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Pluristem Therapeutics, Inc. (NASDAQ/PSTI)

December 9, 2020

BUY: CLI Study is Halted as Low Event Rate in Control Diminutive to the Study's Power

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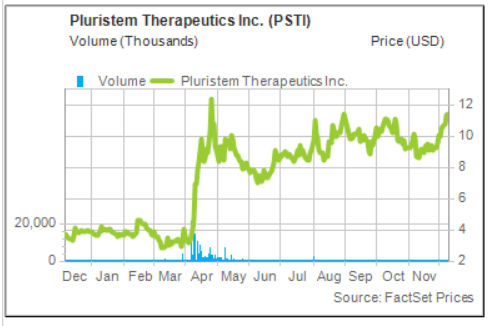
Pluristem announced that the data monitoring committee (DMC) concluded that the Critical Limb Ischemia (CLI) study is unlikely to meet the primary endpoint by the time of the final analysis. The DMC advised the Company that the CLI study population has experienced a substantial low number of events (major amputation of the index leg or death), different from what is known in clinical medicine for the rate of these events in this patient population. The lower than anticipated event rate in the placebo group reduced the statistical power of the study to meet its primary endpoint. We have always assumed a low probability of success for this trial as the control group in CLI has always been impossible to predict across small numbers and the effect size of the active is moderate. We remove CLI from our model, which lowers our target valuation from $12.00 to $9.00.

Current Price	**$6.38**
Price Target	**$9.00**

Estimates	F2020E	F2021E	F2022E
Expenses ($000s)	$ 29,095	$ 30,346	$ 31,559
1Q March	$ 7,195	$ 6,980	$ 7,259
2Q June	$ 7,300	$ 7,283	$ 7,574
3Q September	$ 7,300	$ 7,890	$ 8,122
4Q December	$ 7,300	$ 8,193	$ 8,604
	F2020E	F2021E	F2022E
EPS (diluted)	$ (1.52)	$ (0.86)	$ (0.74)
1Q March	$ (0.46)	$ (0.28)	$ (0.17)
2Q June	$ (0.48)	$ (0.18)	$ (0.18)
3Q September	$ (0.29)	$ (0.20)	$ (0.19)
4Q December	$ (0.29)	$ (0.20)	$ (0.20)
EBITDA/Share	($1.43)	($0.83)	($0.78)
EV/EBITDA (x)	-4.9	-4.7	-4.5
Stock Data			
52-Week Range	$2.82	-	$13.29
Shares Outstanding (mil.)			25.5
Market Capitalization (mil.)			$163
Enterprise Value (mil.)			$144
Debt to Capital			0%
Book Value/Share			$3.12
Price/Book			4.3
Average Three Months Trading Volume (K)			1,334
Insider Ownership			19.3%
Institutional Ownership			10.1%
Short interest (mil.)			5.0%
Dividend / Yield			$0.00/0.0%



Investment Highlights

CLI is Out. Focus Shifts to Muscle Regeneration, Hematopoietic Recovery and ARDS (related to COVID). We note that Pluristem, along with Athersys (ATHX-Buy Rated) and Mesoblast (MESO-Buy Rated), are all in late stage trials for COVID related ARDS. We have not factored into our model success with this program.

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 have removed CLI and omit COVID-ARDS, 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.

Muscle Repair (Hip Fracture) Model Assumptions:

1. We model commercial launch in both the US and EU in FY23.
2. We assume the addressable patient population includes all total hip replacement patients.
3. We assume that the product will enter the market at $30K in the US and $20K in the EU with a 2% annual price increase.
4. We apply a 50% risk cut to account for the stage of development and the same percentage for a profit share with a marketing partner.

Exhibit 1. U.S. (top) and EU (below) Markets for PLX-PAD in the Treatment of Hip Fracture

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%
Parnter 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%
Parnter 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

Hematopoietic Recovery. Pluristem has a Phase 1 open-label trial of PLX-R18 to treat incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT). The phase 1 study is evaluating 24 patients. The trial is a multi-center, open-label, dose-escalating study to evaluate the safety of intramuscular injections of PLX-R18 cells in subjects with incomplete hematopoietic recovery following hematopoietic cell transplantation or HCT. Patients have to have incomplete hematopoietic recovery persistent for six months or more after HCT. There are three cohorts: 1. Three subjects, receiving two administrations of 1M PLX-R18 cells/kg each, separated by a one-week interval; 2. Twelve subjects receiving two administrations of 2M cells/kg each, separated by a one-week interval; and 3) Fifteen subjects receiving two administrations of 4M cells/kg each, separated by a one-week interval. The follow-up period will be twelve months. The primary endpoints are safety and adverse events, laboratory values, and vital signs. Exploratory endpoints include changes in platelet and hemoglobin levels, changes in transfusion frequency, a shift from transfusion dependence to transfusion independence, quality of life, and changes in the serum immunological parameters.

