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Pluristem Therapeutics, Inc. (NASDAQ/PSTI)

December 16, 2019

BUY: Multiple Late Stage Trials – CLI, Muscle, ARS are a Few

Pluristem is a cell therapy company focused on the regenerative medicine space. Pluristem is now in two late-stage pivotal trials in Critical Limb Ischemia (CLI), and Muscle Injury (hip replacement), in our opinion these are the lead drivers for the company. Historically, CLI has been a graveyard for drug developers, as such, success becomes transformative for the company and for patients where the disease represents an unmet medical need.

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Investment Highlights

Placenta Derived Cell Therapy in Critical Limb Ischemia (CLI). We believe that Pluristem could be on the verge of success in what has been historically a very difficult indication to show efficacy, CLI. In addition, the company is working on muscle regeneration following total hip replacement surgery and hematological indications such as acute radiation syndrome (ARS) and support of bone marrow transplantation (BMT) and the related complications. Based on the conditions in which the cells are grown, Pluristem believes they have created differentiated products adapted to the environment and the target indication. These products include PLX-R18, PLX-PAD, and PLX-Immune. We view PLX-PAD as the key driver for the company, although success with any of these products becomes transformative for the company.

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? We provide a review of the “Time to Event Analysis.” We believe the company has given itself the best possible chance for success.** Success in CLI, in our opinion, is transformative for the company, patients, and the cell therapy space.

Beyond CLI. Like CLI, Pluristem is also in a Phase 3 trial for muscle regeneration following arthroplasty for hip fracture. We apply similar assumptions regarding partnerships and timing for commercialization (2023). **PLX-R18 is being developed for Hematological Deficiencies and Acute Radiation Syndrome (ARS).** R18, in a Phase 1/2 trial, demonstrated safety with supporting data for clinical effectiveness. The FDA has cleared Pluristem’s IND (ARS), and it has received FDA orphan drug designation.

Valuation. We model the 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 on top of these 50% and 50% metrics 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.

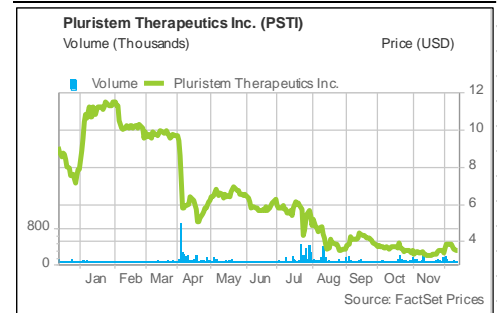
Current Price \$3.49
 Price Target \$12.00

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)	\$ (1.89)	\$ (1.98)	\$ (1.94)
1Q March	\$ (0.46)	\$ (0.46)	\$ (0.45)
2Q June	\$ (0.48)	\$ (0.47)	\$ (0.47)
3Q September	\$ (0.48)	\$ (0.51)	\$ (0.50)
4Q December	\$ (0.48)	\$ (0.53)	\$ (0.53)

EBITDA/Share	(\$1.89)	(\$1.98)	(\$2.03)
EV/EBITDA (x)	-1.2	-1.2	-1.1

Stock Data		
52-Week Range	\$3.11	\$11.90
Shares Outstanding (mil.)	15.7	
Market Capitalization (mil.)	\$55	
Enterprise Value (mil.)	\$36	
Debt to Capital	0%	
Book Value/Share	\$3.12	
Price/Book	4.3	
Average Three Months Trading Volume (K)	7	
Insider Ownership	9.3%	
Institutional Ownership	10.0%	
Short interest (mil.)	0.5%	
Dividend / Yield	\$0.00/0.0%	



Company Background and Description: Israel based Pluristem is developing allogeneic placental derived based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. The lead product is in two Phase 3 trials. One for critical limb ischemia (CLI), and the other for muscle recovery following surgery for hip fracture. Pluristem is in our opinion, differentiated from other companies in the field of regenerative medicine in that the company controls its own manufacturing process. PLX cells are derived from a class of placental cells that are harvested from donated placenta at the time of full-term healthy delivery of a baby. PLX cell products require no tissue matching prior to administration. They are produced using the company's three-dimensional expansion (bio-reactor) technology. We have visited the facility in Israel. The facility complies with the European, Japanese, Israeli, South Korean and U.S. FDA Good Manufacturing Practice requirements and has been approved by the European and Israeli regulators for production of PLX-PAD for the current trials. The next second product candidate, PLX-R18, is under development in the U.S. for Acute Radiation Syndrome (ARS) (via the FDA Animal Rule regulatory pathway) and for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation, or HCT.





