

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

August 12, 2025

- Positive RG6501 (OpRegen[®]) Phase 1/2a Clinical Study 36 Month Results Featured at Clinical Trials at the Summit 2025
- Successfully Reduced-to-Practice Critical Aspect of Commercial-Scale, Cell-Based, GMP Production Processes
- First Chronic Patient Treated in New Clinical Study of OPC1 in Patients with Subacute and Chronic Spinal Cord Injury
- Hosted the 3rd Annual SCI Investor Symposium

CARLSBAD, Calif.--(BUSINESS WIRE)--Aug. 12, 2025-- <u>Lineage Cell Therapeutics. Inc.</u> (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 second 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.

"Following the recent positive 36-month clinical data update with the OpRegen RPE cell therapy program, which is licensed by Genentech and Roche, we continue to remain confident in its potential to address a significant medical need, especially because long term clinical outcomes following a single administration of OpRegen cell therapy are challenging the long-held view that GA is an irreversible condition," stated Brian M. Culley, Lineage CEO. "It is notable that among patients who received extensive one-time coverage of OpRegen RPE cells across the area of atrophy, anatomical and functional benefits have lasted for at least three years, outcomes consistent with meaningful disease stabilization and even improvement."

"In addition to supporting our partners in advancing the OpRegen program, we are equally excited to have reached a milestone with our OPC1 program for the treatment of spinal cord injury, treating our first-ever chronic patient with a new parenchymal spinal delivery system. We also solidified our position as a leader in allogeneic cell process development and manufacturing by reporting in-house GMP production for each of two separate cell-based product candidates from a master and working cell bank system which, in its current form, can support a production capability of several million doses for a single-administration product. This is in addition to continuing to advance our ReSonanceTM program 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 cell manufacturing and related expertise continue to position us as a compelling partner and investment opportunity," added Mr. Culley.

Select Business Highlights

■ RG6501 (OpRegen Cell Therapy)

- Positive RG6501 (OpRegen) Phase 1/2a Clinical Study 36 Month Results featured at <u>Clinical Trials at the Summit</u> (<u>CTS</u>) 2025. 2025 CTS highlights:
 - Gains in Best Corrected Visual Acuity (BCVA) in patients in Cohort 4 (less advanced GA) measured at month 12 remain evident through month 36 following subretinal administration of OpRegen cell therapy;
 - Mean change in BCVA among treated eyes for patients (n=10) completing 3-year follow up was +6.2 letters (compared to +5.5 letters at 24 months) (Early Treatment Diabetic Retinopathy Study (ETDRS) assessment);
 - Improvement in BCVA and outer retinal structure in patients with extensive OpRegen bleb coverage of their GA area was greater than in patients with limited coverage and persisted through month 36
 - Effects were greater on average in the five (5) patients with extensive OpRegen cell therapy coverage of atrophic areas at the time of surgical delivery
 - In these patients' treated eyes, the mean change in BCVA was +9.0 ETDRS letters for those completing 3-year follow-up (compared to +7.4 ETDRS letters at 24 months) (n=5)
 - These data suggest that OpRegen cell therapy may counteract RPE cell dysfunction and loss in GA by providing support to the remaining retinal cells within atrophic areas, and these effects appear durable through at least 36 months after a single administration
- o 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.

o Ongoing efforts to further support development of OpRegen RPE cell therapy under a separate services agreement with Genentech, signed May 2024, including: (i) activities to support the ongoing Phase 1/2a study long term follow-up and the currently enrolling Phase 2a GAlette Study; and (ii) additional technical training and materials related to our cell therapy technology platform to support commercial manufacturing strategies.

■ Manufacturing Capability

- Successfully completed a production run for two different product candidates, each produced from a customized, two-tiered current Good Manufacturing Practice ("cGMP") cell banking system, highlighting the application of the Lineage platform across multiple programs.
 - This production process utilizes a genetically-stable master cell bank created from a single, well-characterized pluripotent cell line, to generate a working cell bank, which then provides the source material for a final cell-based product candidate.
 - This demonstrated cGMP production process should enable the ability to produce millions of doses of a cost-effective, scalable and consistent supply of an allogeneic, cell-based product derived from a single initial cell line, that can be applied across multiple programs.

