# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 ( ☐ ORDER ☐ ORD	OR 15(d) OF THE SECURITIES EXC	HANGE ACT OF 1934
	arterly period ended September 30, 202	
Tot ale qu	OR	
☐ TRANSITION REPORT PURSUANT TO SECTION 13		CHANGE ACT OF 1934
	sition period from to	
	mmission file number <b>001-12830</b>	<del>_</del>
Lineage	Cell Therapeutics,	
	ne of registrant as specified in its charte	
California (State or other jurisdiction of incorporation or organization)		94-3127919 (IRS Employer Identification No.)
	2173 Salk Avenue, Suite 200 Carlsbad, California 92008 of principal executive offices) (Zip cod	e)
(Registrant's teleph	one number, including area code) (442	) 287-8990
Securities regi	stered pursuant to Section 12(b) of t	he 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 during the preceding 12 months (or for such shorter period the requirements for the past 90 days. $\boxtimes$ Yes $\square$ No		
Indicate by check mark whether the registrant has submitted Regulation S-T ( $\S232.405$ of this chapter) during the preceding $\boxtimes$ Yes $\square$ No		
Indicate by check mark whether the registrant is a large accelemerging growth company. See the definitions of "large accompany" in Rule 12b-2 of the Exchange Act.		
Large accelerated filer $\square$	Accelerated filer □	
Non-accelerated filer ⊠ Emerging growth company □	Smaller reporting company ⊠	
If an emerging growth company, indicate by check mark if the or revised financial accounting standards provided pursuant to		xtended transition period for complying with any new
Indicate by check mark whether the registrant is a shell compare	ny (as defined in Rule 12b-2 of the Exc	change Act). □ Yes ⊠ No
The number of common shares outstanding as of November 8,	2024 was 188,837,375.	

# Lineage Cell Therapeutics, Inc.

# **Table of Contents**

		Page
PART I.	FINANCIAL INFORMATION	5
Item 1.	Financial Statements (Unaudited)	5
	Condensed Consolidated Balance Sheets	5
	Condensed Consolidated Statements of Operations	6
	Condensed Consolidated Statements of Comprehensive Loss	7
	Condensed Consolidated Statements of Changes in Shareholders' Equity	8
	Condensed Consolidated Statements of Cash Flows	10
	Notes to the Condensed Consolidated Interim Financial Statements	11
Item 2.	Management's Discussion and Analysis of Financial Condition and Result of Operations	30
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	38
Item 4.	Controls and Procedures	38
PART II.	OTHER INFORMATION	39
Item 1.	<u>Legal Proceedings</u>	39
Item 1A.	Risk Factors	39
Item 2.	<u>Unregistered Sales of Equity Securities</u> , <u>Use of Proceeds</u> , <u>and Issuer Purchases of Equity Securities</u>	39
Item 3.	Defaults Upon Senior Securities	39
Item 4.	Mine Safety Disclosures	39
Item 5.	Other Information	39
Item 6.	<u>Exhibits</u>	40
<u>Signatures</u>		41

#### 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," "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 and broader regional conflict, 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)

	Septe	mber 30, 2024	December 31, 2023		
ASSETS					
CURRENT ASSETS					
Cash and cash equivalents	\$	27,750	\$	35,442	
Marketable securities		4,961		50	
Accounts receivable, net		405		745	
Prepaid expenses and other current assets		1,285		2,204	
Total current assets		34,401		38,441	
NONCURRENT ASSETS					
Property and equipment, net		2,013		2,245	
Operating lease right-of-use assets		2,362		2,522	
Deposits and other long-term assets		606		577	
Goodwill		10,672		10,672	
Intangible assets, net		46,540		46,562	
TOTAL ASSETS	\$	96,594	\$	101,019	
LIABILITIES AND SHAREHOLDERS' EQUITY					
CURRENT LIABILITIES					
Accounts payable and accrued liabilities	\$	4,477	\$	6,270	
Operating lease liabilities, current portion	Ψ	1,083	Ψ	830	
Finance lease liabilities, current portion		54		52	
Deferred revenues, current portion		8,250		10,808	
Total current liabilities		13,864		17,960	
		13,001		17,500	
LONG-TERM LIABILITIES		252		2=2	
Deferred tax liability		273		273	
Deferred revenues, net of current portion		16,050		18,693	
Operating lease liabilities, net of current portion		1,533		1,979	
Finance lease liabilities, net of current portion		80		91	
TOTAL LIABILITIES		31,800		38,996	
Commitments and contingencies (Note 13)					
SHAREHOLDERS' EQUITY					
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of September 30, 2024 and December 31, 2023		_		_	
Common shares, no par value, 450,000 shares authorized as of September 30, 2024 and December 31, 2023; 188,837 and 174,987 shares issued and outstanding					
as of September 30, 2024 and December 31, 2023, respectively		469,268		451,343	
Accumulated other comprehensive loss		(2,890)		(3,068)	
Accumulated deficit		(400,192)		(384,856)	
Lineage's shareholders' equity		66,186		63,419	
Noncontrolling deficit		(1,392)		(1,396)	
Total shareholders' equity		64,794		62,023	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	96,594	\$	101,019	

