



Pluristem have been very busy during the last few quarters in exploiting our unique competitive position in being the only company with the ability to **manufacture mass quantities of cells** in a three dimensional manner. This advantage has attracted the attention of pharmaceutical companies in supporting our out-license business model for our PLacental eXpanded (PLX) cells. We have made significant progress in our clinical trials' schedule in the area of peripheral artery disease (PAD) and muscle injury as well as expanded our PLX product pipeline by enhancing our activity in the area of radiation exposure. Additionally, we are on track with the build out of our new commercial grade manufacturing facility in Haifa and have substantially strengthened our management team.

### **Update on Pluristem's Clinical Trials**

#### **Muscle Injury:**

Pluristem plans to initiate a Phase II dose escalation trial using our PLX cells in muscle injury. Our cells will be administered into muscle routinely traumatized during hip replacement surgery in an effort to improve and shorten the rehabilitation time for the patient. The study will enroll an estimated 18 patients and be conducted at the Klinik für Orthopädie, Charité Hospital, Berlin, Germany. Pluristem has filed the Investigational Medicinal Product Dossier (IMPD) with the Paul-Ehrlich-Institut and will initiate the study upon regulatory approval.

#### **Peripheral Artery Disease (PAD):**

Pluristem's strategy is to provide a comprehensive approach to the PAD market, and we plan to initiate three clinical trials in this area.

Intermittent Claudication (IC): Pluristem plans a dose escalating Phase II trial in IC involving several clinical sites in the United States and Europe. IC is a subset of patients with a less severe form of PAD that afflicts approximately 17 million patients worldwide. We have finalized the study protocol, and will initiate the study upon regulatory approval of the Investigational New Drug (IND) Application in the United States and the IMPD in Europe.

Buerger's Disease: Buerger's Disease, a rare disorder, is a subset of PAD where the patient's vascular insufficiency is caused by an inflammation of the arterial wall rather than a build-up of cholesterol plaque in the artery that is seen in most cases of PAD. Pluristem's PLX-PAD cells have been given orphan drug designation for this indication by the U.S. Food and Drug Administration (FDA). The company plans to initiate a clinical trial in the U.S., Europe and India upon approval of the regulatory applications.

Critical Limb Ischemia (CLI): Pluristem is planning a Phase II/III pivotal trial at multiple sites in the USA and Europe for CLI, the most severe form of PAD that afflicts approximately 3 million patients worldwide. The endpoint for this pivotal trial will be amputation free survival (AFS). Based on recommendations of regulatory experts and potential collaborative partners, Pluristem has made the strategic decision to use only commercial-grade PLX cells for this pivotal clinical trial. These cells will be manufactured in our new facility scheduled to be completed towards the end of 2012. We will then file the necessary documentation with the U.S. FDA and European Medicines Agency (EMA) and upon regulatory approval, will begin this important trial.

## **Radiation Exposure**

Pluristem recently announced the expansion of our activity in using PLX cells for the treatment of radiation exposure following discussions with several governmental authorities seeking effective radiation countermeasures that are readily available and easily administered. Our pre-clinical studies in the treatment of radiation exposure were conducted in collaboration with

### [Professor Raphael Gorodetsky](#)

and his team at the Biotechnology and Radiobiology Laboratory, Sharett Institute of Oncology, Hadassah Medical Center, Jerusalem. In these studies, Pluristem's PLX cells demonstrated statistically significant improvement as mitigators of the acute radiation syndrome (ARS) and as protectants of the bone marrow following radiation exposure in animals. These animals were given lethal doses of radiation and 24 hours later were treated with our PLX cells. We believe that our off-the-shelf PLX cells can be stockpiled and provide a readily available, easily administered therapy which widens the window of treatment for victims of ARS.

### **Strengthened Management Team**

In the past quarter we have focused on building a best in class management team. We have recently welcomed [David Shoshani](#), MD as our Vice President, Clinical Affairs, [Ayelet Chajut](#), PhD as our Vice President Research, [Liat Flaishon](#), MD, PhD as our Business Development Director and [Ronit Monin](#), MSc.Pharm, MPH as our Regulatory Affairs Director. We are honored that they have joined our team and are confident that their experience and expertise will help to insure our future success.

### **Pluristem's New Manufacturing Facility**

We are on schedule with the build-out of our new manufacturing facility; which we believe will be one of the largest state-of-the-art, commercial-grade-capacity, good manufacturing practice (GMP) cell facilities in the world. We expect that our three dimensional (3D) expansion technology for manufacturing mass quantities of cells will give Pluristem competitive advantages for future product commercialization and potential collaborations. These advantages include being able to efficiently produce PLX cells in a controlled manner and the ability to manufacture specific PLX cell products for each indication we pursue.

### **Financial Status**

In our recently released 10-Q quarterly report, Pluristem demonstrated a strong balance sheet

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Mercredi, 29 Février 2012 13:30 -

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with approximately \$43 million in cash and deposits. Additionally, we recently announced receiving a \$2.4M grant by the Israeli government. This is the sixth consecutive year that Pluristem has received this grant in support of our innovative technology.

I hope this letter was informative. If you would like additional information, please do not hesitate to contact us.

Thank you very much,

Zami Aberman  
Chairman, President 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 therapeutic proteins in response to a number of local and systemic inflammatory diseases. PLX cells are grown using our proprietary 3D micro-environmental technology 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,*

**Pluristem : unique competitive position in being the only company with the ability to manufacture mass q**

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Mercredi, 29 Février 2012 13:30 -

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*strategic relationships with major research institutions and a seasoned management team.*