Exhibit 1. Upcoming Milestones and Catalysts

Product	Event	Timing	Significance
PLX-Critical Limb Ischemia	Phase 3, N= 246 (US, EU & Israel) study underway	✓	-
PLX-Critical Limb Ischemia	CLI study half enrolled	Apr-19	-
PLX-Critical Limb Ischemia	Announce Top-line Results (EU)	2020	+++
PLX-Critical Limb Ischemia	Complete Data Set	2021	++
Muscle Injury - Hip Replacement	Phase 3 N=240 patient US, Germany, UK, Denmark & Israel Trial	✓	
Muscle Injury - Hip Replacement	Announce Top-line Results	1H21	++
PLX-R18	Hematologic Deficiencies	ongoing	+
PLX-R18	Acute Radiation Syndrome (ARS) - Start of equivalent pivotal trial	2020	+
PLX-R18	Phase 1, N=24 POC Study: Incomplete Hematopoietic Recovery following Transplant	2020	+

Stock Significance Scale: + of moderate importance; ++ higher level; +++ highly

Source: Dawson James Estimates.

Exhibit 2. Pluristem Therapeutics Pipeline

Indication	Product Candidate	Location	Pre-Clinical	Phase I	Phase II	Phase III	Funding
Critical Limb Ischemia	PLX-PAD	U.S., Europe Israel	→			→	
Hip Fracture	PLX-PAD	U.S., Europe Israel	→			→	
Acute Radiation Syndrome*	PLX-R18	U.S.	Pivotal trial via FDA Animal Rule →				
Intermittent Claudication	PLX-PAD	U.S., Europe South Korea, Israel	→			→	
Graft Versus Host Disease	PLX-PAD	Israel	→				
Incomplete engraftment following BMF*	PLX-R18	U.S., Israel	→				

* FDA Orphan Drug Designation

Source: Pluristem Therapeutics, Inc.

Bull Case. Pluristem is now in two pivotal trials, Critical Limb Ischemia (CLI) and Muscle Recovery – post-hip fracture. If the trials “work,” i.e., the primary endpoints are met with statistical significance, it becomes transformative for patients, the medical community, and the company. So, the key question is, Will it work? The Phase 2 trials that formed the basis of these pivotal trials appear solid. The science behind the mechanism of action is also logical and consistent. The pivotal trial design, especially in CLI, is well thought out to provide what we believe is the best chance of success and is, in our opinion, comprehensive enough that regulators on good news, are likely to be satisfied. New expedited pathways in Regenerative Medicine (21st Century Cures Act in the U.S.) and similar pathways in Europe and Japan, could result in a faster pathway to approval. Key to the positive outlook is the fact that the cells are known to be quite safe, so the balance of risk versus efficacy is already skewed in the company’s favor. We also take note of the special nature of these cells which has resulted in differentiated products such as the PLX-PAD cell line for muscle injury in the context of hip surgery, and critical limb ischemia and PLX-RAD more orientated for Hematopoietic insults such as Acute Radiation Syndrome (ARS) and Hemopoietic recovery following Bone Marrow Transplant or other blood-related deficiency. The different profile of these cell lines based on the manufacturing environment during cell expansion suggests they can be therapeutically designed to treat a variety of ischemic, inflammatory, autoimmune, and hematological disorders. Combine this with allogenic manufacturing, in-house process (we have seen it in Israel, and it is impressive), and it translates to PLX products that are true off-the-shelf ready. Products that do not require matching or manipulation before administration to the patient.

