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Toll-Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Lineage Cell Therapeutics (NYSE/LCTX)

March 23, 2021

BUY: Positive Data on OpRegen for Dry AMD

Lineage announced additional data for OpRegen in Dry AMD – 75% of all Cohort 4 patients experienced improvements in vision (BCVA increases).

Jason H. Kolbert
 Head of Healthcare Research
 646-465-6891
 jkolbert@dawsonjames.com

Investment Highlights

Lineage announced new positive interim results from its ongoing, n=24 patient Phase 1/2a clinical study of OpRegen in Dry AMD. OpRegen is an investigational cell therapy consisting of allogeneic retinal pigment epithelium (RPE) cells administered to the subretinal space for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA). Additional interim data were collected on all 24 patients enrolled in the study, including the 12 patients treated in Cohort 4, which feature less advanced disease, better baseline visual acuity, and smaller areas of GA.

What's the Data? 9/12 (75%) of the Cohort 4 patients' treated eyes were at or above baseline visual acuity at their last assessment, based on per protocol scheduled visits ranging from 3 months to >2 years post-transplant. Improvements in best corrected visual acuity (BCVA) reached up to +19 letters on an EDTRS chart. Among the newly reported data, three (50%) of the more recently treated Cohort 4 patients have exhibited marked improvements in BCVA ranging from +7 to +16 letters at their last scheduled assessments of at least 4.5 months. Two additional Cohort 4 patients remained within 2 letters of their baseline values (one each above and below). One patient measured 7 letters below baseline.

Previously reported structural improvements in the retina and decreases in drusen density have continued with evidence of durable engraftment of OpRegen cells in some treated patients now extending to more than 5 years in the earliest treated patients. A trend towards slower GA progression in treated compared to fellow eyes also continued, although significant changes in GA growth over a 3-month period following treatment are not expected. Overall, OpRegen has been well tolerated with no unexpected adverse events or serious adverse events. *Source: Lineage press release.*

OPC1 for spinal cord injury. This is an oligodendrocyte progenitor cell population derived from pluripotent stem cells. Thus far, the therapy has shown a good safety profile, evidence of durable cell engraftment, and promising motor recovery in the Phase 1/2 trial. Management intends to meet with the FDA to discuss the clinical path forward.

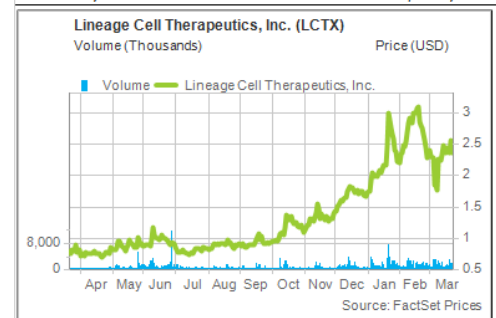
Valuation: Our valuation for Lineage is principally driven by the opportunity in Dry-AMD, narrowed down further by a sub-set of patients with GA. Our model does include modest revenues from the SCI product and from Renevia, but as previously stated, the majority of the valuation is driven by OpRegen. We assume just a 30% probability of success in Dry-AMD and SCI, which drives our \$6.00 target.

Current Price	\$2.37
Price Target	\$6.00

Estimates	F2018A	F2019A	F2020E
Revenues (\$000s)	\$ 4,908	\$ 3,515	\$ 3,550
1Q March	\$ 701	\$ 928	\$ 514
2Q June	\$ 2,547	\$ 779	\$ 386
3Q September	\$ 982	\$ 567	\$ 571
4Q December	\$ 678	\$ 1,241	\$ 2,079
	F2018A	F2019A	F2020E
EPS (diluted)	\$ (0.44)	\$ (0.08)	\$ (0.19)
1Q March	\$ (0.51)	\$ (0.30)	\$ (0.06)
2Q June	\$ (0.04)	\$ (0.20)	\$ (0.04)
3Q September	\$ 0.53	\$ (0.11)	\$ (0.05)
4Q December	\$ (0.41)	\$ 0.53	\$ (0.04)