OPC1

- First chronic spinal cord injury patient treated in the <u>DOSED</u> (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study.
 - First chronic SCI patient treated in DOSED was a neurologically complete SCI injury (American Spinal Injury Association Impairment Scale [AIS] grade A), with a single neurological level of injury (NLI) from levels T1 to T10, and the novel delivery system successfully administered a one-time injection of OPC1.
- Hosted the 3rd Annual Spinal Cord Injury Investor Symposium (3rd SCIIS) in partnership with the Christopher & Dana Reeve Foundation.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities of \$42.3 million as of June 30, 2025, is expected to support planned operations into Q1 2027.

Second Quarter Operating Results

Revenues: Revenue is generated primarily from collaboration revenues, royalties, and other revenues. Total revenues for the three months ended June 30, 2025 were \$2.8 million, a net increase of \$1.4 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 Roche Agreement, as well as deferred revenues recognized upon termination of the VAC platform-related collaboration agreement.

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, 2025 were \$22.5 million, an increase of \$15.2 million as compared to \$7.3 million for the same period in 2024. The overall increase was driven by the \$14.8 million expense recognized for the loss on impairment for the intangible asset related to the VAC platform.

R&D Expenses: R&D expenses for the three months ended June 30, 2025 were \$3.1 million, an increase of \$0.2 million as compared to \$2.9 million for the same period in 2024. The net increase was primarily driven by ongoing activities within our preclinical programs.

G&A Expenses: G&A expenses for the three months ended June 30, 2025 were \$4.6 million, an increase of \$0.2 million as compared to \$4.4 million for the same period in 2024. The net increase was primarily driven by more costs incurred for services provided by third parties.

Loss from Operations: Loss from operations for the three months ended June 30, 2025 were \$19.8 million, an increase of \$13.9 million as compared to \$5.9 million for the same period in 2024. This increase in loss was primarily driven by the impairment expense related to the VAC platform of \$14.8 million, which is a non-recurring transaction.

Other Income/(Expenses): Other income/(expenses) for the three months ended June 30, 2025 reflected other expense of \$10.6 million, compared to other income of \$0.1 million for the same period in 2024. The net change was primarily attributable to the quarterly fair value remeasurement of the warrant liabilities of \$12.7 million primarily due to an increase in our share price as compared to the prior quarter, partially offset by \$1.7 million for exchange rate fluctuations related to Lineage's international subsidiaries.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended June 30, 2025 was \$30.5 million, or \$0.13 per share (basic and diluted), compared to a net loss of \$5.8 million, or \$0.03 per share (basic and diluted), for the same period in 2024. The change was primarily driven by the loss on impairment expense related to a 2019 acquisition and the quarterly fair value remeasurement of the warrant liabilities.

Conference Call and Webcast

Interested parties may access the conference call on August 12, 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 August 19th, 2025, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 7788342.

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 cell therapy, 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) ReSonance (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 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. In some cases, forward-looking statements, 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," "suggest," or the negative version of these words and similar expressions. Such forward-looking statements include, but are not limited to, statements relating to: the potential therapeutic benefits of OpRegen cell therapy in patients with GA secondary to AMD and the significance of the Phase 1/2a clinical study data reported to date; the benefits of our services agreement with Genentech and its impact on advancing the OpRegen cell therapy program; Lineage's ability to produce millions of doses of a cost-effective, and consistent supply of an allogeneic cell, cell-based product derived from a single initial cell line across one or more programs; the plans and expectations with respect to OPC1; the potential continued development of ReSonance (ANP1); Lineage's belief that its pipeline and expertise will position it as a compelling partner and investment opportunity; and that our cash, cash equivalents and marketable securities is sufficient to support our 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 cell therapy or be successful in completing further clinical trials for OpRegen cell therapy and/or obtaining regulatory approval for OpRegen cell therapy in any particular jurisdiction; that competing alternative therapies may adversely impact the commercial potential of OpRegen cell therapy; that OPC1 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). Lineage's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. 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 on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Lineage undertakes no obligation to update any forward-looking statement to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

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

	June 30, 2025		December 31, 2024	
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$ 42,27	1	\$	45,789
Marketable securities	1	7		2,016
Accounts receivable	25	6		638
Prepaid expenses and other current assets	1,30	0		2,554
Total current assets	43,84	4		50,997
NONCURRENT ASSETS				
Property and equipment, net	2,25	5		2,251
Operating lease right-of-use assets	1,81	7		2,144
Deposits and other long-term assets	51	1		614
Goodwill	10,67	2		10,672
Intangible assets, net	31,70	0		46,540

