hadasit shall further notify the Company of any written request made to Hadasit by any industrial member of the Bereshith Consortium for the transfer to such industrial member of the Materials or the Licensed Materials and related know-how or materials which constitute "New Know-how" ("Yeda Hadash") or "Existing Know-how" ("Yeda Kayam") under the Bereshith Regulations, which Hadasit has reason to believe may be used by such industrial member for the development and/or production of products comprising or embodying human stem cell derived RPE Cells for the treatment of retinal degenerative diseases by cell replacement therapy methods, and of any transfer of such Materials or Licensed Materials and related know-how or materials to such industrial member following such request.

5.3. Each of the Parties shall comply (and, to the extent applicable, the Company shall require Sublicensees to undertake to comply, vis-a-vis HMO, prior to the transfer of any Licensed Materials) with the requirements as set out in the approvals of the Ethics Committee for Genetic Studies in Humans of the MOH (the "MOH Ethics Committee") as issued from time to time in relation to each particular activity/study; HMO shall provide copies of the same to the Company upon request, which it may then forward to its Sublicensees. Each of the Parties shall also comply (and, to the extent applicable, the Company shall require Sublicensees to undertake to comply) with all applicable laws and regulations, standards and guidelines, including applicable local and international ethical guidelines (such as the ISSCR guidelines and the American Academy of Science guidelines, to the extent applicable) and the relevant restrictions set out in the R & D Law, including in the use of the Licensed Materials and in respect of any transfer thereof by or from HMO and/or the Company and/or the Sublicensee (as applicable) and in the case of each Party, in the performance of all the obligations of such Party under this Agreement, under the Development Programs and the New Product Development Agreement or the New Research Agreement and in the case of the Company and its Sublicensees, also in the development, production, use and sale of the Licensed Products (to the extent applicable).

5.4. Hadasit hereby represents that HMO holds and maintains all of the required approvals from the MOH Ethics Committee with respect to the Licensed Materials as was required for the performance by Hadasit (directly or through HMO) of this Agreement, and as required for implementing the New Product Development Agreement and the Current Development Program and will act diligently to obtain such approval, if required, with regards to the fulfillment of any of its future obligations hereunder or thereunder. Copies of the approvals pursuant to which the Development Program has and is currently being carried out since inception are attached hereto as Annex H. Hadasit hereby also represents that HMO holds all of the requisite informed consents

signed by the patients on a form a sample of which is attached hereto as Annex I, and that it shall provide copies of consents signed by the patients and/or originals as required for NIH Registration or regulatory approvals, and as permitted under applicable law and in compliance with patient confidentiality requirements.

- 5.5. Without derogating from the foregoing, the Company undertakes that it shall be responsible for obtaining and causing to remain in effect, and shall comply with (and shall require that Sublicensees undertake to comply, directly vis-a-vis HMO, with), such licenses, permits, approvals, and consents, including any MOH Ethics Committee approval, as may be required for performance by the Company and/or Sublicensees of this Agreement, including, the development, manufacture, use and sale of the Licensed Products.
 - 5.6. Hadasit shall procure that HMO shall give notification promptly after the transfer and/or supply of Licensed Materials to the Company as provided herein, to: (i) the MOH Ethics Committee if and as required in any approval granted by it; and (ii) if and as required, the Committee monitoring stem cell research at HMO.
 - 5.7. Company shall use its best efforts to obtain, maintain, cause to remain in effect (and shall, to the extent the Company deems necessary, employ at its expense a R&D coordinator to perform/coordinate these tasks, including responsibility for documentation and the procedures involved), and Company and Hadasit shall comply with, and shall procure the ongoing compliance with, by its representatives, and employees and (in the case of Hadasit), HMO and researchers at HMO, all licenses, permits, approvals and consents, including any additional MOH Ethics Committee approval and any local and international accepted ethical guidelines (such as the ISSCR guidelines and the American Academy of Science guidelines, to the extent applicable) as may be required for the conduct of the Development Program.
 - 5.8. Hadasit will be granted with a right to serve as a leading clinical site in Israel in Phase IIb and Phase III clinical trials in the Field at HMO, provided however that:
 - 5.8.1. There is no regulatory hindrance to perform the clinical trial at HMO;
 - 5.8.2. Hadasit matched the timetable and budget proposal for performing the clinical trial by a comparable institutional third party.
6. Representations and Warranties
- 6.1. Each of the Parties hereby represents and warrants to the other Party that it has the right, power and authority (including full corporate power and authority) to enter into and perform this Agreement and has taken all necessary action to authorize the entry into and performance of this Agreement.
 - 6.2. Hadasit hereby represents and warrants to the Company the following:
 - 6.2.1. Hadasit is the registered owner of the Licensed Patents listed in Part I of Annex A;
 - 6.2.2. HMO and the Researchers have assigned or shall assign, from time to time, their entire right, title, and interest in and to the Licensed Technology to Hadasit or jointly to Hadasit and the Company or solely to the Company, if required under the terms of this Agreement;
 - 6.2.3. HMO is the owner of the Licensed Materials and Hadasit has the right to grant the License to the Licensed Materials in accordance with the terms hereof;

- 6.2.4. subject to the dictates of the IIA or any other granting agency from which the Company may receive funding and the rights of the Company under this Agreement, Hadasit has and shall possess full title and interests in and to the Licensed Technology and has not and will not, during the Term, grant any rights in the Licensed Technology or (subject to the requirements of the Magnet Program and applicable ethical guidelines) the Licensed Materials in the Field;
 - 6.2.5. pursuant to agreements between HMO and Hadasit, Hadasit has the sole authority to enter into this Agreement;
 - 6.2.6. subject to the provisions of Section 5.1, all parts of the Licensed Technology in the Field, are to the best knowledge of Hadasit, and shall remain during the Term free and clear of any prior assignment or option;
 - 6.2.7. Hadasit does not currently own nor is it in possession of any patent or patent application covering technology for the conversion of hESC cells into RPE cells invented by the Researchers other than the Licensed Patents;
 - 6.2.8. Hadasit has not used any Intellectual Property which is not owned by or licensed to the Company pursuant to this Agreement or otherwise in the course of the Development Programs as of the Date of the Second Amendment;
 - 6.2.9. Hadasit has not and will not utilize any Intellectual Property which is independently developed at HMO in the Development Programs without prior coordination with the Company and the Company's prior consent, in writing; and
 - 6.2.10. Hadasit has not received written notice as of the Date of the Second Amendment of any legal suit or proceeding by a third party against it or against HMO contesting its ownership of the Licensed Technology or the Materials or claiming that the practice of the Licensed Technology or the use of the Licensed Materials would infringe the rights of a third party.
- 6.3. Nothing in this Agreement shall constitute a representation or warranty by Hadasit, express or implied, that any results will be achieved by the Development Programs, or that any portion of the Licensed Technology is or will be commercially exploitable or of any use or other value.
- 6.4. Should the Parties agree that Controlled IP is required or useful for the performance of the Development Program or commercialization of a Licensed Product within the Field, then the Parties shall negotiate in good faith a non-exclusive license for such Controlled IP for bundling with the Licensed Technology, with additional royalties. Before Hadasit grants an exclusive license in the Field regarding any portion of the Controlled IP, it will first notify the Company. If the Company notifies Hadasit in writing, within [*] of its receipt of such notice, of its interest in acquiring an exclusive license in the Field to such portion, then the Parties shall enter negotiations therefor. If the Parties are unable to reach agreement regarding license terms being negotiated pursuant to (and subject to the provisions of) this Section 6.4, within [*] days after the commencement of such negotiations, then this Section 6.4 shall no longer apply to such Controlled IP.

7. Reporting and Inspection

- 7.1. The Company shall provide Hadasit at least every [*] a written periodic report concerning all material activities undertaken in respect of the exercise of the Licensed Technology and/or the Licensed Materials furnished to the Company hereunder if conducted outside of Hadasit/HMO ("Development Reports"). The Development Reports shall include a summary of the research progress, a detailed report of the testing results regarding the Licensed Materials, and any other

related work affected by any Affiliate or Sublicensee during the [*] period prior to the report. Development Reports shall also set forth a general assessment regarding the achievement of any milestones, possible changes to the Product Development Program resulting therefrom; the projected – or actual – completion date of the development of Licensed Products and the marketing thereof; sales forecasts, if any have been made in the regular course of the Sublicensee's business; a description of any transaction involving the Licensed Technology, the Licensed Materials and/or any Licensed Product, and shall detail all proposed changes including the reasons therefor. The Company shall also provide to Hadasit a copy of all original safety test results and QC characterization results that will be performed on the Licensed Materials by or on behalf of the Company, and any documentation related thereto, as soon as such results are obtained, and Hadasit shall be free to use such results for any academic, commercial or other purposes outside the Field, and for uses in the Field subject to this Agreement, it being understood and agreed, however, that no commercial use shall be made by Hadasit or HMO unless and until the Parties reach an agreement regarding the reimbursement of a portion of the out of pocket expenses incurred by the Company in producing such results, commensurate to the intended commercial use. Notwithstanding the foregoing, reports provided to the observer appointed by Hadasit to the board of directors of the Company shall constitute reports provided to Hadasit under this Section 7.1, provided that the observer is free to share such reports with Hadasit.

- 7.2. Within [*] after the end of each calendar quarter, commencing from the first Sublicense or Sale of a Licensed Product, the Company shall furnish Hadasit with a full and detailed report certified as being correct by the chief financial officer of the Company, setting out all amounts owing to Hadasit in respect of such previous calendar quarter to which the report refers, and with full details of: (i) the gross commercial sales of all Licensed Products Sold by the Company and Sublicensees during such calendar quarter, (ii) a breakdown of Net Sales according to country, identity of seller, currency of sales, dates of invoices, number and type of Licensed Products sold, (iii) any deductions applicable as provided in the definition of Net Sales, (iv) the exchange rates, if any, used in determining the amount payable to Hadasit in US Dollars and in any calculations of Net Sales and Sublicensing Receipts; and (v) Sublicensing Receipts, including a breakdown of Sublicensing Receipts according to identity of Sublicensees, countries, the nature of the payment, the currency of the payment and date of receipt thereof.
- 7.3. Company shall keep complete and accurate books of account and records, consistent with sound business and accounting principles and practices and in such form and in such details as to enable the determination of the amounts due to Hadasit in terms hereof. The Company shall retain the foregoing books of account relating to a given calendar quarter for [*] years after the end of that calendar quarter.
- 7.4. Once every calendar year following the first Sublicense or Sale of a Licensed Product, and upon reasonable prior written notice, the Company agrees to permit Hadasit or its representatives, at Hadasit's expense, to examine their books, ledgers, and records during regular business hours for the purpose of and to the extent necessary to verify any report required under this Agreement. If any amounts due to Hadasit in respect of any year are determined to have been underpaid, in an amount equal to or greater than [*] of the amount actually paid by the Company to Hadasit in respect of such year, then the Company shall (in addition to paying Hadasit the shortfall along with applicable interest), bear the reasonable costs of such inspection.
- 7.5. During the performance of services pursuant to the Development Program, Hadasit shall instruct [*] that he shall not knowingly utilize Controlled IP or any Intellectual Property which is proprietary to Hadasit (other than Licensed Patents, Hadasit IP or Joint IP) or any third party following an initial evaluation by [*], without the Company's prior written consent. Hadasit shall provide the Company with periodic reports and working plans, but not less often than once per calendar quarter, with respect to the performance of services pursuant to the Development Programs. Hadasit shall ensure that such reports and working plans shall include a statement by Prof. Reubinoff (so long as he is the principal investigator with respect thereto) or any person who may replace him, about whether such reports and/or working plans include (a) to his actual

knowledge, any Controlled IP, and (b) to his actual knowledge without further investigation or inquiry, any Intellectual Property which is proprietary to Hadasit (other than Controlled IP, Licensed Patents, Hadasit IP or Joint IP) or any third party. The Company will be entitled, within [*] following its receipt of such working plans, to request that Hadasit revise a working plan so that such Intellectual Property is excluded. Any additional costs or delays that may result from the Company's request shall be the sole responsibility of the Company.

