

Lineage Cell Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

May 13, 2025

- RG6501 (OpRegen[®]) Phase 1/2a Clinical Study 36 Month Results to be featured June 21st at Clinical Trials at the Summit 2025
- Initiated Clinical Study of OPC1 Delivery Device for Patients with Subacute and Chronic Spinal Cord Injury
- Announced 3rd Annual SCI Investor Symposium with Christopher & Dana Reeve Foundation

CARLSBAD, Calif.--(BUSINESS WIRE)--May 13, 2025-- Lineage Cell Therapeutics. Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel allogeneic, or "off the shelf", cell therapies for serious neurological and ophthalmic conditions, today reported its first quarter 2025 financial and operating results and will host a conference call today at 4:30 p.m. Eastern Time to discuss these results and provide a business update.

"Lineage has grown increasingly confident in OpRegen's potential to address a significant medical need," stated Brian M. Culley, Lineage CEO. "Our optimism is driven in part by OpRegen's uniquely durable treatment effects, lasting up to 24 months, with a 36-month data update from Roche and Genentech forthcoming next month. We are also encouraged by independent first-in-human results recently reported by competitors, which adds validation to an RPE transplant mechanism of action providing functional improvements beyond the reach of currently approved dry AMD therapies. Together, these findings lend support to one-time dosing, a key advantage over the compliance-challenged monthly injections required for anti-complement therapy. While advancing the OpRegen program and the GAlette Study remains a key area of attention, we are equally excited to have recently initiated the DOSED clinical study of OPC1, while progressing ReSonanceTM for the treatment of sensorineural hearing loss and evaluating other strategically selected early-stage initiatives. As our cell therapy platforms gain further validation, we believe our pipeline and expertise position us as a compelling partner and investment opportunity."

Select Business Highlights

• RG6501 (OpRegen)

- RG6501 (OpRegen) Phase 1/2a Clinical Study 36 Month Results to be featured at <u>Clinical Trials at the Summit</u> (<u>CTS</u>) 2025, and will be presented by <u>Christopher D. Riemann, M.D.</u>, Vitreoretinal Surgeon and Fellowship Director, <u>Cincinnati Eye Institute</u> (CEI) and University of Cincinnati School of Medicine, on behalf of <u>Roche</u> and <u>Genentech</u>, a member of the Roche Group.
- Ongoing execution of Lineage's contributions to its <u>collaboration</u> with Roche and Genentech across multiple functional areas, including support for the <u>ongoing</u> Phase 2a clinical study (the "GAlette Study") in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD) at sites in the U.S. and Israel.
 - In addition to testing of other surgical parameters, Genentech currently plans to evaluate two proprietary surgical delivery devices that have potential advantages over available off-the-shelf devices in the GAlette Study.
- Ongoing efforts to further support development of OpRegen RPE cell therapy under a separate services agreement with Genentech, including: (i) activities to support the ongoing Phase 1/2a study long term follow-up and currently enrolling GAlette Study; and (ii) additional technical training and materials related to our cell therapy technology platform to support commercial manufacturing strategies.
- OPC1
 - DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study in subacute and chronic spinal cord patients <u>initiated</u> in February 2025; UC San Diego Health is the first participating study site.
 - Lineage and OPC1 program featured on CNN: "<u>He was paralyzed his last day of high school. How an experimental</u> <u>trial is showing 'unexpected improvement</u>'."
 - 3rd Annual Spinal Cord Injury Investor Symposium (3rd SCIIS) <u>announced</u> in partnership with the Christopher & Dana Reeve Foundation.
 - The 3rd SCIIS will be fully virtual, with interactive and on-demand sessions available starting June 27, 2025.
 - Event aims to bring together those working on treatments for spinal cord injury (SCI), including regulators, key opinion leaders, persons with lived experience, patient and community advocacy organizations and the investment community, to discuss perspectives on current and future treatments, impact and support SCI disease awareness and clinical trial participation through the implementation of patient appropriate clinical endpoints, and importantly, broaden awareness of and investment capital into SCI.

