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Pluristem Therapeutics, Inc. (NASDAQ/PSTI)
December 1, 2021
BUY: Swinging Hips - PLX-PAD Pivotal Trial Fully Enrolled-
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Pluristem announced that its multinational Phase 3 study designed to determine the efficacy, safety, and tolerability of intramuscular administration of allogeneic PLX-PAD cells for the treatment of muscle injury following arthroplasty for hip fracture, is fully enrolled with 240 patients. Topline results are expected in the third calendar quarter of 2022. The company also announced it will host a Key Opinion Leader online event on muscle regeneration following hip fracture surgery

Investment Highlights

Muscle Regeneration – Currently in a Pivotal Trial. Pluristem previously conducted a Phase 2 proof of concept study. The trial was a randomized, placebo-controlled, double-blinded study conducted at the Orthopedic Clinic of the Charité University Medical School under the auspices of the Paul-Ehrlich-Institute (PEI), Germany's health authority. The injured muscle studied was the gluteus medius muscle in the buttock. Total hip replacement surgery via the standard transgluteal approach necessitates injury of the gluteus medius muscle, and postoperative healing is crucial for joint stability and function. Twenty patients in the study were randomized into three treatment groups. Each patient received an injection in the gluteal muscle that had been traumatized during surgery. One group was treated with 150 million PLX-PAD cells per dose (n=7), the second was administered 300 million PLX-PAD cells per dose (n=6), and the third received placebo (n=7). The primary safety endpoint was met, with no serious adverse events reported at either dose level. The study showed that PLX-PAD cells were safe and well-tolerated. The primary efficacy endpoint of the study was the change in maximal voluntary isometric contraction force of the gluteal muscle at six months post-surgery. Efficacy was shown in both PLX-PAD treated patient groups, with the group receiving the 150 million cell dose displaying a statistically significant 500% improvement over the placebo group in the change of the maximal contraction force of the gluteal muscle (p=0.0067). Patients treated at the 300 million cell dose showed a 300% improvement over the placebo (p=0.18).

Valuation. We recently removed the CLI and COVID-ARDS indications from our valuation, for the moment. We assume a 50% probability of clinical success in our market models, which are projected out to 2030. Our models assume dilution and use an assumed 2030 share count. We apply a 30% discount rate and equal weight, average and round to the nearest whole number our free cash flow to the firm (FCFF), discounted EPS (dEPS), and sum-of-the-parts (SOP) models to derive our 12-month price target of \$9.00.

Risks include: (1) Commercial; (2) regulatory; (3) clinical; (4) investment; (5) financial; (6) employee; and (7) intellectual property, among others.

Current Price	\$2.71
Price Target	\$9.00
6 million total number of hip fractures worldwide by 2050	

PLX-PAD is designed to stimulate muscle regeneration - gain muscle strength and volume



Source: Pluristem

Stock Data			
52-Week Range	\$2.44	-	\$11.85
Shares Outstanding (mil.)	32.1		
Market Capitalization (mil.)	\$87		
Enterprise Value (mil.)	\$68		
Debt to Capital	0%		
Book Value/Share	\$3.12		
Price/Book	2.2		
Average Three Months Trading Volume (K)	194		
Insider Ownership	12.5%		
Institutional Ownership	15.2%		
Short interest (mil.)	1.1%		
Dividend / Yield	\$0.00/0.0%		