8. Proprietary Rights

- 8.1. Subject to the provisions of Section 8.3 below, all Intellectual Property developed jointly in the course of the Development Program ("Joint IP") shall be co-owned by the Company and Hadasit.
- 8.2. Subject to the provisions of Section 8.3 below, all Intellectual Property developed solely by Hadasit or HMO under this Agreement in the course of the Development Program shall be solely owned by Hadasit (the "Hadasit IP").
- 8.3. All Intellectual Property developed by HMO Researchers in the course of performing a Consulting Agreement, shall be owned as provided in such Consulting Agreement.
- 8.4. Intellectual Property developed in the course of the Development Program under IIA funding received by the Company and transferred to Hadasit (and as long as such Intellectual Property is subject to the R&D Law as a result of IIA funding) even if developed solely or jointly by Hadasit or HMO, shall (but only if and as required by such Law) be registered solely in the name of the Company unless the IIA agrees otherwise, but treated as Joint IP or Hadasit IP (as the case may be) for all intents and purposes hereunder, including, without limitation, for the purposes of determining Hadasit's entitlement to Royalties and Sublicensing Receipts. In cases where the contribution of HMO Personnel to a Licensed Patent or Joint Patent is significant as determined by the committee appointed in accordance with Section 8.6 below, the Company will, in coordination with Hadasit, apply to the IIA to approve joint ownership.
- 8.5. As between the Parties, all Intellectual Property developed by the Company under this Agreement in or outside the Field, solely or jointly with other third parties (other than Hadasit or, HMO) without the involvement of Hadasit or HMO or without the transfer of any proprietary materials of Hadasit (including but not limited to the Licensed Materials) to such third party shall be solely owned by the Company (the "Company IP").
- 8.6. The Company shall notify Hadasit prior to the filing of any patent application covering the results of the Development Program, and shall provide Hadasit with a copy of the proposed application. A committee comprising of one representative of each Party shall be set up to determine the ownership rights of the Parties in each Licensed Patent and Joint Patent which the Company intends to register pursuant to Section 9.1 below, prior to filing, pursuant to the provisions of this Section 8.

9. Patents

- 9.1. As of the Effective Date, the [*] shall be solely responsible for the filing and prosecution of the Licensed Patents, and the maintenance of all the Licensed Patents and any challenge or opposition relating thereto, at its sole expense, after consultation with [*] with respect thereto. The [*] shall notify [*], upon its written request, of the status of such patenting activities. If [*] licenses to a third party, any of the Licensed Patents outside of the Field, then the Parties shall reach an amicable decision as to the equitable division of the ongoing related patent expenses after license has been granted to that third party.
- 9.2. Hadasit shall cooperate and shall cause the Researchers to cooperate with the Company and/or its representatives, at no additional direct payment by the Company to the Researchers for provision

of this support, as long as no additional lab work is requested outside the scope of the Development Programs, with regard to the preparation, filing, prosecution and maintenance (as the case may be) of the Licensed Patents, including the disclosure to the Company of all relevant information with respect thereto and the execution of all documents which the Company and/or its representatives may request them to sign, from time to time, for the said purpose.

9.3. The Company shall maintain any patents or patent applications of the Licensed Patents pursuant to this Agreement at least in the following territories: United States of America, European Union, Australia, Canada, China, India & Israel, to the extent permitted by applicable law. After approval of any patent in the European Union the Company will validate and maintain such patent in at least the following countries, to the extent permitted by applicable law: UK, France, Germany, Switzerland and Italy. If at any time during the Term the Company decides that it is undesirable, as to 1 (one) or more of the aforesaid territories, to prosecute or maintain any patents or patent applications within the Licensed Patents, it shall give at least [*] days written notice thereof to Hadasit, and upon the expiration of such [*] notice period (or such longer period specified in the Company's notice) the Company shall be released from its obligations to bear the expenses to be incurred thereafter as to such patent(s) or patent application(s). Thereafter, such patent(s) or application(s) shall be deleted from the Licensed Technology in such territory and Hadasit shall be free to grant any rights in and to such patents or patent applications in such territory to third parties, without further notice or obligation to the Company, and the Company shall have no rights whatsoever to exploit such Licensed Patents or patent applications in that territory. In case of Joint IP, the assignment mechanism described in Section 13.5 below shall apply per such territory.

10. Patent Infringement

- 10.1. Each Party shall immediately notify the other Party in writing of any infringement by a third party of any Licensed Patent of which such Party becomes aware, and of any action instituted by a third party concerning any alleged infringement or any allegation by any third party of infringement resulting from the use and commercialization of the Licensed Patents of which such Party becomes aware.
- 10.2. The Company shall be obligated to defend any third party infringement action as aforesaid, at its sole expense, and Hadasit shall reasonably cooperate with the Company, in connection with the investigation and defense of any infringement action as aforesaid at the Company's expense Hadasit shall have the right (but not the obligation) to be represented by counsel of its choice, at its sole expense (except in the case that representation of both Hadasit and the Company by the same counsel will impose a potential conflict of interests, in such case the Company will cover Hadasit's out-of-pocket counsel expenses), however without having power to overrule the Company's sole discretion regarding directing the defense. Notwithstanding the foregoing, the Company shall not compromise or settle such litigation without the prior written consent of Hadasit, which consent shall not be unreasonably withheld or delayed.
- 10.3. Hadasit and HMO shall cooperate and shall cause the Researchers to cooperate with the Company and/or its representatives, in connection with the investigation, prosecution or defense of any infringement action as aforesaid, at the Company's expense and, if required under applicable law, Hadasit shall consent to be named a party to any such action.
- 10.4. The Company shall have full control of such action and full authority to settle such action on terms that the Company shall determine, provided that any settlement of such action shall not derogate from Hadasit's rights under this Agreement. If the settlement adversely affects the interests of Hadasit or involves any act or omission by Hadasit, such settlement shall be subject to Hadasit's prior written approval, which shall not be unreasonably withheld or delayed. Any proceeds received by the Company in any such litigation shall first be applied to cover out-of-pocket costs and thereafter divided [*].

- 10.5. For the removal of doubt, Hadasit shall not itself be obliged to take any action to defend any action as referred to in this Section 10, save as set forth in Sections 10.2 and 10.3.
- 10.6. If the Company fails to take action to defend any action as aforesaid, within [*] days after having been duly served with such lawsuit and/or receiving notice from Hadasit in respect thereof (or within a shorter period, if required to preserve the legal rights of Hadasit and/or HMO under applicable law), then Hadasit shall have the right (but not the obligation) to take such action at its expense and the Company shall cooperate in the investigation and defense of such action, at Hadasit's expense and, if required under applicable law or contract, consent to be named as a party to any such action. Hadasit shall have full control of such action and shall have full authority to settle such action on such terms as Hadasit shall determine. Any recovery in any such litigation shall be for the account of Hadasit only.

11. Confidential Information; Publicity; Publications

- 11.1. Each Party shall maintain in confidence all "Confidential Information" of the other Party, which shall include any and all information relating to this Agreement and the terms thereof, Know-How and all information and reports received by such Party from the other Party, whether in written, oral, electronic or any other form and which has been designated in writing as confidential. Confidential Information shall not include information that:
- 11.1.1. is in the public domain at the time of disclosure or becomes part of the public domain thereafter other than as a result of a violation by the receiving Party of its confidentiality obligations; or
 - 11.1.2. was already known by the receiving Party at the time of disclosure; or
 - 11.1.3. is lawfully obtained from a third party under no obligation of confidentiality;
 - 11.1.4. is independently developed by the receiving Party without the use of the Confidential Information; or
 - 11.1.5. is required by law, court or any competent authority to be disclosed, provided that the receiving Party gives the disclosing Party reasonable prior written notice thereof.
- 11.2. Each Party undertakes and agrees that it shall not, without the prior written consent of the other Party, disclose the Confidential Information to any third party or use the Confidential Information other than for the purposes of this Agreement (including, the exercise of any rights hereunder or in the fulfillment of any obligations hereunder).
- 11.3. Notwithstanding the foregoing, a Party may disclose the Confidential Information to: (i) those of its employees, representatives, advisors, subcontractors, agents or sublicensees as, and to the extent necessary for the exercise by it of its rights hereunder, in the fulfillment of its obligations hereunder and/or for the implementation of the provisions of this Agreement and to potential investors in the Company, provided that it shall first bind such employees, representatives, advisors, subcontractors, agents, sublicensees and potential investors with a similar undertaking of confidentiality and in no event below a reasonable degree of care in writing; and (ii) any competent authority for the purposes of obtaining any approvals, permissions and/or waivers (if any) required for the exercise of the License and/or implementation of this Agreement, or in the fulfillment of any legal duty owed to such competent authority (including a duty to make regulatory filings or to comply with any other reporting requirements).
- 11.4. The Company shall have the right to demand the execution of a confidentiality undertaking protecting the Company and Sublicensee Confidential Information by any researchers, employees, students and other researchers at collaborating research institutions as a condition to their being

allowed to practice the Licensed Technology and to use the Licensed Materials pursuant to Section 2.2.

- 11.5. The confidentiality and non-use undertakings in this Section 11 above shall survive the termination or expiration of this Agreement.
- 11.6. The Company shall not use the names of Hadasit, HMO or any of their respective employees (including, [*] and other Researchers) and Hadasit shall not use the names of the Company or its employees in any announcement, press release, promotional literature, publication, presentation or other publicity in relation to this Agreement, its subject-matter or otherwise, without the prior written consent of other Party, unless such mention is to any competent authority for regulatory approval or in fulfillment of any legal duty owed to such competent authority or is required by applicable law.
- 11.7. [*] shall have the right to publish the Licensed Technology or information connected with or arising from the utilization of the Licensed Materials including in the Field in any scientific journals, manuscripts, book chapters or at any scientific conferences or meetings or to give oral presentations (including lectures or seminars) to third parties relating thereto, it being understood and agreed that no disclosure regarding the Licensed Products that are developed by the Company pursuant to the Development Programs shall be made therein or in any other public disclosure of any nature without the prior coordination of the Company and its written consent, such consent not to be unreasonably withheld or delayed. Notwithstanding the foregoing, any such publication or disclosure shall be on the condition that, to the extent that the information to be published or disclosed is information which is not in the public domain, the said contemplated publication or disclosure shall have been furnished to the Company in advance and in writing and the Company shall have failed to notify Hadasit in writing, within [*] days from receipt of the said draft publication or disclosure, that it identified non-public information that should be protected by a patent application or constitutes Company IP, Confidential Information of the Company or Joint IP. Should the Company notify Hadasit pursuant to the preceding sentence that it would like to file a patent application accordingly, then Hadasit shall postpone such publication or disclosure for a cumulative period of [*] days (as of the submission of Hadasit's written notification as provided herein above), or, at Hadasit's election, the relevant non-public information shall be deleted from such publication or disclosure. If the Company identifies in the proposed publication non-public information which is Company IP, Confidential Information of the Company or Joint IP, the Company will be entitled to request the deletion of such Company IP, Confidential Information of the Company or Joint IP from the publication and Hadasit will accede to such request.
- 11.8. The Parties agree that each publication or presentation as aforesaid shall be made in compliance with accepted scientific standards. The Parties further agree that any publication regarding the Licensed Products that are developed by the Company pursuant to the Development Programs shall only be made after prior coordination with the publication committee set up by the Company (the "Publication Committee"). Without derogating from the foregoing, such publication or presentation shall adequately acknowledge and appropriately reflect the contribution of the Researchers and employees of HMO and/or the Company (if applicable) and the source of information in accordance with customary scientific practice. Each of the Parties acknowledges that it is aware of the importance to the Researchers of publishing their work, and accordingly, it will use its reasonable efforts not to oppose such publications. Without limiting the generality of the foregoing, it is specifically agreed that:
- 11.8.1. On the basis of their contribution to the present Phase I/IIa Trial, [*].
- 11.8.2. The clinical trial findings of the present Phase I/IIa Trial will be submitted for publication within a reasonable period, in accordance with the Company's publication policy and international best practice.

