



Lineage Cell Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

March 10, 2022

- **Established Exclusive Worldwide Collaboration and License Agreement with Roche and Genentech for the Development and Commercialization of RG6501 (OpRegen®) in Transaction Worth up to \$670 Million**
- **Retinal Tissue Restoration and Visual Improvements Reported in Four Patients Treated with RG6501 (OpRegen) for Dry Age-Related Macular Degeneration**
- **Non-Clinical Testing Initiated to Support New Delivery Device for OPC1 Clinical Trials**
- **Worldwide License Agreement Secured for a Cancer Immunotherapy Product Candidate Based on the Lineage VAC Platform**
- **Cash and Cash Equivalents of Approximately \$83 Million as of January 31, 2022**

CARLSBAD, Calif.--(BUSINESS WIRE)--Mar. 10, 2022-- [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 fourth quarter and full year 2021. Lineage management will host a conference call and webcast today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its fourth quarter and full year 2021 financial and operating results and to provide a business update.

"2021 was a transformative year for Lineage, in part because we entered into a worldwide corporate partnership with Roche and Genentech for our OpRegen program for the treatment of ocular disorders," stated Brian M. Culley, Lineage CEO. "We have continued to execute on our strategic plan to position Lineage as a leader in the allogeneic cell transplant revolution, supported by our regenerative medicine technology; manufacturing and differentiation of specific cell types. These cells are transplanted into the body to restore or improve function lost due to aging, injury, or disease. We believe the collaboration of our lead asset with a world-class pharmaceutical partner with extensive ophthalmology capabilities brings significant validation to our technology platform and our approach to product development. As importantly, this transaction adds significant new capital to help support the advancement of our OPC1 program, VAC platform, and the expansion of our regenerative medicine pipeline into new disease settings. Our corporate objectives in 2022 will be focused on the continued advancement of our current clinical programs and making responsible investments in the expansion of our novel approach to cell transplant medicine in disease settings where we believe we can make a meaningful impact. We look forward to announcing our new, internally developed pipeline candidate later this quarter."

Some of the more significant milestones we achieved in 2021 include:

- **Established** an exclusive worldwide collaboration and license agreement with [Roche](#) and [Genentech](#) (the "Roche Collaboration"), for the development and commercialization of OpRegen, a retinal pigment epithelium ("RPE") cell therapy, for the treatment of ocular disorders, including advanced dry age-related macular degeneration ("dry AMD") with geographic atrophy ("GA"), in a transaction worth up to \$670 million in addition to double digit royalties;
- **Reported** a fourth case of retinal restoration with OpRegen; notably, four patients with dry AMD were observed to have areas of GA which diminished or remained unchanged relative to baseline for a period of at least 12 months;
- **Announced** a worldwide license agreement with Immunomic Therapeutics, Inc. for an allogeneic cell-based cancer immunotherapy based on our VAC platform; Lineage received \$2 million upfront and may receive up to \$67 million in development and commercial milestones plus royalties;
- **Entered** into an exclusive agreement with Neurgain Technologies to evaluate a novel delivery system for OPC1 to treat Spinal Cord Injury;
- Expanded our management team with the additions of Chief Financial Officer, Kevin L. Cook, as well as General Counsel, George A. Samuel, III; and
- Expanded our Board of Directors with the appointments of Drs. Anula Jayasuriya, M.D., Ph.D., M.B.A. and Dipti Amin, MBBS, FFPM, MRCGP, DCPSA, DCH, DRCOG, DGM.

Some of the events and milestones anticipated by Lineage in 2022 include:

- Announcement of a new pipeline program from our regenerative medicine cell therapy platform anticipated in March;
- Completion of GMP production of OPC1 via an improved and larger-scale manufacturing process and a new thaw-and-inject formulation; anticipated in Q1 2022;
- FDA interaction to discuss recent manufacturing improvements made to OPC1, anticipated in Q3 2022;
- Initiation of clinical performance and safety testing of the novel Parenchymal Spinal Delivery system device for OPC1, with an anticipated Investigational New Drug ("IND") amendment submission in Q3 2022;
- Updates from the ongoing VAC2 Phase 1 non-small cell lung cancer study; anticipated in Q2 2022;
- An anticipated IND submission for VAC2 in 2H 2022;
- Continued development of a cell-based therapeutic for glioblastoma with our strategic partner, Immunomic Therapeutics; ongoing throughout 2022;

- Evaluation of opportunities for new VAC product candidates based on internally identified or partnered tumor antigens; ongoing throughout 2022;
- Evaluation of partnership opportunities and expansion of existing collaborations; ongoing throughout 2022; and
- Continued participation in numerous investor and partnering meetings and medical and industry conferences to broaden the knowledge of our work.

