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

Pluristem Therapeutics, Inc. (NASDAQ/PSTI)
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BUY: Phase 1 Study Shows Promise in HCT

Jason H. Kolbert
 Head of Healthcare Research
 jkolbert@dawsonjames.com

Pluristem announced promising early data in showing PLX-R18 cells promote engraftment in Hematopoietic Cell Transplantation (HCT).

Investment Highlights

HCT Study Shows Promise: The study enrolled N=21 patients in the U.S. and Israel who were at least three months after the HCT procedure (median: 236 days) and had low blood counts in at least one blood cell lineage. They were assigned to one of three treatment arms: 1 million cells/kg, 2 million cells/kg, or 4 million cells/kg. Each patient received two treatments of the assigned dose.

What did the Data Show? The results demonstrate that PLX-R18 has the potential to stimulate the implanted hematopoietic cells to realize their therapeutic potential and generate improved blood counts over the long term in all three blood cell lineages at once – a meaningful advantage over other existing and proposed treatments.

Available data at six-month follow-up demonstrates:

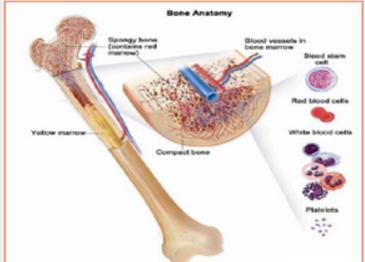
- PLX-R18 was well-tolerated with a favorable safety profile.
- Statistically significant improvement from baseline counts was observed in all cohorts for hemoglobin and platelet counts ($p < 0.05$). The patients in the high-dose arm (4 million cells/kg) exhibited statistically significant improvements in all three blood cell lineages ($p < 0.01$).
- Approximately 60% of patients exhibited improvements in all three blood cell lineages: hemoglobin, neutrophil, and platelet counts, which are above the initial criteria for inclusion in the study.
- Thirteen patients were transfusion-dependent at baseline. Six of those became transfusion independent at six-month follow-up. No patients who were transfusion independent at baseline became transfusion dependent.

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. (1) Commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these and other risks in the Risk Analysis section of this report.

Current Price	\$4.24
Price Target	\$9.00

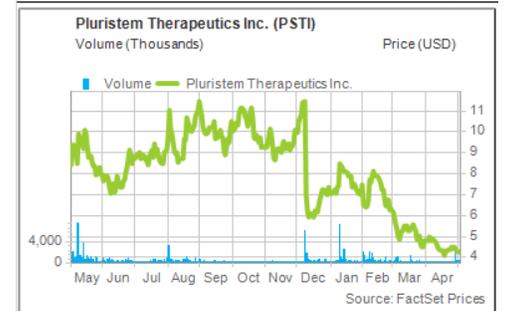
PLX-R18
 Is designed to stimulate the regeneration of damaged bone marrow to produce all blood cells lineages (white, red and platelets)



The diagram illustrates the structure of a bone, including the epiphysis and diaphysis. It shows yellow marrow in the epiphysis and red marrow in the diaphysis. Labels include: Bone Anatomy, Epiphyse, Diaphysis, Yellow marrow, Compacted bone, Blood vessels in bone marrow, Blood stem cell, Red blood cells, White blood cells, and Platelets.

Source: Pluristem

Stock Data			
52-Week Range	\$4.03	-	\$12.15
Shares Outstanding (mil.)	31.7		
Market Capitalization (mil.)	\$135		
Enterprise Value (mil.)	\$116		
Debt to Capital	0%		
Book Value/Share	\$3.12		
Price/Book	4.0		
Average Three Months Trading Volume (K)	1,466		
Insider Ownership	17.7%		
Institutional Ownership	18.4%		
Short interest (mil.)	0.6%		
Dividend / Yield	\$0.00/0.0%		



Please find Important Disclosures beginning on Page 4.

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 1. 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

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 2. Income Statement

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.			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	-	-	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	-	-	128,601	293,971	490,106	811,184	1,111,280	1,528,322	1,926,992	2,379,583
Total Revenues (Product Sales, Grants & Milestones)	-	-	128,601	293,971	490,106	811,184	1,111,280	1,528,322	1,926,992	2,379,583
% Chg										
Expenses										
COGS	-	-	32,150	64,674	98,021	162,237	222,256	305,664	385,398	475,917
% 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	64,340	97,508	131,512	196,397	257,100	341,205	421,650	512,893
Operating Income (Loss) EBIT	(30,346)	(31,559)	64,261	196,464	358,594	614,787	854,181	1,187,117	1,505,343	1,866,690
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)	63,989	196,192	358,323	614,515	853,909	1,186,846	1,505,071	1,866,418
Taxes	-	(1,592)	6,399	29,429	64,498	110,613	170,782	237,369	361,217	522,597
Tax Rate	0%	5%	10%	15%	18%	18%	20%	20%	24%	28%
Net Income (loss)	(30,618)	(30,239)	57,590	166,763	293,825	503,903	683,127	949,477	1,143,854	1,343,821
Net Margin										
Basic EPS	(0.86)	(0.74)	1.41	4.06	7.13	12.19	16.45	22.78	27.33	31.98
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

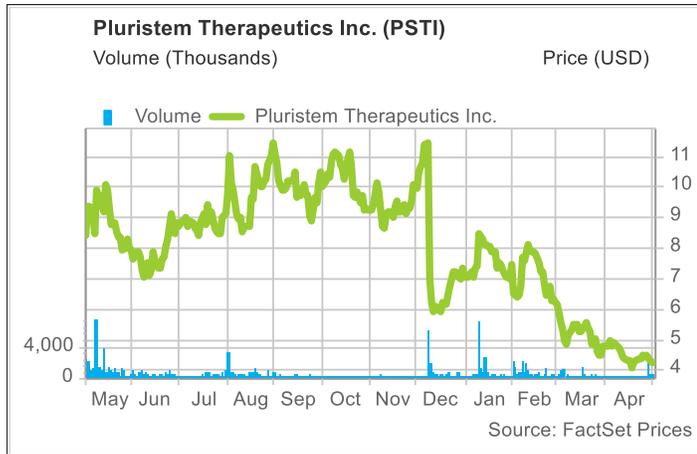
Source: Dawson James estimates

Peer Companies to Pluristem

Athersys (ATHX-Buy Rated)
 Mesoblast (MESO-Buy Rated)
 Brainstorm (BCLI-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
- Update – Buy – May 4, 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;
- 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.

As of: 27-Apr-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	68%	5	24%
Market Perform (Neutral)	10	32%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	31	100%	5	16%

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