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Lineage Cell Therapeutics (NYSE/LCTX)

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BUY: Roche Kicks off a Phase 2a, multicenter, open-label, single-arm clinical study of OpRegen

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Lineage announced that its partner Genentech (Roche-RHBBY-Not Rated), has launched a Phase 2a, multicenter, open-label, single-arm clinical study of OpRegen.

Investment Highlights

The Study Details: The study is intended to optimize subretinal surgical delivery and evaluate the safety and activity of OpRegen in approximately 30, and up to 60 patients with geographic atrophy (GA) secondary to age-related macular degeneration. The primary objectives of the study are to evaluate (i) the proportion of patients with subretinal surgical delivery of OpRegen to target regions under the retina, and (ii) to evaluate the safety of subretinal surgical delivery of OpRegen as measured by the incidence and severity of procedure-related adverse events at 3 months following surgery. A key secondary objective is to evaluate the proportion of patients with qualitative improvement in retinal structure, as determined by Optical Coherence Tomography (SD-OCT) imaging, within three months following surgery.

OpRegen: As we can see from this news (above), Lineage continues to execute the collaboration with Roche across multiple functional areas, including this P2a study. In addition, the partnership is working on OpRegen's manufacturing – manufacturing runs and supporting Chemistry Manufacturing and Controls (CMC) activities and technology transfer. Actively participating in both Joint Advisory and Joint Manufacturing Committees, forums for discussion and planning with respect to next steps in clinical development and related activities. Continuing long-term follow-up of patients from the Phase 1/2a clinical study of OpRegen: Enrolled patients have continued to do well, supporting multi-year durability of a treatment effect.

The Roche Partnership: Roche? The terms: An \$50 million upfront payment with Lineage eligible to receive up to \$620 million in additional development, approval, and sales milestones, as well as double-digit royalties. Genentech has assumed responsibility for the clinical development and commercialization of the OpRegen program.

Valuation: Our valuation for Lineage is principally 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 \$6.00 target.

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


 Source: Lineage
OPC1 Transplant Procedure

Current Price			
Current Price			\$1.25
Price Target			\$6.00
Stock Data			
52-Week Range	\$1.02	-	\$2.71
Shares Outstanding (mil.)			170.0
Market Capitalization (mil.)			\$212
Enterprise Value (mil.)			\$193
Debt to Capital			0%
Book Value/Share			\$1.28
Price/Book			4.5
Average Three Months Trading Volume (K)			192
Insider Ownership			0.6%
Institutional Ownership			45.4%
Short interest (mil.)			0.0
Dividend / Yield			\$0.00/0.0%

