



Lineage Cell Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

March 12, 2020

- **Reported Positive Data from Phase 1/2a Clinical Trial of OpRegen®; All Cohort 4 Patients Have Improved Visual Acuity at Twelve Months or as of Last Visit (Gained Between 8-25 Readable Letters)**
- **Entered into Agreements with Three Companies for Certain IP and Assets**
- **Provided Positive Clinical Update from SCiStar Trial of OPC1 for Spinal Cord Injury**
- **Strengthened Extensive IP Portfolio with the Issuance of 3 New U.S. Patents**
- **Awarded \$3.2 Million in Grants from Israel Innovation Authority and NIH**
- **Extended Anticipated Cash Runway by Implementing Cost Savings Initiatives and Converting Securities into Cash Positions**

CARLSBAD, Calif.--(BUSINESS WIRE)-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, today reported financial and operating results for the fourth quarter and full year ended December 31, 2019. 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 2019 financial and operating results and to provide a business update.

"2019 was a transformative year for Lineage. We established Lineage as a leading cell therapy company with the goal to usher in a new branch of medicine based on transplanting intact cells into the body to restore activity lost to aging, injury, or disease," stated Brian M. Culley, CEO. "We expanded our clinical pipeline by combining three complementary cell therapy assets under one roof, and also significantly reduced our cash burn by eliminating non-core activities. We focused our priorities and rebranded the company with a new leadership team, name, and headquarters in San Diego County. As we enter 2020, we intend to capitalize on the changes we made in 2019 and continue our positive momentum. Our primary goal is to complete enrollment in our Phase 1/2a clinical trial of [OpRegen](#) for dry AMD and collect the data that will guide our late-stage trial design and partnership discussions. We also will continue our efforts to advance the [OPC1](#) program into a randomized trial by introducing commercially enabling enhancements to the manufacturing process. Lastly, we are working with our development partner, [Cancer Research UK](#), and continue to assess clinical data that is being generated from the ongoing Phase 1 trial of [VAC2](#). We are evaluating whether to exercise our option to acquire the data generated in the trial if the data supports that decision. We are excited about the three clinical programs that we are working to advance, each of which represents a potential billion dollar market opportunity."

Significant events and data updates from 2019 and early 2020 include:

- [Successfully](#) dosed two patients in our OpRegen Phase 1/2a clinical trial for the treatment of dry age-related macular degeneration (AMD) with a new thaw-and-inject formulation and a new delivery device, the 510(k)-cleared Subretinal Delivery System (SDS) developed by Gyroscope Therapeutics (Gyroscope). The Gyroscope SDS is designed to precisely and consistently deliver therapeutics to the sub-retinal space via a suprachoroidal route, avoiding: (i) the need for a vitrectomy; (ii) perforation of the retina (retinotomy); and (iii) loss of cells and adverse safety events due to efflux. We have to date reported on two patients dosed with the combination of the new device and formulation. The first patient demonstrated notable improvements in vision, having gained 25 readable letters (or 5 lines) 6 months following administration, as assessed by the Early Treatment Diabetic Retinopathy Scale (ETDRS). This represented an improvement in visual acuity from a baseline of 20/250 to 20/100 in the treated eye. The second patient showed a small improvement in visual acuity in the treated eye at just 14 days following treatment. Both patients had rapid healing at the surgical site with no unexpected complications or any serious adverse events. Improvements for patients in the trial have typically become most evident approximately three to six months after treatment. Treatment for all patients in the trial continues to be well tolerated and all five patients in Cohort 4 (who have better baseline vision and less advanced disease than Cohorts 1-3 patients) registered improvement according to the ETDRS eye chart assessment. Improvements ranged from 8 to 25 additional letters correctly identified for all patients with at least 6 months of follow-up as of December 31, 2019. We expect to dose a total of six patients with the Gyroscope SDS under our current agreement with Gyroscope.
- [Acquired](#) Asterias Biotherapeutics, Inc. in March 2019. As a result of this acquisition, we acquired two additional cell therapy product candidates, OPC1 and VAC2, along with their associated expansion opportunities and other assets. As we integrated the two companies, we reduced costs by about 50% by eliminating duplicate costs and rationalizing non-key projects.
- [Rebranded](#) as Lineage Cell Therapeutics and relocated the corporate headquarters from the San Francisco Bay Area to Carlsbad, California. We also hired experienced biotech professionals to fill critical management positions, including the Chief Financial Officer, General Counsel and Vice President, Business Development.
- [Entered](#) into agreements with three separate companies, with each agreement relating to different parts of Lineage's intellectual property portfolio. All three companies have ongoing commercial operations in areas related to cell therapy. The aggregate up-front cash payment from the three transactions was greater than one million dollars with additional cash and