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

	Th	ree Months End	ded Septe	ember 30,	N	Vine Months End	ed Sep	eptember 30,	
		2024		2023		2024		2023	
REVENUES:									
Collaboration revenues	\$	3,386	\$	957	\$	5,671	\$	5,949	
Royalties, license and other revenues		393		289		960		908	
Total revenues		3,779		1,246		6,631		6,857	
OPERATING EXPENSES:									
Cost of sales		38		169		180		415	
Research and development		3,171		3,741		9,049		11,799	
General and administrative		4,410		4,041		13,770		13,014	
Total operating expenses		7,619		7,951		22,999		25,228	
Loss from operations		(3,840)		(6,705)		(16,368)		(18,371)	
OTHER INCOME (EXPENSES):									
Interest income		397		433		1,322		1,225	
Loss on marketable equity securities, net		(6)		(60)		(21)		(170)	
Foreign currency transaction gain (loss), net		448		(827)		(284)		(1,796)	
Other income (expense)				1		19		544	
Total other income (expenses)		839		(453)		1,036		(197)	
LOSS BEFORE INCOME TAXES		(3,001)		(7,158)		(15,332)		(18,568)	
Provision for income tax benefit				_			_	1,803	
NET LOSS		(3,001)		(7,158)		(15,332)		(16,765)	
Net (income) loss attributable to noncontrolling interest		(33)		48		(4)		54	
NET LOSS ATTRIBUTABLE TO LINEAGE	\$	(3,034)	\$	(7,110)	\$	(15,336)	\$	(16,711)	
Net loss per common share attributable to Lineage basic and diluted	\$	(0.02)	\$	(0.04)	\$	(0.08)	\$	(0.10)	
Weighted-average common shares used to compute basic and diluted net loss per common share		188,835		174,868		186,860		171,880	

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

	Tł	ree Months End	led Septe	Nin	tember 30,			
		2024 2023				2024		2023
NET LOSS	\$	(3,001)	\$	(7,158)	\$	(15,332)	\$	(16,765)
Other comprehensive loss, net of tax:								
Foreign currency translation adjustment		(432)		518		173		1,337
Unrealized gain on marketable debt securities		12		9		5		150
COMPREHENSIVE LOSS	,	(3,421)		(6,631)		(15,154)		(15,278)
Less: Comprehensive (income) loss attributable to								
noncontrolling interest		(33)		48		(4)		54
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE								
COMMON SHAREHOLDERS	\$	(3,454)	\$	(6,583)	\$	(15,158)	\$	(15,224)

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

Three Months Ended September 30, 2024

								Acc	umulated		
									Other		Total
	Commo	. Cl						Con	prehensiv	G.	
		- 10		A	ccumulated Deficit	No	oncontrolling Deficit	e Income / (Loss)		Shareholders'	
	Shares		Amount			_					Equity
BALANCE - June 30, 2024	188,824	\$	467,928	\$	(397,158)	\$	(1,425)	\$	(2,470)	\$	66,875
Shares issued upon exercise of stock options	13		10		_		_		_		10
Stock-based compensation	_		1,330		_		_		_		1,330
Unrealized gain on marketable debt securities	_		_		_		_		12		12
Foreign currency translation adjustment	_		_		_		_		(432)		(432)
Net loss	_				(3,034)		33		_		(3,001)
BALANCE - September 30, 2024	188,837	\$	469,268	\$	(400,192)	\$	(1,392)	\$	(2,890)	\$	64,794

Three Months Ended September 30, 2023

											Total
					Accumulated		ncontrolling	Comprehensiv e			reholders'
BALANCE - June 30, 2023	Shares 174.439	\$	Amount 448,249	\$	Deficit \$ (372,971)		Deficit (1,409)	Income / (Loss) \$ (2,611)		Equity \$ 71,250	
Shares issued through ATM	538	Ψ	784	Ψ	(372,771) —	Ψ	(1, <del>40</del> )	Ψ		Ψ	784
Financing related fees	_		(28)		_		_				(28)
Shares issued upon exercise of stock options	10		8		_		_		_		8
Stock-based compensation	_		1,269		_		_		_		1,269
Unrealized gain on marketable debt securities	_		_		_		_		9		9
Foreign currency translation adjustment	_		_		_		_		518		518
Net loss	_		_		(7,110)		(48)		_		(7,158)
BALANCE - September 30, 2023	174,987	\$	450,282	\$	(380,081)	\$	(1,457)	\$	(2,084)	\$	66,660

