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Pluristem Therapeutics, Inc. (NASDAQ:PSTI)

May 10, 2022

BUY: Reports 3Q22 - \$61M in Cash & Equivalents

Pluristem reported 3Q22 results. Recall that the company has a June year-end. Revenues are de minimis. The company is spending about \$10M a quarter and closed the period with approximately \$61M in cash.

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Investment Highlights

Muscle Regeneration – Currently in a 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.

The Tnuva Group has invested \$7.5 million in a business venture focused on developing synthetic protein products. The NewCo is being established with a pre-money valuation of \$40 million. Tnuva has the option to invest up to an additional \$7.5 million over a period of 12 months following the closing. NewCo will use its own funding and resources to promote its mission with a dedicated management team and staff, and Pluristem has agreed to support the establishment, research, and development activities of NewCo pursuant to a services agreement. Tnuva plans to provide the R&D platform with the goal of developing products.

Is the Opportunity Large? Alternative meat is one of the fastest-growing industries in the world and is estimated to be a US\$140 billion market by 2030. The collaboration combines Pluristem's expertise in mass-scale cell production with Tnuva's R&D in consumer-packaged goods. As part of the collaboration, the parties may expand the collaboration to include cultured dairy and cultured fish products by establishing separate new ventures.

Valuation. We assume a 35% 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 of 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	\$1.43
Price Target	\$9.00
6 million total number of hip fractures worldwide by 2050	

PLX-PAD is designed to stimulate muscle regeneration - gain muscle strength and volume



Source: Pluristem

Stock Data			
52-Week Range	\$1.36	-	\$4.55
Shares Outstanding (mil.)	32.2		
Market Capitalization (mil.)	\$46		
Enterprise Value (mil.)	\$28		
Debt to Capital	0%		
Book Value/Share	\$3.12		
Price/Book	2.2		
Average Three Months Trading Volume (K)	210		
Insider Ownership	21.5%		
Institutional Ownership	10.3%		
Short interest (mil.)	1.9%		
Dividend / Yield	\$0.00/0.0%		

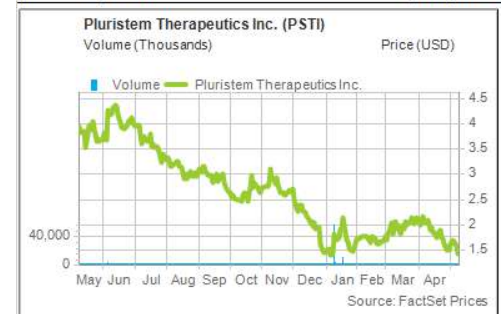


Exhibit 1. Hip Fracture Models

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					2.00%	4.00%	8.00%	10.00%	15.00%	20.00%	25.00%
Total patients treated	-	-	-	-	6,668	13,469	27,208	34,350	52,041	70,082	88,478
Average price per treatment	\$ 30,000	\$ 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%
Parmer revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ 204,042	\$ 420,408	\$ 866,209	\$ 1,115,460	\$ 1,723,721	\$ 2,367,703	\$ 3,049,010
Royalty or profit share (50%)	\$ -	\$ -	\$ -	\$ -	\$ 102,021	\$ 210,204	\$ 433,104	\$ 557,730	\$ 861,861	\$ 1,183,852	\$ 1,524,505
Risk adjustment		65%	65%	65%	65%	65%	65%	65%	65%	65%	65%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ 35,707	\$ 73,571	\$ 151,587	\$ 195,206	\$ 301,651	\$ 414,348	\$ 533,577

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					2.00%	4.00%	8.00%	10.00%	15.00%	20.00%	25.00%
Total patients treated	-	-	-	-	11,093	22,407	45,263	57,144	86,574	116,586	147,190
Average price per treatment	\$ 20,000	\$ 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%
Parmer revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ 226,292	\$ 466,252	\$ 960,665	\$ 1,237,097	\$ 1,911,686	\$ 2,625,891	\$ 3,381,492
Royalty or profit share (50%)	\$ -	\$ -	\$ -	\$ -	\$ 113,146	\$ 233,126	\$ 480,333	\$ 618,548	\$ 955,843	\$ 1,312,946	\$ 1,690,746
Risk adjustment		65%	65%	65%	65%	65%	65%	65%	65%	65%	65%
Total Revenue ('000)	\$ -	\$ -	\$ -	\$ -	\$ 39,601	\$ 81,594	\$ 168,116	\$ 216,492	\$ 334,545	\$ 459,531	\$ 591,761

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, 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 (2021E-2030E)

