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

November 14, 2024

- **OpRegen® Granted Regenerative Medicine Advanced Therapy (RMAT) Designation From FDA**
- **ReSonance™ (ANP1) Preclinical Results Presented at 59th Annual Inner Ear Biology Workshop**
- **Added to 2024 Russell 3000® Index**

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 14, 2024-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported its third 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.

"We were delighted to see our partners' continued commitment to the OpRegen program, in this instance by seeking and successfully obtaining RMAT designation," stated Brian M. Culley, Lineage CEO. "We believe OpRegen continues to showcase itself as an asset with the potential to be 'a transformational medicine' and view the recent RMAT designation as additional positive progress for this pioneering cell transplant program. As we worked to return our second cell transplant program, OPC1 for spinal cord injury, back into the clinic, we also presented promising preclinical results from our third program, ReSonance, for sensorineural hearing loss. We look forward to continuing to create value through the advancement of our clinical and preclinical pipelines, applying both our technology and extensive manufacturing expertise to validate our cell transplant approach."

Recent Operational Highlights

- **RG6501 (OpRegen)**

  - Roche and Genentech, a member of the Roche Group, announced receipt of RMAT designation from the U.S. FDA for OpRegen, for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for the ongoing Phase 2a clinical study (the "GAlette Study") in patients with GA secondary to AMD.
  - Continued activities under the separate services agreement with Genentech to support ongoing development of OpRegen. Lineage has been providing additional clinical, technical, training and manufacturing services 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.

- **OPC1**

  - 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 and FDA interactions continue.

- **ReSonance (ANP1)**

  - Preclinical results presented at 59th Annual Inner Ear Biology Workshop
    - ReSonance manufactured by a proprietary process, developed in-house, at clinical scale, with relevant in-vitro functional activity
    - Immediate-use, thaw-and-inject formulation durably engrafted in multiple preclinical hearing loss models
    - ReSonance is currently being evaluated in a functional model of hearing loss through a collaboration with the University of Michigan Kresge Hearing Research Institute.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities of $32.7 million as of September 30, 2024 is expected to support planned operations into Q1 2026.

Third Quarter Operating Results

Revenues: Revenue is generated primarily from collaboration revenues, royalties, and other revenues. Total revenues for the three months ended September 30, 2024 were $3.8 million, a net increase of approximately $2.5 million as compared to approximately $1.2 million for the same period in 2023. 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 September 30, 2024 were $7.6 million, a decrease of $0.3 million as compared to $7.9 million for the same period in 2023.

R&D Expenses: R&D expenses for the three months ended September 30, 2024 were $3.2 million, a net decrease of approximately $0.6 million as compared to $3.7 million for the same period in 2023. The net decrease was primarily driven by $0.6 million for our OPC1 program, $0.4 million for our preclinical programs, and partially offset by $0.5 million for our OpRegen program.

G&A Expenses: G&A expenses for the three months ended September 30, 2024 were $4.4 million, a net increase of $0.4 million as compared to $4.0 million for the same period in 2023. The net increase was primarily driven by $0.3 million for personnel costs and $0.1 million for stock-based compensation expense.

Loss from Operations: Loss from operations for the three months ended September 30, 2024 were $3.8 million, a decrease of $2.9 million as compared to $6.7 million for the same period in 2023.

Other Income/(Expenses): Other income (expenses) for the three months ended September 30, 2024 reflected other income of $0.8 million, compared to other expenses of approximately ($0.4) million for the same period in 2023. The change was primarily driven by exchange rate fluctuations related to our international subsidiaries.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended September 30, 2024 was $3.0 million, or $0.02 per share (basic and diluted), compared to a net loss attributable to Lineage of $7.1 million, or $0.04 per share (basic and diluted), for the same period in 2023.

Conference Call and Webcast

Interested parties may access the conference call on November 14th, 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 Investors 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 November 21st, 2024, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 2238934.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel, “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) 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 in collaboration with Factor Bioscience Limited. 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 and the potential impacts of RMAT designation on Roche and Genentech’s development of OpRegen or OpRegen’s ultimate success; 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 first quarter of 2026; the impacts to Lineage of our continued inclusion within the Russell 3000 Index; the broad potential for Lineage’s regenerative medicine platform and our ability to develop additional product candidates; and the potential of our platform technology and/or manufacturing capabilities to validate our approach or 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 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 OpRegen may never be proven to provide durable anatomical functional improvements in dry-AMD patients or become a ‘transformational medicine’, 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 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 Israel-Hamas war and broader 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)

	September 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	1,083	830
Finance lease liabilities, current portion	54	52
Deferred revenues, current portion	8,250	10,808
Total current liabilities	13,864	17,960
LONG-TERM LIABILITIES		
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
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)

	Three Months Ended September 30,		Nine Months Ended September 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 CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Nine Months Ended September 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	$ (15,336)	$ (16,711)
Net loss attributable to noncontrolling interest	4	(54)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. 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 (see Note 13 (Commitments and Contingencies))	556	526
Total cash, cash equivalents, and restricted cash	$ 28,306	$ 32,000

View source version on businesswire.com: https://www.businesswire.com/news/home/20241114288784/en/

Lineage Cell Therapeutics, Inc. IR
Ioana C. Hone
(ir@lineagecell.com)
(442) 287-8963

Russo Partners – Media Relations
Nic Johnson or David Schull
(Nic.johnson@russopartnersllc.com)
(David.schull@russopartnersllc.com)
(212) 845-4242

Source: Lineage Cell Therapeutics, Inc.