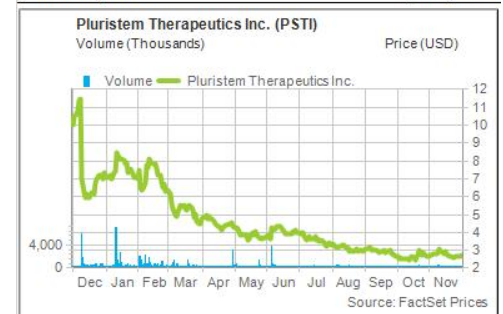


Exhibit 1. Hip Fracture Models

PLX-PAD in Muscle Regeneration (U.S.)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Population Over 45	124,666,421	125,913,085	127,172,216	128,443,938	129,728,378	131,025,661	132,335,918	133,659,277	134,995,870	136,345,829	137,709,287
Increase in population	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Hip Replacements per Year (257/100,000)	320,393	323,597	326,833	330,101	333,402	336,736	340,103	343,504	346,939	350,409	353,913
Market Penetration				0.25%	2.00%	4.00%	8.00%	10.00%	15.00%	20.00%	25.00%
Total patients treated		-	-	825	6,668	13,469	27,208	34,350	52,041	70,082	88,478
Average price per treatment		\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,600	\$ 31,212	\$ 31,836	\$ 32,473	\$ 33,122	\$ 33,785	\$ 34,461
Increase in Cost		2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Parmer revenue ('000)	\$ -	\$ -	\$ -	\$ 24,758	\$ 204,042	\$ 420,408	\$ 866,209	\$ 1,115,460	\$ 1,723,721	\$ 2,367,703	\$ 3,049,010
Royalty or profit share (50%)	\$ -	\$ -	\$ -	\$ 12,379	\$ 102,021	\$ 210,204	\$ 433,104	\$ 557,730	\$ 861,861	\$ 1,183,852	\$ 1,524,505
Risk adjustment		50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ 6,189	\$ 51,010	\$ 105,102	\$ 216,552	\$ 278,865	\$ 430,930	\$ 591,926	\$ 762,252

Source: Dawson James Estimates

PLX-PAD in Muscle Regeneration (EU)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Population Over 45	278,181,270	280,963,083	283,772,714	286,610,441	289,476,545	292,371,311	295,295,024	298,247,974	301,230,454	304,242,758	307,285,186
Increase in population	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Hip Replacements per Year (191.6/100,000)	532,995	538,325	543,709	549,146	554,637	560,183	565,785	571,443	577,158	582,929	588,758
Market Penetration				0.25%	2.00%	4.00%	8.00%	10.00%	15.00%	20.00%	25.00%
Total patients treated		-	-	1,373	11,093	22,407	45,263	57,144	86,574	116,586	147,190
Average price per treatment		\$ 20,000	\$ 20,000	\$ 20,000	\$ 20,400	\$ 20,808	\$ 21,224	\$ 21,649	\$ 22,082	\$ 22,523	\$ 22,974
Increase in Cost		2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Parmer revenue ('000)	\$ -	\$ -	\$ -	\$ 27,457	\$ 226,292	\$ 466,252	\$ 960,665	\$ 1,237,097	\$ 1,911,686	\$ 2,625,891	\$ 3,381,492
Royalty or profit share (50%)	\$ -	\$ -	\$ -	\$ 13,729	\$ 113,146	\$ 233,126	\$ 480,333	\$ 618,548	\$ 955,843	\$ 1,312,946	\$ 1,690,746
Risk adjustment		50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ 6,864	\$ 56,573	\$ 116,563	\$ 240,166	\$ 309,274	\$ 477,921	\$ 656,473	\$ 845,373

Source: Dawson James Estimates

Global Revenue ('000) \$ - \$ - \$ - \$ 13,054 \$ 107,583 \$ 221,665 \$ 456,719 \$ 588,139 \$ 908,852 \$ 1,248,399 \$ 1,607,625

Exhibit 2. Valuation Models: Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS) and Sum of the Parts (SOP)

Average	\$	9.0
Price Target	\$	10.4
Year		2021

DCF Valuation Using FCFF (mln):

units (millions - \$)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(29,095)	(30,346)	(31,559)	16,285	94,196	191,215	381,949	489,985	749,674	991,308	1,278,804
Tax Rate	0%	0%	5%	10%	15%	18%	18%	20%	20%	24%	28%
EBIT(1-t)	(29,095)	(30,346)	(29,981)	14,656	80,066	156,796	313,198	391,988	599,739	753,394	920,739
- Change in NWC											
Free Cash Flow to Firm (FCFF)	(29,095)	(30,346)	(29,981)	14,656	80,066	156,796	313,198	391,988	599,739	753,394	920,739
PV of FCFF	(37,707)	(30,346)	(23,134)	8,726	36,782	55,580	85,663	82,726	97,662	94,663	89,267
Discount Rate	30%										
Long Term Growth Rate	1%										
Terminal Cash Flow	315,244										
Terminal Value YE 2030	30,563										
NPV	490,446										
NPV-Debt	-										
Shares out (thousands)	47,219	2030									
NPV Per Share	10.4										

Source: Dawson James estimates

Current Year	2021
Year of EPS	2030
Earnings Multiple	5
Discount Factor	30%
Selected Year EPS	\$ 21.91
NPV	\$ 10.6

