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Toll-Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 1 North Federal Highway - Suite 500 ♦ Boca Raton, FL 33432

Pluristem Therapeutics, Inc. (NASDAQ/PSTI)

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BUY: FDA Clears Pluristem to Initiate a Phase 2 Trial in COVID Virus Patients with ARDS

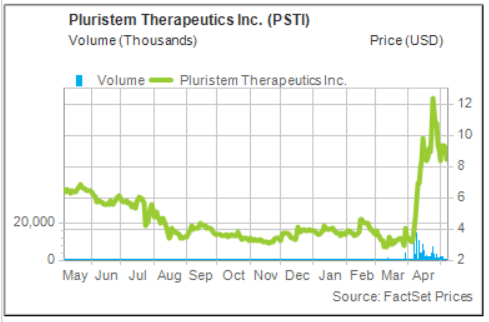
Jason H. Kolbert
Head of Healthcare Research
646-465-6891
jkolbert@dawsonjames.com

The trial is planned as a randomized, double-blind, placebo-controlled, multicenter, parallel-group Phase 2 Study to evaluate the efficacy and safety of Intramuscular Injections of PLX-PAD. The trial is planned to enroll 140 adult patients that are intubated and mechanically ventilated and are suffering from respiratory failure and ARDS. The primary efficacy endpoint of the study is the number of ventilator free days during the 28 days from day 1 through day 28 of the study.

Current Price	**$8.49**
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)	-6.6	-6.3	-6.1

Stock Data	
52-Week Range	$2.82 - $13.29
Shares Outstanding (mil.)	24.9
Market Capitalization (mil.)	$211
Enterprise Value (mil.)	$193
Debt to Capital	0%
Book Value/Share	$3.12
Price/Book	4.3
Average Three Months Trading Volume (K)	107
Insider Ownership	14.3%
Institutional Ownership	9.0%
Short interest (mil.)	6.4%
Dividend / Yield	$0.00/0.0%



Investment Highlights

Pluristem announced in late April that the first U.S. Patient was treated. The patient was treated with PLX cell therapy in the U.S. was at Holy Name Medical Center in New Jersey, an acute care facility that is currently an active site for Pluristem's Phase 3 critical limb ischemia (CLI) study. Prior to treatment with PLX, the patient was critically ill with respiratory failure due to acute respiratory distress syndrome (ARDS) and was under mechanical ventilation in an intensive care unit (ICU) for three weeks.

Seven out of Seven. Recall that last month, April 7, Pluristem announced that seven out of seven COVID ARDS patients (ICU – Ventilators) have survived, thus far. Six patients completed one week follow up; the seventh patient was treated on April 5, 2020. Four of the six (66%) patients that completed one week follow up demonstrated improvement in respiratory parameters. Three of the six, or half of the patients that completed one week follow up, are in advanced stages of weaning from ventilators. Pluristem plans to apply for initiation of a multinational **clinical trial for treatment of complications associated with COVID-19.**

Financing Update. The EU has approved a €50 million nondilutive financing for Pluristem for the development of the PLX platform, with an emphasis on clinical development of PLX cells as a treatment for complications associated with COVID-19. The approved financing will be deployed in three tranches, subject to the achievement of certain clinical, regulatory and scaling up milestones, with the first tranche consisting of €20 million.

Valuation. Our model is primarily driven by projected revenues in CLI and does not include 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-months price target of $12.00.

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 section of this report.

Preliminary data following treatment with PLX cells

- Six of the seven patients have completed the seven day follow up period ("Group A"). The seventh patient has not yet completed seven day follow up. While the treated patients are considered high risk for mortality (Pavan K. Bhatraju et al. https://www.nejm.org/doi/full/10.1056/NEJMoa2004500), the preliminary data demonstrated 100% survival rate as of today.
- Four patients (66%) out of Group A demonstrated improvement in respiratory parameters.
- Three patients (50%) out of Group A are in advanced stages of weaning from ventilators.
- One patient has shown no change in respiratory parameters, is still breathing with the assistance of a ventilator and remains relatively stable.
- One patient has shown deterioration in respiratory parameters.
- Two patients (50%) out of four in Group A with multi-organ failure prior to treatment, showed clinical recovery in addition to the respiratory improvement.

What is ARDS? Acute respiratory distress syndrome (ARDS) occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. Severe pneumonia, and the new Coronavirus too, can result in an infection in the lobes of the lungs, triggering an inflammatory cascade that causes death.

