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Pluristem Therapeutics, Inc. (NASDAQ/PSTI)

July 8, 2021

BUY: Is There a Signal in ARDS? Pluristem will Analyze the Current Data Sets (on-hand now).

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Pluristem has announced plans to analyze the current data sets in COVID-related ARDS. Recall that the company's COVID-19 program includes over 100 patients across two Phase 2 studies in the U.S., Europe, and Israel, plus data from the compassionate use and expanded access programs in the U.S. and Israel. The analysis will be based on 89 patients enrolled in these studies.

Investment Highlights

Why Announce these Plans Now? The decision comes in response to COVID-19's evolution as a disease, as well as changes in the standard of care and a decline in the most severe cases. For the same reason, the Company will not pursue plans announced in December 2020 to expand Pluristem's COVID-19 program to Mexico in collaboration with Innovare R&D. Pluristem expects to announce the topline results of the readout during the fourth quarter of 2021.

Pluristem reported in late May 2020 on the status of COVID-19 infected patients treated with PLX cells under a compassionate use program in Israel and the FDA Single Patient Expanded Access Program in the U.S. All treated patients were in Intensive Care Units (ICU), on invasive mechanical ventilation and suffered from Acute Respiratory Distress Syndrome (ARDS) at the time of treatment. As of today, a total of 18 patients were treated in Israel and in the U.S., of which 8 (1 in the U.S. and 7 in Israel) so far have completed a 28-day follow-up period.

- 87.5% survival rate of patients on invasive mechanical ventilation injected with PLX cells
- 75% of patients no longer in need of any mechanical ventilation
- 62.5% of the patients discharged alive from the hospital
- A 28-day study period is also the primary endpoint timeline for Pluristem's recently announced FDA Phase II study

Beyond COVID ARDS: As part of the clinical readout, Pluristem plans to examine the safety and efficacy of PLX cells for treating ARDS, a condition associated with a number of illnesses in addition to COVID-19 including sepsis, smoke and toxic chemical inhalation, head and chest injuries, and pancreatitis. ARDS continues to pose a significant clinical challenge that affects over 200,000 Americans annually, roughly 10 percent of Intensive Care Unit patients and 23 percent of ventilated patients worldwide.

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	\$3.51
Price Target	\$9.00

Encouraging results from Compassionate Use Programs in the U.S. & in Israel
28-day follow-up for the first 8 ventilator-dependent COVID-19 patients (Reported May 2020)



Source: Pluristem

Stock Data			
52-Week Range	\$3.50	-	\$12.15
Shares Outstanding (mil.)	31.7		
Market Capitalization (mil.)	\$111		
Enterprise Value (mil.)	\$93		
Debt to Capital	0%		
Book Value/Share	\$3.12		
Price/Book	4.0		
Average Three Months Trading Volume (K)	219		
Insider Ownership	14.5%		
Institutional Ownership	21.5%		
Short interest (mil.)	1.0%		
Dividend / Yield	\$0.00/0.0%		



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, 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.			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

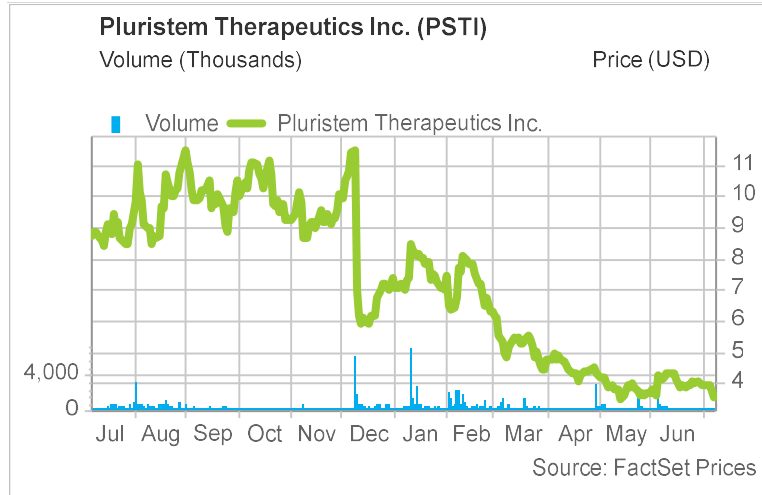
Source: Dawson James estimates

Peer Companies to Pluristem

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

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Information about valuation methods and risks can be found in the "Valuation" and "Risk Analysis" sections of this report.

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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: 30-Jun-21

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	71%	4	17%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	34	100%	4	12%

Analyst Certification:

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