EBITDA/Share	\$0.00	(\$0.23)	(\$0.18)
EV/EBITDA (x)	-	1,592	2,042

Stock Data	
52-Week Range	\$0.70 - \$3.13
Shares Outstanding (mil.)	161.6
Market Capitalization (mil.)	\$383
Enterprise Value (mil.)	\$364
Debt to Capital	0%
Book Value/Share	\$1.28
Price/Book	2.8
Average Three Months Trading Volume (K)	771
Insider Ownership	0.6%
Institutional Ownership	41.9%
Short interest (mil.)	0.0
Dividend / Yield	\$0.00/0.0%



Modeling Assumptions:

1. OpRegen: We assume a 30% probability of success for OpRegen in Dry-Age related Macular degeneration. We model the market as targeting patients with geographic atrophy (25% of the dry-AMD market). Additionally, we assume 75% of the market has access (insurance and represent otherwise viable candidates). We assume two doses of therapy (each eye) with a price of just \$7,500 per unit. We assume the product, based on an abbreviated Phase 2/3 study, could reach the market by 2023. Our model is U.S. based. The opportunity in Europe is equal to, or greater than, the U.S. opportunity. Europe is excluded for conservatism.
2. OPC1: We assume a 30% probability of success for OPC1 in Spinal Cord Injury (SCI) and a \$100k price. While the SCI market is estimated in the U.S. to be close to 15,000 injuries a year, we narrow the market to C4-C7 injuries, ASIA-A through C, for 6,000 annually. We assume the product, based on an abbreviated Phase 2/3 study, could reach the market by 2023. We assign a 30% probability of success to our therapeutic model for OPC1 in spinal cord injury in the U.S.
3. We have not included any other product values in our model for Lineage. This includes VAC2 currently in development by Asterias for non-small cell lung cancer. VAC2 is an allogenic dendritic cell designed to stimulate an immune response to an antigen present in 85%-plus of cancers.

Exhibit 1. Geographic Dry-AMD market model.

Age-Related Macular Degeneration	2016A	2017A	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Prevalence of AMD	30,000,000	31,600,000	33,200,000	34,800,000	36,400,000	38,000,000	39,600,000	41,200,000	42,800,000	44,400,000	46,000,000	47,600,000	49,200,000	49,200,000
Growth Rate	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000	1,600,000
25% of Patients diagnosed with specific geographic atrophy	7,500,000	7,900,000	8,300,000	8,700,000	9,100,000	9,500,000	9,900,000	10,300,000	10,700,000	11,100,000	11,500,000	11,900,000	12,300,000	12,300,000
75% Patients eligibility, with insurance who have access	5,625,000	5,925,000	6,225,000	6,525,000	6,825,000	7,125,000	7,425,000	7,725,000	8,025,000	8,325,000	8,625,000	8,925,000	9,225,000	9,225,000
Market Share	0%	0%	0%	0%	0%	0%	0%	2%	3%	4%	5%	6%	7%	8%
Total Patients for therapy	-	-	-	-	-	-	-	154,500	240,750	333,000	431,250	535,500	645,750	738,000
cost of therapy	-	-	-	-	-	7,500	7,425	7,277	7,131	6,988	6,849	6,712	6,712	6,712
change in cost of therapy	1.00%	1.0%	1.0%	1.0%	1.0%	-1.0%	-1.0%	-2.0%	-2.0%	-2.0%	-2.0%	-2.0%	0.0%	0.0%
number of treatments per patient	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total Revenues (millions)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 675	\$ 1,030	\$ 1,396	\$ 1,772	\$ 2,156	\$ 2,600	\$ 2,972

Source: Dawson James estimates, company reports

Exhibit 2. OPC1 SCI market model.