Pluristem Income Statement (\$ '000)	June 2021	Sept 2021	Dec 2021	March 2022	June 2022	June 2022	June 2023	June 2024	June 2025	June 2026	June 2027	June 2028	June 2029	June 2030
PSTI: YEAR June 30	2021	1Q22A	2Q22A	3Q22A	4Q22E	2022	2023	2024	2025	2026	2027	2028	2029	2030
PLX-PAD CLI- U.S.							-	-	-	-	-	-	-	-
PLX-PAD CLI- EU							-	-	-	-	-	-	-	-
PLX-PAD CLI- Japan							-	-	-	-	-	-	-	-
PLX-PAD Muscle Repair U.S.	-	-	-	-	-	-		51,010	105,102	216,552	278,865	430,930	591,926	762,252
PLX-PAD Muscle Repair EU	-	-	-	-	-	-		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	-	-	-	-	-	-		5,800	9,051	12,556	16,329	20,386	21,209	22,066
Revenues	-	-	-	234	-	-	-	113,383	230,716	469,274	604,468	929,238	1,269,608	1,629,692
Total Revenues (Product Sales, Grants & Milestones)	-	-	-	234	-	-	-	113,383	230,716	469,274	604,468	929,238	1,269,608	1,629,692
% Chg														
Expenses														
COGS	-	-	-	59	-	-	-	24,944	46,143	93,855	120,894	185,848	253,922	325,938
% COGS	28%	25%	25%	25%	25%	25%	25%	22%	20%	20%	20%	20%	20%	20%
R&D	22,773	6,353	6,507	6,156	6,272	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	5,088	4,288	4,553	(5,598)	8,331	8,498	8,668	8,841	9,018	9,198	9,382	9,570	9,761
Total costs & expenses	30,346	11,441	10,795	10,475	674	31,559	32,190	57,778	79,634	128,015	155,737	221,388	290,173	362,915
Operating Income (Loss) EBIT	(30,346)	(11,441)	(10,795)	(10,241)	(674)	(31,559)	(32,190)	55,605	151,082	341,259	448,731	707,849	979,435	1,266,777
Oper Margin														
Other Income expenses - Financial Expenses (net)	272	9	(145)	557	(149)	272	272	272	272	272	272	272	272	272
Pre-tax income	(30,618)	(11,432)	(10,940)	(9,918)	(524)	(32,814)	(32,462)	55,333	150,811	340,987	448,459	707,578	979,164	1,266,505
Taxes	-			(53)	(26)	(79)	(3,246)	8,300	27,146	61,378	89,692	141,516	234,999	354,622
TaxRate	0%	5%	5%	5%	5%	0%	10%	15%	18%	18%	20%	20%	24%	28%
Net Income (loss)	(30,618)	(11,432)	(10,940)	(9,865)	(498)	(32,735)	(29,216)	47,033	123,665	279,610	358,767	566,062	744,164	911,884
Net Margin														
Basic EPS	(0.86)	(0.36)	(0.34)	(0.31)	(0.02)	(1.02)	(0.90)	1.45	3.79	8.53	10.91	17.14	22.44	27.39
Basic Wght Average Shares Outstanding (thousands)	36,786	32,000	32,136	32,261	32,293	32,173	32,374	32,504	32,634	32,765	32,896	33,028	33,160	33,293
Fully Diluted Wgtd Avg Shrs outstanding (Thousands)	41,804	45,664	45,710	45,755	45,801	45,733	45,916	46,100	46,284	46,470	46,656	46,843	47,030	47,219

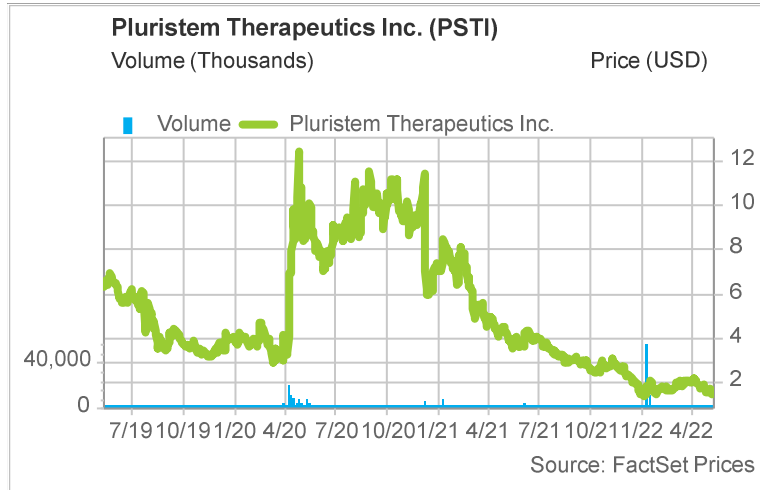
Source: Dawson James estimates

Peer Companies to Pluristem

Tnuva Group (private)

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
- Update – Buy – December 1, 2021 – Price Target \$9.00
- Update – Buy – January 10, 2022 – Price Target \$9.00
- Update – Buy – February 24, 2022 – Price Target \$9.00
- Update – Buy – May 10, 2022 – Price Target \$9.00

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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Current as of 26-Apr-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	32	74%	4	13%
Market Perform (Neutral)	11	26%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	4	9%

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