Bear Case. CLI has been a graveyard for drug developers, and regenerative medicine (cell therapy) isn’t CAR-T. Large trials are required (possibly in the thousands to zero out disease and patient variability), so regardless of the Phase 2 basis, pivotal trials in CLI are a gamble. Muscle injury is a novel indication, and little is known to compare results. Indications for ARS have government implications relative to biodefense, which means predicting procurement contracts is difficult, and pricing tends to be limited. Pluristem capital runway is limited, and investors should expect the company to raise capital. The timing of the raise is tough and likely in the next year based on the current cash balance. So, even if the company reports good data, expectations for a raise on the increase in the stock price could limit a positive reaction. Mixed or negative data could put the company in a difficult position to raise additional capital.

Our Take. The basis for the current pivotal trials in CLI and Muscle injury appears solid, and we believe the design and powering of both pivotal trials is strong, setting the stage for real answers on what cell therapy can and can not do in these disease settings. Based on the timelines, our focus is on the pivotal trials. Several factors sway our opinion positive. 1. Pluristem manufactures the product in-house. 2. Pluristem, by controlling the manufacturing process, has come up with differentiated cell lines tailored toward the therapeutic target. 3. The CLI trial is event-driven and comprehensively designed. 4. Our thesis in cell therapy, regenerative medicine, is and has always been that these cells are safe. As such, the approval hurdle is all about the signal. There are mountains of data that suggest cells are active. We see it in Pluristem’s data, but also in Athersys (ATHX-Buy Rated), Mesoblast (MESO-Not Rated), Lineage (LCTX-Buy Rated) and in Brainstorm (BCLI-Buy Rated). Pluristem’s valuation is at the lowest point in its history. As such, we see a positive risk-to-reward which, combined with our assessment of the potential and the probabilities of success, supports our positive outlook.

Finances. Pluristem reported just under \$20M in cash for the last quarter. We also consider that grants may extend the capital runway further. Our model assumes multiple raises, so our valuation is based on a 2030 fully diluted share count.

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 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.

Exhibit 3. Overview of the Ongoing CLI Phase 3 Study

Design	Phase III, randomized, Double-Blind, Placebo-controlled (2:1)
Study population	CLI subjects with minor tissue loss, unsuitable for revascularization
Countries	Germany, UK, U.S., Poland, Hungary, Czech republic, Bulgaria, Macedonia, Israel
Sample size	246 patients
Doses tested	300M cells vs. Placebo (randomization ratio 2:1)
Administration	IM injections in the affected leg, 2 treatments at 8-week interval
Primary efficacy endpoint	Time to occurrence of major amputation of leg or death (AFS)
Main Secondary & exploratory efficacy endpoints	Composite efficacy endpoint; Pain; Complete wound healing; Quality-of-life; Adjudicated amputations; TcPO ₂ ; cytokine levels
Follow Up length	52 Weeks
Expected Data	H1 2020 (Europe), H1 2021 (U.S.)

Source: Pluristem Therapeutics, Inc.

CLI Modeling Assumptions:
Critical Limb Ischemia:

1. We model commercial launch in FY23 in the EU, and FY24 in the U.S. with Japan too.
2. We model the addressable population to be the 40% of patients with CLI who are unsuitable for revascularization.
3. We place our entry price at \$30K for the U.S., \$20K for the EU, and \$25K for Japan, with price increases of 2%.
4. We apply a 50% success probability based on the stage of development and the complexity of CLI.
5. We assume a 50% profit share from a potential partner in the U.S., the EU and Japan.

