

Member FINRA/SIPC

Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Pluristem Therapeutics, Inc. (NASDAQ:PSTI)

July 13, 2022

Lowering to Neutral from BUY as Pluristem Hip Trial Misses the Primary Endpoint
Jason Kolbert
Managing Director & Senior Analyst
 jkolbert@dawsonjames.com

Pluristem reports the Phase 3 trial investigating muscle regeneration following hip surgery did not meet the primary endpoint, which was the Short Physical Performance Battery (SPPB) test at week 26. The study did show PLX-PAD was effective as an accelerator of muscle strength and regeneration.

Investment Highlights

Pluristem announced topline results from the Phase 3 N=240, double-blind, placebo-controlled study. The study did not meet the primary endpoint, which was the Short Physical Performance Battery (SPPB) test at week 26. The SPPB is a series of physical performance tests used in older persons to assess lower extremity function and mobility.

The company's press release highlights one bright spot: PLX-PAD cells did show that they were an effective accelerator of muscle strength and regeneration. A significant increase in Hip Abduction Strength (HAS) was observed at week 26 and week 52 for patients treated with PLX-PAD (n=120), in the injured leg (p=0.047, p=0.0022) and uninjured leg (p=0.073, p=0.0046), compared to placebo (n=120). This new data confirms the results demonstrated in Pluristem's phase I/II study.

In the injured leg:

- Patients treated with PLX-PAD cells showed an increase of 3.2kg from reference (week 6) to week 26 compared to 1.3kg in the placebo group, a 2kg difference (p=0.047).
- Patients treated with PLX-PAD cells showed an increase of 5.01kg from reference (week 6) to week 52 compared to 0.86kg in the placebo group, a 4kg difference (p=0.0022).

In the uninjured leg:

- Patients treated with PLX-PAD cells showed an increase of 2.3kg from reference (week 6) to week 26 compared to 0.51kg in the placebo group, a 1.8kg difference (p=0.073).
- Patients treated with PLX-PAD cells showed an increase of 3.3kg from reference (week 6) to week 52 compared to a decrease of 0.7kg in the placebo group, a 4kg difference, (p=0.0046).

While the above trends in HAS are positive, the study did miss its primary endpoint. We feel it's prudent to remove our estimates for Hip repair. As a result, we lower our rating from Buy to Hold and remove our price target.

Valuation. We remove our estimates around PLX-PAD Cells for hip repair. As a result, we can no longer support a Buy rating. At minimum, we expect it will be years before Pluristem can redesign and execute a successful clinical program around muscle regeneration.

Risks include: (1) Commercial; (2) regulatory; (3) clinical; (4) investment; (5) financial; (6) employee; and (7) intellectual property, among others.

| | |
|---------------|--------|
| Current Price | \$1.19 |
| Price Target | NA |

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 | \$1.06 | - | \$3.80 |
| Shares Outstanding (mil.) | 32.3 | | |
| Market Capitalization (mil.) | \$38 | | |
| Enterprise Value (mil.) | \$20 | | |
| Debt to Capital | 0% | | |
| Book Value/Share | \$3.12 | | |
| Price/Book | 2.2 | | |
| Average Three Months Trading Volume (K) | 98 | | |
| Insider Ownership | 19.3% | | |
| Institutional Ownership | 9.4% | | |
| Short interest (mil.) | 1.2% | | |
| Dividend / Yield | \$0.00/0.0% | | |



Source: FactSet Prices

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, if 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.

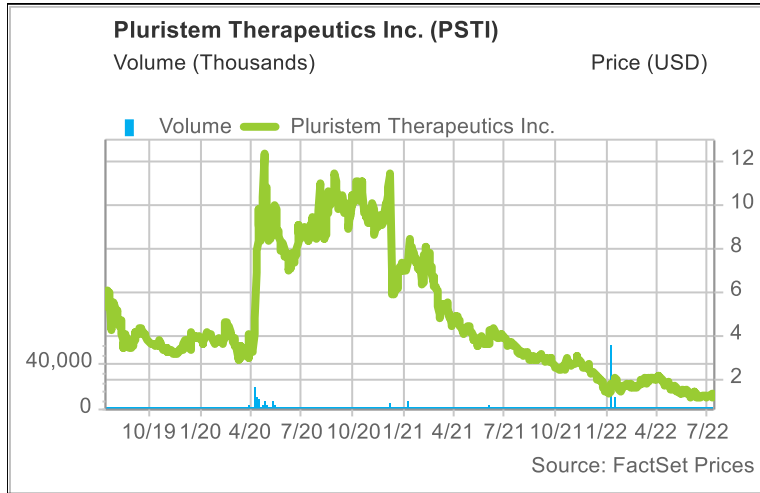
Exhibit 1. Income Statement (2021E-2030E)

| Pluristem Income Statement (\$ '000) | June 2021 | 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. | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| PLX-PAD Muscle Repair EU | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 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 | - | - | - | 5,800 | 9,051 | 12,556 | 16,329 | 20,386 | 21,209 | 22,066 |
| Total Revenues (Product Sales, Grants & Milestones) | - | - | - | 234 | - | - | - | 5,800 | 9,051 | 12,556 | 16,329 | 20,386 | 21,209 | 22,066 |
| % Chg | | | | | | | | | | | | | | |
| Expenses | | | | | | | | | | | | | | |
| COGS | - | - | - | 59 | - | - | - | 1,276 | 1,810 | 2,511 | 3,266 | 4,077 | 4,242 | 4,413 |
| % 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 | 34,110 | 35,301 | 36,672 | 38,109 | 39,618 | 40,493 | 41,390 |
| Operating Income (Loss) EBIT | (30,346) | (11,441) | (10,795) | (10,241) | (674) | (31,559) | (32,190) | (28,310) | (26,250) | (24,116) | (21,781) | (19,232) | (19,284) | (19,323) |
| 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) | (28,582) | (26,521) | (24,388) | (22,052) | (19,503) | (19,555) | (19,595) |
| Taxes | - | | | (53) | (26) | (79) | (3,246) | (4,287) | (4,774) | (4,390) | (4,410) | (3,901) | (4,693) | (5,487) |
| Tax Rate | 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) | (24,295) | (21,748) | (19,998) | (17,642) | (15,603) | (14,862) | (14,108) |
| Net Margin | | | | | | | | | | | | | | |
| Basic EPS | (0.86) | (0.36) | (0.34) | (0.31) | (0.02) | (1.02) | (0.90) | (0.75) | (0.67) | (0.61) | (0.54) | (0.47) | (0.45) | (0.42) |
| 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

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
- Rating Change - Neutral – July 13, 2022 – Price Target \$NA

Dawson James Securities, Inc. (the “Firm”) is a member of the Financial Industry Regulatory Authority (“FINRA”) and the Securities Investor Protection Corporation (“SIPC”).

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with PLURISTEM THERAPEUTICS in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has not received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director, or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of June 16, 2022, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts, or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

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

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Rating Definitions:

- 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.

Current as of 16-Jun-22

| | Company Coverage | | Investment Banking | |
|----------------------------|------------------|------------|--------------------|-------------|
| Ratings Distribution | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 31 | 72% | 4 | 13% |
| Market Perform (Neutral) | 12 | 28% | 0 | 0% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0% |
| Total | 43 | 100% | 4 | 9% |

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.