Spinal Paralysis (OPC1)	2016A	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Acute spinal cord injury (C4-C7 ASIA A-C)	6,000	6,060	6,121	6,182	6,244	6,306	6,369	6,433	6,497	6,562	6,628	6,694	6,761	6,829
Growth Rate of incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Market Share (%): SCI Patients	0%	0%	0%	0%	0%	0%	2%	4%	6%	10%	15%	30%	40%	40%
Target Patient Population	0	0	0	0	0	6,306	6,369	6,433	6,497	6,562	6,628	6,694	6,761	6,829
Patients who have access, insurance-75%	0	0	0	0	0	4,730	4,777	4,825	4,873	4,922	4,971	5,021	5,071	5,121
Unit Cost of Therapy	-	-	-	-	\$	100,000	\$ 100,000	\$ 101,000	\$ 102,010	\$ 103,030	\$ 104,060	\$ 105,101	\$ 106,152	\$ 106,152
Change in Cost of Therapy	1%	1%	1%	1%	1%	0%	0%	1%	1%	1%	1%	1%	1%	1%
Treated Patients	-	-	-	-	-	-	96	193	292	492	746	1,506	2,028	2,049
Number of Units per Patient	1	1	1	1	1	1	1	2	2	2	2	2	2	2
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total Revenues (Millions)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3	\$ 12	\$ 18	\$ 30	\$ 47	\$ 95	\$ 129	\$ 130

Source: Dawson James estimates, company reports

Valuation. It is difficult to predict probabilities of success from phase 1/2a data. As such, we use a low probability of success for OpRegen and OPC1 of just 30%. We model OpRegen in dry macular degeneration with geographic atrophy, as well as OPC1 in SCI, although the real driver is dry-AMD as a result of the large market size. We do not model any revenues from these programs until 2022. Our models also factor in funding (dilution) using a 2029 share count of 300M shares versus the last reported share count of ~150M.

We triangulate FCF, discounted EPS, and sum-of-the-parts models and select a 30% discount rate across these three models. The 30% discount is based on the early nature of the company's products. For companies with high visibility and positive cash flow we typically use a discount rate of 10%; for companies with products generating revenues, approaching cash flow break even or better, we typically use a 15% discount rate. We then average and equally weight each model, rounded to the nearest whole number, to derive a net present value, which is where we set our target price. Investors should recognize that this modeling exercise, which is projected eight years forward, is based on the current (limited) data and estimates. As such, our ability to predict a 12-month target is strained. The price of the stock is likely to be driven in the near term by factors such as news flow, early trial data, and cyclic concerns of financings (dilution). One possible catalyst may be the approval of Renevia in Europe, which could lead to an out-license deal that could bring in additional capital to the company.

Exhibit 3. Free Cash Flow Model (\$)

Average	6.0
Price Target	8.8
Year	2021

DCF Valuation Using FCF (mln):

Units ('000)	2018A	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
EBIT	(47,130)	19,642	(32,647)	(45,665)	(82,592)	399,281	679,084	975,932	1,381,424	2,232,682	2,207,257	2,522,568
Tax Rate	0%	0%	0%	0%	0%	0%	0%	10%	15%	20%	25%	28%
EBIT (1-t)	(47,130)	19,642	(32,647)	(45,665)	(82,592)	399,281	679,084	878,339	1,174,210	1,786,146	1,655,443	1,816,242
CapEx	(9,704)	-	-	-	-	-	-	-	-	-	-	-
Depreciation	(794)	(118)	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(57,628)	19,524	(32,647)	(45,665)	(82,592)	399,281	679,084	878,339	1,174,210	1,786,146	1,655,443	1,816,242
PV of FCF	(97,391)	32,996	(42,441)	(45,665)	(63,532)	236,261	309,096	307,531	316,249	370,047	263,822	222,652
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	6,325,532											
Terminal Value YE2027	775,444											
NPV	2,649,463											
NPV-Debt	-											
Shares out ('000)	300,935	2029E										
NPV Per Share	8.8											

Source: Dawson James estimates

Exhibit 4. Discounted-EPS Model (\$)

Current Year	2021
Year of EPS	2029
Earnings Multiple	5
Discount Factor	30%
Selected Year EPS	9.67
NPV	5.9

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		5%	10%	15%	20%	25%	30%
Earnings Multiple	2	13.09	9.02	6.32	4.50	3.25	2.37
	5	32.73	22.56	15.81	11.25	8.11	5.93
	10	65.46	45.12	31.62	22.49	16.23	11.86
	15	98.19	67.68	47.42	33.74	24.34	17.78
	20	130.92	90.24	63.23	44.99	32.45	23.71
	25	163.65	112.80	79.04	56.23	40.57	29.64
	30	196.38	135.36	94.85	67.48	48.68	35.57
	35	229.11	157.91	110.66	78.73	56.79	41.50

Source: Dawson James estimates

Exhibit 5. Sum-of-the-Parts Model.

