



## **Pluristem's CEO Letter to Shareholders**

Dear Pluristem Shareholders,

In 2012 we have made great progress and moved closer to fulfilling our vision of being a leader in developing and manufacturing cell therapies. We have had significant achievements in many areas including:

1. Clinical trials development activity
2. Exploring new potential product candidates
3. Enhancing our IP position
4. Insured financial soundness and joining the Tel Aviv 75 and 100 indexes
5. Constructing a new state of the art manufacturing facility for our PLX Cells

### **Clinical trials development activity**

Achievements in clinically developing our products attest to the hard work, dedication and ingenuity that our team demonstrates on a daily basis. In 2012 our milestones included:

1. The initiation of an FDA-approved Phase II clinical trial using PLX cells for the treatment of Intermittent Claudication (IC), a form of Peripheral Artery Disease (PAD)
2. The approval by the Paul Ehrlich Institute (PEI), the German medical regulatory body, to commence a Phase I/II clinical trial for the rehabilitation of injured gluteal muscles following a total hip replacement
3. The filing with the FDA for Orphan Drug Status in using our PLX cells in the treatment of Aplastic Anemia (a disease involving bone marrow failure)
4. The successful treatment of critically ill patients under a compassionate use program at the Hadassah Medical Center in Jerusalem
5. The development of a Point-of-Care thawing device for our PLX Cells
6. The invitation by the U.S. National Institutes of Health (NIH) to submit our PLX cells to their scientific teams to evaluate them in animal models of acute radiation syndrome (ARS)
7. The formation of a Peripheral Artery Disease Steering Committee and a Hematological Diseases Clinical Advisory Board (CAB)

### **Exploring new potential product candidates**

We have conducted several preclinical studies this year and the results of these studies demonstrate that our PLX cells may be effective in a number of indications. Because we can produce specific PLX products tailored towards the mechanism of a disease, this allows us to expand these indications. We discovered and developed a dedicated composition of PLX cells tailored to possess unique characteristics found to be beneficial in the treatment of Acute Radiation Syndrome and bone marrow illness.

In the pulmonary area, we were able to improve lung function and reduce the pulmonary fibrosis that occurs in Interstitial Lung Disease (ILD). In the cardiac area, we have demonstrated that the cardiac function in diabetic animals with heart failure was improved by using our PLX cells.

### **Enhancing our IP position**

During 2012 we have invested significant efforts in strengthening our IP position. We have filed several new patent families covering new indications, new devices and manufacturing processing. We were also granted several patents and filed new applications at the National Phase stage. As of December 2012, all of this activity has led to Pluristem fully owning 22 granted patents and 95 pending applications.

### **Insured financial soundness and inclusion into the Tel Aviv 75 and 100 indices**

We are very proud to be included in the Tel Aviv 75 and Tel Aviv 100 indices. The TA-100 Index is one of the TASE's leading indices and is comprised of the shares of the 100 largest Israeli companies ranked by market capitalization. As a result, we now have exposure with more institutional, long-term investors who are now able to invest in our stock due to our inclusion in these indices. This is a good step in the right direction for our company as we look to bring in more institutional investors to become long-term shareholders of our stock. During 2012 we raised \$34 million net in a secondary offering. With our strong cash position of approximately \$65M with no debt, we are well positioned to support our research and development as well as our clinical programs with a goal of bringing PLX cells to the market for several indications.

### **Constructing new “state-of-the-art” manufacturing facility for our PLX Cells**

We have recently initiated the final validation steps for our new Good Manufacturing Process (GMP) facility prior to taking possession. I am extremely proud of our team in meeting milestones for the completion of this state of the art facility. We have also been hard-at-work optimizing our manufacturing process, including the scale up and automation processes, to accommodate the potential future commercial production of our

PLX cells. We have 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.

We are very proud of the immense progress that our team has made this year. 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.

I wish you and your families a happy, healthy and fruitful 2013.

Thank you very much for your continued support.

Zami Aberman  
Chairman and CEO

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. (NASDAQCM:PSTI) (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.

Pluristem has a strong patent and patent applications 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](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, when we discuss the successful treatment of critically ill patients under a compassionate use program at the Hadassah Medical Center in Jerusalem, when we discuss that our PLX cells may be effective in a number of indications based on preclinical studies that were conducted this year, when we discuss that we now have exposure with more institutional, long-term investors who are now able to invest in our stock due to our inclusion in the TA indices, when we discuss that we are well positioned to support our research and development as well as our clinical programs with a goal of bringing PLX cells to the market for several indications, when we discuss the potential future commercial production of our PLX cells and when we discuss the "integral runs" that will enable us to move the production line into our new manufacturing facility effectively. 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 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.

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