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

Nine Months Ended September 30, 2024

									cumulated		
									Other prehensiv		Total
	Common Shares			Accumulated		Noncontrolling			e Sh		reholders'
	Shares		Amount		Deficit		Deficit	Income / (Loss)			Equity
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	287		229		_		_				229
Stock-based compensation	_		3,762		_		_		_		3,762
Unrealized gain on marketable debt securities			_		_		_		5		5
Foreign currency translation adjustment	_		_		_		_		173		173
Net loss	_		_		(15,336)		4		_		(15,332)
BALANCE - September 30, 2024	188,837	\$	469,268	\$	(400,192)	\$	(1,392)	\$	(2,890)	\$	64,794

Nine Months Ended September 30, 2023

_	Common Shares				Accumulated Noncontrolling			Accumulated Other Comprehensiv e		Total reholders'
DALANCE D L 21 2022	Shares	_	Amount	Ф	Deficit (2.62, 270)	Deficit		Income / (Loss)		 Equity 71.026
BALANCE - December 31, 2022	170,093	\$	440,280	\$	(363,370)	\$ (1,	403)	\$	(3,571)	\$ 71,936
Shares issued through ATM	4,775		6,625		_		—		_	6,625
Financing related fees	_		(221)		_		_		_	(221)
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	66		55		_		_		_	55
Stock-based compensation	_		3,580		_		_		_	3,580
Unrealized gain on marketable debt securities	_		_		_		_		150	150
Foreign currency translation adjustment	_		_		_		_		1,337	1,337
Net loss	_		_		(16,711)		(54)		_	(16,765)
BALANCE - September 30, 2023	174,987	\$	450,282	\$	(380,081)	\$ (1,	457)	\$	(2,084)	\$ 66,660

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

		Nine Months Ended September 30, 2024 20:					
CACH ELONIC EDOM OBERATING A CONTINUE		2024		2023			
CASH FLOWS FROM OPERATING ACTIVITIES:	•	(15.226)	¢.	(16.711)			
Net loss attributable to Lineage Net loss attributable to noncontrolling interest	\$	(15,336)	\$	(16,711)			
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc.		4		(34)			
to net cash used in operating activities:							
Loss on marketable equity securities, net		21		170			
Accretion of income on marketable debt securities		(184)		(647)			
Depreciation and amortization expense		436		419			
Change in right-of-use assets and liabilities		(31)		86			
Amortization of intangible assets		22		98			
Stock-based compensation		3,762		3,580			
Deferred income tax benefit		_		(1,803)			
Foreign currency remeasurement and other loss		309		1,892			
Changes in operating assets and liabilities:							
Accounts receivable		339		(141)			
Prepaid expenses and other current assets		891		56			
Accounts payable and accrued liabilities		(1,778)		(3,456)			
Deferred revenue		(5,201)		(6,036)			
Net cash used in operating activities		(16,746)		(22,547)			
CASH FLOWS FROM INVESTING ACTIVITIES:							
Proceeds from the sale of marketable equity securities		18		196			
Purchases of marketable debt securities		(8,761)		(16,403)			
Maturities of marketable debt securities		4,000		53,497			
Purchase of equipment		(200)		(583)			
Net cash (used in) provided by investing activities		(4,943)		36,707			
CASH FLOWS FROM FINANCING ACTIVITIES:							
Proceeds from employee options exercised		229		88			
Common shares received and retired for employee taxes paid		(23)		(37)			
Proceeds from sale of common shares		14,070		6,625			
Payments for offering costs		(113)		(199)			
Repayment of finance lease liabilities		(40)		(41)			
Net cash provided by financing activities		14,123		6,436			
Effect of exchange rate changes on cash, cash equivalents and restricted cash		(120)		(532)			
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND							
RESTRICTED CASH		(7,686)		20,064			
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:							
At beginning of the period		35,992		11,936			
At end of the period	\$	28,306	\$	32,000			
SUPPLEMENTAL DISCLOSURES:							
Cash paid for interest	\$	6	\$	8			
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:							
Property and equipment expenditures in accounts payable	\$	11	\$	8			
Reconciliation of cash, cash equivalents and restricted cash, end of period:							
Cash and cash equivalents	\$	27,750	\$	31,474			
Restricted cash included in deposits and other long-term assets	<b>*</b>	27,723	Ŧ	52,.,1			
(see Note 13 (Commitments and Contingencies))		556		526			
Total cash, cash equivalents, and restricted cash	\$	28,306	\$	32,000			

## 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. In September 2024, Roche and Genentech announced receipt of Regenerative Medicine Advanced Therapy ("RMAT") designation from the U.S. Food and Drug Administration ("FDA") for OpRegen for the treatment of GA secondary to dry AMD.