royalties due upon reaching certain development milestones or product sales.

- **Reported** a positive clinical update from our ongoing Phase 1/2a clinical trial of OPC1 known as [SCiStar](#) for the treatment of acute spinal cord injury (SCI). The overall safety profile of OPC1 remained excellent with robust motor recovery in the arms/hands maintained through year 2 follow-ups to date. Gains in motor function for patients assessed to date continued, representing tremendously meaningful improvements to quality of life and independence.
- Awarded \$3.2 million in grants from the [Israel Innovation Authority](#) and the [National Institutes of Health](#) and published or presented multiple papers and abstracts describing our work.
- Obtained patents associated with the manufacture of our unique cell types, adding additional protections to all three of our clinical programs. Also obtained patent rights describing the use of induced pluripotent stem cells, an alternate option for generating differentiated cells for transplant and treatment of diseases, further broadening the potential application of our work.
- Granted a Conformité Européenne (CE) Mark for Renevia[®], the Company's facial aesthetics product, with an intended use in adults for the treatment of facial lipoatrophy. The CE Mark enables us to sell Renevia in Europe and we are actively pursuing a commercialization partner for this activity.
- **Announced** that after reviewing promising preliminary data from the ongoing OpRegen Phase 1/2a clinical trial, our independent data safety monitoring board removed the protocol-mandated treatment stagger. Accordingly, we are opening two new U.S. clinical sites to accelerate patient enrollment and broaden surgical experience among dry AMD experts.

Potential key events for 2020:

- **Complete patient enrollment** in the U.S. with the Gyroscope SDS in the ongoing Phase 1/2a clinical trial of OpRegen for the treatment of dry AMD.
- **Present new OpRegen data** from the ongoing Phase 1/2a clinical trial in May 2020 and as available throughout the year.
- **Meet with the U.S. Food and Drug Administration (FDA)** to discuss the further clinical development of OpRegen.
- **Evaluate partnership opportunities** for the OpRegen program.
- **Enhance commercial utility of OPC1** program by introducing commercially enabling improvements to the manufacturing process in our GMP manufacturing facility.
- **Meet with the FDA** to discuss the manufacturing and further clinical development of OPC1.
- **Provide further clinical updates** from the SCiStar Trial for SCI.
- **Evaluate partnership opportunities** for Renevia in Europe.
- **Evaluate VAC2 clinical data** from the initial patients in the ongoing Phase 1 trial in NSCLC (non-small cell lung cancer) run by Cancer Research UK and evaluate potential early exercise of option to acquire data.
- **Continue engagement** with the investment and medical communities with participation at medical and healthcare industry conferences, ongoing throughout 2020.
- **Strengthen existing partnerships** with the [National Institutes of Health](#), the [Israel Innovation Authority](#), the [California Institute for Regenerative Medicine](#), and [Cancer Research UK](#).

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled \$30.7 million as of December 31, 2019. Marketable securities include our remaining ownership of unrestricted securities in OncoCyte, AgeX Therapeutics, and Hadasit Bio-Holdings Ltd (Hadasit).

During 2019, we were able to fund our operations primarily by selling a portion of our marketable securities. We sold 6,250,000 shares of OncoCyte's common stock for net proceeds of approximately \$10.7 million. We also sold 765,889 shares of AgeX common stock for net proceeds of approximately \$1.8 million and 1,048,147 shares of Hadasit common stock for net proceeds of approximately \$1.7 million. On January 2, 2020, we sold 2,383,090 shares of OncoCyte stock for net proceeds of approximately \$5.0 million. We continue to hold approximately 6 million shares of OncoCyte stock that are valued at \$13.8 million as of March 10, 2020. All of our marketable securities are now in companies in which we hold less than 10% of the outstanding shares.