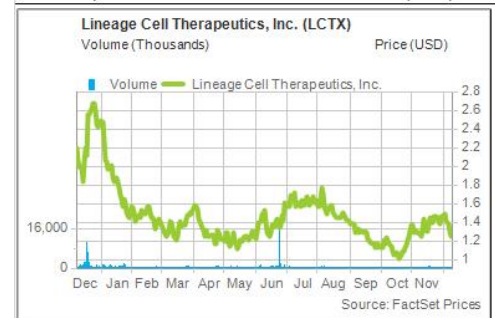


Exhibit 1. Income Statement

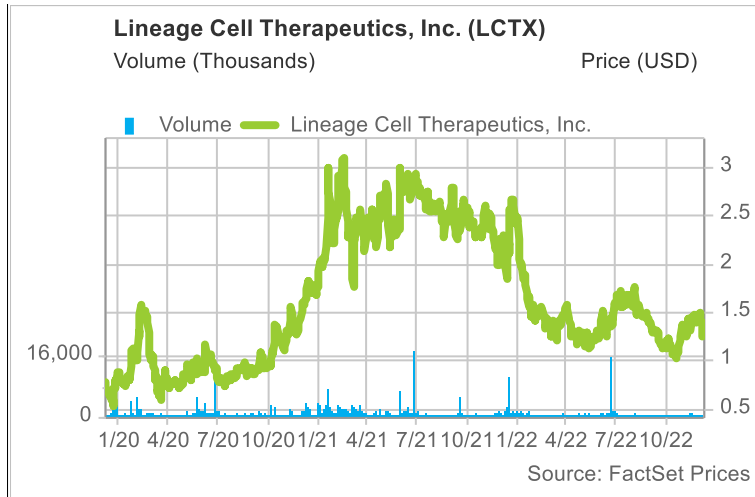
Lineage: Income Statement (\$000)															
YE December 31	2019A	2020A	2021A	1Q22A	2Q22A	3Q22A	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Spinal Cord Injury Therapy		-	-	-	-	-	-	-	-	-	-	-	-	3,230	32,619
Dry Macular Degeneration												354,414	718,814	1,485,951	2,971,902
Renevia															
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	372	405	406	217	1,400	1,414	1,428	1,442	1,457	1,471	1,486	1,501
Subscription & Advertisement Revenues	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Collaboration Revenues	257	260	1,120	4,865	4,148	2,592	2,500	14,105	8,000	8,080	8,161	8,242	8,325	8,408	8,492
Total Revenue	3,515	3,550	4,341	5,237	4,553	2,998	2,717	15,505	9,414	9,508	9,603	364,113	908,313	1,499,075	3,014,514
Cost of Goods (sales)	(412)	(271)	(1,426)	(176)	(215)	(235)	(200)	(826)	-	-	-	(63,795)	(143,763)	(223,377)	(450,678)
				29%	29%	29%	29%		#DIV/0!	#DIV/0!	#DIV/0!	18%	16%	15%	15%
Research & Development	(17,948)	(14,358)	(33,914)	(2,988)	(3,302)	(3,592)	(3,500)	(13,382)	(20,073)	(28,102)	(28,664)	(29,238)	(29,822)	(30,419)	(31,027)
Acquired in Process Research & Development															
General & Administrative	(24,031)	(19,225)	(18,212)	(8,469)	(5,270)	(4,422)	(4,400)	(22,561)	(22,787)	(23,014)	(23,245)	(23,477)	(23,712)	(23,949)	(24,188)
Total Expenses	(41,979)	(33,583)	(53,552)	(11,633)	(8,787)	(8,249)	(8,100)	(36,769)	(42,860)	(51,117)	(51,909)	(116,509)	(197,297)	(277,745)	(505,894)
Loss from Operation	(38,876)	(30,304)	(49,211)	(6,396)	(4,234)	(5,251)	(5,383)	(21,264)	(33,446)	(41,609)	(42,306)	247,604	711,016	1,221,330	2,508,620
Interest Income (expense)	1,685														
Gain on AgeX shares and deconsolidation of AgeX	-		2	1	51	384									
Gain on Sale equity method in Ascendance	-		6,027	(735)	(709)	(233)									
Gain / Loss Oncocyte	2,421		(2,299)	221	2										
Loss on Equity (Asterias)	6,744		523	(184)	(1,892)	(475)									
Unrealized Gain on marketable equity securities	(2,898)		205												
Other Income (expenses) net	2,532		1,486												
Total other income (expense), net															
Pretax Income	19,642	(32,647)	(43,270)	(7,093)	(6,782)	(5,575)	(5,383)	(24,833)	(33,446)	(41,609)	(42,306)	247,604	711,016	1,221,330	2,508,620
Tax Benefit	(19,234)					47									
Net loss attributable to non-controlling interest	118	49	251	6	19	(541)		(516)	-	-	-	-	-	-	-
Taxes	7										(4,231)		177,754	427,465	1,003,448
Tax Rate											0%	0%	25%	35%	40%
GAAP Net Income (Loss)	(11,709)	(32,420)	(43,019)	(7,087)	(6,763)	(6,069)	(5,383)	(25,302)	(33,446)	(41,609)	(38,075)	247,604	533,262	793,864	1,505,172
			8												
Total comprehensive loss	(11,709)	(32,420)	(43,269)	(7,087)	(6,763)	(6,069)	(5,383)	(25,302)	(33,446)	(41,609)	(38,075)	247,604	533,262	793,864	1,505,172
GAAP-EPS	(0.08)	(0.22)	(0.26)	(0.04)	(0.04)	(0.04)	(0.03)	(0.15)	(0.20)	(0.24)	(0.22)	1.44	3.08	4.57	8.62
GAAP-EPS (Dil)	(0.08)	(0.19)	(0.23)	(0.02)	(0.02)	(0.04)	(0.05)	(0.14)	(0.04)	0.08	0.32	0.60	0.87	1.12	1.12
Wgtd Avg Shrs (Bas)	145,533	150,268	164,502	169,647	169,731	169,786	169,956	169,780	170,381	171,064	171,749	172,437	173,128	173,821	174,518
Wgtd Avg Shrs (Dil)	145,533	170,114	276,477	292,191	292,483	292,775	293,068	292,629	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:

- Initiated – Buy – February 7, 2019 – Price Target \$6.00
- Updated – May 28, 2019 – Price Target \$6.00
- Updated – August 12, 2019 – Price Target \$6.00
- Updated – September 19, 2019 – Price Target \$6.00
- Updated – October 15, 2019 – Price Target \$6.00
- Updated – January 9, 2020 – Price Target \$6.00
- Updated – November 6, 2020 – Price Target \$6.00
- 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

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Current as of 7-Dec-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	77%	2	9%
Market Perform (Neutral)	6	20%	0	0%
Market Underperform (Sell)	1	3%	0	0%
Total	30	100%	2	7%

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