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 December 2023, 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. 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. Since that time we have been engaging with the FDA to aid in their review, including through an informal teleconference meeting with the CBER and CDRH divisions of the FDA held on November 12, 2024. Based on that discussion we plan to submit an additional amendment to the IND and final protocol with clarifying information to the FDA by the end of the year. We currently anticipate that the FDA will complete its review of this amendment in Q1 2025 and we do not expect any further feedback or additional information requests that would delay start of the study. We currently plan to

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.

- ANP1, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating hearing loss.
- *PNC1*, an allogeneic photoreceptor cell transplant currently being developed for the treatment of vision loss due to photoreceptor dysfunction or damage.
- RND1, a novel, hypoimmune iPSCs line being developed in collaboration with Factor Bioscience Limited, as assignee from 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 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 September 30, 2024:

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

<sup>(1)</sup> Includes shares owned by Lineage and ES Cell International Pte. Ltd.

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

# Liquidity

At September 30, 2024, we had \$32.7 million of cash, cash equivalents and marketable securities. At September 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 September 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 September 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 nine months ended September 30, 2024.

### Recently Issued Accounting Pronouncements Not Yet Adopted

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.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). ASU 2023-07 expands disclosures about a public entity's reportable segments and requires more enhanced information about a reportable segment's expenses, interim segment profit or loss, and how a public entity's chief operating decision maker uses reported segment profit or loss information in assessing segment performance and allocating resources. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. ASU 2023-07 should be applied retrospectively to all prior periods presented in the financial statements. We are currently assessing the new guidance and we believe this will not have a significant impact on our consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"). The purpose of ASU 2024-03 is to improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization, and depletion) in commonly presented expense captions (such as cost of sales, SG&A, and research and development) ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. We are currently assessing the impact that this new guidance will have on our consolidated financial statements.

#### 3. Revenue

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

	Th	ree Months En	ded Sep	tember 30,	N	Nine Months End	ed September 30,		
		2024 2023		2023		2024		2023	
Revenues under collaborative agreements		_							
Upfront license fees (1)	\$	3,386	\$	957	\$	5,671	\$	5,949	
Total revenues under collaborative agreements		3,386		957		5,671		5,949	
Royalties, license and other revenues (2)		393	_	289		960		908	
Total revenue	\$	3,779	\$	1,246	\$	6,631	\$	6,857	

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.

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 September 30, 2024 was \$28.1 million, of which \$24.3 million is reported as deferred revenues. The \$28.1 million is expected to be converted to revenue substantially by December 2026.

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

	Septem	ber 30, 2024	December 31, 2023		
Accounts receivable, net - beginning of the year (1)	\$	676	\$	297	
Accounts receivable, net - end of the period (1)	\$	392	\$	676	
Contract liabilities (1)					
Deferred revenues - beginning of the year	\$	29,501	\$	37,146	
Deferred revenues - end of the period	\$	24,300	\$	29,501	

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

Included within royalties, license and other revenues recognized for the nine months ended September 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.

#### 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):

	Septembe	er 30, 2024	December 31, 2023		
Marketable debt securities					
Included within cash and cash equivalents (1)	\$	7,332	\$	8,856	
Included within marketable securities	\$	4,949	\$	_	
Marketable equity securities					
Included within marketable securities	\$	12	\$	50	

<sup>(1)</sup> 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 September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024							
Financial Assets:	Amo	rtized Cost	Unrealiz	ed Gains	Unrealiz	ed Losses	Fa	ir Value
U.S. Treasury securities	\$	12,274	\$	7	\$		\$	12,281
Total	\$	12,274	\$	7	\$		\$	12,281
				December 3	31, 2023			
Financial Assets:	Amo	rtized Cost	Unrealiz	ed Gains	Unrealiz	ed Losses	Fa	ir Value
U.S. Treasury securities	\$	8,855	\$	1	\$		\$	8,856
Total	<u>\$</u>	8,855	\$	1	\$		S	8,856

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of September 30, 2024 or December 31, 2023. The Company believes that any 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 September 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	E	stimated Fair Value
In one year or less	\$ 12,274	\$	12,281
Total available-for-sale debt securities	\$ 12,274	\$	12,281

# 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 have consisted 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. Subsequent to June 30, 2024, Lineage no longer owned any shares of OCX.

