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# INSTITUTIONAL RESEARCH

## *COVID-19*

## UPDATE REPORT

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

## Pluristem Therapeutics, Inc. (NASDAQ/PSTI)

***August 27, 2020***

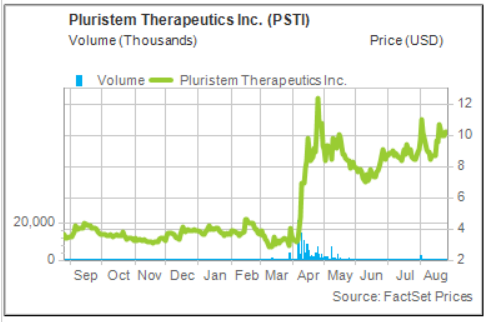
## BUY: COVID-19 – ARDS Expanded Access Granted

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

*Pluristem announced that the FDA has cleared the company's Expanded Access Program (EAP) for the use of its PLX-PAD cells to treat Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19 outside of the company's ongoing Phase 2 COVID-19 study in the U.S. The program provides a pathway for patients that are not eligible for inclusion in the Phase II clinical trial to be treated with PLX-PAD cells. The EAP will include up to 100 patients, with the resulting data collected and evaluated alongside Pluristem's clinical trial. Alongside the EAP in the U.S., Pluristem will continue to advance its two ongoing COVID-19 Phase 2 clinical trials of its PLX-PAD product candidate for the treatment of severe ARDS in the U.S. and Europe, and treat patients under the compassionate use program in Israel.*

| | |
|---|---|
| **Current Price** | **$10.73** |
| **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) | -8.7 | -8.3 | -8.0 |
| Stock Data | | | |
| 52-Week Range | $2.82 | - | $13.29 |
| Shares Outstanding (mil.) | | | 25.5 |
| Market Capitalization (mil.) | | | $274 |
| Enterprise Value (mil.) | | | $255 |
| Debt to Capital | | | 0% |
| Book Value/Share | | | $3.12 |
| Price/Book | | | 4.3 |
| Average Three Months Trading Volume (K) | | | 1,334 |
| Insider Ownership | | | 19.3% |
| Institutional Ownership | | | 10.1% |
| Short interest (mil.) | | | 5.0% |
| Dividend / Yield | | | $0.00/0.0% |




## Investment Highlights

**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

**Germany too.** Pluristem also announced earlier this month that Germany's health regulatory agency, the Paul Ehrlich Institute (PEI), has cleared the company's Phase 2 clinical protocol for its study titled, "A Randomized, Controlled, Multicenter, Parallel-Group Phase II Study to Evaluate the Efficacy and Safety of Intramuscular Injections of PLX PAD for the Treatment of severe COVID-19." N=40 patients hospitalized with severe cases of COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS) will be enrolled in the study. 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. Safety and survival follow-up will be conducted on day 60, week 26, and week 52. Recall that this study is in addition to the current Phase 2 COVID-19, N=140 trial in the U.S.

**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-month price target of $12.00.

**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 the 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.

**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 |

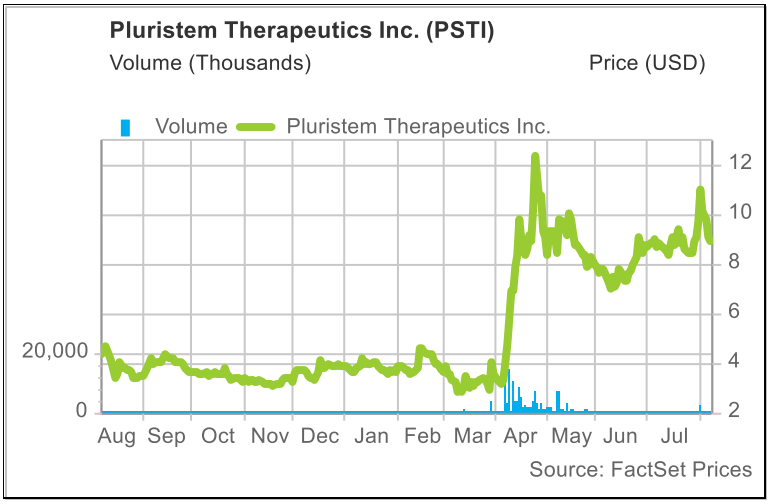
*Source: Dawson James estimates*

Peer Companies to Pluristem

Athersys (ATHX-Buy Rated)
Mesoblast (MESO-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

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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) **Neutra**l: The analyst believes the price of the stock is fairly valued for the next 12-18 months;
3) **Sel**l: 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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| | Company Coverage | | Investment Banking | |
|---|---|---|---|---|
| **Ratings Distribution** | # 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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