

# Lineage Cell Therapeutics Reports Second Quarter 2024 Financial Results and Provides Business Update

August 8, 2024

- 24 Month Visual Acuity Benefits from a Single Administration with OpRegen® Reported at 2024 Retinal Cell & Gene Therapy Innovation Summit
- Supported OpRegen for Geographic Atrophy in Phase 2a Study in Collaboration with Roche and Genentech
- Initiated Activities Under Recently Established Services Agreement with Genentech to Support Ongoing Development of OpRegen Program
- OPC1 Clinical Study Start Up Preparations Ongoing
- Hosted 2<sup>nd</sup> Annual Spinal Cord Injury Investor Symposium

CARLSBAD, Calif.--(BUSINESS WIRE)--Aug. 8, 2024-- <u>Lineage Cell Therapeutics</u>, <u>Inc.</u> (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported its second quarter 2024 financial and operating results. The Company will host a conference call today at 4:30 p.m. Eastern Time to discuss these results and to provide a business update.

"The second quarter was highlighted by clinical and preclinical execution alongside expanded awareness and data updates on our lead program," stated Brian M. Culley, Lineage CEO. "As the cell transplant field expands and continues to deliver exciting clinical outcomes, we are excited about our validating partnership and the collective expertise of the team at Roche and Genentech, as well as their ongoing leadership of the OpRegen program through presentations at scientific conferences and internal thought leader events, including Roche's Virtual Ophthalmology Day, hosted just last month. We continue to support the ongoing Phase 2a clinical study and also have initiated activities under the recently established services agreement with Genentech, enabling our partners to take advantage of our cell transplant expertise to more fully investigate the potential of the OpRegen program. In parallel, we are focused on activities in support of returning our second cell transplant program, OPC1, into the clinic this year for the treatment of spinal cord injury, a condition with growing awareness of its unmet need and commercial opportunity."

"Importantly, our continued inclusion within the Russell 3000<sup>®</sup> Index, can help our efforts to broaden investor awareness of, and support for, Lineage as a uniquely positioned cell transplant company, one with a pharma-validated lead program and a platform technology of internally-owned clinical and preclinical assets, which is focused on growing our internally-owned cGMP capabilities in support of process and intellectual property development," added Mr. Culley.

# **Recent Operational Highlights**

#### • RG6501 (OpRegen)

- Continued execution under our <u>collaboration</u> with Roche and Genentech, a member of the Roche Group, across multiple functional areas, including support for the <u>ongoing</u> Phase 2a clinical study in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
- o Initiated activities under recently established services agreement with Genentech to support ongoing development of OpRegen. Lineage is providing additional clinical, technical, training and manufacturing services, fully funded by Genentech, that further support the ongoing advancement and optimization of the OpRegen program and include: (i) activities to support the ongoing Phase 1/2a study and currently-enrolling Phase 2a study; and (ii) additional technical training and materials related to Lineage's cell therapy technology platform to support commercial manufacturing strategies.
- Positive clinical data from long-term follow-up of patients from the Phase 1/2a clinical study of OpRegen <u>presented</u> by David Telander, MD, PhD, Retinal Consultants Medical Group, at the 2024 Retinal Cell & Gene Therapy Innovation Summit.
  - Mean best corrected visual acuity (BCVA) gain of 5.5 letters at 24 months (n=10) in Cohort 4 patients (less advanced GA)
  - Mean BCVA gains greater among patients with improvement in outer retinal structure (n=5, +7.4 letters)
  - Maintenance or increases in external limiting membrane (ELM) and retinal pigment epithelium (RPE) layer area at 24 months observed in patients with extensive coverage of OpRegen across the areas of GA (n=5)
  - Data suggest OpRegen may counteract RPE cell dysfunction and cell loss in patients with GA by providing support to remaining retinal cells, with multi-year effects observed following a single administration
- Preclinical results from a surgical development study of OpRegen presented by Rachel N. Andrews, DVM, PhD, DACVP, Genentech, a member of the Roche Group, at <u>2024 Association for Research in Vision and Ophthalmology</u> Annual Meeting (2024 ARVO).

#### OPC1

o DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical

- study for the treatment of subacute and chronic spinal cord patient start-up activities continue.
- Hosted the 2<sup>nd</sup> Annual Spinal Cord Injury Investor Symposium, in partnership with the Christopher & Dana Reeve Foundation.

#### **Balance Sheet Highlights**

Cash, cash equivalents, and marketable securities of \$38.5 million as of June 30, 2024 is expected to support planned operations into Q4 2025.

#### **Second Quarter Operating Results**

Revenues: Lineage's revenue is generated primarily from collaboration revenues and royalties. Total revenues for the three months ended June 30, 2024 were \$1.4 million, a net decrease of \$1.8 million as compared to approximately \$3.2 million for the same period in 2023. The decrease was primarily driven by less collaboration and licensing revenue recognized from deferred revenues under the collaboration and license agreement with Roche.

Operating Expenses: Operating expenses are comprised of research and development (R&D) expenses and general and administrative (G&A) expenses. Total operating expenses for the three months ended June 30, 2024 were \$7.3 million, a decrease of \$0.9 million as compared to \$8.2 million for the same period in 2023.