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

	Thre	Three Months Ended September 30,			Nine Months Ended Septem			ember 30,
	20	024		2023		2024		2023
Loss on marketable equity securities, net	\$	(6)	\$	(60)	\$	(21)	\$	(170)
Less: Loss recognized in earnings on marketable equity securities sold		_		23		4		23
Unrealized loss recognized on marketable equity securities held at end of period, net	\$	(6)	\$	(37)	\$	(17)	\$	(147)

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

	Septemb	er 30, 2024	December 31, 2023		
Equipment, furniture and fixtures	\$	3,742	\$	3,614	
Leasehold improvements		2,262		2,313	
Right-of-use assets - finance lease		202		198	
Accumulated depreciation and amortization		(4,193)		(3,880)	
Property and equipment, net	\$	2,013	\$	2,245	

Depreciation and amortization expense was \$141,000 and \$143,000 for the three months ended September 30, 2024 and 2023, respectively, and \$436,000 and \$419,000 for the nine months ended September 30, 2024 and 2023, respectively. These amounts include amortization expense for right-of-use finance lease assets of \$13,000 and \$14,000 for the three months ended September 30, 2024 and 2023, respectively, and \$41,000 and \$37,000 for the nine months ended September 30, 2024 and 2023, respectively.

# 6. Goodwill and Intangible Assets, Net

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

	Septen	nber 30, 2024	December 31, 202		
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	

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.

Lineage amortizes its intangible assets over an estimated period of 5 to 10 years on a straight-line basis. Lineage recognized \$0 and \$33,000 in amortization expense of intangible assets during the three months ended September 30, 2024 and 2023, respectively, and \$22,000 and \$98,000 during the nine months ended September 30, 2024 and 2023, respectively.

## 7. Accounts Payable and Accrued Liabilities

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

	<b>September 30, 2024</b>	December 31, 2023		
Accounts payable	\$ 1,599	\$ 2,05		
Accrued compensation	2,494	3,12		
Accrued liabilities	384	1,09		
Total	\$ 4,477	\$ 6,27		

# 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.

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.

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.

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

• 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 September 30, 2024 and December 31, 2023 (in thousands):

Fair Value Measurements Using

Significant

**Quoted Prices in** 

29,935

		lance at iber 30, 2024	Ident	Markets for tical Assets Level 1)	Observa	ant Other ble Inputs vel 2)	In	servable puts evel 3)
Assets:								
Money market fund (1)	\$	14,466	\$	14,466	\$	_	\$	_
Marketable debt securities (1)		7,332		7,332		_		_
Marketable debt securities		4,949		4,949		_		_
Marketable equity securities (2)		12		12		_		_
Total assets measured at fair value	\$	26,759	\$	26,759	\$	_	\$	_
				Fair <sup>*</sup>	Value Meas	surements Us	sing	
		llance at ther 31, 2023	Active Ident	Fair ed Prices in Markets for tical Assets Level 1)	Signific Observa	surements Us ant Other ble Inputs vel 2)	Sign Unob In	ificant servable puts evel 3)
Assets:			Active Ident	ed Prices in Markets for tical Assets	Signific Observa	ant Other ble Inputs	Sign Unob In	servable puts
Assets:  Money market fund (1)			Active Ident	ed Prices in Markets for tical Assets	Signific Observa	ant Other ble Inputs	Sign Unob In	servable puts
	Decem	ber 31, 2023	Active Ident (1	ed Prices in Markets for tical Assets Level 1)	Signific Observa (Le	ant Other ble Inputs	Sign Unobe In (Le	servable puts

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.

29,935

# 9. Related Party Transactions

Total assets measured at fair value

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 an affiliate of Mr. Bradsher, 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 such expenses.

On February 6, 2024, Lineage 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 Lineage's common shares. The offering price was \$1.04 per common share. The offering closed on February 8, 2024. Broadwood Partners, L.P. purchased 6,730,770 common shares in the offering and Don Bailey, a member of Lineage's board of directors, purchased 96,155 shares in the offering.

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. Subsequent to June 30, 2024, Lineage no longer owned any shares of OCX.

# 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 September 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 September 30, 2024 and December 31, 2023, there were 188,837,375 and 174,986,671 common shares issued and outstanding, respectively.

### At-The-Market Offering Program

In May 2020, Lineage entered into a Controlled Equity Offering<sup>™</sup> 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. 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. Lineage did not sell any common shares under the 2024 Prospectus Supplement during the three months ended September 30, 2024. As of September 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.