Exhibit 4. U.S. Market for PLX-PAD in the Treatment of CLI

PLX-PAD in Critical Limb Ischemia (U.S.)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total Population	327,745,577	330,039,796	332,350,075	334,676,525	337,019,261	339,378,396	341,754,045	344,146,323	346,555,347	348,981,235	351,424,103	353,884,072	356,361,260
Increase in population	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%
Incidence of CLI (0.075%)	245,809	247,530	249,263	251,007	252,764	254,534	256,316	258,110	259,917	261,736	263,568	265,413	267,271
Patients Unsuitable for Revascularization (40%)	98,324	99,012	99,705	100,403	101,106	101,814	102,526	103,244	103,967	104,694	105,427	106,165	106,908
Market Penetration				0.00%	0.00%	4.00%	8.00%	12.00%	16.00%	24.00%	28.00%	32.00%	35.00%
Total patients treated	-	-	-	-	-	4,073	8,202	12,389	16,635	25,127	29,520	33,973	37,418
Average price per treatment	-	-	-	\$ 30,000	\$ 30,600	\$ 31,212	\$ 31,836	\$ 32,473	\$ 33,122	\$ 33,785	\$ 34,461	\$ 35,150	\$ 35,853
Increase in Cost	-	-	-	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Partner revenue ('000)	-	-	-	\$ -	\$ -	\$ 127,112	\$ 261,124	\$ 402,316	\$ 550,980	\$ 848,901	\$ 1,017,263	\$ 1,194,139	\$ 1,341,537
Royalty or profit share (50%)	-	-	-	\$ -	\$ -	\$ 63,556	\$ 130,562	\$ 201,158	\$ 275,490	\$ 424,450	\$ 508,632	\$ 597,069	\$ 670,768
Risk adjustment	-	-	-	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 31,778	\$ 65,281	\$ 100,579	\$ 137,745	\$ 212,225	\$ 254,316	\$ 298,535	\$ 335,384

Source: Dawson James Estimates

PLX-PAD in Critical Limb Ischemia (EU)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total Population	509,270,000	510,543,175	511,819,533	513,099,082	514,381,829	515,667,784	516,956,954	518,249,346	519,544,969	520,843,832	522,145,941	523,451,306	524,759,934
Increase in population	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%
Incidence of CLI (0.1%)	381,953	382,907	383,865	384,824	385,786	386,751	387,718	388,687	389,659	390,633	391,609	392,588	393,570
Patients Unsuitable for Revascularization (40%)	152,781	153,163	153,546	153,930	154,315	154,700	155,087	155,475	155,863	156,253	156,644	157,035	157,428
Market Penetration				0.00%	0.00%	4.00%	8.00%	12.00%	16.00%	24.00%	28.00%	32.00%	35.00%
Total patients treated	-	-	-	-	-	6,188	12,407	18,657	24,938	37,501	43,860	50,251	55,100
Average price per treatment	-	-	-	\$ 20,000	\$ 20,400	\$ 20,808	\$ 21,224	\$ 21,649	\$ 22,082	\$ 22,523	\$ 22,974	\$ 23,433	\$ 23,902
Increase in Cost	-	-	-	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Partner revenue ('000)	-	-	-	\$ -	\$ -	\$ 128,760	\$ 263,327	\$ 403,898	\$ 550,675	\$ 844,639	\$ 1,007,633	\$ 1,177,549	\$ 1,316,987
Royalty or profit share (50%)	-	-	-	\$ -	\$ -	\$ 64,380	\$ 131,664	\$ 201,949	\$ 275,337	\$ 422,319	\$ 503,817	\$ 588,774	\$ 658,494
Risk adjustment	-	-	-	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 32,190	\$ 65,832	\$ 100,975	\$ 137,669	\$ 211,160	\$ 251,908	\$ 294,387	\$ 329,247