Source: Dawson James estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
		20%	25%	30%	35%	40%	45%
Earnings Multiple	10	\$51.65	\$34.34	\$23.20	\$15.91	\$11.06	\$ 7.78
	15	\$77.47	\$51.51	\$34.80	\$23.86	\$16.58	\$ 11.68
	20	\$103.30	\$68.68	\$46.40	\$31.81	\$22.11	\$ 15.57
	25	\$129.12	\$85.85	\$57.99	\$39.76	\$27.64	\$ 19.46
	30	\$154.95	\$103.02	\$69.59	\$47.72	\$33.17	\$ 23.35
	35	\$180.77	\$120.18	\$81.19	\$55.67	\$38.70	\$ 27.24
	40	\$206.60	\$137.35	\$92.79	\$63.62	\$44.22	\$ 31.14
	45	\$232.42	\$154.52	\$104.39	\$71.57	\$49.75	\$ 35.03

Pluristem Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	Term Val
PLX-PAD in Critical Limb Ischemia (U.S.)	1%	30%	4	0%	\$671	\$2,313
NPV						\$0.00
PLX-PAD in Critical Limb Ischemia (EU)	1%	30%	4	0%	\$658	\$2,271
NPV						\$0.00
PLX-PAD in Critical Limb Ischemia (JP)	1%	30%	6	0%	\$140	\$484
NPV						\$0.00
PLX-PAD Muscle Repair U.S.	1%	30%	3	70%	\$300	\$1,034
NPV						\$6.28
PLX-R18 BARDA Contracts for ARS	1%	30%	5	70%	\$50	\$172
NPV						\$0.62
PLX-R18 Incomplete Bone Marrow Recovery	1%	30%	5	50%	\$25	\$86
NPV						\$0.22
Net Margin						90%
MM Shrs OS						47
Total						\$7

Source: Dawson James estimates

Risk Analysis

Investment Risk: The company faces multiple investment risks. These range from product management, market share adoption, regulatory, and commercialization to the competitive environment associated risks.

Clinical and regulatory risk: Pluristem is currently in the process of completing its FDA clinical trials. There is no assurance that its product will be approved by the FDA, and that even if approved, if it 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. 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: Pluristem's core management team is experienced, including its president and CEO, CBO, and CFO. Pluristem plans to bring its proposed products to market as efficiently as possible, and the company's success will depend heavily 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 additional capital in the marketplace to continue to fund operations through more trials and, eventually, an NDA and possible commercial launch. 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.

Exhibit 1. Income Statement (2021E-2030E)

Pluristem Income Statement (\$ '000)	June 2021	June 2022	June 2023	June 2024	June 2025	June 2026	June 2027	June 2028	June 2029	June 2030
PSTI: YEAR June 30	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
PLX-PAD CLI- U.S.			-	-	-	-	-	-	-	-
PLX-PAD CLI- EU			-	-	-	-	-	-	-	-
PLX-PAD CLI- Japan			-	-	-	-	-	-	-	-
PLX-PAD Muscle Repair U.S.	-	-	6,189	51,010	105,102	216,552	278,865	430,930	591,926	762,252
PLX-PAD Muscle Repair EU	-	-	6,864	56,573	116,563	240,166	309,274	477,921	656,473	845,373
PLX-R18 BARDA Contracts for ARS	-	-	48,792	49,475	50,166	50,863	51,568	52,280	14,841	15,034
PLX-R18 Incomplete Bone Marrow Recovery	-	-	2,787	5,800	9,051	12,556	16,329	20,386	21,209	22,066
Revenues	-	-	64,633	162,859	280,882	520,137	656,036	981,518	1,284,450	1,644,726
Total Revenues (Product Sales, Grants & Milestones)	-	-	64,633	162,859	280,882	520,137	656,036	981,518	1,284,450	1,644,726
% Chg										
Expenses										
COGS	-	-	16,158	35,829	56,176	104,027	131,207	196,304	256,890	328,945
% COGS	28%	25%	25%	22%	20%	20%	20%	20%	20%	20%
R&D	22,773	23,228	23,693	24,166	24,650	25,143	25,646	26,158	26,682	27,215
R&D Adjustment (participation Chief Scientist)										
SG&A (net)	7,574	8,331	8,498	8,668	8,841	9,018	9,198	9,382	9,570	9,761
Total costs & expenses	30,346	31,559	48,348	68,663	89,667	138,188	166,051	231,844	293,141	365,922
Operating Income (Loss) EBIT	(30,346)	(31,559)	16,285	94,196	191,215	381,949	489,985	749,674	991,308	1,278,804
Oper Margin										
Other Income expenses - Financial Expenses (net)	272	272	272	272	272	272	272	272	272	272
Pre-tax income	(30,618)	(31,831)	16,013	93,924	190,943	381,678	489,713	749,402	991,037	1,278,533
Taxes	-	(1,592)	1,601	14,089	34,370	68,702	97,943	149,880	237,849	357,989
Tax Rate	0%	5%	10%	15%	18%	18%	20%	20%	24%	28%
Net Income (loss)	(30,618)	(30,239)	14,412	79,836	156,573	312,976	391,771	599,522	753,188	920,544
Net Margin										
Basic EPS	(0.86)	(0.74)	0.35	1.95	3.80	7.57	9.44	14.38	18.00	21.91
Basic Wght Average Shares Outstanding (thousands)	36,786	40,695	40,858	41,022	41,186	41,351	41,517	41,683	41,850	42,018
Fully Diluted Wgtd Avg Shrs outstanding (Thousands)	41,804	45,733	45,916	46,100	46,284	46,470	46,656	46,843	47,030	47,219

