# Lineage Cell Therapeutics Reports Second Quarter 2023 Financial Results and Provides Business Update

August 10, 2023

- **Enrollment Continues in Phase 2a Clinical Study of RG6501 (OpRegen®) in Patients with GA Secondary to AMD Under Management of Genentech, a Member of the Roche Group**
- **FDA Type B Meeting Response Provides Path for New OPC1 Delivery Device**
- **Positive Topline Data Reported from Phase 1 VAC2 Study for the Treatment of NSCLC**
- **Lineage Added to Russell 3000® Index**
- **Established and Presented 1st Annual Spinal Cord Injury Investor Symposium**

CARLSBAD, Calif.--(BUSINESS WIRE)--Aug. 10, 2023-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported financial and operating results for the second quarter ended June 30, 2023 and will host a conference call today at 4:30 p.m. Eastern Time to discuss these results.

"The Lineage team continued to execute across multiple fronts during the second quarter, advancing our clinical and preclinical cell transplant programs and supporting our valuable alliances," stated Brian M. Culley, Lineage CEO. "The most important area of attention was our partnership with Roche and Genentech and continued support for the ongoing Phase 2a clinical study of OpRegen in patients with GA secondary to AMD, which has been enrolling patients from multiple sites in the U.S. Through presentations at medical and scientific conferences, we also sought to increase awareness of OpRegen's potential to provide durable anatomical and functional improvements to patients with advanced dry AMD. In partnership with CIRM and the Christopher & Dana Reeve Foundation, we created and presented the 1st Annual Spinal Cord Injury Investor Symposium, which brought together stakeholders to share expertise on spinal cord injury and reflects the receipt of a new and clarified path we obtained from FDA for an IND amendment for our OPC1 program. We also reported positive clinical results from a Phase 1 study of VAC2 in non-small cell lung cancer alongside our partner, Cancer Research UK. Looking ahead, we will continue to focus on making progress across our pipeline while maintaining our rigorous commitment to disciplined spending. Overall, we believe the use of differentiated allogeneic cell transplants can provide a meaningful impact for patients and are encouraged by the progress we and others have made in this field."

**Recent milestones and activities included:**

- **RG6501 (OpRegen)**
  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for the ongoing Phase 2a multi-center clinical study in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD):
    - Additional sites expected to come online this year for the Phase 2a study.
    - Preliminary evidence of durable anatomical and functional improvements following administration of OpRegen cells from the Phase 1/2a clinical study was presented at 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and other medical and scientific meetings, including durable improvement observed in one patient with long-term follow-up available (4 years).

- **Type B meeting response from FDA facilitates IND amendment submission for clinical testing of novel OPC1 spinal cord delivery system**
  - IND amendment preparation underway, with plans to submit to FDA in Q4.

- **Announced encouraging topline results from Phase 1 clinical study of VAC2 in advanced non-small cell lung cancer (NSCLC) in partnership with Cancer Research UK (CRUK)**
  - VAC2 appeared to be well tolerated in all treated patients and the adverse events observed were modest and expected from a therapy designed to generate a robust and durable immune response to tumor antigens.
  - Response data in these refractory patients was encouraging with five of eight participants demonstrating a best response of immune-related stable disease and three patients demonstrating immune-related progressive disease. Three of eight treated patients also reached the 2-year survival endpoint.
  - Two patients demonstrated durable responses against segments of the applicable tumor antigen and two other patients had transient responses as assessed via enzyme-linked immunospot (ELISPOT) assays.

- **Added to the broad-market Russell 3000® Index**
  - Our inclusion in the broader index can help to expand investor awareness, increase institutional ownership, and provide additional liquidity in our stock.

- **Established and presented the 1st Annual Spinal Cord Injury Investor Symposium (SCIIS)**.

- The goals of this collaborative effort included an increase in disease awareness, improving the probability of success in product development, and supporting clinical trial participation by focusing on topics such as patient-appropriate clinical endpoints. We are grateful to the sponsors and collaborators for this inaugural event, including CIRM, the Christopher & Dana Reeve Foundation, the Sanford Stem Cell Institute at the University of California San Diego, and AbbVie.

**Balance Sheet Highlights**

Cash, cash equivalents, and marketable securities totaled $45.9 million as of June 30, 2023, which is expected to support planned operations into Q4 2024.

**Second Quarter Operating Results**

*Revenues*: Lineage's revenue is generated primarily from licensing fees, royalties, collaboration revenues, and research grants. Total revenues for the three months ended June 30, 2023 were $3.2 million, a net decrease of $1.4 million as compared to approximately $4.6 million for the same period in 2022. The decrease was primarily driven by less collaboration and licensing revenue recognized from deferred revenues from the Roche 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, 2023 were $8.1 million, a decrease of $0.5 million as compared to $8.6 million for the same period in 2022.

