



## **Pluristem Issues Letter to Shareholders**

HAIFA, Israel, January 30, 2014 -- [Pluristem Therapeutics Inc.](http://www.pluristem.com) (NASDAQCM: PSTI) (TASE:PLTR), a leading developer of placenta-based cell therapies, today issued a Letter to Shareholders from its CEO, Zami Aberman. The company also announced that it has launched a revised corporate website, [www.pluristem.com](http://www.pluristem.com), the content of which is not part of this press release, where investors and other interested parties can find extensive information about Pluristem and its cell therapies.

Dear Pluristem Shareholders,

We are proud to have begun 2014 with the announcement of top-line results of our Phase I/II muscle injury study. The study demonstrated safety and, with respect to the subjects treated with 150 million PLX-PAD cells, showed statistically significant improvements in its primary and secondary efficacy end points of increased muscle volume and strength when PLX-PAD cells were compared to placebo. Pluristem intends to build on these results as we plan further development of PLX-PAD cells for the orthopedic and sports injury markets. The company has also been in discussions with representatives of orthopedic companies about potential collaborations for the use of PLX-PAD in these markets.

The results of our muscle injury trial are in line with the successful outcome of our two Phase I/II clinical trials in critical limb ischemia (CLI). That trial demonstrated a significant improvement in its primary end point of amputation-free survival (AFS) when compared to historical data.

The results from these multiple clinical trials suggest that PLX-PAD cells are safe and can significantly improve patients' health. They also validate the superiority of our PLX cells and proprietary 3D culturing technology over current standard of care treatments.

2013 saw Pluristem achieve the following milestones:

- Completed construction and initiated operations at our new state of the art GMP-approved facility in Haifa
- Installed our 3D cell culturing systems into our new facility and demonstrated that the system implementation has maintained the quality of the PLX cell product
- Consummated an out-licensing and partnership agreement with CHA

Bio&Diostech for the South Korean market

- Initiated a Phase I study in Pulmonary Arterial Hypertension (PAH) to be conducted in Australia with United Therapeutics
- Returned to enrollment for the Phase II study in Intermittent Claudication (IC) following the FDA's clinical hold lift
- Advanced IC trials into Germany, Israel and South Korea markets in addition to the US market
- Initiated and pursued efforts to introduce PLX-PAD into the preeclampsia market
- Demonstrated potential efficacy in tendon injuries and in the gastrointestinal manifestations of Graft versus Host Disease (GvHD)
- Increased the company's patent portfolio

- Our New State-of-the-Art 3D Cell Manufacturing Facility

In January 2013 we took possession of our new state-of-the-art, good manufacturing practices (GMP) facility. This facility has the capacity to produce over 150,000 doses of PLX cells utilizing a totally automated manufacturing process that contains at its core our proprietary 3D bioreactor technology. Additionally, our new facility allows for the development of different PLX cells products, such as PLX-PAD and PLX-RAD. In 2013 we completed the comparability studies between our old and new facilities and we are currently awaiting the U.S. Food and Drug Administration's (FDA) response on our submissions. This January, Germany's health authority approved our new facility. We can now supply cells produced with our advanced, fully automated and proprietary 3D technology platform for clinical trials or commercialization of cell products, once approved, in Germany.

- The CHA Bio&Diostech Agreement

We recently consummated our second out-licensing and partnership agreement with a healthcare company. Pluristem's agreement with South Korean-based CHA Bio&Diostech creates an opportunity for us to accelerate the clinical activity of our PLX cells.

The first indication agreed upon by Pluristem and CHA is in the area of Peripheral Artery Disease (PAD). CHA bears the entire cost of developing PLX cells for the indication of PAD in South Korea while Pluristem provides the cells. Upon commercialization, Pluristem and CHA Bio&Diostech will establish a 50/50 joint venture (JV) for marketing to South Korea.

We view our cooperation with CHA Bio&Diostech as long term strategic partnership. Based on the size and the opportunities of the South Korean market for PAD-related indications, we strive to expand our presence and activity in this dynamic territory. According to the research firm [Clearstate](#), 1 million people in South Korea have PAD and the growth forecast of the disease is estimated to be moderate-to-high.

CHA will participate in our multinational Phase II IC trial which recently has been

approved by the South Korean Ministry of Food and Drug Safety (MFDS). Additionally, an advanced CLI clinical trial is anticipated with CHA in South Korea.