TOTAL ASSETS	\$	90,799	\$ 113,218
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES			
Accounts payable and accrued liabilities	\$	4,451	\$ 5,437
Operating lease liabilities, current portion		998	1,097
Finance lease liabilities, current portion		50	55
Deferred revenues, current portion		5,257	7,388
Total current liabilities		10,756	 13,977
LONG-TERM LIABILITIES			
Deferred tax liability		273	273
Deferred revenues, net of current portion		12,751	14,433
Operating lease liabilities, net of current portion		1,058	1,295
Finance lease liabilities, net of current portion		48	67
Warrant liabilities		18,801	6,161
TOTAL LIABILITIES		43,687	 36,206
Commitments and contingencies (Note 13)			
SHAREHOLDERS' EQUITY			
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of June 30, 2025 and December 31, 2024		_	_
Common shares, no par value, 450,000 shares authorized as of June 30, 2025 and December 31, 2024; 228,356 and 220,416 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively		490,551	484,722
Accumulated other comprehensive loss		(4,098)	(2,876)
Accumulated deficit		(438,068)	(403,465)
	_	<u>· </u>	
Lineage's shareholders' equity		48,385	78,381
Noncontrolling deficit	_	(1,273)	(1,369)
Total shareholders' equity		47,112	77,012
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	90,799	\$ 113,218

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,			
	202	2025 2024		2025	2024		
REVENUES:							
Collaboration revenues	\$ 2	2,532 \$	1,098	\$ 3,802	\$ 2,285		
Royalties, license and other revenues		233	310	465	567		
Total revenues	2	2,765	1,408	4,267	2,852		
OPERATING EXPENSES:							
Cost of royalties		39	44	75	142		
Research and development	3	3,106	2,868	6,220	5,878		
General and administrative	4	,560	4,363	9,417	9,360		
Loss on impairment of intangible asset (Note 6 and Note 13)	14	,840	_	14,840	_		
Total operating expenses	22	2,545	7,275	30,552	15,380		
Loss from operations	(19),780)	(5,867)	(26,285	(12,528)		
OTHER INCOME (EXPENSES):							
Interest income, net		454	463	932	925		
Loss on marketable equity securities, net		(2)	(10)	(7) (15)		
Change in fair value of warrant liability	(12	2,740)	_	(10,435) —		
Foreign currency transaction gain (loss), net	1	,678	(378)	1,447	(732)		

Other income (expense), net	26	19	(159)	19
Total other income (expenses)	(10,584)	94	(8,222)	197
NET LOSS	(30,364)	(5,773)	(34,507)	(12,331)
Net (income) loss attributable to noncontrolling interest	(100)	13	(96)	29
NET LOSS ATTRIBUTABLE TO LINEAGE	\$ (30,464)	\$ (5,760)	\$ (34,603)	\$ (12,302)
Net loss per common share attributable to Lineage basic and diluted	\$ (0.13)	\$ (0.03)	\$ (0.15 ₎	\$ (0.07)
Weighted-average common shares used to compute basic and diluted net loss per common share	228,356	188,813	227,212	185,861

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

(UNAUDITED)	Six Months Ended June 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	\$ (34,603)	\$ (12,302)
Net income (loss) attributable to noncontrolling interest	96	(29)
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 impairment of intangible asset	14,840	_
Loss on marketable equity securities, net	7	15
Accretion of income on marketable debt securities	(10)	(102)
Depreciation and amortization expense	335	295
Change in right-of-use assets and liabilities	(88)	(20)
Amortization of intangible assets	_	22
Stock-based compensation	2,455	2,432
Change in fair value of warrant liability	10,435	_
Foreign currency remeasurement and other loss	(1,455)	767
Changes in operating assets and liabilities:		
Accounts receivable	381	508
Prepaid expenses and other current assets	1,271	516
Accounts payable and accrued liabilities	(459)	(1,245)
Deferred revenue	(3,813)	(1,816)
Net cash used in operating activities	(10,425)	(10,959)
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	2,000	_
Purchase of equipment	(111)	(88)
Net cash (used in) provided by investing activities	1,889	(8,831)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	_	219
Common shares received and retired for employee taxes paid	(15)	(23)
Proceeds from sale of common shares under ATM, net of offering costs	_	68
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	5,232	· <u>—</u>
Payment of financed insurance premium	(452)	_
Payment of finance lease liabilities	(28)	(27)
Net cash provided by financing activities	4,737	14,126
Effect of exchange rate changes on cash, cash equivalents and restricted cash	220	(158)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH CASH, CASH EQUIVALENTS AND RESTRICTED CASH:	(3,579)	(5,822)

 At beginning of the period
 46,354
 35,992

 At end of the period
 \$ 42,775
 \$ 30,170

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