In conjunction with the sale of AgeX shares to Juvenescence Limited (Juvenescence) in 2018, we also hold a \$21.6 million promissory note bearing 7% annual interest that matures on August 30, 2020. As of December 31, 2019, the outstanding principal and accrued interest on the note was \$23.6 million. If, prior to August 30, 2020, Juvenescence completes an initial public offering resulting in gross proceeds of at least \$50.0 million, the promissory note automatically converts into the Juvenescence securities. Lineage has the right to review Juvenescence's financial statements twice per year.

In summary, as of December 31, 2019, the value of the Company's cash, cash equivalents, marketable securities, and the balance of the Juvenescence promissory note due August 2020 were in excess of \$54 million.

The Company has implemented significant cost savings initiatives and anticipates that net operational spend for 2020 will be approximately \$16 million. This planned spending level represents a significant reduction from 2019 spending levels of \$32 million and 2018 spending levels of \$43 million for Lineage and Asterias combined. Lineage acquired Asterias on March 8, 2019. Assuming the Juvenescence note is paid in cash at maturity, the Company believes that it is funded well into 2021 as a result of these cost savings initiatives.

Fourth Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from royalties, licensing fees, research grants and the sale of research products. Total revenues for the three months ended December 31, 2019 were \$1.2 million, an increase of \$0.4 million as compared to \$0.8 million for the same period in 2018.

The increase was primarily related to a \$0.7 million increase in royalties and licensing fees, offset by a \$0.2 million decrease in grant revenue and \$0.1 million decrease in the sale of research products.

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, 2019 were \$8.0 million, a decrease of \$2.8 million as compared to \$10.8 million for the same period in 2018.

R&D Expenses: R&D expenses for the three months ended December 31, 2019 were \$3.5 million, a decrease of \$0.3 million as compared to \$3.8 million for the same period in 2018. The decrease was primarily related to decreases of \$0.7 million in Renevia and HyStem expenses and a decrease of \$0.2 million in OpRegen expenses, offset by an increase of \$0.6 million in OPC1 and VAC2 expenses (these programs were acquired in the Asterias merger).

G&A Expenses: G&A expenses for the three months ended December 31, 2019 were \$4.5 million, a decrease of \$2.5 million as compared to \$7.0 million for the same period in 2018. The decrease was primarily attributable to a \$1.8 million decrease in salaries, benefits and severance costs primarily related to terminated personnel, a \$0.5 million reduction in severance, legal, accounting and other expenses related to the Asterias Merger, a \$0.3 million reduction in accounting and consulting expenses and a \$0.2 million reduction in travel expenses, offset by a \$0.2 million increase in rent expense, which is primarily related to the implementation of ASC 842 Leases in 2019.

Loss from Operations: Loss from operations for the three months ended December 31, 2019 was \$6.9 million, a decrease of \$3.2 million as compared to \$10.1 million for the same period in 2018.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended December 31, 2019 reflected other income, net of \$1.5 million, compared to other expense, net of (\$35.2) million for the same period in 2018. The variance was primarily related to changes in the value of equity method investments and marketable equity securities for the applicable periods.

Net loss attributable to Lineage: The net loss attributable to Lineage for the three months ended December 31, 2019 was \$4.5 million, or \$0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of \$45.0 million, or \$0.35 per share (basic and diluted), for the same period in 2018.

Full Year Operating Results

Note regarding AgeX: On August 30, 2018, Lineage deconsolidated AgeX from its consolidated financial statements due to the sale by Lineage of 14,400,000 shares of AgeX common stock to Juvenescence and the related decrease of Lineage's ownership position in AgeX. Accordingly, Lineage ceased recognizing revenue and expenses related to AgeX and its programs on such date.