Balance Sheet Highlights

Cash and cash equivalents totaled \$55.7 million as of December 31, 2021. In January 2022, we received a \$50.0 million upfront payment related to the Roche Collaboration and made subsequent payments pursuant to Lineage's downstream obligations.

Fourth Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the three months ended December 31, 2021 were approximately \$1.2 million, an increase of \$0.8 million as compared to \$0.4 million for the same period in 2020. The increase was related to royalties and licensing fees, which was primarily driven by licensing revenues in connection with collaboration agreements entered into in 2021.

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 December 31, 2021 were \$29.2 million, an increase of \$23.1 million as compared to \$6.1 million for the same period in 2020. The overall increase was substantially driven by \$20.6 million in higher OpRegen-related expenses, mainly due to accruals for future financial obligations payable to the Israel Innovation Authority ("IIA") and Hadasit Medical Research Services and Development Ltd ("Hadasit"), related to the receipt of the \$50.0 million upfront payment under the Roche Collaboration.

R&D Expenses: R&D expenses for the three months ended December 31, 2021 were \$24.8 million, an increase of \$22.2 million as compared to \$2.6 million for the same period in 2020. The increase was substantially driven by the \$21.0 million accrual for future financial obligations payable to IIA and Hadasit. Other drivers of the increased variance were related to \$1.0 million and \$0.6 million in higher expenses to support the development of the OPC1 and VAC programs, respectively.

G&A Expenses: G&A expenses for the three months ended December 31, 2021 were \$4.4 million, an increase of \$0.9 million as compared to \$3.5 million for the same period in 2020. The increase was primarily attributable to increases of \$0.3 million in legal and litigation expenses, \$0.3 million in salaries and related benefits, and \$0.3 million in share-based compensation expense.

Loss from Operations: Loss from operations for the three months ended December 31, 2021 was \$28.2 million, an increase of \$22.3 million as compared to \$5.9 million for the same period in 2020, principally owing to collaboration-related expense accruals of \$21.0 million which were not deferrable expenses, and as such, do not align with current period revenues due to revenue deferral accounting standards.

Other Income, Net: Other income, net for the three months ended December 31, 2021 was \$0.2 million, compared to other income, net of \$6.9 million for the same period in 2020. The variance was primarily related to changes in the value of marketable equity securities for the applicable periods.

Net Income/(Loss) Attributable to Lineage: The net loss attributable to Lineage for the three months ended December 31, 2021 was (\$29.0) million, or (\$0.17) per share (basic and diluted), compared to a net income attributable to Lineage of \$2.0 million, or \$0.01 per share (basic and diluted), for the same period in 2020. The large year-over-year change was principally due to the collaboration-related expense accruals amounting to (\$0.12) per share which were not deferrable expenses, and as such, do not align with current period revenues due to revenue deferral accounting standards.

Full Year Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the year ended December 31, 2021 were \$4.3 million, an increase of \$2.5 million as compared to \$1.8 million for the same period in 2020. The increase was primarily related to a \$2.0 million increase in royalty revenues, and a \$1.1 million increase in licensing revenues in connection with collaboration agreements, partially offset by a \$0.6 million decrease in grant revenues.

Operating Expenses: Operating expenses are comprised of R&D expenses and G&A expenses. Total operating expenses for the year ended December 31, 2021 were \$52.1 million, an increase of \$24.2 million as compared to \$27.9 million for the same period in 2020. The overall increase was substantially driven by \$19.9 million in higher OpRegen-related expenses, mainly due to accruals for future financial obligations payable to IIA and Hadasit, related to the receipt of the \$50.0 million upfront payment under the Roche Collaboration.

R&D Expenses: R&D expenses for the year ended December 31, 2021 were \$33.9 million, an increase of \$21.6 million as compared to \$12.3 million for the same period in 2020. The increase was substantially driven by the \$21.0 million accrual for future financial obligations payable to the IIA and Hadasit. Other drivers of the net increase variance were \$2.2 million in higher manufacturing and device development costs to support the OPC1 program, offset by \$0.3 million in lower VAC program expenses.

G&A Expenses: G&A expenses for the year ended December 31, 2021 were \$18.2 million, an increase of approximately \$2.6 million as compared to \$15.6 million for the same period in 2020. The increase was primarily related to increases of \$1.3 million in legal, litigation and patent expenses, \$0.9 million in share-based compensation expenses, and \$0.3 million in payroll and related benefits expense.