Cash, cash equivalents, and marketable securities of \$47.9 million as of March 31, 2025, is expected to support planned operations into Q1 2027.

First Quarter Operating Results

Revenues: Revenue is generated primarily from collaboration revenues, royalties, and other revenues. Total revenues for the three months ended March 31, 2025 were \$1.5 million, a net increase of \$0.1 million as compared to \$1.4 million for the same period in 2024. The increase was primarily driven by more collaboration 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 March 31, 2025 were \$8.0 million, a decrease of \$0.1 million as compared to \$8.1 million for the same period in 2024.

R&D Expenses: R&D expenses for the three months ended March 31, 2025 were \$3.1 million, an increase of \$0.1 million as compared to \$3.0 million for the same period in 2024. The net increase was primarily driven by \$0.2 million for our preclinical programs, partially offset by \$0.1 million for our other research and development programs.

G&A Expenses: G&A expenses for the three months ended March 31, 2025 of \$4.9 million were primarily in line with expenses for the same period in 2024.

Loss from Operations: Loss from operations for the three months ended March 31, 2025 was \$6.5 million, a decrease of \$0.2 million as compared to \$6.7 million for the same period in 2024.

Other Income/(Expenses): Other income/(expenses) for the three months ended March 31, 2025 reflected other income of \$2.4 million, compared to other income of \$0.1 million for the same period in 2024. The net increase was primarily driven by changes in fair value of the warrant liabilities.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended March 31, 2025 was \$4.1 million, or \$0.02 per share (basic and diluted), compared to a net loss of \$6.5 million, or \$0.04 per share (basic and diluted), for the same period in 2024.

Conference Call and Webcast

Interested parties may access the conference call on May 13, 2025, 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 May 20th, 2025, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 1789489.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing allogeneic, or "off the shelf", cell therapies for serious neurological and ophthalmic conditions. 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 degeneratior; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ReSonance (ANP1), an auditory neuronal progenitor cell therapy for the potential treatment of subjunction loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed under a gene editing partnership. For more information, please visit www.lineagecell.com or follow the company on X/Twitter @LineageCell.

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 potential therapeutic benefits of OpRegen in patients with GA secondary to AMD or OpRegen's ultimate success; the benefits of our services agreement with Genentech and its impact on advancing the OpRegen program; the potential effect of the Spinal Cord Symposium, including accelerating development in SCI research and treatment; Lineage's belief that potential development partners and investors will find Lineage's pipeline of internally-owned assets and cell-based know-how desirable as they are further demonstrated and validated; and that Lineage's cash, cash equivalents and marketable securities is sufficient to support its planned operations into the first quarter of 2027. 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 expend our cash, cash equivalents and marketable securities more quickly than expected; that development activities, preclinical activities, and 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 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 competing alternative therapies may adversely impact the commercial potential of OpRegen; that OpRegen may ultimately be proven to provide functional improvements from a one-time does beyond the reach of currently approved therapies; that OPC1 may not advance further in any clinical trials, and if it does, that any such clinical trials may not be successful; that the ongoing Israeli regional conflict 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 subsequent 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, except as required by law. All forward-looking statements are expressly qualified in their entirety by these cautionary statements.

