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Lineage Cell Therapeutics (NYSE/LCTX)

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BUY: FDA Clears IND (amendment) for OPC1 Cell Transplant for Spinal Cord Injury

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Recent news reported that the FDA has OK'd an amendment for OPC1, (allogeneic oligodendrocyte progenitor cell transplant), for the treatment of spinal cord injury (SCI). Under the amendment the company has initiated activities to open its first clinical site in the DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) study to evaluate the safety and utility of a novel spinal cord delivery device in subacute and chronic SCI patients.

Investment Highlights

Spinal Cord Injury: Initial site opening is expected to occur in the second quarter of 2024, following customary trial preparations and submission in the first quarter of a grant application to the California Institute for Regenerative Medicine (CIRM) for potential partial financial support of the DOSED clinical study. The DOSED clinical study in particular is intended to evaluate the safety and performance of a new delivery device, which is compatible with our forthcoming immediate-use formulation, and which does not require cessation of patient ventilation during administration. We believe these improvements can lead to a safer surgical procedure for surgeons and patients. This study also will mark the first time that OPC1 is administered to chronic SCI patients, and we will be collecting efficacy assessments in addition to the primary outcome measures of safety.

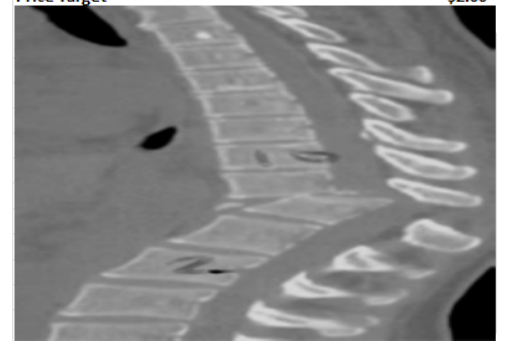
Quarter's Snapshot: Lineage spent \$7.1M in the third quarter for a net loss of \$0.03 per share. The company closed the period with \$31M in cash and another \$10M in securities or \$41M in cash and equivalents.

Why is LCTX Down? The news flow associated with RG6501 (OpRegen) has been positive, so why is the stock making new lows? Good question. It may be that investors see the fact that it is still early days for OpRegen (Phase 2 with relatively small patient numbers) combined with a year plus or minus of operating capital. The progress on OpGen has been slower than we expected, as a result, we are pushing our estimates for commercialization out to 2028. We are also assuming dilution as the company is likely to be raising capital. In terms of SCI, it is early days, and as such we do not see it as a catalyst for the stock price right now.

Valuation: We have increased our shares outstanding to reflect our assumption that the company raises capital. We push out our revenue assumptions to 2028. Our valuation for Lineage remains driven by the opportunity in Dry AMD, narrowed down further by a subset of patients with GA. We assume just a 30% probability of success in Dry AMD and SCI, which drives our \$2.00 target.

Risks to our thesis include: (1) clinical trial; (2) commercial; (3) employee; (4) financial; (5) intellectual property; (6) partnership; and (7) regulatory.

Current Price \$1.06
Price Target \$2.00



Source: Lineage

Stock Data

52-Week Range	\$0.84	-	\$1.57
Shares Outstanding (mil.)	188.5		
Market Capitalization (mil.)	\$200		
Enterprise Value (mil.)	\$180		
Debt to Capital	0%		
Book Value/Share	\$1.28		
Price/Book	2.7		
Average Three Months Trading Volume (K)	358		
Insider Ownership	0.6%		
Institutional Ownership	51.7%		
Short interest (mil.)	0.0		
Dividend / Yield	\$0.00/0.0%		