Hematopoietic Recovery Model Assumptions:

1. We model commercial launch in FY23 due to the early stage of development.
2. We assume that the number of Hematopoietic Cell Transplants will increase by 2% per year due to an aging population.
3. We assume that 15% of procedures result in poor graft function, which could be addressed by PLX-R18.
4. We place an entry price at $30K with a 2% annual increase.
5. We apply a 50% risk adjustment to account for the early stage of development.

Exhibit 2. U.S. Market for PLX-PAD in the Treatment of Hematopoietic Recovery

PLX-R18 in Hematopoietic Recovery (US)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Number of Hematopoietic Cell Transplants	23,347	23,814	24,290	24,776	25,271	25,777	26,292	26,818	27,354	27,901	28,459
Increase in Number of Procedures	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Poor Graft Function (15%)	3,502	3,572	3,643	3,716	3,791	3,866	3,944	4,023	4,103	4,185	4,269
Market Penetration				5.00%	10.00%	15.00%	20.00%	25.00%	30.00%	30.00%	30.00%
Total patients treated				186	379	580	789	1,006	1,231	1,256	1,281
Average price per treatment				$ 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%
Revenue ('000)				$ 5,575	$ 11,599	$ 18,102	$ 25,111	$ 32,657	$ 40,772	$ 42,419	$ 44,133
Risk adjustment				50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)				**$ 2,787**	**$ 5,800**	**$ 9,051**	**$ 12,556**	**$ 16,329**	**$ 20,386**	**$ 21,209**	**$ 22,066**

Source: Dawson James Estimates

Acute Radiation Sickness (ARS). In October of 2017, Pluristem announced it had received orphan drug designation for its PLX-R18 cell therapy for the prevention and treatment of acute radiation syndrome (ARS). Pluristem has demonstrated in a pilot study in non-human primates (NHP) with ARS that PLX-R18 cells improve survival and accelerate the recovery of blood cells. More specifically, in irradiated non-human primates, treatment with 4, 10, and 20 million PLX-R18 cells/kg resulted in survival rates of 83%, 86%, and 67%, respectively, compared to only 50% in the control group. There was a trend towards enhanced neutrophil and lymphocyte recovery. In addition to enhanced survival and blood cell recovery, safety data demonstrated that the PLX-R18 cells had no effect on non-irradiated NHPs. These data suggest that individuals can be treated with PLX-R18 cells without the need to determine the degree of radiation exposure, which would save critical time in a mass-casualty disaster. Data from this study is the basis for the pivotal study to support approval using the FDA Animal Rule Regulatory pathway, where animal efficacy data and human safety data are used to demonstrate the efficacy of a drug candidate when human trials are not feasible. The ARS pilot study in NHPs is positive for Pluristem. This, combined with the orphan designation, supports the commercial potential. The study further validates our belief in allogeneic cells' potential to induce blood cell recovery to halt ARS.

Acute Radiation Syndrome Model Assumptions:

1. We model product launch in FY23.
2. We assume the product will sell to BARDA under Project Bio Shield at a heavily discounted rate vs. retail price for PLX-R18 cells.
3. We assume that BARDA will stockpile enough treatments to cover around a third of the population of a major US City, through contracted purchases.
4. We assume a contract price of $2.5K per unit.
5. We apply a 50% risk adjustment to account for the stage of development and bureaucratic uncertainty associated with government contracts.

Exhibit 3. U.S. Market for PLX-PAD in ARS

PLX-R18 in Acute Raditation Sickness	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Average size of a top 50 US city	955,637	962,326	969,062	975,846	982,677	989,555	996,482	1,003,458	1,010,482	1,017,555	1,024,678
Population growth	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%
Population Coverage	0.00%	0.00%	0.00%	4.00%	8.00%	12.00%	16.00%	20.00%	24.00%	25.00%	26.00%
Units Stockpiled	-	-	-	39,034	78,614	118,747	159,437	200,692	242,516	254,389	266,416
Units Purchased in Year	-	-	-	39,034	39,580	40,133	40,691	41,254	41,824	11,873	12,028
Average price per unit	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500
Revenue ('000)	$ -	$ -	$ -	$ 97,585	$ 98,951	$ 100,331	$ 101,726	$ 103,136	$ 104,560	$ 29,683	$ 30,069
Risk adjustment	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	**$ -**	**$ -**	**$ -**	**$ 48,792**	**$ 49,475**	**$ 50,166**	**$ 50,863**	**$ 51,568**	**$ 52,280**	**$ 14,841**	**$ 15,034**