#### 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 September 30, 2024, there were 21,727,737 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)	A Exe	eighted verage rcise Price er share)	Weighted Average Remaining Contractual Term (years)	Intri	gregate sic Value ousands)
Balance at December 31, 2023	10,824	\$	1.42	8.63	\$	4
Options granted	6,567	\$	1.11			
Options exercised	(20)	\$	1.40			
Options expired/forfeited/cancelled	(563)	\$	1.37			
Balance at September 30, 2024	16,808	\$	1.30	8.45	\$	1
Options exercisable at September 30, 2024	5,492	\$	1.42	7.57	\$	_
Options exercisable and expected to vest at September 30, 2024	16,808	\$	1.30	8.45	\$	1

	Number of RSUs Outstanding	Av Da	Weighted Verage Grant Ite Fair Value per Share
Balance at December 31, 2023	668	\$	1.11
RSUs forfeited	(100)	\$	0.21
RSUs vested	(67)	\$	1.50
Balance at September 30, 2024	501	\$	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)	E	Weighted Average xercise Price (per share)
Balance at December 31, 2023	10,839	\$	1.83
Options exercised	(267)	\$	0.75
Options expired/forfeited/cancelled	(504)	\$	2.15
Balance at September 30, 2024	10,068	\$	1.84
Options exercisable at September 30, 2024	9,589	\$	1.81

# Stock-Based Compensation Expense

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

	Thi	ee Months End	ded Sept	ember 30,	Ni	ine Months End	ded September 30,	
		2024		2023		2024	2023	
Research and development	\$	172	\$	260	\$	476	\$	729
General and administrative		1,158		1,009		3,286		2,851
Total stock-based compensation expense	\$	1,330	\$	1,269	\$	3,762	\$	3,580

As of September 30, 2024, total unrecognized compensation costs related to unvested stock options and unvested RSUs under all equity plans, was \$9.5 million, which is expected to be recognized as expense over a weighted average period of approximately 2.6 years for stock options and 1.3 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 nine months ended September 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):

	I nree and Nine Month	s Ended September
	2024	2023
Stock options	26,876	23,168
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.

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 nine months ended September 30, 2024, no GILTI was included in the Company's tax provision; any GILTI incurred would be fully offset by net operating loss carryforwards. For the three and nine months ended September 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 nine months ended September 30, 2024 or for the three months ended September 30, 2023. For the first quarter of 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"). Monthly base rent for the first twelve months of the Extended Term was \$25,200, and is subject to 3% annual increases. Rent was abated for months two through four of the Extended Term. As security for the performance of its obligations under the lease, Lineage provided the landlord a security deposit of \$17,850, which is included in deposits and other long-term assets on the condensed consolidated balance sheet as of September 30, 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.

#### Carlshad 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 was originally set to expire 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 September 30, 2024.

## Cell Cure Lease

As of September 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 September 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 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 \$456,000 as of September 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):

	Nin	e Months End	led Septer	nber 30,
	20	24		2023
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	\$	913	\$	833
Operating cash flows from finance leases	\$	6	\$	8
Financing cash flows from finance leases	\$	40	\$	41
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	\$	597	\$	_
Finance leases	\$	36	\$	79

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

	Septo	ember 30, 2024	Dece	ember 31, 2023
Operating leases				
Right-of-use assets	\$	2,362	\$	2,522
Right-of-use lease liabilities, current	\$	1,083	\$	830
Right-of-use lease liabilities, noncurrent		1,533		1,979
Total operating lease liabilities	\$	2,616	\$	2,809
Finance leases				
Right-of-use assets	\$	202	\$	198
Accumulated amortization		(74)		(67)
Right-of-use assets, net	\$	128	\$	131
Right-of-use lease liabilities, current	\$	54	\$	52
Right-of-use lease liabilities, noncurrent		80		91
Total finance lease liabilities	\$	134	\$	143
Weighted average remaining lease term				
Operating leases		2.7 years		3.5 years
Finance leases		2.6 years		3.0 years
Weighted average discount rate				
Operating leases		6.3 %	ó	6.5%
Finance leases		7.0%	ó	6.9 %

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

	Opera	ating Leases	Fina	ance Leases
Year Ending December 31,				
2024	\$	293	\$	16
2025		1,165		64
2026		730		39
2027		677		28
Total lease payments		2,865		147
Less imputed interest		(249)		(13)
Total	\$	2,616	\$	134

Operating lease expense was \$0.3 million and \$0.9 million for each of the three and nine months ended September 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 September 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.

# 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 September 30, 2024, the aggregate cap amount was approximately \$94.8 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 milestones payments. Additional milestone fees and sales-based milestone payments would be payable for other products or indications, and mid-single-digit royalty payments are payable on sales of commercial products.