- 11.8.3. The contents and interpretation of publications of the study trials will be determined by the Publication Committee. Two (2) Hadassah representatives will be part of the Publications Committee until completion of the current Phase I/IIa Trial and publication of the results thereof. Thereafter at least one (1) Hadassah representative will be part of the Publications Committee during any period in which clinical studies or research is being performed at HMO.

12. Indemnification and Insurance

The Company shall defend, indemnify and hold harmless the Researchers, Hadasit, HMO, and their respective officers, employees, and agents (hereinafter collectively, the "Indemnitees") from and against any loss, damage, liability and expense (including legal fees), charges, damages and/or product liability claim (all of the foregoing, collectively "Loss") which may result from the exercise of the License and/or use or exploitation of the Licensed Technology and/or the Licensed Materials by the Company, its Affiliates or any of its subcontractors, Distributors or Sublicensees provided, however that:

- 12.1. the Company's liability under this Section 12 shall be proportionately reduced to the extent the Loss was caused or increased by the negligence or willful misconduct of an Indemnitee, or by any act or omission by an Indemnitee in violation of applicable laws and regulations or in breach of this Agreement;
- 12.2. the Company is notified promptly in writing of any claim or action for which indemnity is or may be sought from the Company pursuant to this Section 12, such notice to set out the details of such complaint or claim;
- 12.3. the Indemnitee has not made any admissions or taken any action or proceeding relating to such claim or action which may prejudice the defense thereof, or compromised or settled such claim or action, without the prior written consent of the Company;
- 12.4. the Company shall have sole control over the defense with counsel of its own choice and the right to settle or compromise such claim or action, within its sole discretion provided that any settlement of such action that adversely affects the interests of Hadasit or involves any act or omission by Hadasit shall be subject to Hadasit's prior written approval, which shall not be unreasonably withheld or delayed; and
- 12.5. Hadasit and HMO shall cooperate fully, and shall cause the Researchers and the employees and agents of Hadasit and HMO respectively, to cooperate fully with the Company and its legal representatives, in the investigation and defense of such claim or action, including the provision of such records, information and testimony, such witnesses and the attendance of such conferences, discovery proceedings, hearings, trials and appeals as may reasonably be requested by the Company in connection therewith, at the Company's sole expense (except in the case that representation of both Hadasit and the Company by the same counsel will impose a potential conflict of interests, in such case the Company will cover Hadasit's out-of-pocket counsel expenses).
- 12.6. The Indemnitee shall be entitled, at its discretion, to engage separate legal counsel to represent such Indemnitee with respect to any such claim or action, at its sole expense.
- 12.7. Neither Party shall be liable to the other Party for any special, punitive, indirect, incidental or consequential damages of any kind, including lost profits, arising out of, or in connection with this Agreement, even if such Party is advised of the possibility thereof.
- 12.8. During the Term, Cell Cure shall maintain, at its cost, insurance against legal liability and other risks associated with its activities and obligations under this Agreement, in such amounts which in any case shall not be less than \$ 4,000,000 (four million dollars) subject to such deductibles and

on such terms as are customary for a company such as Cell Cure for the activities to be conducted by it under this Agreement. The named insured under such insurances shall be the Company, the inventors, the Scientists, Hadasit and HMO and the beneficiaries thereof shall include also the respective employees, officers and directors of Hadasit and HMO. The policy or policies so issued shall include a "cross-liability" provision pursuant to which the insurance is deemed to be separate insurance for each named insured (without right of subrogation as against any of the insured under the policy, or any of their representatives, employees, officers, directors or anyone in their name) and shall further provide that the insurer will be obliged to notify each insured in writing at least 30 (thirty) days in advance of the expiry or cancellation of the policy or policies. Cell Cure shall furnish Hadasit with evidence of such insurance at Hadasit's request.

13. Termination

- 13.1. This Second Amendment shall be deemed as having come into full force and effect upon the Date of the Second Amendment and shall remain in effect unless it expires or is terminated in accordance with any of the provisions of this Section 13 (the "Term").
- 13.2. This Agreement shall automatically terminate upon the end of the Royalty Period for all Licensed Products following whereby the Company shall have a fully paid up license to continue to exploit the License without having to pay Hadasit any Royalties or Sublicensing Receipts.
- 13.3. Either Party may terminate this Agreement hereunder by serving a written notice to such effect on the other Party upon or after:
 - 13.3.1. the commitment of a material breach hereof by the other Party, which has not been cured by the Party in breach within 60 (sixty) days after receipt of a written notice from the other Party in respect of such breach; or
 - 13.3.2. the granting of a winding-up order in respect of the other Party, or upon an order being granted against the other Party for the appointment of a receiver or a liquidator in respect of a substantial portion of such other Party's assets, or if such other Party passes a resolution for its voluntary winding-up; provided that such order or act as aforesaid is not cancelled or withdrawn within 60 (sixty) days of the grant of such order or the performance of such act.
- 13.4. Without derogating from the foregoing, Hadasit shall be entitled to terminate this Agreement, by providing 60 (sixty) days' prior written notice to the Company, if:
 - 13.4.1. The Company, its Affiliates or Sublicensees fail to continue the clinical development of Licensed Products in the RPE Field over a consecutive period of [*] months, or following receipt of regulatory approval for Licensed Products in the RPE Field, fails to take any actions to commercialize or sell the Licensed Products over a consecutive [*] month period and does not resume such activities during the notice period;
 - 13.4.2. The Company fails to provide a Development Report within a [*] months period and the Company fails to remedy this within the notice period;
 - 13.4.3. The Company fails to pay Hadasit any payment pursuant to this Agreement, the New Product Development Agreement or the New Research Agreement, when due and does not remedy such failure within [*] days of Hadasit's notice, provided that Hadasit is in full compliance with its obligations under such Agreement, it being understood and agreed that the right to terminate pursuant to this subsection shall not apply to any amounts that are disputed by the Company; or

- 13.4.4. the Company or any of its Affiliates, Sublicensees, or Distributors contests the validity of any of the Licensed Patents.
- 13.5. Upon the due termination of this Agreement by Hadasit for any of the grounds set forth in Section 13.3 and 13.4 above:
- 13.5.1. all Company IP relating to Licensed Products, including without limitation the results of all clinical trials and all regulatory data, submissions and correspondence, and the Company's share in the Joint IP (including, for the avoidance of doubt, Joint IP registered solely in the name of the Company pursuant to Section 8.3) and the Company's rights in any Hadasit IP that was registered jointly or solely in the name of the Company pursuant to Section 8.3, shall be assigned to Hadasit, subject to its compliance with its undertakings to the IIA. For that purpose, upon submission of an application related to the Joint IP, and upon the registration of any Hadasit IP in the name of the Company pursuant to Section 8.3, the Company shall sign a deed of assignment of the Company's interests in the Joint IP or Hadasit IP (as applicable) to Hadasit, detailing the Joint IP or Hadasit IP application. Such assignment shall be held under trust by the patent attorney appointed by the Company to handle the Licensed Patents pursuant to Section 9 above. Upon termination of this Agreement in accordance with Sections 13.3, 13.4 or 13.5 above, any and all such deeds of assignments so held in trust shall be surrendered to Hadasit within 30 (thirty) calendar days of its written demand, stating the grounds for due termination.
- 13.5.2. In the event that the Company IP so assigned to Hadasit shall be licensed to a third party (either alone or together with Hadasit IP and/or Joint IP) and shall generate proceeds to Hadasit, then Hadasit shall pay to the Company [*] of the Net Proceeds actually received by Hadasit in respect of such license to such third party, until such time as the Company shall have received, in aggregate, an amount equal to [*] the amount of the documented capital investment actually expended out-of-pocket by the Company in order to develop the Licensed Products, less any amounts received or receivable by the Company from third parties in connection with the Licensed Products prior to the assignment of the Company IP and the Joint IP, as certified by external independent auditors agreed upon by the Parties. Hadasit shall pay to the Company amounts, if any, payable under this Section 13.5, within [*] days of receipt of the relevant Net Proceeds. For the avoidance of doubt, the provisions of this Subsection 13.5.2 shall only apply in the event that Hadasit grants a license of Company IP to third parties. If Hadasit grants a license only of Joint IP and/or Hadasit IP to third parties without a license of Company IP, the Company will not be entitled to the compensation set forth in this Section 13.5.2.
- For the purpose of this Section, "Net Proceeds" means royalties or license fees actually received by Hadasit in respect of such license of Company IP alone or together with Hadasit IP and/or Joint IP, to a third party (excluding funds for research or development at HMO or payments for the supply of services) after deduction of all costs, fees and expenses incurred by Hadasit in connection with such license (including, patent costs, and all attorney's fees and expenses and other costs and expenses in connection with the negotiation and conclusion of such license).
- 13.6. Upon termination hereof for any reason, each Party shall be entitled to collect any debt then owed to it by the other Party hereunder.
- 13.7. Save as explicitly stipulated otherwise in any Agreement, any provision, that by its nature, is intended to survive termination, shall survive the termination or expiration of this Agreement.

14. Assignment

- 14.1. Neither Party shall be entitled to assign this Agreement or any or all of its rights, interests, or obligations hereunder to a third party without the prior written consent of the other Party, which consent shall not be withheld or delayed unreasonably and any unauthorized assignment or transfer shall be deemed null and void. A merger of the Company with another entity whereby the Company is not the surviving entity, or the acquisition of all or substantially all of the Company's assets or business, shall be deemed to be an assignment, under which the Company shall be entitled to assign all its rights and/or obligations, provided that: (i) the Company provides written notice to Hadasit of such assignment, merger or acquisition, and (ii) the assignee shall undertake in writing to be bound by all of the terms and conditions of this Agreement.
- 14.2. Notwithstanding the foregoing, the Company shall be entitled to assign all its rights and/or obligations hereunder to any of its Affiliates, or to any entity that acquires all or substantially all of the Company's shares, assets or business in accordance with the provisions set out in Section 14.1 above. The Company shall provide Hadasit with written notice of any such assignment and a written undertaking by the assignee to be bound by the terms of this Agreement.
- 14.3. Save as provided in Section 14.1 above, the Company will not be entitled to assign or encumber any or all of its rights or obligations under this Agreement or arising therefrom without the prior written consent of Hadasit.