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 their 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 their 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 their proposed products to market as efficiently as possible, and their 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 4. Income Statement

Pluristem Income Statement ($ '000)	June 2020	June 2021	June 2022	June 2023	June 2024	June 2025	June 2026	June 2027	June 2028	June 2029	June 2030
PSTI: YEAR June 30	**2020E**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
PLX-PAD CLI- U.S.				31,778	65,281	100,579	137,745	212,225	254,316	298,535	335,384
PLX-PAD CLI- EU				32,190	65,832	100,975	137,669	211,160	251,908	294,387	329,247
PLX-PAD CLI- Japan				-	-	7,671	15,633	31,860	40,581	49,621	70,226
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		-	-	-	-	-	-	-	-	-	-
PLX-R18 Incomplete Bone Marrow Recovery		-	-	2,787	5,800	9,051	12,556	16,329	20,386	21,209	22,066
Revenues	-	-	-	79,809	244,496	439,941	760,321	1,059,712	1,476,042	1,912,151	2,364,549
Total Revenues (Product Sales, Grants & Milestones)	-	-	-	79,809	244,496	439,941	760,321	1,059,712	1,476,042	1,912,151	2,364,549
% Chg											
Expenses											
COGS	-	-	-	19,952	53,789	87,988	152,064	211,942	295,208	382,430	472,910
% COGS	30%	28%	25%	25%	22%	20%	20%	20%	20%	20%	20%
R&D	22,326	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)	(1,794)										
SG&A (net)	7,213	7,574	8,331	8,498	8,668	8,841	9,018	9,198	9,382	9,570	9,761
Total costs & expenses	29,095	30,346	31,559	52,142	86,623	121,479	186,225	246,786	330,749	418,682	509,886
Operating Income (Loss) EBIT	(29,095)	(30,346)	(31,559)	27,667	157,873	318,462	574,096	812,926	1,145,293	1,493,469	1,854,663
Oper Margin											
Other Income expenses - Financial Expenses (net)	206	272	272	272	272	272	272	272	272	272	272
Pre-tax income	(29,189)	(30,618)	(31,831)	27,395	157,601	318,190	573,825	812,655	1,145,022	1,493,198	1,854,391
Taxes	-	-	(1,592)	2,740	23,640	57,274	103,288	162,531	229,004	358,367	519,229
Tax Rate	*0%*	*0%*	*5%*	*10%*	*15%*	*18%*	*18%*	*20%*	*20%*	*24%*	*28%*
Net Income (loss)	(29,189)	(30,618)	(30,239)	24,656	133,961	260,916	470,536	650,124	916,017	1,134,830	1,335,161
Net Margin											
Basic EPS	(1.52)	(0.86)	(0.74)	0.60	3.27	6.33	11.38	15.66	21.97	27.11	31.77
Basic Wght Average Shares Outstanding (thousands)	20,431	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)	22,932	41,804	45,733	45,916	46,100	46,284	46,470	46,656	46,843	47,030	47,219

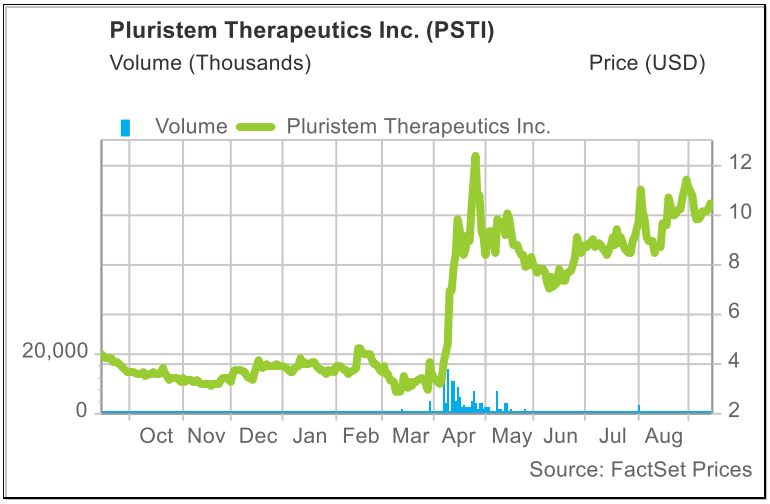
Source: Dawson James estimates 2021-2030

Peer Companies to Pluristem

Athersys (ATHX-Buy Rated)
Mesoblast (MESO-Buy Rated)
Brainstorm (BCLI-Buy 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

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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.

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.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	78%	4	19%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

Analyst Certification:

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