



**Dear fellow stockholders,**

A common objective drives our efforts at Pluristem: to bring innovative, effective treatments to patients suffering from conditions with few or no adequate treatment options. With exciting progress made on many fronts since the start of 2015, Pluristem has moved closer to reaching this objective. We have accomplished a key element of our strategic plan to significantly shorten the time to commercialization of our PLX-PAD cells in critical limb ischemia (CLI), while also advancing development of PLX-R18, our second product. We have reported additional positive findings from our successful Phase II muscle trial, which already met its primary and secondary endpoints last year. Pluristem has also made meaningful additions to its robust patent portfolio. We anticipate new accomplishments in 2015, and look forward to sharing them with you.

***Meaningful progress in executing our strategic plan***

A key element of Pluristem's strategic plan has been to reduce time to commercialization of our PLX-PAD cells in critical limb ischemia (CLI). To achieve this we applied to the new Adaptive Pathways pilot project in Europe and to the new regulatory pathway for regenerative therapy created under the Regenerative Medicine Law in Japan. In 2014, both Europe and Japan began offering unique opportunities to bring new products to market more quickly. Each country may now allow for limited commercialization of a product after a single successful initial trial, followed by further data collection and analysis after marketing has begun in order to evaluate the product for full marketing authorization. After the two programs were announced, we began working immediately to apply for the chance to commercialize PLX-PAD cells following a Phase II study and to circumvent the need for a long and expensive Phase III study. Building on the positive results of our two completed Phase I trials in CLI, we prepared and submitted applications to both new pathways.

On May 18, 2015, Pluristem announced that its PLX cell program in critical limb ischemia (CLI) was selected for the European Medicines Agency's Adaptive (EMA) Pathways pilot project, the goal of which is to improve timely access for patients to new medicines. Pluristem's successful application could significantly curtail the time and financial investment needed to bring the product to market. The acceptance into the Adaptive Pathways will provide Pluristem with detailed guidance and frequent, high-level communications with the Adaptive Pathways discussion group and other relevant stakeholders while preparing a trial protocol for submission to the EMA. A successful phase II study could then be the basis for a limited marketing authorization of the PLX-PAD cells in the subset of CLI tested in the trial, and also the potential for expansion of the indication or even expansion to other indications with PLX-PAD. Pluristem's manufacturing facility was approved in 2014 by EMA's Qualified Person after inspection of the

manufacturing facility and the 3D cell expansion technology platform. The Approved factory is capable of producing up to 150,000 doses per year and is ready to supply PLX-PAD as needed. Subject to a successful Phase II trial and with the EMA's conditional approval, Pluristem anticipates that PLX-PAD cells could enter the market in 2018 to treat patients with the clearly defined subtype of CLI studied in the trial.

On May 13, 2015 the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) recognized the current quality and commercial-scale manufacturing methods of PLX-PAD cells for use in CLI trials in Japanese patients. This was a crucial step towards Pluristem's acceptance into Japan's new accelerated pathway for regenerative medicines. This pathway permits a regenerative medicine product to reach patients without having to complete lengthy and expensive Phase III clinical trials. An exploratory study whose results show that a product is safe and likely to be effective can be sufficient for the product to receive conditional, time-limited marketing authorization. Following approval, the product is subject to post-marketing safety monitoring in conjunction with surveillance and study to further confirm its efficacy and safety. The new Regenerative Medicine Law presents an exceptional opportunity for Pluristem, and we eagerly await the PMDA's decision regarding our application to the pathway.

### ***Opportunities for additional partnerships***

Pluristem continues working to establish additional business collaborations with pharmaceutical companies. The new opportunities in Europe and Japan have translated into substantial interest from potential partners who would like to work together with us in both geographic regions. We are hopeful that we will achieve additional partnership for our CLI program over the next twelve months, and are also discussing partnerships for our muscle injury program and our emerging clinical program for PLX-R18, our second product. The first planned study of PLX-R18 in humans would be a Phase I trial to be submitted later this year. More details about the program are provided below.

### ***Strong clinical progress***

- Recruitment for our multinational, double blind, randomized, placebo controlled Phase II trial in intermittent claudication(IC) has recruited 88 of a total of 150 patients. With 25 active sites recruiting in the U.S., Germany, Israel, and South Korea, we anticipate completion of recruitment by the first quarter 2016. The safety data collected in this trial could potentially be used to support a submission to either the EMA or the PMDA for limited marketing authorization of PLX-PAD in CLI. IC can progress to CLI, a more severe diagnosis, and the pathophysiology is similar for these two subtypes of peripheral artery disease.
- In January 2014, we reported that a Phase II trial of PLX-PAD cells in muscle injury had clearly achieved both its primary and key secondary endpoints, with statistically significant findings of greatly

increased muscle strength and muscle volume in patients whose muscle was injured and then treated with PLX cells versus placebo. Earlier this year Pluristem reported good safety data at 12 months follow up of patients from this trial, as well as findings showing that the contralateral, non-operated leg muscle of patients who had received cells in their injured leg was much stronger than the non-operated leg muscle of patients who had received placebo. This finding was also statistically significant. The implication of this latest finding is that PLX-PAD cells may potentially treat additional muscle indications such as muscle atrophy or muscle wasting; these can occur in multiple contexts such as rehabilitation after long periods of immobility.