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

	Mai	rch 31, 2025	D	ecember 31, 2024
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	47,886	\$	45,789
Marketable securities		19		2,016
Accounts receivable		213		638
Prepaid expenses and other current assets		1,866		2,554
Total current assets		49,984		50,997
NONCURRENT ASSETS				
Property and equipment, net		2,149		2,251
Operating lease right-of-use assets		1,904		2,144
Deposits and other long-term assets		504		614
Goodwill		10,672		10,672
Intangible assets, net		46,540		46,540
TOTAL ASSETS	\$	111,753	\$	113,218
LIABILITIES AND SHAREHOLDERS' EQUITY CURRENT LIABILITIES				
Accounts payable and accrued liabilities	\$	4,978	\$	5,437
Operating lease liabilities, current portion		1,124		1,097
Finance lease liabilities, current portion		56		55
Deferred revenues, current portion		6,931		7,388
Total current liabilities		13,089		13,977
LONG-TERM LIABILITIES				
Deferred tax liability		273		273
Deferred revenues, net of current portion		13,611		14,433
Operating lease liabilities, net of current portion		1,013		1,295
Finance lease liabilities, net of current portion		51		67
Warrant liabilities		6,061		6,161
TOTAL LIABILITIES		34,098		36,206
Commitments and contingencies (Note 13)				
SHAREHOLDERS' EQUITY				
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of March 31, 2025 and December 31, 2024		_		_
Common shares, no par value, 450,000 shares authorized as of March 31, 2025 and December 31, 2024; 228,356 and 220,416 shares issued and outstanding as of March 31, 2025 and December 31,				
2024, respectively		489,313		484,722
Accumulated other comprehensive loss		(2,681)		(2,876)
Accumulated deficit		(407,604)		(403,465)
Lineage's shareholders' equity		79,028		78,381
Noncontrolling deficit		(1,373)		(1,369)
Total shareholders' equity		77,655		77,012
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	111,753	\$	113,218

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

	Three Months Ended March 31,				
	2025			2024	
REVENUES:					
Collaboration revenues	\$	1,270	\$	1,187	
Royalties, license and other revenues		232		257	
Total revenues		1,502		1,444	
OPERATING EXPENSES:					
Cost of sales		36		98	
Research and development		3,114		3,010	
General and administrative		4,857		4,997	
Total operating expenses		8,007		8,105	
Loss from operations		(6,505)		(6,661)	
OTHER INCOME (EXPENSES):					
Interest income, net		478		462	
Loss on marketable equity securities, net		(5)		(5)	
Change in fair value of warrant liability		2,305		—	
Foreign currency transaction loss, net		(231)		(354)	
Other income (expense), net		(185)		_	
Total other income (expenses)		2,362		103	
NET LOSS		(4,143)		(6,558)	
Net loss attributable to noncontrolling interest		4		16	
NET LOSS ATTRIBUTABLE TO LINEAGE	\$	(4,139)	\$	(6,542)	
Net loss per common share attributable to Lineage basic and diluted	\$	(0.02)	\$	(0.04)	
Weighted-average common shares used to compute basic and diluted net loss per common share		226,054		182,909	

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

	Three Months Ended March 31,			
	2025		2024	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss attributable to Lineage	\$	(4,139)	\$	(6,542)
Net loss attributable to noncontrolling interest		(4)		(16)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:				
Issuance costs for common stock warrant liabilities		183		—
Loss on marketable equity securities, net		5		5
Accretion of income on marketable debt securities		(10)		—
Depreciation and amortization expense		164		153
Change in right-of-use assets and liabilities		(11)		(10)
Amortization of intangible assets		—		22
Stock-based compensation		1,217		1,163
Change in fair value of warrant liability		(2,305)		—

Foreign currency remeasurement and other loss	282	371
Changes in operating assets and liabilities:		
Accounts receivable	424	668
Prepaid expenses and other current assets	692	195
Accounts payable and accrued liabilities	(105) (574)
Deferred revenue	(1,279) (1,218)
Net cash used in operating activities	(4,886) (5,783)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturities of marketable debt securities	2,000	—
Purchase of equipment	(97) (38)
Net cash (used in) provided by investing activities	1,903	(38)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	-	- 132
Common shares received and retired for employee taxes paid	(15) (23)
Proceeds from sale of common shares under ATM, net of offering costs	_	- 36
Proceeds from sale of common shares under registered direct financing, net of offering costs	_	- 13,889
Proceeds from sale of common shares with warrants under registered direct financing, net of offering		
costs	5,297	
Payment of financed insurance premium	(224	,
Payment of finance lease liabilities	(14) (13)
Net cash provided by financing activities	5,044	14,021
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(73) (70)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	1,988	8,130
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	46,354	35,992
At end of the period	\$ 48,342	\$ 44,122

View source version on businesswire.com: https://www.businesswire.com/news/home/20250513604475/en/

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