R&D Expenses: R&D expenses for the three months ended June 30, 2024 were \$2.9 million, a net decrease of \$1.0 million as compared to \$3.9 million for the same period in 2023. The net decrease was primarily driven by \$0.6 million for our OPC1 program and \$0.3 million for our preclinical programs.

G&A Expenses: G&A expenses for the three months ended June 30, 2024 were approximately \$4.3 million, a net increase of approximately \$0.1 million as compared to \$4.2 million for the same period in 2023. The increase was primarily driven by stock-based compensation expense and personnel costs.

Loss from Operations: Loss from operations for the three months ended June 30, 2024 were \$5.9 million, an increase of \$0.9 million as compared to \$5.0 million for the same period in 2023.

Other Income/(Expenses): Other income (expenses) for the three months ended June 30, 2024 reflected other income of \$0.1 million, compared to other expenses of (\$0.2) million for the same period in 2023. The change was primarily driven by exchange rate fluctuations related to Lineage's international subsidiaries, fair market value changes in marketable equity securities, and interest income earned within our money market accounts.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended June 30, 2024 was \$5.8 million, or \$0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of \$5.2 million, or \$0.03 per share (basic and diluted), for the same period in 2023.

#### **Conference Call and Webcast**

Interested parties may access the conference call on August 8<sup>th</sup>, 2024, by dialing (800) 715-9871 from the U.S. and Canada and should request the "Lineage Cell Therapeutics Call." A live webcast of the conference call will be available online in the <u>Investors</u> section of Lineage's website. A replay of the webcast will be available on Lineage's website for 30 days and a telephone replay will be available through August 15<sup>th</sup>, 2024, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 6024260.

#### About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel or "off-the-shelf," cell therapies to address unmet medical needs. Lineage's programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells 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 are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient's functional activity. Lineage's neuroscience focused pipeline currently includes: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed in collaboration with Eterna Therapeutics Inc. For more information, please visit <a href="www.lineagecell.com">www.lineagecell.com</a> or follow the company on

#### **Forward-Looking Statements**

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "aim," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions. Lineage's forward-looking statements are based upon its current expectations and beliefs and involve assumptions that may never materialize or may prove to be incorrect. Such statements include, but are not limited to, statements relating to: the benefits of our new services agreement with Genentech and its impact on advancing the OpRegen program; the commencement of the DOSED clinical study for OPC1; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into the fourth quarter of 2025; the impacts to Lineage of our continued inclusion within the Russell 3000 Index; and the potential of our platform technology and/or manufacturing capabilities to create value. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, but not limited to, the following risks: that we may need to allocate our cash

to unexpected events and expenses causing us to use our cash, cash equivalents and marketable securities more quickly than expected; that clinical trials of our product candidates may not commence, progress or be completed as expected due to many factors within and outside of our control; that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; that OpRegen may never be proven to provide durable anatomical functional improvements in dry-AMD patients, that competing alternative therapies may adversely impact the commercial potential of OpRegen; that Roche and Genentech may not successfully advance OpRegen or be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; that the ongoing Israel-Hamas war may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; and those risks and uncertainties inherent in Lineage's business and other risks discussed in Lineage's filings with the Securities and Exchange Commission (SEC). Further information regarding these and other risks is included under the heading "Risk Factors" in Lineage's periodic reports with the SEC, including Lineage's most recent Annual Report on Form 10-K filed with the SEC and its other reports, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Lineage undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made

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

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

Lineage's shareholders' equity	68,300	63,419
Noncontrolling deficit	(1,425)	(1,396)
Total shareholders' equity	66,875	62,023
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 102,802	\$ 101,019

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

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

	Six Months Ended June 30,			
	2024		2023	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss attributable to Lineage	\$	(12,302)	\$	(9,601)
Net loss attributable to noncontrolling interest		(29)		(6)

Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:

Loss on marketable equity securities, net	15	110
Accretion of income on marketable debt securities	(102	(516)
Depreciation and amortization expense	295	276
Change in right-of-use assets and liabilities	(20	) 81
Amortization of intangible assets	22	65
Stock-based compensation	2,432	2,311
Deferred income tax benefit	_	- (1,803)
Foreign currency remeasurement and other loss	767	1,011
Changes in operating assets and liabilities:		
Accounts receivable	508	(147)
Prepaid expenses and other current assets	516	(270)
Accounts payable and accrued liabilities	(1,245	) (3,941)
Deferred revenue	(1,816	(5,080)
Net cash used in operating activities	(10,959	(17,510)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	18	_
Purchases of marketable debt securities	(8,761	
Maturities of marketable debt securities		47,664
Purchase of equipment	(88	,
Net cash (used in) provided by investing activities	(8,831	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	219	80
Common shares received and retired for employee taxes paid	(23	) (37)
Proceeds from sale of common shares	14,070	5,789
Payments for offering costs	(113	) (174)
Repayment of finance lease liabilities	(27	(29)
Net cash provided by financing activities	14,126	5,629
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(158	) (192)
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,822	) 22,512
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	35,992	11,936
At end of the period	\$ 30,170	\$ 34,448

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