Source: Dawson James Estimates

PLX-PAD in Critical Limb Ischemia (JP)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total Population	126,873,000	126,746,127	126,619,381	126,492,761	126,366,269	126,239,902	126,113,663	125,987,549	125,861,561	125,735,700	125,609,964	125,484,354	125,358,870
Increase in population	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%	-0.10%
Incidence of CLI (0.1%)	95,155	95,060	94,965	94,870	94,775	94,680	94,585	94,491	94,396	94,302	94,207	94,113	94,019
Patients Unsuitable for Revascularization (40%)	38,062	38,024	37,986	37,948	37,910	37,872	37,834	37,796	37,758	37,721	37,683	37,645	37,608
Market Penetration				0.00%	0.00%	0.00%	0.00%	3.00%	6.00%	12.00%	15.00%	18.00%	25.00%
Total patients treated	-	-	-	-	-	-	-	1,134	2,266	4,526	6,652	6,776	9,402
Average price per treatment	-	-	-	\$ 25,000	\$ 25,500	\$ 26,010	\$ 26,530	\$ 27,061	\$ 27,602	\$ 28,154	\$ 28,717	\$ 29,291	\$ 29,877
Increase in Cost	-	-	-	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Partner revenue ('000)	-	-	-	\$ -	\$ -	\$ -	\$ -	\$ 30,684	\$ 62,533	\$ 127,439	\$ 162,322	\$ 198,484	\$ 280,904
Royalty or profit share (50%)	-	-	-	\$ -	\$ -	\$ -	\$ -	\$ 15,342	\$ 31,266	\$ 63,719	\$ 81,161	\$ 99,242	\$ 140,452
Risk adjustment	-	-	-	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 7,671	\$ 15,633	\$ 31,860	\$ 40,581	\$ 49,621	\$ 70,226

Source: Dawson James Estimates

Exhibit 5. Ongoing Hip Fracture Phase 3 Study

Design	Phase III, randomized, Double-Blind, Placebo-controlled
Study population	Patients suffering from muscle injury following arthroplasty for hip fracture
Countries	U.S., Germany, UK, Denmark, Israel
Sample size	240 patients
Doses tested	150M cells vs. Placebo (randomization ratio 1:1)
Administration	IM injections in the operated leg on the day of surgery
Primary efficacy endpoint	Short Physical Performance Battery (SPPB) score at week 26
Main Secondary & exploratory efficacy endpoints	Muscle strength, muscle mass & volume, hospitalization time, lower extremity measure
Follow Up length	26 (efficacy), 52 weeks (safety)
Expected Data	H2 2020

Source: Pluristem Therapeutics, Inc.

The Basis for the Current Muscle Regeneration - 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).

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 6. 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%	1.00%	2.00%	3.00%	5.00%	7.00%	10.00%	12.00%
Total patients treated	-	-	-	825	3,334	6,735	10,203	17,175	24,286	35,041	42,470
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%
Partner revenue ('000)	\$ -	\$ -	\$ -	\$ 24,758	\$ 102,021	\$ 210,204	\$ 324,828	\$ 557,730	\$ 804,403	\$ 1,183,852	\$ 1,463,525
Royalty or profit share (50%)	\$ -	\$ -	\$ -	\$ 12,379	\$ 51,010	\$ 105,102	\$ 162,414	\$ 278,865	\$ 402,202	\$ 591,926	\$ 731,762
Risk adjustment		50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ 6,189	\$ 25,505	\$ 52,551	\$ 81,207	\$ 139,433	\$ 201,101	\$ 295,963	\$ 365,881

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%	1.00%	2.00%	3.00%	5.00%	7.00%	10.00%	12.00%
Total patients treated	-	-	-	1,373	5,546	11,204	16,974	28,572	40,401	58,293	70,651
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%
Partner revenue ('000)	\$ -	\$ -	\$ -	\$ 27,457	\$ 113,146	\$ 233,126	\$ 360,250	\$ 618,548	\$ 892,120	\$ 1,312,946	\$ 1,623,116
Royalty or profit share (50%)	\$ -	\$ -	\$ -	\$ 13,729	\$ 56,573	\$ 116,563	\$ 180,125	\$ 309,274	\$ 446,060	\$ 656,473	\$ 811,558
Risk adjustment		50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ 6,864	\$ 28,286	\$ 58,281	\$ 90,062	\$ 154,637	\$ 223,030	\$ 328,236	\$ 405,779

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 must 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 7. 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 they 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 8. 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

Valuation: We model PLX-PAD in the treatment of critical limb ischemia and post-surgery hip fracture and PLX-R18 in Hematopoietic recovery as well as ARS. 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 9. Free Cash Flow Model