15. Severability

The provisions of this Agreement are severable and, if any provision of this Agreement is held to be invalid, illegal or unenforceable under applicable law, then such provision shall be modified as set out below and the balance of this Agreement shall be interpreted as if such provision were so modified and shall be enforceable in accordance with its terms. The Parties shall negotiate in good faith in order to agree on the terms of an alternative provision which complies with applicable law and achieves, to the greatest extent possible, the same effect as would have been achieved by the invalid, illegal or unenforceable provision.

16. Governing Law and Jurisdiction

This Agreement shall be governed in all respects by the laws of Israel and the Parties hereby submit to the exclusive jurisdiction of the competent courts in Jerusalem.

17. Notices

Any notice or other communication required to be given by one Party to the other under this Agreement shall be in writing and shall be deemed to have been served: (i) if personally delivered, when actually delivered; or (ii) if sent by facsimile, the next business day after receipt of confirmation of transmission; or (iii) 5 (five) days after being mailed by certified or registered mail, postage prepaid (for the purposes of proving such service, it being sufficient to prove that such notice was properly addressed and posted) to the respective addresses of the Parties set out below, or to such other address or addresses as any of the Parties hereto may from time to time in writing designate to the other Parties hereto pursuant to this Section 17:

If to the Company:
Cell Cure Neurosciences Ltd.
[*]

With a copy (which will not constitute notice):
[*]

If to Hadasit:
Hadasit Medical Research and Development Ltd.

[*]
[*]

18. Execution of Ancillary Agreements.

- 18.1. Contemporaneously with or as soon as practical following the execution of this Agreement the Parties will execute the New Development Agreement and the New Consulting Agreements.
- 18.2. No later than [*] months prior to the completion of the period for the performance of the Current Development Program, the Parties shall execute the New Research Agreement.

19. Miscellaneous

- 19.1. The headings in this Agreement are intended solely for convenience or reference and shall be given no effect in the interpretation of this Agreement.
- 19.2. Save as expressly provided in Section 12 above, this Agreement does not, and is not intended to, create or confer any enforceable rights or remedies upon a third party (being any person other than the Parties to this Agreement and their permitted successors and assignees).
- 19.3. If applicable laws require that taxes be withheld from any amounts due to Hadasit under this Agreement, the Company shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) deliver to Hadasit a statement including the amount of tax withheld and justification therefore, and such other information as may be necessary for tax credit purposes.
- 19.4. The Parties hereby confirm their understanding whereby the Additional Research Agreement is null and void, and no Party shall have any claim against the other in relation to the subject matter thereof.
- 19.5. This Agreement, constitutes the entire agreement between the Parties hereto in respect of the subject-matter hereof, and supersedes all prior agreements or understandings between the Parties relating to the subject-matter hereof, including, without limitation, the Original Agreement, the First Amendment and the Letter Agreement. This Agreement may be amended only by a written document signed by the Parties hereto. In the event of any contradiction between this Agreement (and its Annexes) and the provisions of the Product Development Agreement, the New Product Development Agreement, or the New Research Agreement between the Parties, the provisions of this Agreement (and its Annexes) shall prevail.
- 19.6. This Agreement may be executed in any number of counterparts (including counterparts transmitted by fax or by electronic mail in PDF format), each of which shall be deemed to be an original, but all of which taken together shall be deemed to constitute one and the same instrument.
- 19.7. No waiver by any Party hereto, whether express or implied, of its rights under any provision of this Agreement shall constitute a waiver of such Party's rights under such provisions at any other time or a waiver of such Party's rights under any other provision of this Agreement. No failure by any Party hereto to take any action against any breach of this Agreement or default by another Party hereto shall constitute a waiver of the former Party's rights to enforce any provision of this Agreement or to take action against such breach or default or any subsequent breach or default by such other Party.
- 19.8. Nothing contained in this Agreement shall be construed to place the Parties in a relationship of partners or parties to a joint venture or to constitute either Party an agent, employee or a legal

representative of the other Party and neither Party shall have power or authority to act on behalf of the other Party or to bind the other Party in any manner whatsoever.

- 19.9. Hadasit hereby represents and warrants that it is authorized to represent and to bind HMO with respect to the matters contained herein and that HMO shall abide by the terms and conditions of this Agreement as if it were a party hereto.
- 19.10. Each Party agrees to execute, acknowledge and deliver such further documents and instruments and to do any other acts, from time to time, as may be reasonably necessary, to effectuate the purposes of this Agreement.

[Remainder of Page Intentionally Left Blank]

Signature Page

[Second Amended and Restated Research and License Agreement]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement as of the Effective Date.

/s/ Charles S. Irving
CELL CURE NEUROSCIENCES LTD.

By: Dr. Charles S. Irving
Title: C.E.O.
Date:

/s/ Tamar Raz /s/ Carole Grumbach
HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD.

By: Tamar Raz
Title: C.E.O.
Date:

By: Carole Grumbach
Title: VP Finance & Contracts
Date:

I hereby confirm that I will abide by the instructions issued to me by Hadasit pursuant to Section 7.5 of the Agreement and to the provisions of Section 11.7 of this Agreement.

/s/[*]
[*]
Date:

List of Annexes:

Annex A(I) Licensed Patents

Annex A(II) Hadasit IP

Annex A(III) Joint IP

Annex A (IV) OCS funded IP

Annex B Licensed Materials and related documentation

Annex C New Consulting Agreements

Annex D New Product Development Agreement

Annex E New Research Agreement

Annex F Form of MTA

Annex G Projected Development Milestones for Photoreceptor Fields

Annex H Approvals

Annex I Informed Consent Form

April 27, 2017

Annex A
Patents

Part I – Licensed Patents on the Effective Date (status as of the Date of the Second Amendment)

[*]

Part II – Hadasit IP

[*]

Part III – Joint IP

[*]

Part IV – OCS Funded

[*]

Annex B – Licensed Materials

[*]

ANNEX C

AMENDED AND RESTATED CONSULTING AGREEMENT

This Amended and Restated Consulting Agreement (this "Agreement") is entered into by and between Hadasit Medical Research Services and Development Ltd., a company duly incorporated under the laws of Israel ("Hadasit"), [*] (the "Scientist") and Cell Cure Neurosciences Ltd., a corporation organized under the laws of Israel (the "Company"), as from the Effective Date (defined below).

WHEREAS, Hadasit is a wholly owned subsidiary of Hadassah Medical Organization ("HMO") and is authorized to enter into this Agreement and to procure that the Scientist will utilize HMO's facilities and agents for purposes of this Agreement; and

WHEREAS, the Scientist is an employee of HMO; and

WHEREAS, the parties (together with [*]) entered into the Consulting Agreement dated [*] (the "Previous Consulting Agreement"), whereby the Company received from Hadasit certain consulting services, that were provided through the Scientist, solely in respect of the development of the Company's OpRegen™ product ("OpRegen") pursuant to the Product Development Agreement which was entered into between the Company and Hadasit as of August 30, 2009 (the "Previous Product Development Agreement"), under the terms and conditions thereof; and

WHEREAS, the Company wishes to continue to receive certain consulting services from the Scientist, in respect to both the development of OpRegen, and any Additional Projects which the Company may engage in from time to time (as defined herein) (collectively, the "Work") under the terms and conditions set forth below.

NOW THEREFORE, the parties agree as follows:

1. Pursuant to the terms and conditions of this Agreement, during the term of this Agreement the Scientist shall be appointed as a consultant to the Company and shall continue to act as the Company's [*].
2. The Scientist shall report directly to the [*] of the Company (the "[*]") and perform the Work in accordance with his directives.
3. During the term of this Agreement, and as reasonably requested by the Company, the Scientist shall, [*].
4. The Scientist shall exercise skill, care and diligence in the performance of the Work. The Scientist undertakes to comply with all applicable laws, rules, regulations and ethical rules in the performance of the Work under this Agreement. The provisions of this Section 4 shall not be deemed to derogate from any undertakings or obligations of Hadasit towards the Company under any other relevant agreements between the Company and Hadasit, as may be in force from time to time.
5. This Agreement shall be effective subject to the Second Amended and Restated License Agreement between the Company and Hadasit going into effect (the "License Agreement" and the "Effective Date", respectively) and unless earlier terminated pursuant to any of the provisions of Section 7 below, shall remain in force until the date of the dosing of the 1st patient in the Phase IIb clinical trial of OpRegen or the date of the dosing of the first patient in a Phase III clinical trial of OpRegen, whichever is the first to occur.
6. The Company may terminate this Agreement upon 30 (thirty) days prior written notice specifying the breach (the "Notice Period"), if the Scientist:
 - 6.1.1. is convicted of a felony or is held liable by a court of competent jurisdiction for fraud against the Company;
 - 6.1.2. is accused of embezzlement of the Company's funds;

- 6.1.3. alleges that he is an employee of the Company;
 - 6.1.4. challenges the validity of the Company's Intellectual Property and/or Company IP (as both terms are defined in the Second Amendment) or breaches the provisions of Section 14 below.
 - 6.1.5. breaches Sections 8 or 11 of the License Agreement and does not remedy such breach, if capable of being remedied, within the Notice Period;
 - 6.1.6. is in material breach of any other obligations hereunder does not remedy such breach, if capable of being remedied, within the Notice Period. .
7. Hadasit may terminate this Agreement by 30 (thirty) days prior written notice.
 8. Hadasit and the Scientist hereby represent and warrant that:
 - 8.1. the Scientist has the experience and capability to perform the Work in accordance with this Agreement; and
 - 8.2. the terms of this Agreement do not conflict with or contravene the terms of employment of the Scientist by any entity or institution and/or any regulations and/or policies of such entity or institution which may be applicable to the Scientist.
 9. The Scientist shall devote [*] (on average) for the performance of the Work. Hadasit shall be entitled to a fixed monthly consulting fee for the time worked by the Scientist up to the average monthly hours per calendar month above, which shall be equal to [*] (the "Monthly Consulting Fee"). In the event that the number of hours worked by the Scientist on average exceeds the monthly average set forth above, then the Company shall pay to Hadasit an additional fee equal to [*], which shall be calculated and payable in the manner set forth in Section 10 below (the "Additional Consulting Fee", and together with the Monthly Consulting Fee, the "Consulting Fee"). For the avoidance of doubt, [*]. The Parties will meet at [*] following the Effective Date to review and discuss the actual number of hours worked by the Scientist over the preceding [*], and if the number of hours worked by the Scientist deviates by more than [*] from the monthly average set forth above, the [*] may propose changes to the arrangement set forth herein, provided that no such changes shall be made unless agreed to in writing by all of the parties.
 10. Payment of the Monthly Consulting Fee and the Additional Consulting Fee (if applicable) shall be made in [*]. Payment of the Monthly Consulting Fee shall be made by the Company to Hadasit by no later than [*] after the submission of an itemized invoice by Hadasit for each month, indicating the tasks performed by the Scientist during such month and the time devoted by each of them to such tasks. At the end of each consecutive three-month period commencing on the Effective Date (each a "Quarter") Hadasit shall send to the Company a statement setting forth the average monthly hours worked by the Scientist in such Quarter, and in the event that the average monthly hours worked by the Scientist in such Quarter exceeds [*], the Company shall pay to Hadasit the Additional Consulting Fee due for such excess hours by no later than [*] after the submission of Hadasit's invoice for the same.
 11. The Company shall [*] which may be due and payable by Hadasit or the Scientist in respect of the Consulting Fee, in accordance with applicable law.
 12. No additional consideration will be payable to Hadasit or the Scientist in connection with the performance of the Work other than as expressly set out hereunder. For the avoidance of any doubt, the Scientist is not entitled to any consideration whatsoever directly from the Company in respect to the Work or under this Agreement and Hadasit shall be solely responsible for any consideration due to the Scientist for his involvement in carrying out the Work, including any social or other benefits.
 13. Should part of the Work need to be performed outside of the HMO facilities, all [*]. For the removal of doubt it is agreed that all Work outside HMO facilities shall be coordinated in advance with the Scientist, and shall be subject to his availability taking into consideration his pre-existing commitments and his duties at HMO.
-

14. The Scientist agrees and undertakes that for as long as he is engaged by or otherwise performs services for the Company in his capacity as [*] and for a period of [*] thereafter, as applicable, he [*].