*R&D Expenses*: R&D expenses for the three months ended June 30, 2023 were $3.9 million, a net increase of $0.6 million as compared to $3.3 million for the same period in 2022. The net increase was primarily driven by $0.4 million in higher OpRegen program-related expenses, and $0.3 million in non-clinical-related expenses to support the OPC1 program.

*G&A Expenses*: G&A expenses for the three months ended June 30, 2023 were $4.2 million, a net decrease of approximately $1.1 million as compared to $5.3 million for the same period in 2022. The decrease was primarily driven by $0.5 million in lower litigation and legal expenses, and an overall reduction in costs incurred for services by third parties, consulting costs, and stock-based compensation expense.

*Loss from Operations*: Loss from operations for the three months ended June 30, 2023 was $5.0 million, an increase of $0.8 million as compared to $4.2 million for the same period in 2022.

*Other Income/(Expenses), Net*: Other income (expenses), net for the three months ended June 30, 2023 reflected other expense, net of ($0.2) million, compared to other expense, net of ($2.5) million for the same period in 2022. The net 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 from our marketable debt securities.

*Net Loss Attributable to Lineage*: The net loss attributable to Lineage for the three months ended June 30, 2023 was $5.2 million, or $0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of $6.8 million, or $0.04 per share (basic and diluted), for the same period in 2022.

**Conference Call and Webcast**

Interested parties may access today's conference call and webcast, 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 August 17, 2023, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 1144985.

**About Lineage Cell Therapeutics, Inc.**

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage's programs are based on its robust proprietary cell-based therapy platform and associated in-house development and manufacturing capabilities. With this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered as a means of helping the body mount an effective immune response to cancer. Lineage's clinical and preclinical programs are in markets with billion dollar opportunities and include five allogeneic ("off-the-shelf") product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development for the treatment of geographic atrophy secondary to age-related macular degeneration, is being developed under a worldwide collaboration with Roche and Genentech, a member of the Roche Group; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer; (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; and (v) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage. For more information, please visit www.lineagecell.com or follow the company on 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. Such statements include, but are not limited to, statements relating to: the significance of the Phase 2a clinical study of OpRegen and the expansion of the study to additional clinical sites; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into the fourth quarter of 2024; plans and expectations regarding publications and presentations related to our programs, the timing of anticipated regulatory submissions to the FDA related to our programs, including OPC1, the potential future achievements of our clinical, preclinical and development programs, the initiation of clinical trials and the availability of clinical data updates related to our programs; plans and expectations regarding existing collaborations; the effect of the SCIIS, including increasing disease

awareness, the probability of success in product development, and clinical trial participation; the potential effects of being added to the Russel 3000 Index; our ability to broaden awareness of our mission, programs and accomplishments; and the potential of our cell therapy platform and our ability to provide an meaningful impact for patients. 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 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 feedback received from the FDA for OPC1 may not enable further clinical development; 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. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. 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, except as required by law.

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

| | June 30, 2023 (Unaudited) | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $ 33,886 | $ 11,355 |
| Marketable securities | 12,039 | 46,520 |
| Accounts receivable, net | 443 | 297 |
| Prepaid expenses and other current assets | 2,123 | 1,828 |
| Total current assets | 48,491 | 60,000 |
| NONCURRENT ASSETS | | |
| Property and equipment, net | 5,310 | 5,673 |
| Deposits and other long-term assets | 588 | 627 |
| Goodwill | 10,672 | 10,672 |
| Intangible assets, net | 46,627 | 46,692 |
| **TOTAL ASSETS** | $ 111,688 | $ 123,664 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| **CURRENT LIABILITIES** | | |
| Accounts payable and accrued liabilities | $ 4,685 | $ 8,608 |
| Lease liabilities, current portion | 933 | 916 |
| Financing lease, current portion | 54 | 36 |
| Deferred revenues | 10,379 | 9,421 |
| Other current liabilities | 1 | - |
| Total current liabilities | 16,052 | 18,981 |
| LONG-TERM LIABILITIES | | |
| Deferred tax liability | 273 | 2,076 |
| Deferred revenues, net of current portion | 21,688 | 27,725 |
| Lease liability, net of current portion | 2,304 | 2,860 |
| Financing lease, net of current portion | 113 | 84 |
| Other long-term liabilities | - | 2 |
| TOTAL LIABILITIES | 40,430 | 51,728 |
| SHAREHOLDERS' EQUITY | | |
| Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of June 30, 2023 and December 31, 2022 | - | - |
| Common shares, no par value, 250,000 shares authorized; 174,439 and 170,093 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively | 448,249 | 440,280 |

| | | |
|---|---|---|
| Accumulated other comprehensive loss | (2,611) | (3,571) |
| Accumulated deficit | (372,971) | (363,370) |
| Lineage Cell Therapeutics, Inc. shareholders' equity | 72,667 | 73,339 |
| Noncontrolling deficit | (1,409) | (1,403) |
| Total shareholders' equity | 71,258 | 71,936 |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | $ 111,688 | $ 123,664 |