	LT Gr	Discount Rate	Yrs to Mkt	% Success	Peak Sales (M)	NPV
Spinal Cod Paralysis	1%	30%	3	30%	\$222	\$765
NPV						\$0.17
Dry Macular Degeneration	1%	30%	3	30%	\$5,052	\$17,421
NPV						\$3.95
Renevia	1%	30%	2	50%	\$40	\$139
NPV						\$0.07
Net Margin						50%
Shares Outstanding (M) in 2029E						301
Total						\$4.2

Source: Dawson James estimates

Risk Analysis

Clinical and regulatory risk. Lineage is currently in a Phase 1/2a clinical trial in both of its pipeline products focused on spinal cord injury and macular degeneration. There is no assurance that either product will be approved for any additional indications and even if approved, will be reimbursed by insurance or successfully commercialized.

Commercial risk. The focus of the company is on successfully developing its products and eventually bringing them to the mass market. It is important to note that the market opportunity in macular degeneration is large and may take precedence over that of spinal cord injury opportunity. We can make no assurances that the company will be able to achieve a critical level of market share to become profitable in this indication and/or in additional planned indications.

Employee risk. Lineage management is new, with a new CEO and CFO. The success of the company will depend, to a great extent, upon the experience, abilities and continued services of its senior officers, sales staff, and key scientific personnel.

Financial risk. The company may need to raise capital in the marketplace relatively soon, and there can be no assurances that the company will be able to successfully raise capital and do so on favorable terms.

Intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and the company may infringe on third parties' patents.

Reimbursement and insurance payment risk. Insurance payment for products may be an additional hurdle for adoption.

Subsidiary Risk. We assume there is value in the ownership of AGEX and Oncocyte, but we are not forecasting or modeling the value of these minority-owned companies.

Exhibit 6. Income Statement.