15. Should the Company intend to commence [*]

[*].

16. To remove any doubt, it is emphasized that no employee-employer, partnership, joint venture or principal-agent relationship exists between the Company on the one hand, and the Scientist and/or Hadasit on the other hand. The parties hereby deny and waive any demand, claim and/or allegation that an employment relationship of any kind has resulted from this Agreement or from the performance of the Work. It is agreed between the parties that, in the event that a duly authorized legal body or other authorized forum, orders the Company to grant Hadasit and/or the Scientist the rights and privileges of an employee for the Work performed in accordance with this Agreement, the applicable Party will not be entitled to the Consulting Fee as provided in Section 9 above, but to the Consulting Fee less any amount that the Company will have to pay following the decision of a duly authorized legal body or other authorized forum. Hadasit shall reimburse the Company in respect of any cost or expense (including reasonable legal fees and expenses), imposed on and when incurred, by the Company against decision by any competent judicial authority, of the existence of an employment relationship between the Company, on the one hand, and the Scientist and/or Hadasit on the other hand.

17. [*] will indemnify and hold harmless [*] (the "Indemnitees"), from and against any losses, charges, damages and/or product liability claim which may result from [*] (a "Claim"), except and to the extent (on a percentage contribution basis) that such losses, charges, damages or product liability [*].

Without limiting the generality of the foregoing, the [*].

18. The following provisions of the License Agreement are hereby incorporated into this Agreement by reference, mutatis mutandis: Sections 11 (Confidential Information; Publicity; Publications), 14 (Assignment), 15 (Severability), 16 (Governing Law and Jurisdiction) and 18 (Miscellaneous) as supplemented by the provisions of Section 19 – 21 below.

19. It is hereby agreed that any Intellectual Property that is conceived or developed by the Scientist in the course of performing any Work shall [*].

20. Except as set forth in the License Agreement, the New Product Development Agreement (as defined in the License Agreement), and the Clinical Trial Agreement between Hadasit and the Company originally dated December 1, 2014, no interviews, publications or disclosures regarding the Company and its products may be given or made by the Scientist in any form or media without the prior written consent of the [*], the Company's medical communications committee or any other committee established for such purpose by the Company or its parent. .

21. The provisions of Section 17 (Notices) of the License Agreement are hereby incorporated into this Agreement by reference, mutatis mutandis and for the purposes of this Agreement the details for the Scientist are as follows:

[*]

22. This Agreement constitutes the entire agreement between the parties hereto in respect of the subject-matter hereof, and supersedes all prior agreements or understandings between the parties relating to the subject-matter hereof, including but not limited to the Previous Consulting Agreement, which shall be deemed as having terminated on the Effective Date. This Agreement may be amended only by a written document signed by the parties hereto. In the event of any contradiction between this Agreement and the provisions of the License Agreement (as supplemented herein) the provisions of the License Agreement (as supplemented herein) shall prevail.

[Remainder of Page Intentionally Left Blank]

[Execution Page for Amended and Restated Consulting Agreement]

IN WITNESS WHEREOF the parties hereto have set their signatures as of the date set forth below.

Hadasit Medical Research
Services & Development Ltd.

Cell Cure Neurosciences Ltd.

By: _____
Name: _____
Title: _____
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

[*]
Date: _____

ANNEX D

PRODUCT DEVELOPMENT AGREEMENT

This Product Development Agreement (the "Agreement") is entered into on 15 June 2017 (the "Execution Date") and deemed effective as of June 15, 2016 (the "Effective Date") by and between (i) HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LIMITED, a company duly incorporated under the laws of Israel, with its registered address at P.O.Box 12000, Jerusalem 91120, ("Hadasit"), and (ii) CELL CURE NEUROSCIENCES LTD., a corporation organized under the laws of the State of Israel, with its registered office located at Jerusalem BioPark, Hadassah University Hospital, Ein Kerem, Jerusalem (hereinafter: the "Company") (each a "Party" and collectively, the "Parties").

WHEREAS, Hadasit and the Company have entered into a Second Amended and Restated License Agreement dated 15 June 2017 (the "License Agreement") and to which this Agreement is attached, pursuant to which the Company has been granted a license from Hadasit to certain Licensed Technology in the Field (as both terms are defined therein); and

WHEREAS, the Parties are parties to a Product Development Agreement dated on or around August 30, 2009 (the "Existing Product Development Agreement");

WHEREAS, the Parties wish to enter into this Agreement, to replace the Existing Product Development Agreement and to govern the conduct of the Current Development Program referred to in the License Agreement, as from the Effective Date.

NOW THEREFORE, in consideration of the mutual covenants herein contained, the Parties hereby agree as follows:

NOW THEREFORE, the Parties agree as follows:

1. DEFINITION

All capitalized terms not otherwise defined herein shall have the meanings ascribed to them in the License Agreement.

2. SCOPE OF WORK

- 2.1. During the Term (as defined below) Hadasit, [*] and the members of the HMO Team (as defined below) shall use their commercially reasonable efforts and professionally and diligently perform the work specified in the Work Plan which is attached hereto as Schedule A (the "Work") in accordance with the Budget (defined below), which shall not exceed [*] per year (including overheads). The Parties acknowledge that the HMO Team has performed a portion of the Work under the Work Plan between the Effective Date and the Execution Date, and such work shall be deemed to have been performed pursuant to this Agreement for all intents and purposes.
- 2.2. The Work Plan contains a detailed break-down of the duties, obligations and responsibilities of Hadasit. The Work Plan includes, among other things, a time frame for the preparation and delivery of the Licensed Materials that have not yet been provided to the Company pursuant to Annex B of the License Agreement.
- 2.3. The Work shall be performed solely at the HMO Facilities or on the premises of the Company.
- 2.4. In the performance of the Work, [*] and his team shall not knowingly utilize Controlled IP or any Intellectual Property which is proprietary to Hadasit (other than Licensed Patents, Hadasit IP or Joint IP) or any third party, without the Company's prior written consent.

- 2.5. The Work Plan may be supplemented and updated from time to time in accordance with actual progress and the production needs of the Company, provided that any changes in the tasks or time frames must be mutually agreed by the CEO of the Company and by [*]. Any change in Schedule A shall require the written consent of Hadasit and the Company.
- 2.6. Hadasit hereby represents and warrants that it is authorized to enter into this agreement and shall procure that HMO provides the necessary resources to enable Hadasit and [*] to perform their obligations hereunder.

3. [*] AND HIS TEAM

- 3.1. The Work Plan shall be conducted under the direct supervision of Professor [*], a researcher at Hadassah Medical Organization [*]. In the event that [*] ceases to be available for purpose of the Work, Hadasit shall be responsible, within [*] days from the date [*] is no longer available for such purpose, for the procurement of a substitute by a suitably qualified person, who shall be acceptable to the Company, in its sole discretion. In the event that Hadasit fails to provide a substitute for [*] within the prescribed [*] day period, then the Company shall, as its sole remedy, be entitled to terminate this Agreement by rendering Hadasit written notice with immediate effect.
- 3.2. The Work shall be performed by a team comprising employees of HMO, Hadasit, the Hadassah Medical Organization and the Research Fund of the Hadassah Medical Organization (the "HMO Team"), who shall be dedicated to the Work for a number of hours equivalent to up to [*] full time employees (the "FTE's"). The initial members of the HMO Team are set forth in Schedule A. [*] shall be entitled to add and replace members of the HMO Team from time to time, and to change number of hours dedicated by each of them to the Work, provided that the total number of hours shall not exceed [*] FTEs and provided that all members of the HMO Team shall have the qualifications, training and experience necessary to perform the tasks assigned to them. [*] shall notify the Company of any change in the personnel comprising the HMO Team and the hours to be worked by them, and shall provide the Company with the names, qualifications and experience of new members. Moreover, [*] will be receptive to the preferences of the Company regarding new members of the HMO Team.
- 3.3. Hadasit may not employ or otherwise utilize the services of any person who is not an employee of Hadasit or HMO or of the Research Fund of the Hadassah Medical Organization in connection with the Work, unless it informs the Company in writing of the identity of such person, his/her status of an external services provider, and obtained the prior written consent of the Company. It is understood that numerous tasks comprising the Work will be performed by HMO Team in collaboration with the Company's personnel. Subject to the obligations of confidentiality set forth herein, the Company will provide the HMO Team with the same access to the Company's data and materials as is afforded to Company personnel who are involved in the Work, on an "as needed" basis.

4. INDEPENDENT CONTRACTORS

In the context of this Agreement, the business relationship of Hadasit, HMO, the Research Fund of the Hadassah Medical Organization and [*] and his team to the Company is that of an independent contractor and not of a partner, joint venturer, employer, employee or any other kind of relationship. Hadasit shall reimburse the Company in respect of any cost or expense (including reasonable legal fees and expenses), imposed on and when incurred, by the Company against decision by any competent judicial authority, of the existence of an employment relationship between the Company, on the one hand, and [*] and his team and/or Hadasit and/or HMO on the other hand.

5. REPORTING

- 5.1. Hadasit will prepare and keep complete and accurate records of the status and progress of the Work in notebooks in accordance with the Company's format and procedures, and in compliance with the applicable laws, rules and regulations, including any rules and regulations stipulated by the Israel Innovations Authority (the "IIA") with respect to those tasks that are funded pursuant to an IIA funded project. All such service documentation will be promptly and fully disclosed to the Company by Hadasit upon request and also shall be made available at Hadasit's site promptly upon request for inspection, copying, review as well as audit during any inspections conducted pursuant to this Agreement. Hadasit agrees to promptly take any steps that are requested by the Company as a result of an audit to cure deficiencies in the research documentation.
- 5.2. Research documentation shall be retained by Hadasit as reasonably required by the Company. Hadasit and [*] shall cooperate with the authorized representatives of the Company in connection with any concern, inquiry, instruction or demand raised or made by such representatives in connection with the performance of the Work.
- 5.3. During the Term, Hadasit shall furnish the Company with a written technical report prepared by a senior researcher indicating the progress of each work stream every [*]. For certain projects that are marked with an asterisk in Schedule A, a progress report will be provided once every [*]
- 5.4. Hadasit shall provide, if requested by the Company, with a final report within [*] of the completion of each separate project identified as such in the Research Work Plan, or the termination of this Agreement.

6. INSPECTION

At any time during the Term, Hadasit will permit the Company and/or its designated representatives, [*], to visit the HMO Facilities to monitor Hadasit's performance of the Work, examine and inspect the HMO Facilities, review all records, procedures and other materials related to the Work, and audit the results of the Work, all as deemed necessary and appropriate by the Company.

