



Pluristem CEO Issues Shareholder Update

HAIFA, Israel, September 22, 2021 - [Pluristem Therapeutics Inc. \(Nasdaq: PSTI\) \(TASE: PSTI\)](#), a leading biotechnology company, today issued an update to its shareholders from its Chief Executive Officer and President Yaky Yanay.

Dear Shareholders,

Less than three months into a new fiscal year, there are several important developments on the horizon for Pluristem, including four studies heading to clinical readout in the coming quarters. These studies align with our mission to develop novel cell therapy product candidates, built using Pluristem's advanced technology.

Clinical Pipeline: Milestones

During the coming year, we expect to meet multiple clinical milestones, which represent significant potential for our cellular platform.

First, our Phase I study evaluating PLX-R18 cells in subjects with incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT) demonstrated positive topline results as [reported](#) in April 2021, and we expect to present full data readout in the fourth quarter of this calendar year. We also expect to continue the development of the program and to initiate a Phase II study in hematological indication. Second, we expect topline results in the fourth quarter of this calendar year for both of our Phase II studies of PLX-PAD cells to treat acute respiratory distress syndrome (ARDS) associated with COVID-19 in the U.S., Europe, and Israel. Third, our Phase III study evaluating PLX-PAD cells to support muscle regeneration after hip fracture surgery has enrolled more than 95 percent of its patients and is expected to complete enrollment in October 2021.

Clinical Pipeline: Milestones* / calendar year

Q4 2021		
Clinical studies	Phase	
Muscle regeneration following Hip fracture	III	End of enrollment
ARDS associated with COVID-19	II	Topline results
HCT	I	Full data readout

* Expected milestones

Figure 1 - Clinical Pipeline: Milestones



Strategic Plan: Platform Expansion

In the last decade, we have developed an automated and robust current Good Manufacturing Practice (cGMP) manufacturing platform for allogeneic cells originating from the fetal and maternal cells from the placenta. Using this platform, we can produce large quantities of high-quality cells suitable for a variety of applications and uses. The manufacturing platform enables us to develop targeted pipelines of cellular product candidates including induced or modified PLX cells:

Induced PLX cells: These cells from the placenta are induced with different cytokines to transiently alter their secretion profile. Our first product candidate under this technology is PLX-R18. The positive data presented in the hematology study in April 2021 supports our approach of targeting cells with superior activity per indication. We expect to continue developing this platform for inducing cells and are in advanced development to complete additional targeted product candidates of this nature.

Modified PLX cells using CRISPR technology: We are also working on integrating CRISPR's revolutionary genetic engineering technology to potentially engineer PLX cells with novel and targeted functionality. Combined with our placenta-derived cell manufacturing platform, Pluristem would use CRISPR technology to potentially develop a new class of ex vivo modified allogenic PLX cell therapy product candidates to address new indications.

In short, we have developed a reliable, stable, and cost-effective cell expansion platform. We believe that using the placenta as a unique cell source combined with our innovative research, development, and high-quality manufacturing capabilities will be the engine that drives this platform technology towards the successful development of additional PLX cell therapy product candidates and indications.

We are excited to continue developing the powerful therapeutic capabilities of placental cells while using our advanced technology to push boundaries.

Summary: Key Competitive Advantage

What is Pluristem's biggest advantage? Our talented management team and I asked this question in recent months as part of our five-year strategic discussions. The outcome is clear: Develop effective and innovative cellular product candidates while assuring manufacturing capacity on the back end when the product candidate is ready for market. We believe that this is our defining competitive advantage. Over the years, we have received interest from potential partners to use our platform for pharmaceuticals and other industries. Pluristem intends to use its unmatched



technological advantage to establish mutually advantageous partnerships towards the best utilization and optimization of our assets for the benefit of our shareholders.

Sincerely,

Yaky Yanay
CEO & President

About Pluristem Therapeutics

Pluristem is pushing the boundaries of science and engineering to reimagine pharmacological treatments and improve the standard of care. The Company's cell therapies advance the field of regenerative medicine, with potentially groundbreaking applications for treating damaged muscle, hematology deficiencies, and inflammation. Pluristem sources its therapeutic cells from the placenta, an ethically accepted and potent source. Cells are easy to collect and do not require blood or tissue matching. Cells from one placenta can treat 20,000 patients. The Company's manufacturing platform, the bioreactor, is a patented and validated state-of-the-art 3D cell expansion system, designed to mimic the human body. Pluristem's method is uniquely accurate, cost-effective, and consistent batch-to-batch.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses the expected timing of the topline results from its Phase II studies of PLX-PAD cells to ARDS associated with COVID-19 and the presentation of the full data readout of the HCT Phase I study evaluating PLX-R18 cells, the expected completed enrollments in its Phase III study evaluating PLX-PAD cells to support muscle regeneration after hip fracture surgery, its expectation that it will continue the development of its platform for inducing cells and is in advanced development to complete additional targeted product candidates of this nature, its intention to use CRISPR technology to potentially develop a new class of ex vivo modified allogenic PLX cell therapy product candidates to address new indications and that it intends to use its technological advantage to establish mutually advantageous partnerships towards the best utilization and optimization of its assets. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem only and are subject to several factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted



by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

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