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

# Other Contingent Obligations

We have obligations under license agreements and grants received from government entities to make future payments to third parties, which become due and payable on the achievement of certain development, regulatory and commercial milestones or on the sublicense of our rights to another party. These commitments include sublicense fees, milestone payments, redemption fees and royalties. Sublicense fees are payable to licensors or government entities when we sublicense underlying intellectual property to third parties; the fees are based on a percentage of the license-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 September 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-forstock 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 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

# **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. In addition, Lineage has entered into

indemnification agreements with officers and members of its board of directors that will require Lineage, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as officers or directors. The potential future payments Lineage could be required to make under the indemnification agreements described in this paragraph 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 described in this paragraph. Accordingly, Lineage has not recorded any liabilities for these agreements as of September 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. In September 2024, Roche and Genentech announced receipt of Regenerative Medicine Advanced Therapy ("RMAT") designation from the U.S. Food and Drug Administration ("FDA") for OpRegen for the treatment of GA secondary to dry AMD.

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 December 2023, 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. 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. Since that time we have been engaging with the FDA to aid in their review, including through an informal teleconference meeting with the CBER and CDRH divisions of the FDA held on November 12, 2024. Based on that discussion we plan to submit an additional

amendment to the IND and final protocol with clarifying information to the FDA by the end of the year. We currently anticipate that the FDA will complete its review of this amendment in Q1 2025 and we do not expect any further feedback or additional information requests that would delay start of the study. We currently plan to commence enrolling the DOSED study as soon as feasible after submitting these updates.

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.
- ANP1, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating hearing loss.
- PNC1, an allogeneic photoreceptor cell transplant currently being developed for the treatment of vision loss due to photoreceptor dysfunction or damage.
- RND1, a novel, hypoimmune iPSCs line being developed in collaboration with Factor Bioscience Limited, as assignee from 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 nor the broader regional conflict that has developed since.

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 and broader regional conflict that has developed since, 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 nine months ended September 30, 2024.

### **Results of Operations**

### Comparison of Three and Nine Months Ended September 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 September 30,				Percent Increase	Nine Months Ended September 30,				_	Oollar icrease	Percent Increase		
	 2024		2023		Decrease)	(Decrease)	2024		2023		(Decrease)		(Decrease)	
Collaboration revenues	\$ 3,386	\$	957	\$	2,429	254%	\$	5,671	\$	5,949	\$	(278)	(5)%	
Royalties, license and other revenues	393		289		104	36%		960		908		52	6%	
Total revenues	\$ 3,779	\$	1,246	\$	2,533	203%	\$	6,631	\$	6,857	\$	(226)	(3)%	

For the three months and nine months ended September 30, 2024, the \$2.5 million increase and \$0.2 million decrease in total revenues, was primarily related to collaboration revenues recognized under the Roche Agreement, resulting from updates 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 within deferred revenue at the beginning of each reporting period. 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 September 30,		Dollar Increase		Percent Increase	Nine Montl Septemb				Dollar Increase		Percent Increase	
	2024		2023	(De	ecrease)	(Decrease)		2024		2023	(I	Decrease)	(Decrease)
Cost of sales	\$ 38	\$	169	\$	(131)	(78)%	\$	180	\$	415	\$	(235)	(57)%
Research and development	\$ 3,171	\$	3,741	\$	(570)	(15)%	\$	9,049	\$	11,799	\$	(2,750)	(23)%
General and administrative	4,410		4,041		369	9%		13,770		13,014		756	6%
Total	\$ 7,619	\$	7,951	\$	(332)	(4)%	\$	22,999	\$	25,228	\$	(2,229)	(9)%

Research and development expenses. For the three months ended September 30, 2024, the \$0.6 million quarter-over-quarter decrease in total research and development expenses was attributable to: (i) a \$0.6 million decrease related to our OPC1 program; (ii) a \$0.4 million net decrease for our preclinical programs; (iii) a \$0.1 million decrease for our other research and development programs; and (iv) partially offset by a \$0.5 million increase for our OpRegen program.

For the nine months ended September 30, 2024, the \$2.8 million year-over-year decrease in total research and development expenses was attributable to: (i) a \$1.6 million decrease related to our OPC1 program; (ii) a \$1.0 million net decrease for our preclinical programs; (iii) a \$0.4 million decrease for our other research and development programs; and (iv) partially offset by a \$0.2 million increase for our OpRegen program.

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 September 30,								Nine Months Ended September 30,							
	Amount			Percent of Total			Am	ount		Percent	of Total					
	 2024		2023	2024	2023		2024		2023	2024	2023					
OpRegen <sup>®</sup>	\$ 1,746	\$	1,284	55%	34%	\$	4,561	\$	4,381	50%	37%					
OPC1	844		1,402	27%	38%		2,661		4,236	29%	36%					
ANP1	574		415	18%	11%		1,518		1,556	17%	13%					
PNC1	_		115	0%	3%		156		348	2%	3%					
RND1	2		444	0%	12%		9		751	0%	6%					
Other programs and non-program expenses	5		81	0%	2%		144		527	2%	5%					
Total research and development expenses	\$ 3,171	\$	3,741	100%	100%	\$	9,049	\$	11,799	100%	100%					

General and administrative expenses. For the three months ended September 30, 2024, the \$0.4 million quarter-over-quarter increase in general and administrative expenses was primarily attributable to (i) a \$0.3 million increase in personnel costs and (ii) \$0.1 million increase in stock-based compensation expense.