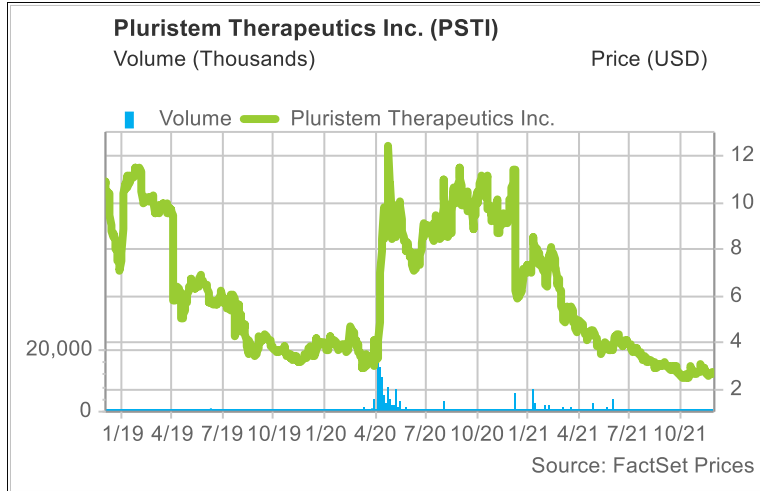
Source: Dawson James estimates

Peer Companies to Pluristem

Athersys (ATHX-Buy Rated)
 Mesoblast (MESO-Buy Rated)
 Brainstorm (BCLI-Neutral Rated)
 Lineage (LCTX-Buy Rated)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – December 16, 2019 – Price Target \$12.00
- Update – Buy – February 10, 2020 – Price Target \$12.00
- Update – Buy – March 4, 2020 – Price Target \$12.00
- Update – Buy – March 12, 2020 – Price Target \$12.00
- Update – Buy – March 18, 2020 – Price Target \$12.00
- Update – Buy – March 30, 2020 – Price Target \$12.00
- Update – Buy – April 7, 2020 – Price Target \$12.00
- Update – Buy – April 14, 2020 – Price Target \$12.00
- Update – Buy – April 24, 2020 – Price Target \$12.00
- Update – Buy – May 8, 2020 – Price Target \$12.00
- Update – Buy – May 14, 2020 – Price Target \$12.00
- Update – Buy – June 10, 2020 – Price Target \$12.00
- Update – Buy – August 10, 2020 – Price Target \$12.00
- Update – Buy – August 27, 2020 – Price Target \$12.00
- Update – Buy – September 15, 2020 – Price Target \$12.00
- Update – Buy – October 7, 2020 – Price Target \$12.00
- Update – Buy – December 9, 2020 – Price Target \$9.00
- Update – Buy – May 4, 2021 – Price Target \$9.00
- Update – Buy – July 8, 2021 – Price Target \$9.00
- Update – Buy – December 1, 2021 – Price Target \$9.00

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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 table 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.

Current as of... 15-Nov-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	5	20%
Market Perform (Neutral)	11	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	5	14%

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