- Progress in the United Therapeutics Collaboration

Pluristem signed this out-licensing and partnership agreement with United Therapeutics in 2011 for the use of PLX-PAD cells in the treatment of Pulmonary Arterial Hypertension (PAH).

Following favorable preclinical studies, United Therapeutics received approval in April 2013 to perform a human Phase I dose escalation study in Australia using our PLX-PAD cells in patients diagnosed with PAH. The study is currently enrolling patients.

- New Indications

In addition to the human Phase I and Phase II trials for the indications mentioned above, in 2013 we identified and documented potential efficacy in preclinical trials using our PLX cells for three important new indications: preeclampsia, tendon injury, and graft versus host disease (GvHD).

Independent studies conducted at the Texas A&M College of Medicine using our PLX-PAD cells in preclinical animal models of preeclampsia effectively improved several parameters of the disease. The study results were subsequently presented in May 2013 at the Society for Gynecological Investigation Summit held in Jerusalem. The potential for PLX-PAD cells to be used as a novel therapeutic for the treatment of preeclampsia is very exciting because there is currently no acceptable treatment for this potentially lethal disease, save terminating the pregnancy.

Orthopedic researchers at New York's Hospital for Special Surgery (HSS) conducted an independent study using our PLX cells in animal models of tendon injury. These studies validated our strategy to pursue the development of PLX cells for tendon injuries and represent an expansion of our orthopedic and sports injury franchise.

PLX cells have also demonstrated efficacy in the treatment of GvHD in animal models, an often lethal complication of bone marrow transplantation (BMT), with our PLX cells demonstrating a statistically significant improvement in the GvHD score versus controls. We are in discussions with a leading U.S. hematology cancer research center involving a Phase I clinical trial using our PLX-PAD cells in GvHD.

- Expanded Patent Portfolio

Our intellectual property portfolio is a critical asset to our company. Pluristem was issued several U.S. and non-U.S. patents, which bring our patent count to 27 issued patents and over 100 patent applications.

Based on the achievements in the past year, we believe that Pluristem's cell therapies has the potential to become the cell therapy medicine breakthrough of the 21<sup>st</sup> century. The scientific community agrees that cell therapies hold great promise in the future of

medicine. We believe that our 3D cell manufacturing platform that can produce large, commercial scale consistent batches of cells, when combined with the efficacy our cells have demonstrated to date, create a powerful combination unique to Pluristem. We've built a stronger team and a stronger company in 2013 and we look forward to achieving additional milestones and continuing to build value in 2014. The entire Pluristem team wishes you and your families a happy, healthy and prosperous 2014.

Thank you very much for your continued support.

Zami Aberman

Chairman and CEO

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapies. The Company's patented PLX (PLacental eXpanded) cells are a drug delivery platform that releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory and ischemic diseases. PLX cells are grown using the company's proprietary 3D micro-environmental technology and are an "off-the-shelf" product that requires no tissue matching prior to administration.

Pluristem has a strong intellectual property position, company-owned GMP certified manufacturing and research facilities, strategic relationships with major research institutions, and a seasoned management team. For more information visit [www.pluristem.com](http://www.pluristem.com), the content of which is not part of this press release.

### **Safe Harbor Statement**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, we are using forward-looking statements, when we discuss our plans to further develop PLX-PAD cells for the orthopedic and sports injury markets, when we discuss PLX-PAD cells being safe and can significantly improve patients' health, or the superiority of our PLX cells and proprietary 3D culturing technology over current standard of care treatments, when we discuss our relationship with CHA bio, how we strive to expand our presence and activity in South Korea and our planned CLI clinical trial, when we discuss our plans to pursue the development of PLX cells for new indications, when we discuss our belief that our cell therapies have the potential to become the cell therapy medicine breakthrough of the 21st century, when we discuss the powerful combination our 3D cell manufacturing platform create together with the efficacy our cells have demonstrated to date, or when we discuss our anticipation for 2014. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem only, and are subject to a number of 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; we may encounter delays or obstacles in

launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real surgical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; 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.

Contact:

Pluristem Therapeutics Inc.:

Karine Kleinhaus, MD, MPH  
Director of Investor Relations  
1-914-512-4109  
[karinek@pluristem.com](mailto:karinek@pluristem.com)

Daya Lettvin  
Investor & Media Relations Director  
+972-54-674-5580  
[daya@pluristem.com](mailto:daya@pluristem.com)