Loss from Operations: Loss from operations for the year ended December 31, 2021 was \$49.2 million, an increase of \$22.8 million as compared to \$26.4 million for the same period in 2020, principally owing to collaboration-related expense accruals of \$21.0 million which were not deferrable expenses, and as such, do not align with current period revenues due to revenue deferral accounting standards.

Other Income, Net: Other income, net for the year ended December 31, 2021 was \$5.9 million, compared to other income, net of \$4.5 million for the same period in 2020. The net variance was primarily related to the changes in the value of marketable equity securities for the applicable periods.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the year ended December 31, 2021 was \$43.0 million, or \$0.26 per share (basic and diluted), compared to a net loss attributable to Lineage of \$20.6 million, or \$0.14 per share (basic and diluted), for 2020. The large year-over-year change is principally due to collaboration-related expense accruals amounting to \$0.13 per share which were not deferrable expenses, and as such, do not align with current period revenues due to revenue deferral accounting standards.

Conference Call and Webcast

Interested parties may access the conference call by dialing (866) 888-8633 from the U.S. and Canada and (636) 812-6629 from elsewhere outside 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 March 18, 2022, by dialing (855) 859-2056 from the U.S. and Canada and (404) 537-3406 from elsewhere outside the U.S. and Canada and entering conference ID number 7718167.

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 programs are in markets with billion dollar opportunities and include three allogeneic (“off-the-shelf”) product candidates: (i) OpRegen, a retinal pigment epithelium transplant therapy in Phase 1/2a development for the treatment of dry age-related macular degeneration, which is now 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; and (iii) VAC2, an allogeneic 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. 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 collaboration and license agreement with Roche and Genentech and activities expected to occur thereunder, the milestone and royalty consideration payable to Lineage and Lineage’s planned use of proceeds therefrom, the potential benefits of treatment with OpRegen, the potential success of other existing partnerships and collaborations, the broad potential for Lineage’s regenerative medicine platform and Lineage’s ability to expand the same, Lineage’s plans to advance its spinal cord injury and oncology programs and announce new disease settings where it plans to deploy its technology, the projected timing of milestones of future studies, including their initiation and completion, the projected timing of interactions with the FDA to discuss product designation, manufacturing plans and improvements, and later-stage clinical development, the potential opportunities for the establishment or expansion of strategic partnerships and collaborations and the timing thereof, and the potential for Lineage’s investigational allogeneic cell therapies to generate clinical outcomes beyond the reach of traditional methods and provide safe and effective treatment for multiple, diverse serious or life threatening conditions. 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 risk that competing alternative therapies may adversely impact the commercial potential of OpRegen, which could materially adversely affect the milestone and royalty payments payable to Lineage under the collaboration and license agreement, the risk that Roche and Genentech may not be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; the risk that Lineage might not succeed in developing products and technologies that are useful in medicine and demonstrate the requisite safety and efficacy to achieve regulatory approval in accordance with its projected timing, or at all; the risk that, even if one or more of Lineage’s product candidates are approved and commercialized, Lineage may never attain profitability; the risk that Lineage is unable to raise sufficient additional capital to fund its operations; the risk that Lineage may not be able to manufacture sufficient clinical and, if approved, commercial quantities of its product candidates in accordance with current good manufacturing practice; the risks related to Lineage’s dependence on other third parties, and Lineage’s ability to establish and maintain its collaborations with these third parties; the risk that government-imposed bans or restrictions and religious, moral, and ethical concerns about the use of hES cells could prevent Lineage or its partners from developing and successfully marketing its stem cell product candidates; the risk that Lineage’s intellectual property may be insufficient to protect its products; the risk that the COVID-19 pandemic or geopolitical events may directly or indirectly cause significant delays in and substantially increase the cost of development of Lineage’s product candidates, as well as heighten other risks and uncertainties related to Lineage’s business and operations; 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 and Quarterly Report on Form 10-Q 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.

Tables to follow

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 55,742	\$ 32,585
Marketable equity securities	2,616	8,977
Trade accounts and grants receivable, net	50,840	4

Prepaid expenses and other current assets	2,351	2,433
Total current assets	111,549	43,999
NONCURRENT ASSETS		
Property and equipment, net	4,872	5,630
Deposits and other long-term assets	630	616
Goodwill	10,672	10,672
Intangible assets, net	46,822	47,032
TOTAL ASSETS	\$ 174,545	\$ 107,949
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 27,969	\$ 6,813
Lease liabilities, current portion	801	746
Financing lease, current portion	30	16
Deferred revenues	18,119	193
Liability classified warrants, current portion	197	1
Total current liabilities	47,116	7,769
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Deferred revenues, net of current portion	32,454	-
Lease liability, net of current portion	1,941	2,514
Financing lease, net of current portion	30	26
Liability classified warrants and other long-term liabilities	30	437
TOTAL LIABILITIES	83,647	12,822
	-	-
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2021 and 2020, respectively	-	-
Common shares, no par value, authorized 250,000 shares; 169,477 and 153,096 shares issued and outstanding as of December 31, 2021 and 2020, respectively	434,529	393,944
Accumulated other comprehensive loss	(5,211)	(3,667)
Accumulated deficit	(337,097)	(294,078)
Lineage Cell Therapeutics, Inc. shareholders' equity	92,221	96,199
Noncontrolling (deficit)	(1,323)	(1,072)
Total shareholders' equity	90,898	95,127
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 174,545	\$ 107,949