Revenues: Lineage's revenue is generated primarily from royalties, licensing fees, research grants and the sale of research products. Total revenues for the year ended December 31, 2019 were \$3.5 million, a decrease of \$1.5 million as compared to \$5.0 million for the same period in 2018. The decrease was primarily related to a \$1.5 million decrease in grant revenue and a \$0.7 million decrease in subscription and advertising revenues, partially offset by a \$0.8 million increase in royalties from product sales and license fees.

Operating Expenses: Operating expenses are comprised of R&D expenses and G&A expenses. Total operating expenses for the year ended December 31, 2019 were \$42.0 million, a decrease of \$4.5 million as compared to \$46.5 million for the same period in 2018.

R&D Expenses: R&D expenses for the year ended December 31, 2019 were \$17.9 million, a decrease of \$3.9 million as compared to \$21.8 million for the same period in 2018. The decrease was primarily related to a decrease of \$4.6 million related to the AgeX deconsolidation and the absence of AgeX R&D expenses incurred after August 30, 2018, a decrease of \$3.8 million in Renevia and HyStem expenses and a decrease of \$0.2 million in OpRegen expenses, offset by an increase of \$4.8 million in OPC1 and VAC2 expenses (these programs were acquired in the Asterias merger).

G&A Expenses: G&A expenses for the year ended December 31, 2019 were \$24.0 million, a decrease of \$0.7 million as compared to \$24.7 million for the same period in 2018. The decrease was primarily attributable to a \$3.1 million decrease in AgeX related general and administrative expenses, a \$1.4 million decrease in salaries, benefits and severance costs primarily related to terminated personnel, a \$1.1 million reduction in legal and patent expenses and a \$0.7 million reduction in consulting expenses, offset by a \$5.6 million increase in severance, legal, accounting and other expenses related to the Asterias Merger.

Loss from Operations: Loss from operations for the year ended December 31, 2019 was \$38.9 million, a decrease of \$2.9 million as compared to \$41.8 million for the same period in 2018.

Other Income/(Expenses), Net: Other income/(expenses), net for the year ended December 31, 2019 reflected other income, net of \$19.6 million, compared to other expense, net of (\$5.3) million for the same period in 2018. The variance was primarily related to the 2018 gain on the sale of AgeX shares and deconsolidation of AgeX and changes in the value of equity method investments and marketable equity securities for the applicable periods.

Net loss attributable to Lineage: The net loss attributable to Lineage for the year ended December 31, 2019 was \$11.7 million, or \$0.08 per share (basic and diluted), compared to a net loss attributable to Lineage of \$46.0 million, or \$0.36 per share (basic and diluted), for 2018.

Conference Call and Webcast

Lineage will host a conference call and webcast today, at 1:30 pm PT/4:30 pm ET to discuss its fourth quarter and full year 2019 financial results and to provide a business update. 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 20, 2020, 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 3827019.

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, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC2, a cancer immunotherapy of antigen-presenting dendritic cells in Phase 1 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," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "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 Lineage's anticipated net operational spend, manufacturing plans, enrollment activities, discussions with Cancer Research UK regarding data generated from the ongoing trial of VAC2, data presentations, clinical trial advancement, drug evaluation, planned meetings with the FDA and partnership evaluations. 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 risks and uncertainties inherent in Lineage's business and other risks in Lineage's filings with the Securities and Exchange Commission (the 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 Annual Report on Form 10-K filed with the SEC on March 14, 2019 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 CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 9,497	\$ 23,587
Marketable equity securities	21,219	7,154
Promissory note from Juvenescence	23,616	-
Trade accounts and grants receivable, net	317	767
Landlord receivable	-	840
Receivables from affiliates, net	7	2,112
Prepaid expenses and other current assets	2,863	1,898
Total current assets	57,519	36,358
NONCURRENT ASSETS		
Property and equipment, net	8,175	5,835
Deposits and other long-term assets	864	505
Promissory note from Juvenescence	-	22,104
Equity method investment in OncoCyte, at fair value	-	20,250
Equity method investment in Asterias, at fair value	-	13,483
Goodwill	10,672	-
Intangible assets, net	48,248	3,125
TOTAL ASSETS	\$ 125,478	\$ 101,660
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,226	\$ 6,463
Financing lease and right-of-use liabilities, current portion	1,223	237
Promissory notes, current portion	-	70
Deferred grant revenue	45	42
Total current liabilities	6,494	6,812
LONG-TERM LIABILITIES		
Deferred tax liability	3,315	-

