

Pluristem's CEO Letter to Shareholders

October 09, 2012

Dear Pluristem Shareholders,

The past several months has positioned Pluristem as a leader in the development of cell therapies, with a strong balance sheet and with multiple potential products. Most notably, Pluristem now has approximately \$70 million dollars in cash with no debt, targeting future clinical trials in Bone Marrow Transplant failure indications following the treatment of critically ill patients under a compassionate use program, commenced an FDA-approved Phase II clinical trial using PLX cells for the treatment of Intermittent Claudication, began scaling up production capacity of PLX cells, expanded the potential markets for our PLX cells, and received regulatory approval to conduct clinical trials at a number of new sites, including Germany and India. These achievements attest to the hard work, dedication and ingenuity that our team demonstrates on a daily basis. I am pleased to share a summary of our most recent accomplishments:

Increased cash position to approximately \$70 million

Having just raised \$34 million net in a secondary offering, our cash position is now at approximately \$70 million, with no debt. With this strengthened balance sheet, we are well positioned to support all of our clinical programs with a goal of bringing PLX cells to the market for several indications.

Targeting future clinical trials in Bone Marrow Transplant failure indications following the treatment of critically ill patients under a compassionate use program

Pluristem's PLX cells treated critically ill patients under a compassionate use program at the Hadassah Medical Center in Jerusalem. Patients who had failed bone marrow transplantations were treated with our PLX cells. Following the improvement of their clinical condition and hematology counts after treatment, Pluristem believes these cases demonstrate the potential our treatment holds for the recovery of bone marrow following bone marrow transplant failure as well as their potential use in other hematological diseases. We are establishing an international Clinical Advisory Board (CAB) to advise the Company surrounding the best target indications in the Bone Marrow Failure space and proposed future clinical trials.

Phase II clinical trial in the field of peripheral artery disease

We are also excited to have begun our FDA-approved Phase II clinical trial using PLX cells for the treatment of Intermittent Claudication (IC), a form of peripheral artery disease (PAD). Activity at the first site at Duke University Medical Center began in early September and we have already received Institutional Review Board (IRB) approval for the trial protocol for five out of our eleven U.S. clinical site locations. We also plan to open clinical sites in Germany and Israel as part of our worldwide activity. There are approximately 14 million IC patients worldwide.

Phase I/II clinical trial in muscle injury

Pluristem received approval from the Paul Erhlich Institute (PEI), the medical regulatory body in Germany, to commence a Phase I/II randomized, double blind, placebo controlled study to assess the safety and efficacy of PLX cells given intramuscularly (IM) for the rehabilitation of injured gluteal muscles following a total hip replacement.

Phase II clinical trial in Buerger's Disease

Pluristem received permission from the Indian Ministry of Health to proceed with a Phase II clinical trial for the treatment of Buerger's disease patients. If successful, we anticipate that following this Phase II trial we will begin a larger multi-national Phase III study in the U.S., Europe and India.

Orphan Drug Application for Aplastic Anemia

Pluristem also filed an FDA request for Orphan Drug Status for the use of our PLX cells in the treatment of Aplastic Anemia (a disease involving bone marrow failure). We have already successfully received orphan drug status from the FDA for our PLX cell therapy for the treatment of Buerger's disease.

New State of the Art Adherent Stromal Cells manufacturing process

We have also been hard-at-work optimizing our manufacturing process, including scale up and automation processes in order to accommodate future commercial production of our PLX cells. We initiated the "integral runs" that incorporate all the scale up and automation processes into a seamless production line. These "integral runs" will enable us to move the production line into our new manufacturing facility effectively.

New State-of-the-Art GMP manufacturing facility

In the last 1 ½ years we have also been working closely with our subcontractors to build our new Good Manufacturing Process (GMP) manufacturing facility. We anticipate that our new manufacturing facility will be ready by the end of the year. We plan to move the new production line into the new facility and meeting our planned milestone of starting the integration of the new PLX production line in our new GMP facility. Large-scale manufacturing capabilities for our PLX cells is vital to the success of our clinical trials and the potential commercialization of PLX products.

New fields of research

The results of preclinical studies demonstrate that our PLX cells may be effective in reducing pulmonary fibrosis and improving lung function in Interstitial Lung Disease. The positive results of these studies show promise for the use of PLX cells for the treatment of a range of pulmonary diseases and we anticipate conducting additional studies in this area.

We also received an invitation from the U.S. National Institutes of Health (NIH) to submit our PLX cells to their scientific teams for their evaluation in animal models for use in acute radiation syndrome (ARS). Additionally, Pluristem recently renewed a five-year Collaborative Research Agreement with the Berlin-Brandenburg Center for Regenerative Therapy at the Charité University of Medicine in Berlin. The Berlin-Brandenburg Center will continue to perform bench-top as well as pre-clinical studies using our PLX cells.

We are very proud of the immense progress that our team has made over the past few months. With so many major milestones on the horizon, we look forward to keeping you updated on the progress of our clinical trials, partnerships and other activities in the coming months.

As we have now just celebrated the arrival of the new Jewish year, I wish you and your families a happy, healthy and fruitful new year.

Thank you very much for your continued support.

Zami Aberman Chairman and CEO

About Pluristem Therapeutics

Pluristem Therapeutics Inc. (NASDAQCM: <u>PSTI</u>) (TASE:PLTR) 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 is focusing on the development of PLX cells administered locally to potentially treat systemic diseases and potentially obviating the need to use the intravenous route.

Data from two phase I studies indicate that Pluristem's first PLX product candidate, PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease when given locally. Additionally, Pluristem is developing PLX-PAD for cardiac ischemia, PLX-BMP for Acute Radiation Exposure, Bone Marrow Transplant Failure and Chemotherapy induced Bone Marrow Aplasia, PLX-ORTHO for orthopedic indications and PLX-PAH for Pulmonary Hypertension in collaboration with United Therapeutics. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis.

Pluristem has a strong patent portfolio, 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, the content of which is not part of this press release. Follow Pluristem on Twitterwww.pluristem.com, the content of which is not

<u>CLICK HERE</u> to watch a video where CLI patients and doctors involved with the clinical trials share their stories, 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 how we are positioned to support our clinical programs with a target to bring PLX cells to the market for several indications, when we discuss how the compassionate treatment cases demonstrate the potential our treatment holds for the recovery of bone marrow following bone marrow transplant failure as well as potentially in other hematological diseases, when discuss our plan to open clinical sites in Germany and in Israel, when we discuss our expectation to begin a multinational phase III study in Burger's disease, when we discuss our expectation that our new manufacturing facility will be ready by the end of the year, when we discuss our future commercial production and commercialization of PLX cells, when we discuss how studies we conducted show promise for use of PLX cells for the treatment of a range of pulmonary diseases and how we anticipate conducting additional studies in this area. when we say that the Berlin-Brandenburg Center will continue to perform bench-top as well as pre-clinical studies using our PLX cells, when we say that data from two phase I studies indicates that PLX-PAD is safe and potentially effective for the treatment of end stage peripheral artery disease, or when we discuss how pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications. These forward-looking statements 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 our clinical trials; 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.

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