PLX Cells Appears to Impact ARDS. PLX cells are allogeneic mesenchymal-like cells that have immunomodulatory properties that induce the immune system's natural regulatory T cells and M2 macrophages, and thus may prevent or reverse the dangerous overactivation of the immune system. Accordingly, PLX cells may potentially reduce the fatal symptoms of COVID-19 induced pneumonia and pneumonitis. Previous pre-clinical findings of PLX cells revealed significant therapeutic effects in animal studies of pulmonary hypertension, lung fibrosis, acute kidney injury, and gastrointestinal injury, which are potential complications of the severe COVID-19 infection. Pluristem announced an agreement with the BIH Center for Regenerative Therapy (BCRT) and the Berlin Center for Advanced Therapies (BeCAT) at Charite' University of Medicine Berlin to expand its existing framework and research agreement and conduct a joint project evaluating the therapeutic effects of Pluristem's patented PLX cell product candidates for potential treatment of the respiratory and inflammatory complications associated with the COVID-19 coronavirus. This now represents the third regenerative medicine (Athersys – ATHX Buy rated & Mesoblast MESO-Buy Rated) firm evaluating cells for the treatment of ARDS.

Our Focus for Pluristem Remains on Critical Limb Ischemia (CLI). Pluristem is currently in a Phase 3 trial for the treatment of CLI. We could see top-line data as early as next year. Our model assumes commercialization with a partner and 50% economics in Europe by 2023, with the U.S. the following year. Given the development of expedited pathways in the cell therapy space (U.S., Europe, and Japan) and the very strong established safety profile (as well as U.S. Fast Track Designation), our assumption that a second pivotal trial is required could be conservative. **So, the key question is, will it work?**

The Critical Limb Ischemia (CLI) Trial Design is Smart. Pluristem is doing a time-to-event analysis (with the event being either major amputation or all-cause mortality) between the placebo and treatment arms using Kaplan-Meier curves. For example, if the Treatment arm has few events in the early phase of the study, whereas the Control has considerable events in the early phase, even if the two arms have similar long-term outcomes (say at one year), an advantage is assigned to the treatment because it delays the onset of the event. **This design may have a certain advantage when one understands that cell therapy, in general, does not provide immediate relief as it is based on angiogenesis (growth of microcapillaries), which takes time.** An assumption that within a short period of time (e.g., a couple of months post-treatment), there will be a significant separation of the curves is not likely. We also recognize that there may be a possible tradeoff in some of the other assumptions.

1. A premise in the design is that most events happen initially (during the first half-year of treatment) and that the typical survival curves get almost flat by the end of the first year, could be flawed. Our analysis of the literature suggests that as time goes on, advanced CLI patients with multiple co-morbidities also have high mortality rates. So although the amputation rates might flatten out, death rates keep moving forward. It's hard to know until we see the data.
2. Pluristem believes that the Treatment arm will have an early advantage over Control in event rates and that the rate will be constant throughout the three-year follow-up. The literature suggests that Rutherford (R)-5 patients have higher kidney disease, chronic heart failure, coronary artery disease, and diabetes versus R4 patients. So, the idea that salvaging the leg will significantly lower the death rate in this cohort may not be logical, particularly when we consider the average age of the patients (70's) and the nature of the co-morbidities (kidney failure, heart disease).
3. Our concerns for being optimistic relate to (a) the KM curves may not flatten out after six months; (b) the synergistic effect between limb salvage and mortality may be real, but not enough to significantly affect mortality rates in a population that is elderly with significant co-morbidities; (c) the claim that the Treatment arm will have a quick advantage over the Control, which will be maintained over a three-year period, might be overly optimistic, and; (d) it's unknown if U.S. FDA will accept anything but AFS as a primary endpoint.

Valuation: We model PLX-PAD in the treatment of critical limb ischemia and post-surgery hip fracture and PLX-R18 in Hematopoietic recovery. Our model is projected through 2030. We assume a partnership for commercialization with 50% economics. A risk adjustment is also applied to our therapeutic models. This is based on the clinical development stage and the associated risks we see. These include the complexity of the trial and the indication, and the historical precedents, to derive our 50% probability of success factor. Also, we apply a 30% discount rate to the Free Cash Flow, Discounted EPS and Sum-of-the-Parts models which are then equal-weighted and rounded to the nearest whole number to derive our 12-month price target of $12.00.