For the nine months ended September 30, 2024, the \$0.8 million year-over-year increase in general and administrative expenses was primarily attributable to: (i) a \$0.4 million increase in personnel costs and (ii) \$0.4 million increase in stock-based compensation expense.

# Other income and (expenses)

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

	 Three Months Ended September 30,		Dollar Increase		Percent Increase			onths Ended ember 30,		Dollar Increase		Percent Increase	
Other income (expenses)	2024		2023	(D	ecrease)	(Decrease)		2024		2023	(D	ecrease)	(Decrease)
Interest income	\$ 397	\$	433	\$	(36)	(8)%	\$	1,322	\$	1,225	\$	97	8%
Loss on marketable equity													
securities, net	(6)		(60)		54	90%		(21)		(170)		149	88%
Foreign currency transaction gain (loss), net	448		(827)		1,275	154%		(284)		(1,796)		1,512	84%
Other income (expense)	_		1		(1)	(100)%		19		544		(525)	(97)%
Total	\$ 839	\$	(453)	\$	1,292	285%	\$	1,036	\$	(197)	\$	1,233	626%

<u>Interest income</u>. Interest income was lower for the three months ended September 30, 2024 as compared to the same period in the prior year primarily driven by lower balances within our money market funds, Interest income was greater for the nine months ended September 30, 2024 as compared to the same period in the prior year primarily due to a nominal increase in interest rates within our marketable debt security holdings and our money market funds.

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 nine months ended September 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.

<u>Foreign currency transaction gain (loss), net.</u> Foreign currency transaction gain (loss), net, for each of the three and nine months ended September 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 nine months ended September 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.

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 in the first quarter of 2023. 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 and six months ended September 30, 2023, and did not record a deferred tax benefit for the three and nine months ended September 30, 2024.

# Liquidity and Capital Resources

# Overview

During the nine months ended September 30, 2024, we incurred a loss from operations of \$16.4 million and had negative cash flow from operations of \$16.7 million. As of September 30, 2024, our accumulated deficit was \$400.2 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 September 30, 2024, we had \$32.7 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 nine months ended September 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 September 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

	Nine Months Ended September							
(in thousands)		2024		2023				
Cash provided by (used in):								
Operating activities	\$	(16,746)	\$	(22,547)				
Investing activities		(4,943)		36,707				
Financing activities		14,123		6,436				
Effect of exchange rate changes on cash, cash equivalents								
and restricted cash		(120)		(532)				
Net (decrease) increase in cash, cash equivalents, and restricted cash	\$	(7,686)	\$	20,064				

### Cash used in operating activities

Net cash used in operating activities was \$16.7 million for the nine months ended September 30, 2024, which primarily reflects the loss from operations of \$16.4 million plus the changes in operating assets and liabilities of \$5.7 million. These items were partially offset by the non-cash expenses of \$3.8 million for stock-based compensation and \$0.5 million for depreciation and amortization. The foreign currency remeasurement had no effect on cash flows

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

# Cash (used in) provided by investing activities

Cash used in investing activities for the nine months ended September 30, 2024 was \$4.9 million and primarily resulted from the purchase of U.S. Treasury securities, net of proceeds from maturities of U.S. Treasury securities.

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

# Cash provided by financing activities

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

# 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 September 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 September 30, 2024, the aggregate cap amount was approximately \$94.8 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 September 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 September 30, 2024, under the terms of the leases for the facilities from which Cell Cure and Lineage operate, a total of \$2.9 million of rent payments will become due, of which \$0.3 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, geopolitical conflicts, political and economic instability, inflation and relatively high interest rates, and other macroeconomic factors.

We believe that our \$32.7 million in cash, cash equivalents and marketable securities at September 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

			Inco	rporation by Reference	
Exhibit Number	Description	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
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				

<sup>\*</sup> Filed herewith

<sup>#</sup> Furnished herewith

# **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.

Date: November 14, 2024

/s/ Brian M. Culley

Brian M. Culley

Chief Executive Officer

Date: November 14, 2024

/s/ Jill Ann Howe

Chief Financial Officer

### 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(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles:
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 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(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 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 September 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.

//D: N.C.II	
/s/ Brian M. Culley	
Brian M. Culley	
Chief Executive Officer	
(Principal Executive Officer)	
/s/ Jill Ann Howe	
Jill Ann Howe	
Chief Financial Officer	

Date: November 14, 2024

(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.