**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, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| **REVENUES:** | | | | |
| Collaboration revenues | $ 2,871 | $ 4,148 | $ 4,992 | $ 9,013 |
| Royalties and license fees | 354 | 405 | 619 | 777 |
| Total revenues | 3,225 | 4,553 | 5,611 | 9,790 |
| Cost of sales | (127) | (215) | (246) | (391) |
| Gross profit | 3,098 | 4,338 | 5,365 | 9,399 |
| **OPERATING EXPENSES:** | | | | |
| Research and development | 3,873 | 3,302 | 8,058 | 6,290 |
| General and administrative | 4,249 | 5,270 | 8,973 | 13,739 |
| Total operating expenses | 8,122 | 8,572 | 17,031 | 20,029 |
| Loss from operations | (5,024) | (4,234) | (11,666) | (10,630) |
| **OTHER INCOME (EXPENSES):** | | | | |
| Interest income, net | 382 | 51 | 792 | 51 |
| Unrealized loss on marketable equity securities, net | (150) | (709) | (110) | (1,444) |
| Gain on revaluation of warrant liability | - | 2 | 1 | 223 |
| Other expenses, net | (411) | (1,892) | (427) | (2,075) |
| Total other income (expenses), net | (179) | (2,548) | 256 | (3,245) |
| **LOSS BEFORE INCOME TAXES** | (5,203) | (6,782) | (11,410) | (13,875) |
| Deferred income tax benefit | - | - | 1,803 | - |
| **NET LOSS** | (5,203) | (6,782) | (9,607) | (13,875) |
| Net (income) loss attributable to noncontrolling interest | (26) | 19 | 6 | 25 |
| **NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.** | $ (5,229) | $ (6,763) | $ (9,601) | $ (13,850) |
| NET LOSS PER COMMON SHARE: | | | | |
| BASIC | $ (0.03) | $ (0.04) | $ (0.06) | $ (0.08) |
| DILUTED | $ (0.03) | $ (0.04) | $ (0.06) | $ (0.08) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: | | | | |
| BASIC | 170,592 | 169,731 | 170,361 | 169,689 |
| DILUTED | 170,592 | 169,731 | 170,361 | 169,689 |

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

| | Six Months ended June 30, | |
|---|---|---|
| | **2023** | **2022** |

| | | |
|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss attributable to Lineage Cell Therapeutics, Inc. | $ (9,601) | $ (13,850) |
| Net loss allocable to noncontrolling interest | (6) | (25) |
| Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash (used in) provided by operating activities: | | |
| Accretion of income on marketable debt securities | (516) | - |
| Unrealized loss on marketable equity securities, net | 110 | 1,444 |
| Depreciation expense, including amortization of leasehold improvements | 276 | 296 |
| Change in right-of-use assets and liabilities | 81 | (7) |
| Amortization of intangible assets | 65 | 65 |
| Stock-based compensation | 2,311 | 2,341 |
| Gain on revaluation of warrant liability | (1) | (223) |
| Deferred income tax benefit | (1,803) | - |
| Foreign currency remeasurement and other gain | 1,012 | 2,331 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (147) | 50,111 |
| Prepaid expenses and other current assets | (270) | 594 |
| Accounts payable and accrued liabilities | (3,941) | (19,230) |
| Deferred revenue and other liabilities | (5,080) | (9,005) |
| Net cash (used in) provided by operating activities | (17,510) | 14,842 |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchases of marketable debt securities | (12,635) | - |
| Maturities of marketable debt securities | 47,664 | - |
| Purchase of equipment and other assets, net | (444) | (143) |
| Net cash provided by (used in) investing activities | 34,585 | (143) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from employee options exercised | 80 | 388 |
| Common shares received and retired for employee taxes paid | (37) | (17) |
| Proceeds from exercise of subsidiary warrants, net | - | 99 |
| Proceeds from sale of common shares | 5,789 | 148 |
| Payments for offering costs | (174) | (57) |
| Repayment of financing lease liability | (29) | (15) |
| Net cash provided by financing activities | 5,629 | 546 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (192) | (161) |
| **NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH** | 22,512 | 15,084 |
| CASH, CASH EQUIVALENTS AND RESTRICTED CASH: | | |
| At beginning of the period | 11,936 | 56,277 |
| At end of the period | $ 34,448 | $ 71,361 |

View source version on businesswire.com: https://www.businesswire.com/news/home/20230810282524/en/

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

**LifeSci Advisors**
Daniel Ferry
(daniel@lifesciadvisors.com)
(617) 430-7576

**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.