Exhibit 1. Free Cash Flow Model

Average	$	12.0
Price Target	$	13.1
Year		2020

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)	27,667	157,873	318,462	574,096	812,926	1,145,293	1,493,469	1,854,663
Tax Rate	0%	0%	5%	10%	15%	18%	18%	20%	20%	24%	28%
EBIT(1-t)	(29,095)	(30,346)	(29,981)	24,900	134,192	261,139	470,759	650,341	916,235	1,135,037	1,335,357
- Change in NWC											
Free Cash Flow to Firm (FCFF)	(29,095)	(30,346)	(29,981)	24,900	134,192	261,139	470,759	650,341	916,235	1,135,037	1,335,357
PV of FCFF	(29,095)	(23,415)	(17,850)	11,439	47,567	71,424	99,350	105,902	115,124	110,044	99,896
Discount Rate	30%										
Long Term Growth Rate	1%										
Terminal Cash Flow	352,779										
Terminal Value YE 2030	26,391										
NPV	616,777										
NPV-Debt	-										
Shares out (thousands)	47,219	2030									
NPV Per Share	13.1										

Source: Dawson James.

Exhibit 2. Discounted EPS Model

Current Year		2020
Year of EPS		2030
Earnings Multiple		5
Discount Factor		30%
Selected Year EPS	$	31.77
NPV	$	11.9

Source: Dawson James estimates

	Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS					
Earnings Multiple	20%	25%	30%	35%	40%	45%
10	$51.32	$34.12	$23.05	$15.80	$10.98	$ 7.73
15	$76.98	$51.18	$34.57	$23.70	$16.48	$ 11.60
20	$102.63	$68.23	$46.10	$31.61	$21.97	$ 15.47
25	$128.29	$85.29	$57.62	$39.51	$27.46	$ 19.33
30	$153.95	$102.35	$69.15	$47.41	$32.95	$ 23.20
35	$179.61	$119.41	$80.67	$55.31	$38.45	$ 27.07
40	$205.27	$136.47	$92.19	$63.21	$43.94	$ 30.94
45	$230.93	$153.53	$103.72	$71.11	$49.43	$ 34.80

Source: Dawson James.

Exhibit 3. Sum-of-the-Parts Model

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	50%	$671	$2,313
NPV						$4.29
PLX-PAD in Critical Limb Ischemia (EU)	1%	30%	4	50%	$658	$2,271
NPV						$4.21
PLX-PAD in Critical Limb Ischemia (JP)	1%	30%	6	50%	$140	$484
NPV						$0.53
PLX-PAD Muscle Repair U.S.	1%	30%	4	50%	$300	$1,034
NPV						$1.92
PLX-R18 BARDA Contracts for ARS	1%	30%	5	0%	$50	$172
NPV						$0.00
PLX-R18 Incomplete Bone Marrow Recovery	1%	30%	5	50%	$25	$86
NPV						$0.12
Net Margin						50%
MM Shrs OS						47
Total						$11

Source: Dawson James.

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 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

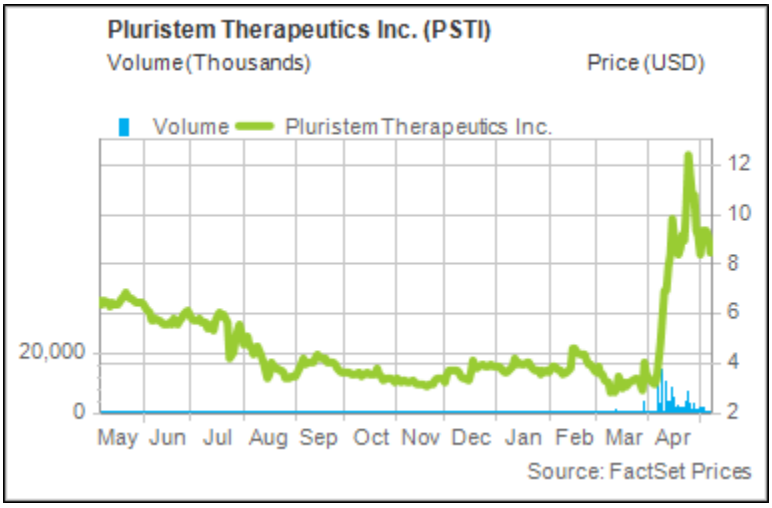
Source: Dawson James estimates.

Peer Companies to Pluristem

Athersys (ATHX-Buy Rated)
Mesoblast (MESO-Not 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

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	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	92%	3	14%
Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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