7. COMPENSATION FOR WORK

- 7.1. The Company will pay compensation to Hadasit for the performance of the Work as set forth in Schedule B hereto (the "Budget"). Payments for the Work performed following the Execution Date will be paid in quarterly advance installments starting from [*]. Following the Execution Date Hadasit shall issue to the Company an invoice for the Work performed prior to the Execution Date, in an amount not to exceed [*], and the Company shall pay the amount due no later than [*] from receipt of Hadasit's invoice or [*] following the Execution Date, whichever is the later. It is agreed that Hadasit shall provide written quarterly reports within [*] of the end of each calendar quarter showing a breakdown of FTEs actually allocated to the Work during the preceding quarter, in comparison to the Budget, for purposes of reconciliation.
- 7.2. The Budget (as may be updated in accordance with the provisions of this Agreement) includes a breakdown of the components comprising of the compensation as follows: (a) costs of the salaries of up to [*] FTEs (not including [*]), and (b) overheads (which include [*]'s management and Hadasit overheads). The Company shall be allowed to provide supplies and outsourced services required for the Work to Hadasit.
- 7.3. If required under Israel law, the Company shall [*] to any payments made under this Agreement to Hadasit. Any payment shall be made against the provision of tax invoice by Hadasit.
- 7.4. Other than as set forth in the Budget, Hadasit shall not be entitled to any other payment, remuneration or consideration of any type from the Company for the performance of the Work and/or under this Agreement. For the avoidance of doubt, neither [*] nor any other member of his team is entitled to any consideration whatsoever directly from the Company in respect of the Work

and/or under this Agreement and Hadasit shall be solely responsible for any consideration due to them for their involvement in the performance of the Work including but not limited to any salary, social benefits or severance pay.

7.5. Hadasit shall be solely responsible for the payment of [*] required by applicable law to be made in connection with this Agreement. The Company shall [*], as prescribed by applicable law, unless Hadasit provides the Company with [*].

8. PROPRIETARY RIGHTS

The provisions of Section 8 of the License Agreement shall govern with respect to Intellectual Property and other proprietary rights.

9. CONFIDENTIAL INFORMATION AND PUBLICATIONS

9.1. The provisions of Section 11 of the License Amendment shall govern with respect to Confidential Information and publications.

9.2. Upon the written demand of the Company, Hadasit and [*] shall immediately return to the Company, at the [*] expense, all the materials, samples, graphics, writings and information in other tangible forms, containing any proprietary and/or Confidential Information provided by and belonging to the Company pursuant to this Agreement, and any copies of such information, provided that Hadasit shall be entitled to retain one copy for its records with its legal counsel.

10. INDEMNIFICATION, INSURANCE, LIMITED LIABILITIES

10.1. Indemnification. The Company shall defend, indemnify and hold harmless [*], Hadasit, HMO, the Research Fund of the Hadassah Medical Organization and any of their employees, agents or contractors (collectively the "Indemnitees") promptly upon their first demand from and against [*]; provided, however:

10.1.1. that the Company's indemnification obligations under this Section 8 shall be proportionately reduced to the extent the loss was [*];

10.1.2. that the Company is notified in writing as soon as practicable under the circumstances of any Claim potentially subject to indemnification;

10.1.3. that any Indemnitee has not made any admission in respect of such Claim or proceeding or has taken any action relating to such Claim or proceeding prejudicial to the defense of it without the prior written consent of the Company, and that such consent is not to be unreasonably withheld.

10.2. Notice and Assumption of Defense. Hadasit shall promptly provide the Company with written notice of the receipt of any claim, suit, demand or notice with respect thereto. Hadasit shall allow the [*] to assume the defense of any such Claim, including the right to select counsel of its choosing and the right to compromise or settle any loss. The Indemnitee shall be entitled, at its discretion, to engage separate legal counsel to represent such Indemnitee with respect to any such claim or action, at its sole expense. If the [*] is required to defend any Claim, [*] shall, and shall cause the applicable Indemnitee to, at the [*] expense, cooperate fully in the defense thereof and furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the [*] in connection therewith. In no event shall [*] compromise, settle or otherwise admit any liability with respect to any Claim subject to indemnification under this Agreement without the prior written consent of the [*].

- 10.3. Disclaimer of Warranty. Nothing contained in this Agreement shall be construed as a warranty by Hadasit and [*] that the results of the Work will be useful or commercially exploitable or of any value whatsoever. In addition, and without derogating from the aforementioned Hadasit and [*] disclaim all warranties, either express or implied, with respect to the Work, including without limitation implied warranties of merchantability, efficacy and fitness for a particular purpose. The entire risk arising out of the use of the Work results remains solely with the [*].
- 10.4. Limitation on liability.
- 10.4.1. Without derogating from the above, if Hadasit or [*] are found liable (whether under contract, tort (including negligence) or otherwise), the cumulative liability thereof for all claims whatsoever related to the Work or otherwise arising out of this Agreement, shall not [*] under this Agreement.
- 10.4.2. Without derogating from the above, neither Party shall be liable for penalties or liquidated damages or for special, indirect, consequential or incidental damages of any type or kind (including, without limitation, lost profits) regardless of whether any such losses or damages are characterized as arising from breach of contract, breach of warranty, tort, strict liability or otherwise, even if such party is advised of the possibility of such losses or damages, or if such losses or damages are foreseeable. Nothing herein is intended to exclude or limit liability for death or personal injury caused by either Party.

11. TERM AND TERMINATION

- 11.1. This Agreement shall be deemed effective as of the Effective Date and shall remain in effect until June 14, 2019, unless earlier terminated or extended as set forth herein (the "Term"). Any extension shall be based on the Company's current needs. Notwithstanding the foregoing, to the extent that this Agreement imposes any obligations on Hadasit that did not apply under the Existing Development Agreement, such obligations shall only enter into effect as of the Execution Date.
- 11.2. Any Party may terminate this Agreement upon the filing by any person of a petition for the winding-up or liquidation or the appointment of a receiver on most of the assets of either Hadasit or the Company, if such petition is not dismissed within [*] days. In addition, each Party may terminate this Agreement without further notice in case another Party has breached a material term of this Agreement and did not cure such breach within [*] days of delivery of a written notice from the non-defaulting Party.
- 11.3. Termination of this Agreement by a Party shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination. The rights and duties under Sections 4, 5, 6, 8, 9, 10, this 11.3, 12, 13, 14 and 16 will survive the termination or expiration of this Agreement.

12. ASSIGNMENTS

This Agreement, and the rights and obligations hereunder, may not be assigned by any Party without the express written consent of the other Parties, which shall not be unreasonably withheld. The Company may assign this Agreement to an affiliate, or to a third party in the context of an M&A Transaction, provided that the Company shall provide the other Parties with written notice of any such M&A Transaction and an undertaking of the assignee to be bound by the terms of this Agreement. For the purposes hereof, the term "M&A Transaction" shall mean a transaction in which all or substantially all of the shares or assets of the Company are acquired by or assigned to a third party.

13. TERMINATION OF EXISTING PRODUCT DEVELOPMENT AGREEMENT

The Existing Product Development Agreement is hereby terminated as of the Effective Date.

14. ARBITRATION

In the event of a controversy between the Parties as to its execution or interpretation, the Parties shall refer the controversy to a mutually agreed upon arbitrator, who shall be nominated within [*] days from the date a Party has requested for same. In the event no such agreement is reached within said fourteen (14) days, the arbitrator shall be nominated by the competent court. The arbitrator shall give his verdict within [*] months from the date of his nomination and shall be subject to the substantive laws of [*].

Without derogating from this Section 14 above, each of the Parties reserves the right to file an application for temporary or preliminary injunctive relief, writ of attachment, writ of possession, temporary protective order and/or appointment of a receiver on the grounds that the arbitration award to which the applicant may be entitled may be rendered ineffectual in the absence of such relief.

15. APPLICABLE LAW; JURISDICTION

Without derogating from Section 14 above, this Agreement shall be governed by and construed in accordance with the [*].

16. ENTIRE AGREEMENT; SEVERABILITY; AMENDMENTS

This Agreement, including the Schedules attached hereto, represents the entire agreement between the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings, agreements and discussions between them, oral or written, with respect to the subject matter hereof and thereof. In the event of any inconsistency between this Agreement and the Schedules attached hereto, the terms of this Agreement shall govern. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof. This Agreement may be amended only by a written document signed by the Parties.

17. NOTICES

All notices permitted or required by this Agreement shall be in writing, in English and shall be deemed to have been duly served (i) if personally delivered, when actually delivered; (ii) if sent by facsimile or by electronic mail in PDF format, upon transmission thereof (receipt of which has been confirmed by the recipient); or (iii) 5 (five) business days after being mailed, postage prepaid, return receipt requested, if sent by registered mail and addressed to the address of the Parties set out below or to such other address or addresses as any Party may from time to time in writing designate to the other Party pursuant to this Section 16.

If to the Company:
Cell Cure Neurosciences Ltd.
[*]

If to Hadasit
Hadasit Medical Research Services and Development Ltd
[*]

If to [*]
[*]

[Signatures appear on the following page]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement effective as of the date first set forth above.

Cell Cure Neurosciences Ltd.
Name: Dr. Charles Irving
Title: CEO

HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD.
Name: _____
Title: _____

I hereby confirm that I have read and understood this Agreement and that I will abide by its terms.

Professor [*]

Schedule A

Work Plan
[*]

Schedule B

Compensation and Payment

[*]

Annex E

See Annex D

Annex F

Form of MTA

MATERIAL TRANSFER AGREEMENT
RELATING TO THE TRANSFER OF
BIOLOGICAL, CHEMICAL AND OTHER TANGIBLE MATERIALS
FOR RESEARCH PURPOSES ONLY

This Agreement between Hadasit Bio-Holdings Ltd. (hereafter "Hadasit"), located at, and:

Prof./Dr.
(hereinafter "the Requesting Scientist")

of: _____ (hereinafter "the Institute")

located at: _____

WHEREAS:

The Institute is engaged in Research and development in the field of _____ ("the Field");

and WHEREAS:

Hadasit has developed _____ ("the Materials") under the supervision of _____ ("the Researcher"); and related to the research project in the area of: _____ ("the Project");

and WHEREAS:

[*]

IN WITNESS WHEREOF The parties have caused this Agreement to be duly executed by the respective duly authorized officers as follows :

Authorized representative of Hadasit

By:	By:
Name:	Name:
Title:	Title:
Date:	Date:

Authorized representative of the Institute

By:	By:
Name:	Name:
Title:	Title:
Date:	Date:

Signature of the Requesting Scientist:

Date:

Annex G

Projected Development Milestones for Photoreceptor Fields

[*]

ANNEX H
Approvals

September 6, 2009

Approval of the CEO of Hadassah Medical Organization to the extension of the Experiment with human beings

Dear Professor Binyamin Reubinoff,

Genetic therapy
Hadassah Medical Center

Application file number in the Helsinki committee: [*]
The experiment number in the Ministry of Health: 920041227

Subject of the experiment:

Producing of connective cell tissues from the umbilical cord remnant obtained after birth in order to use it in the research and development of the embryonic stem cells of a human.

Protocol number [*] Date: December 10, 2004

Consent form: 5 Date: October 4, 2004.

Researcher Notebook: [*] Date: October 4, 2004.

