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Pluristem Therapeutics, Inc. (NASDAQ/PSTI)
September 15, 2020
BUY: A Pivotal Year

Pluristem is "heading into a pivotal year with four clinical readouts expected, including an interim analysis of the Phase 3 study in Critical Limb Ischemia (CLI), top-line efficacy results of the Phase 3 study in muscle regeneration following hip fracture, top-line efficacy results of the Phase 2 study in COVID-19 and data analysis of the Phase 1 study in incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT)".

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Investment Highlights

CHINA Virus Update. Pluristem has shifted the clinical site openings from the New York area to other regions in the U.S., as the spread of the China virus changes. Expectations are that enrollment may be completed in the first quarter of calendar year 2021. Recall that in the U.S., under the Expanded Access Program, up to 100 patients suffering from severe COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS), who are not eligible for inclusion in the Phase 2 study, may be treated with PLX-PAD, and the gathered data will be evaluated alongside the Phase 2 study data. In Europe, the company is advancing the Phase 2 clinical study, which has been cleared in Germany to commence patient enrollment, and in Israel, Pluristem is treating patients under the per-patient Compassionate Use program.

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

Phase 3 CLI Study and Interim Data Analysis. In the fourth quarter of calendar 2020, the company expects to announce the interim analysis results from the global Phase 3 study of PLX-PAD in CLI.

Valuation. Our model is primarily driven by projected revenues in CLI and omits COVID-ARDS. As such, this represents upside to our valuation math. We model the remaining indications and apply a 50% partnership plus a probability of just 50% 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 \$12.00.

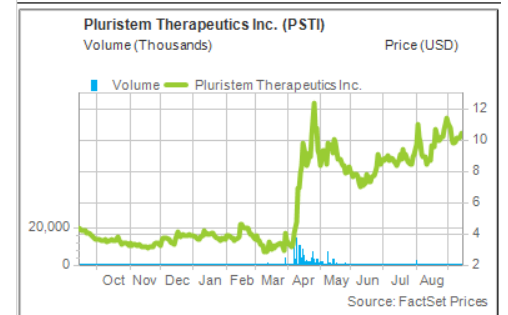
Current Price	\$10.24
Price Target	\$12.00

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)	-8.3	-7.9	-7.6

Stock Data			
52-Week Range	\$2.82	-	\$13.29
Shares Outstanding (mil.)	25.6		
Market Capitalization (mil.)	\$262		
Enterprise Value (mil.)	\$243		
Debt to Capital	0%		
Book Value/Share	\$3.12		
Price/Book	4.0		
Average Three Months Trading Volume (K)	356		
Insider Ownership	20.2%		
Institutional Ownership	10.1%		
Short interest (mil.)	4.5%		
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 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 party's 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 Wght 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

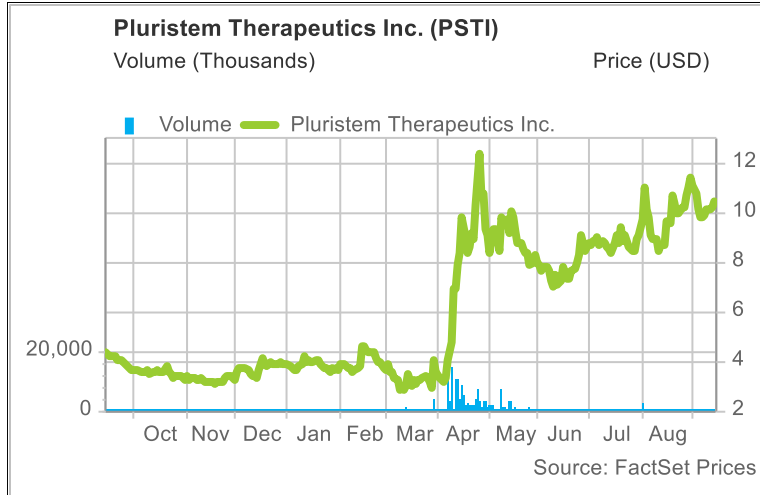
Source: Dawson James estimates

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

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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.

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	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	85%	4	17%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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