Average	\$	12.0
Price Target	\$	14.2
Year		2020

DCF Valuation Using FCFE (mln):

units (millions - \$)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(29,095)	(30,346)	(31,559)	64,261	196,464	358,594	614,787	854,181	1,187,117	1,505,343	1,866,690
Tax Rate	0%	0%	5%	10%	15%	18%	18%	20%	20%	24%	28%
EBIT(1-t)	(29,095)	(30,346)	(29,981)	57,835	166,994	294,047	504,125	683,345	949,694	1,144,060	1,344,017
- Change in NWC											
Free Cash Flow to Firm (FCFF)	(29,095)	(30,346)	(29,981)	57,835	166,994	294,047	504,125	683,345	949,694	1,144,060	1,344,017
PV of FCFE	(29,095)	(23,415)	(17,850)	26,569	59,194	80,425	106,392	111,277	119,328	110,918	100,544
Discount Rate	30%										
Long Term Growth Rate	1%										
Terminal Cash Flow	355,067										
Terminal Value YE 2030	26,562										
NPV	670,850										
NPV-Debt	-										
Shares out (thousands)	47,219	2030									
NPV Per Share	14.2										

Source: Dawson James.

Exhibit 10. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	5
Discount Factor	30%
Selected Year EPS	\$ 31.98
NPV	\$ 12.0

Source: Dawson James estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple	10	20%	25%	30%	35%	40%	45%
	15	\$51.65	\$34.34	\$23.20	\$15.91	\$11.06	\$ 7.78
	20	\$77.47	\$51.51	\$34.80	\$23.86	\$16.58	\$ 11.68
	25	\$103.30	\$68.68	\$46.40	\$31.81	\$22.11	\$ 15.57
	30	\$129.12	\$85.85	\$57.99	\$39.76	\$27.64	\$ 19.46
	35	\$154.95	\$103.02	\$69.59	\$47.72	\$33.17	\$ 23.35
	40	\$180.77	\$120.18	\$81.19	\$55.67	\$38.70	\$ 27.24
	45	\$206.60	\$137.35	\$92.79	\$63.62	\$44.22	\$ 31.14
		\$232.42	\$154.52	\$104.39	\$71.57	\$49.75	\$ 35.03

Exhibit 10. 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	50%	\$50	\$172
NPV						\$0.25
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 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 their 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 11. 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		-	-	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	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	64,340	97,508	131,512	196,397	257,100	341,205	421,650	512,893
Operating Income (Loss) EBIT	(29,095)	(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)	206	272	272	272	272	272	272	272	272	272	272
Pre-tax income	(29,189)	(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%	0%	5%	10%	15%	18%	18%	20%	20%	24%	28%
Net Income (loss)	(29,189)	(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	(1.52)	(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)	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

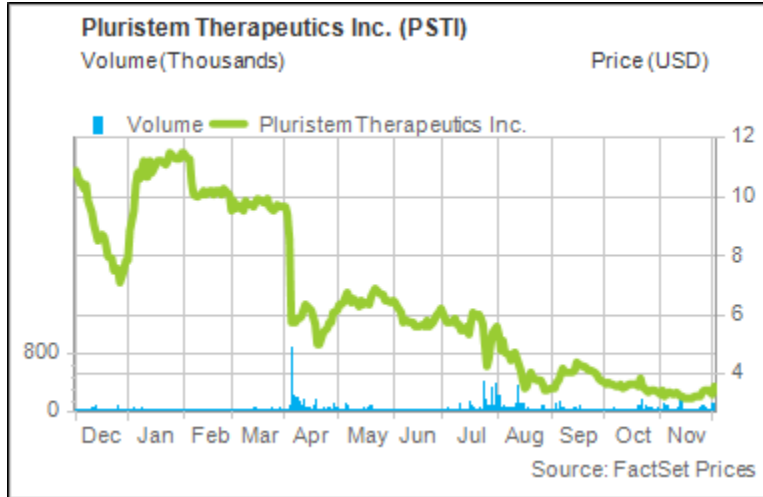
Source: Dawson James estimates.

Companies mentioned in this report

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

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Market Outperform (Buy)	25	89%	3	12%
Market Perform (Neutral)	3	11%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	28	100%	3	11%

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