Name of the Main Initiator of the Experiment: Professor Binyamin Reubinoff
HIN Number- None

By virtue of consent that I received from the CEO of the Israeli Ministry of Health, I have the right to approve the experiments with human beings in Hadassah Medical Institution. After the application to make such experiment was approved by the Helsinki Committee on August 27, 2009, and after I was convinced that the experiment was in accordance with the principles of the Helsinki Declaration and the Israeli Public Health Regulations-1980, and that the agreement between the Initiator of the experiment, the Leading researcher and the Medical Institution complies with the principals of experiments on human beings, I hereby approve the extension of the experiment.

The terms of the approval:

1. The clinical trial will be done in accordance with the Helsinki Declaration and in accordance with the principals of Experimenting with Human Beings in Israel (2006) and in accordance with the international updated regulations in such experiments.
 2. This approval of the experiment for the clinical trial is subject to the Helsinki Committee conditions.
- 1. The Helsinki Committee Conditions are as following:**
2. The expiration date of the experiment is October 31, 2010.
 3. The patient will receive a treatment, only after an explanation has been given to the patient or his representative. The patient must sign an informed consent form.
 4. Any change, amendment or deviation from the protocol of the clinical trial/experiment, requires the written approval of the Ethics Committee or the Ministry of Health.

5. The leading researcher shall report to the Helsinki Committee and to the “Main Initiator of the Experiment” regarding any serious adverse event that occurred during the trial or the termination of the trial (as detailed in section 15.1.1 of the procedure, within 48 hours of the event being known to him). The Helsinki Committee will review the submitted report and will forward its opinion to the Ministry of Health.
6. In order to extend the term of the experiment, an application must be submitted (2 months prior the expiration date of the experiment). In the application for the extension, the leading researcher must describe his progress in the experiment. If such application is not be submitted timely, the experiment will not be extended and will be terminated.
7. At the end of the experiment, the leading researcher, shall submit a summary of the experiment and its results.
8. The approval of the research is only for the specific researcher (that applied) and the medical institution, and cannot be transferred.
9. It is forbidden to publish any information regarding the experiment in the mass media (newspaper, radio, tv, internet), however, it is allowed to publish the experiment in scientific journals/ conferences or in order to recruit participants.
10. The supply of the experiment products, the storage of the products, and the way that the drugs are provided to the patients are the leading researcher’s responsibility. If there is a usage of drugs, it should be in accordance with the institution pharmacy, unless the Helsinki Committee approved otherwise.
11. Every drug that is given to any participant in the experiment, will be provided by the hospital’s pharmacy, with a prescription stating the participant’s name. It is forbidden to accept drugs and give them to patients, directly from the supplier.
12. If there is a need to file a request to the Ministry of Health to import a drug, this consent must be submitted as an exhibit.
13. The person who will submit such request has the responsibility to keep this approval in his records.
14. Every participant that is participating in the experiment, will receive a copy of his signed informed consent to participate in the experiment.
15. The leading researcher will keep all the application documents for this experiment, that he filed with the Helsinki Committee and all the documents that were collected during the experiment, at least for a period of 15 years from the termination date of the experiment.
16. This approval of the experiment, does not apply on soldiers. If there is a willingness to include a soldier in the experiment, the IDF (The Israeli Army) must approve it.
17. The doctor that is responsible for the experiment must notify the patient’s family doctor regarding the patient’s participation in the experiment and regarding the services that he is getting/ got in the experiment.

Best of luck,
Sincerely,
Professor Shlomo Mor Yosef
General Director
Hadassah Medical Organization

Copy to: Application file in the Helsinki Committee.

January 11, 2010

Approval of the CEO of Hadassah Medical Organization to the extension of the Experiment with humans

Dear Professor Binyamin Reubinoff,
Genetic therapy
Hadassah Medical Center

Application file number in the Helsinki committee: [*]
The experiment number in the Ministry of Health: 2004-027

Subject of the experiment:

Producing lines of human embryonic stem cells - an infinite potential source of cells for transplantation.
Protocol number 31.3.04 Date: November 8, 2006
Consent form: 2 Date: November 8, 2006
Researcher Notebook: [*] Date: November 8, 2006
Name of the Main Initiator of the Experiment: None
HIN Number- None

By virtue of consent that I received from the CEO of the Israeli Ministry of Health, I have the right to approve the experiments with human beings in Hadassah Medical Institution. After the application to make such experiment was approved by the Helsinki Committee on January 5, 2010, and after I was convinced that the experiment was in accordance with the principles of the Helsinki Declaration and the Israeli Public Health Regulations-1980, and that the agreement between the Initiator of the experiment, the Leading researcher and the Medical Institution complies with the principals of experiments on human beings, I hereby approve the extension of the experiment.

The terms of the approval:

1. The clinical trial will be done in accordance with the Helsinki Declaration and in accordance with the principals of Experimenting with Human Beings in Israel (2006) and in accordance with the international updated regulations in such experiments.
2. This approval of the experiment for the clinical trial is subject to the Helsinki Committee conditions.
- 1. The Helsinki Committee Conditions are as following:**
2. The expiration date of the experiment is January 31, 2011.
3. The patient will receive a treatment, only after an explanation has been given to the patient or his representative. The patient must sign an informed consent form.
4. Any change, amendment or deviation from the protocol of the clinical trial/experiment, requires the written approval of the Ethics Committee or the Ministry of Health.
5. The leading researcher shall report to the Helsinki Committee and to the "Main Initiator of the Experiment" regarding any serious adverse event that occurred during the trial or the termination of the trial (as detailed in section 15.1.1 of the procedure, within 48 hours of the event being known to him). The Helsinki Committee will review the submitted report and will forward its opinion to the Ministry of Health.
6. In order to extend the term of the experiment, an application must be submitted (2 months prior the expiration date of the experiment). In the application for the extension, the leading researcher must describe his progress in the experiment. If such application is not be submitted timely, the experiment will not be extended and will be terminated.

7. At the end of the experiment, the leading researcher, shall submit a summary of the experiment and its results.
8. The approval of the research is only for the specific researcher (that applied) and the medical institution, and cannot be transferred.
9. It is forbidden to publish any information regarding the experiment in the mass media (newspaper, radio, tv, internet), however, it is allowed to publish the experiment in scientific journals/ conferences or in order to recruit participants.
10. The supply of the experiment products, the storage of the products, and the way that the drugs are provided to the patients are the leading researcher's responsibility. If there is a usage of drugs, it should be in accordance with the institution pharmacy, unless the Helsinki Committee approved otherwise.
11. Every drug that is given to any participant in the experiment, will be provided by the hospital's pharmacy, with a prescription stating the participant's name. It is forbidden to accept drugs and give them to patients, directly from the supplier.
12. If there is a need to file a request to the Ministry of Health to import a drug, this consent must be submitted as an exhibit.
13. The person who will submit such request has the responsibility to keep this approval in his records.
14. Every participant that is participating in the experiment, will receive a copy of his signed informed consent to participate in the experiment.
15. The leading researcher will keep all the application documents for this experiment, that he filed with the Helsinki Committee and all the documents that were collected during the experiment, at least for a period of 15 years from the termination date of the experiment.
16. This approval of the experiment, does not apply on soldiers. If there is a willingness to include a soldier in the experiment, the IDF (The Israeli Army) must approve it.
17. The doctor that is responsible for the experiment must notify the patient's family doctor regarding the patient's participation in the experiment and regarding the services that he is getting/ got in the experiment.

Best of luck,
Sincerely,
Professor Shlomo Mor Yosef
General Director
Hadassah Medical Organization
Copy to: Application file in the Helsinki Committee.

Annex I
Informed Consent

Application Number in the Helsinki Committee: [*]

I, the undersigned: Name: _____ ID number: _____ Address: _____ Zip: _____ :

1. Hereby declare that I agree to participate in the medical experiment that is described in this document.
2. I declare that at the time of signing this document, I do not participate in any other experiment that requires any usage of any other drug/ or product, and I declare, commit and promise that I will not participate in any other medical experiment during the period of time of this experiment.
3. I declare that I was informed by ____ [name of the researcher] that:
 - a) The Leading Researcher is Professor Binyamin Reubinoff, received an approval form the CEO of the Institution to perform this experiment on human beings, as described in the Israeli Public Health Regulations -1980.
 - b) The Leading Researcher is affiliated with the Initiator of the experiment. Leading Researcher is Professor Binyamin Reubinoff.
 - c) The subject of the experiment is: Producing of connective tissue cells from the umbilical cord remnant obtained after birth, for their usage in research and development of embryonic stem cells of a human being. Protocol Number: [*]
 - d) I am free to choose not to participate in the medical experiment, and I'm free to choose to leave the experiment and to terminate my participation in the experiment at any time I choose, and this is without jeopardizing my right to receive the appropriate medical treatment.
 - e) In the event that I need to answer to any questionnaire, I have the right not to answer all or part of the questions.
 - f) It is promised to me that my identity will be kept anonymous to all the people involved in the experiment and my identity will not be published in any publication, including medical publications.
 - g) The medical Institution is providing reasonable insurance to the researchers, doctors, and the medical team that are taking part in the medical experiment (against potential legal proceedings by the participants in the experiment and any third party), however, it will not hurt/forfeiture my rights to proceed with a legal procedure against them.
 - h) There is a possibility that I will get the products of the experiment without any payment, even after 3 years from the termination date of the experiment, if there is no other substantive medical procedure for me and if the Leading Researcher will recommend that. In addition, if the drug/ the product of the experiment will not be approved by the State of Israel, I will also be able to receive the product/ the drugs as described in this paragraph (for free, even 3 years after the termination of the experiment).
 - i) It is promised to me, that during the process/ experiments, any question that I might have will be answered, as much as it is possible to answer it. Also, I will have the right to advice a third part/ family doctor/ family member etc. in regards of any decision that I need to make in connection with this experiment or whether I should continue to participate in it.
 - j) In Medical experiments where there is a female participant (in a childbearing age), in the event of pregnancy during the experiment, the female participant will receive an advice as regarding to the health of her fetus.

k) In any case where there is a problem regarding the medical experiment, I will be able to call Professor Reuben Binyamin, at any time 24/7 at his number 02-6778589.

l) I declare that I received a detailed information regarding the experiment as follows:

a. The goals of the experiment: Producing of connective tissue cells from the umbilical cord remnant obtained after birth, for their usage in research and development of embryonic stem cells of a human being. Those stem cells have the ability to turn into any cell of the human body. They can be used in research and development of new drugs and even in transplantation.

b. The number of the participants in the experiment are 20-30.

c. The term of the experiment is one hour of explanation and interview, where the doctor will take a blood sample from you. After giving birth, a part of yours umbilical cord will be taken, and then nothing else will be required from you and you will be free to go.

d. Methods: you are welcome to donate your umbilical cord after giving birth. Usually this part of the umbilical cord is destroyed anyways. Donation of the umbilical cord will be accepted only from a healthy women. The experiment on the umbilical cord will be subject to the ethical principles and the umbilical cord will be kept frozen and might be used in the future for several years, and it might be used in Israel and abroad. It will not be used for any experiment in genetics.

It is hereby clarified that all of your identity information (yours and your child's info), will be deleted, so that you will stay completely anonymous. The umbilical cord will get a new identification number and the information that identify you will be kept in a code form. The reason for that is that in a case that in the future a new disease will be discovered, it will be possible to reach out to you. The chances that anyone will be in touch with you in the future are very low. Your information that will be kept in a code form, will be confidential, and will be kept only in the Hadasah's hospital Safe. The Hospital manager will need to approve any contact with you (in the future) (prior calling you back etc.). Since there is a low chance that someone will contact you in the future, this experiment is considered to be an experiment with "identified samples".