Lineage: Income Statement (\$000)															
YE December 31	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Spinal Cord Injury Therapy		-	-	-	-	-	-	2,866	11,695	17,895	30,424	46,554	94,979	129,184	130,476
Dry Macular Degeneration								-	674,532	1,030,069	1,396,272	1,772,071	2,156,441	2,600,414	2,971,902
Renevia		-	-	-	-	-	542	1,504	12,034	17,327	23,581	27,067	27,065	27,062	26,791
Net revenue								2,866	686,226	1,047,963	1,426,697	1,818,625	2,790,530	2,729,598	3,102,378
Grant Revenues	2,037	348	287	229	1,193	2,057	2,078	2,099	2,120	2,141	2,162	2,184	2,206	2,228	2,250
Royalties from Product Sales and license fees	1,221	166	99	342	626	1,233	1,246	1,258	1,271	1,283	1,296	1,309	1,322	1,335	1,349
Subscription & Advertisement Revenues	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sales of Research Products & Services	257	-	-	-	260	260	262	265	267	270	273	276	278	281	284
Total Revenue	3,515	514	386	571	2,079	3,550	3,586	6,488	689,884	1,051,658	1,430,428	1,822,393	2,794,336	2,733,442	3,106,260
Cost of Goods (sales)	(412)	(94)	(75)	(102)	-	(271)	-	(831)	(192,143)	(261,991)	(342,407)	(327,352)	(446,485)	(409,440)	(465,357)
Research & Development	(17,948)	(3,339)	(2,805)	(3,566)	(4,648)	(14,358)	(14,646)	(19,039)	(28,559)	(39,982)	(40,782)	(41,598)	(42,430)	(43,278)	(44,144)
Acquired in Process Research & Development															
General & Administrative	(24,031)	(4,519)	(3,908)	(3,628)	(7,170)	(19,225)	(34,605)	(69,209.28)	(69,901)	(70,600)	(71,306)	(72,019)	(72,740)	(73,467)	(74,202)
Total Expenses	(41,979)	(7,858)	(6,713)	(7,194)	(11,818)	(33,583)	(49,250)	(89,080)	(290,604)	(372,574)	(454,496)	(440,970)	(561,654)	(526,185)	(583,702)
Loss from Operation	(38,876)	(7,438)	(6,402)	(6,725)	(9,739)	(30,304)	(45,665)	(82,592)	399,281	679,084	975,932	1,381,424	2,232,682	2,207,257	2,522,558
Interest Income (expense)	1,685	405	380	252											
Gain on AgeX shares and deconsolidation of AgeX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gain on Sale equity method in Ascendance	-	1,258	2,470	120											
Gain / Loss Oncocyte	2,421	(1,338)	(4,146)	(2,003)											
Loss on Equity (Asterias)	6,744	35	(6)	55											
Unrealized Gain on marketable equity securities	(2,898)	(1,350)	1,174	351											
Other Income (expenses) net	2,532														
Total other income (expense), net															
Pretax Income	19,642	(8,428)	(6,530)	(7,950)	(9,739)	(32,647)	(45,665)	(82,592)	399,281	679,084	975,932	1,381,424	2,232,682	2,207,257	2,522,558
Tax Benefit	(19,234)			178											
Net loss attributable to non-controlling interest	118	29	8	12		49	-	-	-	-	-	-	-	-	-
Taxes	7										97,593	207,214	446,536	551,814	706,316
Tax Rate											10%	15%	20%	25%	28%
GAAP Net Income (Loss)	(11,709)	(8,399)	(6,522)	(7,760)	(9,739)	(32,420)	(45,665)	(82,592)	399,281	679,084	878,339	1,174,210	1,786,146	1,655,443	1,816,242
Total comprehensive loss	(11,709)	(8,399)	(6,522)	(7,760)	(9,739)	(32,420)	(45,665)	(82,592)	399,281	679,084	878,339	1,174,210	1,786,146	1,655,443	1,816,242
GAAP-EPS	(0.08)	(0.06)	(0.04)	(0.05)	(0.06)	(0.22)	(0.26)	(0.45)	2.18	3.69	4.75	6.33	9.58	8.85	9.67
GAAP-EPS (Dil)	(0.08)	(0.06)	(0.04)	(0.05)	(0.04)	(0.19)	(0.23)	(0.17)	(0.04)	0.08	0.32	0.60	0.87	1.12	1.12
Wgtd Avg Shrs (Bas)	145,533	149,807	149,821	149,973	151,473	150,268	174,374	182,595	183,327	184,061	184,799	185,539	186,282	187,028	187,778
Wgtd Avg Shrs (Dil)	145,533	149,807	149,821	149,973	230,854	170,114	276,477	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:

Asterias (AST)

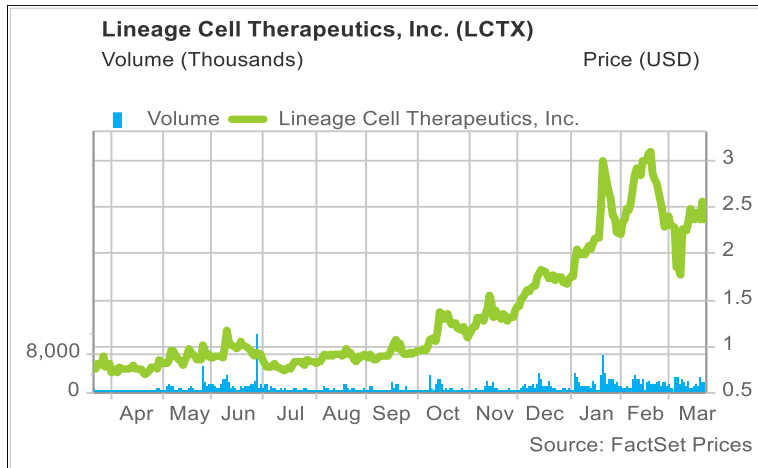
AgeX (AGX)

Oncocyte (OCS)

Juvenescence (private)

Important Disclosures:

Price Chart:



Price target and ratings 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

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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;
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The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	69%	6	30%
Market Perform (Neutral)	9	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

Analyst Certification:

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