Deferred rent liabilities, net of current portion	-	244
Deferred revenues	200	-
Right-of-use lease liability, net of current portion	3,868	1,854
Financing lease, net of current portion	77	104
Liability classified warrants and other long-term liabilities	277	400
TOTAL LIABILITIES	14,231	9,414

Commitments and contingencies

SHAREHOLDERS' EQUITY

Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2019 and 2018, respectively	-	-
Common shares, no par value, authorized 250,000 shares; 149,804 and 127,136 shares issued and outstanding as of December 31, 2019 and 2018, respectively	387,062	354,270
Accumulated other comprehensive (loss) income	(681)	1,426
Accumulated deficit	(273,422)	(261,856)
Lineage Cell Therapeutics, Inc. shareholders' equity	112,959	93,840
Noncontrolling interest (deficit)	(1,712)	(1,594)
Total shareholders' equity	111,247	92,246
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 125,478	\$ 101,660

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
REVENUES:				
Grant revenue	\$ 409	\$ 587	\$ 2,037	\$ 3,572
Royalties from product sales and license fees	831	80	1,221	392
Subscription and advertisement revenues	-	-	-	691
Sale of research products and services	1	91	257	333
Total revenues	1,241	758	3,515	4,988
Cost of sales	(123)	(52)	(412)	(302)
Gross profit	1,118	706	3,103	4,686
OPERATING EXPENSES:				
Research and development	3,486	3,780	17,948	20,955
Acquired in-process research and development	-	-	-	800
General and administrative	4,504	7,033	24,031	24,726
Total operating expenses	7,990	10,813	41,979	46,481
Loss from operations	(6,872)	(10,107)	(38,876)	(41,795)
OTHER INCOME/(EXPENSES):				
Interest income (expense), net	407	433	1,685	711
Gain on sale of marketable equity securities	366	-	2,421	-
Gain on sale of equity method investment in OncoCyte	-	-	546	-
Gain on sale of equity method investment in Ascendance	-	-	-	3,215
Gain on sale of AgeX shares and deconsolidation of AgeX	-	-	-	78,511
Unrealized (loss) gain on marketable equity securities	236	523	(2,898)	1,158

Unrealized (loss) gain on equity method investment in OncoCyte at fair value	-	(16,435)	8,001	(47,985)
Unrealized (loss) gain on equity method investment in Asterias at fair value	-	(14,789)	6,744	(35,449)
Loss on equity method investment in AgeX at fair value	-	(4,181)	-	(4,181)
Unrealized gain (loss) on warrant liability	261	(97)	611	384
Other income (expense), net	262	(677)	2,532	(1,699)
Total other income (expense), net	1,532	(35,223)	19,642	(5,335)
LOSS BEFORE INCOME TAXES	(5,340)	(45,330)	(19,234)	(47,130)
Income tax benefit	784	346	7,407	346
NET LOSS	(4,556)	(44,984)	(11,827)	(46,784)
Net loss attributable to noncontrolling interest	74	32	118	794
NET LOSS ATTRIBUTABLE TO LINEAGE	<u>\$ (4,482)</u>	<u>\$ (44,952)</u>	<u>\$ (11,709)</u>	<u>\$ (45,990)</u>
NET (LOSS) PER COMMON SHARE: BASIC AND DILUTED	<u>\$ (0.03)</u>	<u>\$ (0.35)</u>	<u>\$ (0.08)</u>	<u>\$ (0.36)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	<u>149,794</u>	<u>126,990</u>	<u>145,533</u>	<u>126,903</u>

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200312005759/en/): <https://www.businesswire.com/news/home/20200312005759/en/>

Lineage Cell Therapeutics, Inc. IR

Ioana C. Hone
ir@lineagecell.com
(442) 287-8963

Solebury Trout IR

Gitanjali Jain Ogawa
Gogawa@troutgroup.com
(646) 378-2949

Source: Lineage Cell Therapeutics, Inc.