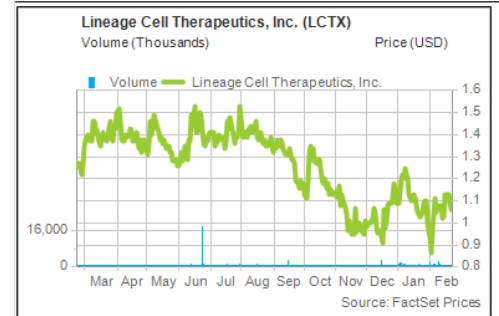


Exhibit 1. Income Statement

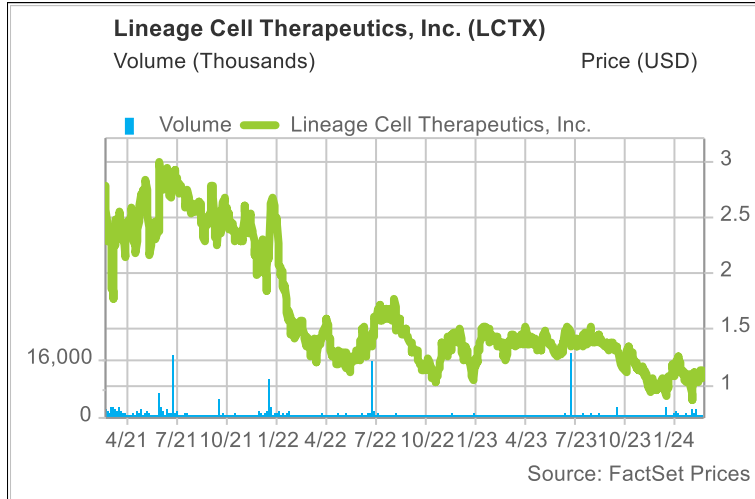
Lineage: Income Statement (\$000)															
YE December 31	2019A	2020A	2021A	2022A	1Q23A	2Q23A	3Q23A	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Spinal Cord Injury Therapy		-	-	-	-	-	-	-	-	-	-	-	-	3,230	32,619
Dry Macular Degeneration												354,414	718,814	1,485,951	2,971,902
Renevia															
Net revenue												354,414	898,517	1,489,180	3,004,521
Grant Revenues	2,037	2,057	445		-	-	-	-	-	-	-	-	-	-	-
Royalties from Product Sales and license fees	1,221	1,233	2,776	1,336	265	354	289	441	1,349	1,363	1,376	1,390	1,404	1,418	1,432
Subscription & Advertisement Revenues															
Collaboration Revenues	257	260	1,120	13,367	2,121	2,871	957	2,051	8,000	8,080	8,161	8,242	8,325	8,408	8,492
Total Revenue	3,515	3,550	4,341	14,703	2,386	3,225	1,246	2,492	9,349	9,443	9,537	364,047	908,246	1,499,007	3,014,445
Cost of Goods (sales)	(412)	(271)	(1,426)	(728)	(119)	(127)	(169)	-	(415)	-	-	(63,795)	(143,763)	(223,377)	(450,678)
					28%	28%	28%	28%	#DIV/0!	#DIV/0!	#DIV/0!	18%	16%	15%	15%
Research & Development	(17,948)	(14,358)	(33,914)	(13,987)	(4,185)	(3,873)	(3,741)	(9,182)	(20,981)	(29,373)	(29,960)	(30,559)	(31,171)	(31,794)	(32,430)
Acquired in Process Research & Development															
General & Administrative	(24,031)	(19,225)	(18,212)	(22,508)	(4,724)	(4,249)	(4,041)	(9,719)	(22,733)	(22,960)	(23,190)	(23,422)	(23,656)	(23,893)	(24,132)
Total Expenses	(41,979)	(33,583)	(53,552)	(37,223)	(9,028)	(8,249)	(7,951)	(18,901)	(44,129)	(52,333)	(53,150)	(117,776)	(198,589)	(279,064)	(507,240)
Loss from Operation	(38,876)	(30,304)	(49,211)	(22,520)	(6,642)	(5,024)	(6,705)	(16,408)	(34,779)	(42,890)	(43,613)	246,271	709,657	1,219,943	2,507,206
Interest Income (expense)	1,685			829		382									
Gain on AgeX shares and deconsolidation of AgeX	-		2				(60)								
Gain on Sale equity method in Ascendance	-		6,027												
Gain / Loss Oncocyte	2,421		(2,299)												
Loss on Equity (Asterias)	6,744		523	(2,194)											
Unrealized Gain on marketable equity securities	(2,898)		205	225		(150)									
Other Income (expenses) net	2,532		1,486			(411)									
Total other income (expense), net			-		435		(826)								
Pretax Income	19,642	(32,647)	(43,270)	(25,812)	(6,207)	(5,203)	(7,158)	(16,408)	(34,976)	(42,890)	(43,613)	246,271	709,657	1,219,943	2,507,206
Tax Benefit	(19,234)			(541)	1,803										
Net loss attributable to non-controlling interest	118	49	251	80	32	(26)	48		54	-	-	-	-	-	-
Taxes	7										(4,361)		177,414	426,980	1,002,882
Tax Rate											0%	0%	25%	35%	40%
GAAP Net Income (Loss)	(11,709)	(32,420)	(43,019)	(26,353)	(4,372)	(5,229)	(7,110)	(16,408)	(33,119)	(42,890)	(39,252)	246,271	532,242	792,963	1,504,323
			8												
Total comprehensive loss	(11,709)	(32,420)	(43,269)	(25,685)	(4,372)	(5,229)	(7,110)	(16,408)	(33,119)	(42,890)	(39,252)	246,271	532,242	792,963	1,504,323
GAAP-EPS	(0.08)	(0.22)	(0.26)	(0.15)	(0.03)	(0.03)	(0.04)	(0.09)	(0.19)	(0.24)	(0.22)	1.39	3.00	4.45	8.40
GAAP-EPS (Dil)	(0.08)	(0.19)	(0.23)	(0.14)	(0.01)	(0.01)	(0.01)	(0.01)	(0.04)	0.08	0.32	0.60	0.87	1.12	1.12
Wgtd Avg Shrs (Bas)	145,533	150,268	164,502	169,792	170,127	170,592	174,868	175,043	172,657	175,481	176,184	176,890	177,598	178,310	179,024
Wgtd Avg Shrs (Dil)	145,533	170,114	276,477	292,629	293,361	293,655	293,948	294,242	293,802	294,979	296,160	297,347	298,538	299,734	300,935

