



Dear Shareholders,

As we close in on the end of the calendar year, it is important to look back upon all that we at Pluristem have accomplished over the last 12 months, but it is even more crucial to focus the majority of our energies on the challenges and opportunities awaiting Pluristem Therapeutics in 2012 and beyond.

Here is a recap of our recent achievements, which have put the company on course for a very successful future.

### **Phase I CLI Study Data**

In early November we announced positive 12-month data from our Phase I open-label, dose-escalation clinical trials, conducted under protocols approved by the Food & Drug Administration (FDA) in the U.S. and the Paul-Ehrlich-Institute (PEI) in Germany. PLX-PAD cells met all the clinical studies' protocol endpoints, demonstrating a safe immunologic profile at all dosage levels and suggesting that PLX-PAD is potentially effective in treating patients suffering from Critical Limb Ischemia (CLI). The results demonstrated no significant safety issues and proved that PLX-PAD cells can be safely given IM to patients without matching, even when the patients are dosed twice from the same placental source. These results, together with the great effort we invest in our manufacturing and operating capabilities, will provide us significant advantages when marketing PLX in the future.

### **United Therapeutics Update**

As you know, during the recently-closed first quarter of our fiscal year we recognized our first revenues from our exclusive out-license agreement with United Therapeutics Corporation (NasdaqGS: UTHR) for the use of Pluristem's PLacental eXpanded (PLX) cells to develop and commercialize a cell-based product for the treatment of Pulmonary Hypertension (PH). We are pleased with the collaboration to-date and are working closely with United Therapeutics on ensuring that we hit the upcoming key milestones in our quest to develop and receive regulatory approval for a product treating PH.

### **Manufacturing Facility Construction**

One of the cornerstones of Pluristem's strategy is to manufacture our PLacental eXpanded (PLX) based products and then enter into strategic partnerships with large pharmaceutical companies around the world for marketing and distribution, as we had done with United Therapeutics.

To that end, we reported in October that we had signed a deal with Biopharmax Group Ltd., a company specializing in the design and construction of biotechnological and pharmaceutical facilities, to handle the build-out of a new cGMP manufacturing facility in Israel that will meet regulatory authorities' requirements. We expect the facility to be completed by the end of the 2012 calendar year. This facility will allow us to significantly scale up our manufacturing capacity and will enable us to produce PLX cells for the treatment of over 150,000 patients annually, meeting the expected near-term demand for our products.

### **Financial Status**

In our recently released 10-Q quarterly report, we were pleased to record our first revenues. These revenues are the result of the licensing deal with United Therapeutics and they are a meaningful validation of our platform technology. We have a strong balance sheet with over \$45 million in cash and cash equivalent and short term bank deposits. We have successfully maintained a controlled and modest burn rate, despite making significant progress. Although we expect our burn rate to increase in the coming year, resulting from initiation of advanced clinical trials, no significant increase in manufacturing expenses is foreseen, due to our efficient production process. This advantage will become more and more noticeable as we progress with our clinical trials.

### **Our Potential Impact**

Before I close, I wanted to outline for you why our work at Pluristem is so important. Of course, we work hard on increasing shareholder value, but there is a different kind of impact to be felt if we are able to successfully develop our product candidates. The first therapy that Pluristem is focusing on is for CLI, where in the United States (U.S.) alone, patients undergo more than 160,000 major limb amputations per year. Current data suggest that approximately 20% of CLI patients will die within the first 6 to 12 months after disease onset and many others will require amputation within six months of diagnosis. Approximately half of all diabetes patients diagnosed with CLI will undergo a major amputation following diagnosis, and many will require a second amputation within 3 to 5 years.

The overall U.S. hospitalization and amputation rate associated with CLI has increased since 1985, suggesting a growing incidence of CLI and a substantial unmet medical need to improve outcomes for these patients beyond conventional treatments. All this adds up to a total annual cost of between \$10 billion and \$20 billion for treating U.S. CLI patients. Economic modeling indicates that even a 25% reduction in amputations has the potential to create annual savings for the U.S. health care system of up to \$3 billion. This is just a conservative model and for one therapy only.

In conclusion, Pluristem has an opportunity to impact society, and it is important for our shareholders to understand that through the development of our CLI product, we

are working towards fulfilling our mission of bringing significant changes to the lives of patients around the world.

We thank you for your continued support, and we look forward to providing you with more exciting news in the coming months on both the business and the technology aspects of Pluristem.

Thank you very much,

Zami Aberman  
Chairman and CEO

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR) is a leading developer of standardized cell therapy products for the treatment of life threatening diseases. The company's patented PLX (PLacentaleXpanded) cells drug delivery platform releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory 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. 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. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in nerve pain and muscle damage, when administered locally, and in inflammatory bowel disease, MS and stroke, when administered systemically.

Pluristem has a strong patent portfolio, 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), or follow us on Twitter [@Pluristem](https://twitter.com/Pluristem), the contents of which are not part of this press release.

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**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 ability to implement our business model and enter into strategic partnerships with pharmaceutical companies in the future, when we discuss our product development and clinical trials plans, receipt of regulatory approvals, or plans and expectations with respect to our various clinical trials, and the expansion of the use of our PLX cells into additional product candidates, when we discuss our plans and beliefs concerning our new facility and expected production volume, when we discuss our burn rate or when we discuss the safety and potential effectiveness of PLX-PAD for the treatment of CLI. 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; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce or commercialize 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.