Since the fact that the cell tissues are going to be in contact with the stem cells, that are going to be transplanted into patients bodies in the future, the U.S. government requires that your medical history will be recorded and collected. Donation of umbilical cords will be accepted only from healthy people and a blood sample will be taken.

In addition, your blood sample will be kept frozen for additional tests, if such tests will be needed in the future. However, the chances for that are very low. In any case, if your blood samples will need to be tested again, the hospital will reach out to you and explain you the reason for that and you will need to approve it. (Any such contact with you, will be after getting the approval of the Hospital's Manager to such contact).

Your blood test results will be given to you.

e. Benefits of the experiment for you: None

f. Risks that are known from participating in the experiment: none

g. Circumstances when the experiment might terminated: if the child or the parents are not healthy.

h. The researcher might notify the participant with his test results after the participant decided to terminate his participation in the experiment. However, the blood test results will be provided to the participant anyways.

i. Explanation of substantive treatments (their benefits and risks): and any relevant information will be provided to the participant.

j. Other relevant information: Since the child cannot agree to participate in the experiment, you as the parent can agree to participate and to donate the umbilical cord to the experiment.

4. I declare that I agree to the terms above, and that understand all the terms above and I am giving an informed consent, from my free will. I declare that I received a copy of my informed consent, dated and signed.

5. By signing this document, I consent that the Initiator of the research, the medical institution, and the Helsinki Committee will have an access to my personal medical information. The access to this information will be made with respect, while maintaining my confidentiality. My medical information will be used only and only for the medical experiment.

Name of the participant _____ Signature _____ Date _____

Declaration of the Researcher:

This consent by the participant, was obtained after I explained to the participant all the information above, and after I made sure that the participant understands and agrees to the above.

Researcher Name _____ Signature _____ Date _____

Informed Consent Form to participate in an experiment with human beings

First and last name:
ID Number:
Address and Zip Code:

For the spouse:
First and last name:
ID Number:
Address and Zip Code:

1. We hereby declare that we agree to participate in a medical experiment as described in this document.
2. We hereby declare that we do not participate in any other medical experiment at the time of the signature on this document and we declare that we will not participate in any other medical experiment during the time of this experiment.
3. I declare that _____ [name of researcher], explained to me that:
 - a. The leading researchers are: Professor Neri Laufer and Binyamin Reubinoff, and that they received an approval form the CEO of the Institution to perform this experiment on human beings, as described in the Israeli Public Health Regulations -1980.
 - b. The Leading Researcher- Neri Laufer, is affiliated with the Initiator of the experiment- Professor Reubinoff Binaymin.
 - c. The subject of the experiment is: Producing lines of human embryonic stem cellsà “an infinite potential source of cells for transplantation”.
 - d. We are free to choose not to participate in the medical experiment, and we are free to choose to leave the experiment and to terminate our participation in the experiment at any time we choose, and this is without jeopardizing our right to receive the appropriate medical treatment.
 - e. It is promised to me that our identity will be kept anonymous to all the people involved in the experiment and our identity will not be published in any publication, including medical publications.
 - f. The medical Institution is providing reasonable insurance to the researchers, doctors, and the medical team that are taking part in the medical experiment.
 - g. In some cases, in the recommendation of the Leading Researcher and subject to the approval of the Helsinki Committee, I will get the products of the experiment without any payment, up to 3 years from the termination date of the experiment, and I will be under medical supervision during this period of time.
 - h. It is promised to me, that during the process/ experiments, any question that I might have will be answered, as much as it is possible to answer it. Also, I will have the right to advice a third part/ family doctor/ family member etc. in regards of any decision that I need to make in connection of this experiment or whether I should continue to participate in it.
 - i. In any case where there is a problem regarding the medical experiment, I will be able to call Professor Laufer, 02-6776424.
 - j. In the event that I need to answer any questionnaire, I have the right not to answer all or part of the questions.
 - k. We understand that we cannot participate in any other experiment during the term of this experiment.

- l. We understand that after signing this document we will receive a copy of it.
- m. In Medical experiments where there is a female participant (in a childbearing age), in the event of pregnancy during the experiment, the female participant will receive an advice as regarding to the health of her fetus.
4. We declare that we received a detailed information regarding the experiment as follows:
 - a. The goals of the experiment: Producing stem cells from a fetus that was created in IVF procedure (In Vitro Fertilization). Those cells can be used in research and development of new drugs and even for transplantation (to cure diabetes etc).
 - b. The experiment will accept only fertilized eggs donations that were frozen at least 5 years ago, or longer than that (that are not going to be used for pregnancy process). Both spouses must agree to the donation. If the egg was fertilized from a sperm donation, only the women consent is necessary. These fertilized eggs will not be used to create a fetus.
 - c. The stem cells that will be produced in this experience will be kept frozen and will be used in research and development and transplantations for years.
 - d. The stem cells will be used in Israel and abroad for the purposes of research and might be used in transplantations in accordance with the ethical rules. You will not get any information regarding such transplantations and you will not be able to influence such transplantations.
 - e. Since the goal is to use these stem cells in transplantations, you will go through a few medical tests and interviews similar to the tests that people do before giving a blood donation. In the interview you will be asked as to your medical history and family medical history. You will give a blood sample and the sample will be kept frozen. If there will be a need to test your blood again in the future, you will need to give a separate consent for that. The blood test results will be provided to you.
 - f. The fetus donors will not get any financial compensation for their donation.

Detailed information regarding the research:

Producing stem cells of a fetus → a resource of potential cells for transplantation.

1. **The goals of the research**

Many diseases are caused by cell dysfunction. In many cases, it is impossible to improve their dysfunction by drugs or surgery and the only way to treat this problem is to transplant cells or organs.

The lack of cells, organs and tissues that are available for transplantation could be solved by producing stem cells of a fetus. These stem cells of a fetus are produced from a fetus at the 5th or 6th day after fertilizations. After producing these stem cells of a fetus, the fetus will not be able to continue his existence. These stem cells are able to reproduce indefinitely and they can turn into any cell in the human body (blood cells, heart cells, nerve cells etc.). Therefore, these stem cells can be used as a resource of cells for a future transplantation and to cure a wide range of diseases (such as diabetes etc.).

The stem cells of a fetus have been produced by us successfully and by a few other scientists around the world. The stem cells of a fetus that exist today have been produced with the intention of being applied in studies and research and they are probably not suitable for treating patients.

The goal of the study is to produce new stem cells of a fetus, under new conditions that will enable the use of these cells in transplantation. The new stem cells of a fetus that will be produced will also be used to promote research and development of drugs beyond their possible usage in transplantations. The use of the stem cells will be done in accordance with the ethical rules.

2. Methods

The protocol of this research and the explanatory form that is used in the application for the donation of the fetuses were prepared in accordance with the guidelines of the Israeli Bioethics Committee and in accordance with the ethical principles that were published by the NIH in 1999. The protocol of this research and the informed consent form for this research, were prepared with the approval of the Helsinki Committee for Genetic Experiments (and approved by the Israeli Ministry of Health).

The candidates for the fetus donation are couples or women that their eggs were fertilized by an anonymous donor.

- Only fertilized eggs and frozen embryos that were frozen 5 years ago or longer than that will be accepted. The donation will be accepted only after both spouses agreed to the donation (must be informed consent, from a free will). If the embryos was created from a sperm donation, there will be need only for the woman's informed consent.
- You have the right to request the storage of the fertilized eggs for a total period of 10 years.
- The embryos that are donated by you will be used only for the production of embryonic stem cells. The production of stem cells succeeds only in some embryos and not in all of them.
- It is important to note that the fetuses that are donated by you will never be returned to a womb of another woman.
- It should be mentioned that the embryos will not survive after they are used for the production of stem cells.
- The research on the embryos and the stem cells will be conducted in accordance with the ethical rules. The use of the stem cells for transplantation will be conducted only subject to the approval of the ethical committees.
- The stem cells that will be produced and the cells that will be developed in this process might be kept frozen for a future use in research and development.
- The goal of this experiment is to promote research in the field of human embryonic stem cells and the use of these cells in transplantations. The cells that will be produced within the framework of this research will be provided to researchers around the world subject to their commitment that their research will be conducted in accordance with ethical rules. The cell recipients will not transfer the cells to other third parties without explicit written consent from the researchers in this research.
- You will not receive any tests results from this research or any information regarding the research findings.
- If stem cells will be produced from your fetuses, these stem cells might be used in research related to human transplantation. No information will be given to you in this matter and you will not have any right or influence on these transplantations.
- Any labeling that identifies that the embryos belong to you, will be removed prior to the production of the embryonic stem cells.
- The cells that will be produced from the fetuses (that will be donated by you), will receive a name code in order to keep the information confidential. Your information will be kept in a code form and will be confidential. This information will be kept only in the Hadasah's hospital Safe. The Hospital manager will need to approve any contact with you (in the future) (calling you back etc.). Since there is a low chance that someone will contact you in the future, this experiment is considered to be an experiment with "identified samples".

- Since the goal is to use these stem cells in transplantations, you will go through a few medical tests and interviews similar to the tests that people do before giving a blood donation. In the interview you will be asked as to your medical history and family medical history. You will give a blood sample and the sample will be kept frozen. If there will be a need to test your blood again in the future, you will need to give a separate consent for that. The blood test results will be provided to you.
3. **Duration**- 1 hour or two hours, you will go through an interview and a blood sample will be taken.
4. **The benefit to the participants in the experiment:**
- You will not get any financial compensation for the donation of the fetus.
 - The goal of the research is not to benefit you directly.
 - It is possible that the stem cells of your fetus will have an economical value in the market. You will not get any profit if somehow these cells will be sold.
5. **The risks:** none
6. **Possible discomfort:** Discomfort from giving a blood sample.
7. **Relevant information:**
- Before you are giving you consent to participate in this experiment we want to highlight the following points:
 - o Your consent or your refusal to participate in the study will have no impact on the medical treatment that you are getting.
 - o The ethical claims that support the production of stem cells from a human embryos are:
 - The alternative to the donation will be the destruction of these frozen embryos. In addition, the regulations allow the destruction of the frozen embryos, after being frozen for more than five years (unless the parents asked otherwise).
 - The removal and the growth of embryos cells (that were received in a donation), into a new tissue, does not constitute any violation of the human dignity or any ethical rules.
 - Explanation pages to the patient are attached [please answer-yes/no]? No.

Informed Consent Form to participate in an experiment with human beings

1. We hereby declare that we agree to participate in a medical experiment as described in this document and we agree to this experiment from a free will after we understood the experiment.
2. By signing this document, we consent that the Initiator of the research, the Medical Institution, and the Helisinki Committee will have an access to my personal medical information. The access to this information will be made with respect, while maintaining my confidentiality. Our medical information will be used only and only for the medical experiment.
3. I agree that the information regarding my participation in this experiment will be delivered to my family doctor. According to the law, this information will not be used, but only for medical observation.

Name of the participant in the research: _____ signature: _____ date: _____

Declaration of the Researcher:

This consent by the participant, was obtained after I explained to the participant all the information above, and after I made sure that the participant understands and agrees to the above.

Researcher Name: Alex Simon. Signature: _____ Date: March 31, 2004.

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: August 8, 2024

/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: August 8, 2024

/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 June 30, 2024 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: August 8, 2024

/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.