Source: Dawson James estimates, company reports

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Updated – March 9, 2021 – Price Target \$6.00
- Updated – March 23, 2021 – Price Target \$6.00
- Updated – May 3, 2021 – Price Target \$6.00
- Updated – June 2, 2021 – Price Target \$6.00
- Updated – June 25, 2021 – Price Target \$6.00
- Updated – July 20, 2021 – Price Target \$6.00
- Updated – November 30, 2021 – Price Target \$6.00
- Updated – December 20, 2021 – Price Target \$6.00
- Updated – March 7, 2022 – Price Target \$6.00
- Updated – March 11, 2022 – Price Target \$6.00
- Updated – May 3, 2022 – Price Target \$6.00
- Updated – June 2, 2022 – Price Target \$6.00
- Updated – August 19, 2022 – Price Target \$6.00
- Updated – October 4, 2022 – Price Target \$6.00
- Updated – November 21, 2022 – Price Target \$6.00
- Updated – December 9, 2022 – Price Target \$6.00
- Updated – February 8, 2023 – Price Target \$6.00
- Updated – February 24, 2023 – Price Target \$6.00
- Updated – March 13, 2023 – Price Target \$6.00
- Updated – April 26, 2023 – Price Target \$6.00
- Updated – July 25, 2023 – Price Target \$6.00
- Updated – September 22, 2023 – Price Target \$6.00
- Price Target Change – November 20, 2023 – Price Target \$6.00 to \$2.00
- Updated – February 22, 2024 – Price Target \$2.00

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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Current as of 20-Feb-24

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	19	55.88%	4	11.80%
Market Perform (Neutral)	15	44.12%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.70%

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