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

	Year Ended December 31,	
	2021	2020
REVENUES:		
Royalties	\$ 2,776	\$ 773
Collaboration revenues	1,120	-
Grant revenues	445	1,053
Total revenues	4,341	1,826
Cost of sales	(1,426)	(385)
Gross profit	2,915	1,441
OPERATING EXPENSES:		
Research and development	33,914	12,317
General and administrative	18,212	15,571
Total operating expenses	52,126	27,888

Loss from operations	(49,211)	(26,447)
OTHER INCOME, NET:		
Interest income, net	2	1,039
Gain on sale of marketable securities	6,024	4,560
Unrealized loss on marketable equity securities	(2,299)	(3,782)
Gain on extinguishment of debt	523	-
Unrealized gain (loss) on warrant liability	205	(174)
Other income, net	1,486	2,880
Total other income, net	5,941	4,523
LOSS BEFORE INCOME TAXES	(43,270)	(21,924)
Income tax benefit	-	1,239
NET LOSS	(43,270)	(20,685)
Net loss attributable to noncontrolling interest	251	36
NET LOSS ATTRIBUTABLE TO LINEAGE	\$ (43,019)	\$ (20,649)
NET LOSS PER COMMON SHARE:		
BASIC AND DILUTED	\$ (0.26)	\$ (0.14)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC AND DILUTED	164,502	150,044

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

	Year Ended December 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	\$ (43,019)	\$ (20,649)
Net loss attributable to noncontrolling interest	(251)	(36)
Adjustments to reconcile net loss attributable to Lineage to net cash used in operating activities:		
Gain on sale of marketable equity securities	(6,024)	(4,560)
Unrealized loss on marketable equity securities	2,299	3,782
Deferred tax benefit	-	(1,239)
Depreciation expense, including amortization of leasehold improvements	663	823
Amortization of right-of-use assets	14	72
Amortization of intangible assets	210	1,216
Stock-based compensation	3,519	2,227
Common stock issued for services	202	119
Change in unrealized (gain) loss on warrant liability	(205)	174
Write-off of security deposit	-	150
Amortization of deferred license fee	-	(200)
Foreign currency remeasurement and other (gain)	(1,566)	(2,957)
Loss (gain) on sale of assets	24	(20)
Realized loss on warrant exercise	-	44
Gain on extinguishment of debt	(523)	-
Changes in operating assets and liabilities:		
Accounts and grants receivable	(857)	287
Accrued interest receivable	-	(1,008)
Receivables from affiliates, net of payables	-	7
Prepaid expenses and other current assets	(72)	1,575
Accounts payable and accrued liabilities	21,645	308
Deferred revenue and other liabilities	380	132
Net cash used in operating activities	(23,561)	(19,753)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of OncoCyte common shares	10,064	10,941

Proceeds from the sale of AgeX common shares	-	1,290
Proceeds from the sale of HBL common shares	21	830
Purchase of property and equipment	(354)	(64)
Proceeds from sale of assets	14	23
Security deposit paid and other	-	18
Net cash provided by investing activities	9,745	13,038

CASH FLOWS FROM FINANCING ACTIVITIES:

Proceeds from employee options exercised	7,240	-
Proceeds from payment of Juvenescence promissory note	-	24,624
Common shares received and retired for employee taxes paid	(54)	(27)
Proceeds from sale of common shares	30,865	5,127
Payments for offering costs	(1,101)	(356)
Repayment of financing lease liabilities	(20)	(26)
Proceeds from Paycheck Protection Program ("PPP") Loan	-	523
Net cash provided by financing activities	36,930	29,865
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(20)	(63)

NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH

	23,094	23,087
At beginning of year	33,183	10,096
At end of year	\$ 56,277	\$ 33,183

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

Cash paid during year for interest	\$ 13	\$ 20
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SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:

Receivable from sale of common shares in at the market offering	\$ 147	\$ 269
Receivable from exercise of stock options	\$ 189	\$ -

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Source: Lineage Cell Therapeutics, Inc.