- Pluristem has made meaningful progress with the PLX-R18 program. This cell product targets hematological indications. Earlier this year we reported the U.S. National Institutes of Health's (NIH) significant positive results from their second preclinical trial of PLX-R18 cells for the treatment of the bone marrow component of Acute Radiation Syndrome (ARS). After exposure to high levels of radiation, bone marrow is severely damaged and can lose its ability to produce white and red blood cells and platelets, which sometimes leads to death. In animals who were exposed to high levels of radiation, survival and recovery of bone marrow function were substantially increased in those who received PLX-R18 as compared to those who received placebo. This trial also described the mechanism of action of PLX-R18 cells, showing their secretion of therapeutic proteins, followed by the recovery sequence of progenitor and then mature hematopoietic cells, and finally production of normal levels of white and red cells and platelets and their successful migration into the bloodstream. The NIH trials have been in small animal models. We and the NIH representative will have a Pre-IND meeting with the FDA to agree on the design and the protocol of the large animal studies required to approve PLX-R18 for treatment of the bone marrow component of Acute Radiation Syndrome under the Animal Rule. We strongly believe that following potential FDA approval, The NIH will approve the financing of the large animal studies, having financed the small animal studies. Positive data from large animal studies would be sufficient for an application to the FDA for approval in this indication, since human efficacy trials are not feasible in ARS.
- Building on data from more than 2 dozen animal trials studying PLX-R18 cells in hematologic indications, Pluristem is preparing a protocol for a Phase I trial to test these cells as a treatment for incomplete engraftment following hematopoietic cell transplantation. We anticipate submitting this protocol to the FDA by the end of 2015.

### ***Expansion of our patent portfolio to support our strategy***

Since the start of 2015, Pluristem has been granted key patents from Europe, Israel, South Africa, China, South Korea, Mexico and Russia. The European Medicines Agency's selection of Pluristem's PLX-PAD program in CLI for the Adaptive Pathways pilot project, together with patent No. EP2200622, granted in 2014 and titled "Adherent Cells From Adipose or Placenta Tissues and Use Thereof in Therapy", whose claims cover treatment of ischemia with placental-derived cells propagated using a 3D culture, place Pluristem in a unique position to move forward with its CLI program in Europe.

### ***Additional activities***

Other activities in the cell therapy arena also contribute to maintain our position as a leader in cell therapy. We continue to study the mechanism of action and capabilities of our cells and to share this knowledge with the scientific community and the cell therapy industry. Pluristem management has presented at 9 major scientific and industry conferences since January 2015. As active members in the Alliance for Regenerative Medicine and the International Society for Cellular Therapy, Pluristem continues to support the development of the regenerative medicine industry as a whole.

### ***Over the next 12 months we are looking forward to continuing our momentum and achieving several additional milestones***

- Submission of a Phase II study protocol to several national authorities for PLX-PAD cells in critical limb ischemia, after having received advice during discussions with the EMA
- Submission of a Phase I/II study protocol to the PMDA for PLX-PAD cells in critical limb ischemia
- Submission of a Phase I study protocol to the FDA for PLX-R18 cells in incomplete engraftment following hematopoietic cell transplantation
- Advancing a partnership with a pharmaceutical company to partner our CLI and/or Muscle injury programs.
- Completion of the recruitment for our multinational Phase II study in IC
- Preliminary data from the Phase I trial in pulmonary arterial hypertension being conducted by our partner United Therapeutics

We will continue to execute our long-term strategy to bring innovative and effective treatments to market in a timely fashion and to become a leader in the development and manufacture of cell therapies. We recognize and appreciate your continued support, and look forward to sharing upcoming achievements with you.

Sincerely,

Zami Aberman  
Chairman and Chief Executive Officer

For Pluristem Conference presentation, May 25, 2015-  
[http://www.pluristem.com/images/Pluristem\\_for\\_TASE\\_Combined.pdf](http://www.pluristem.com/images/Pluristem_for_TASE_Combined.pdf)

### 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 moving closer to reaching our objective to bring innovative, effective treatments to patients, when we discuss our anticipation for new accomplishments in 2015, when we discuss potential of approving our cells

for the treatment of CLI via the Adaptive Pathway to significantly curtail the time and investment needed to bring this product to market, when we discuss our anticipation that PLX-PAD cells could enter the market in 2018 to treat patients with the clearly defined subtype of CLI studied in the trial, when we discuss achieving additional partnership for our CLI program over the next twelve months, when we discuss our planned study of PLX-R18 in humans, the timing of its submission and related FDA and NIH approvals, when we discuss the timing for completion of recruitment for our phase II IC trial, when we discuss that PLX-PAD cells may potentially treat additional muscle indications, when we discuss the timing for submission of Phase II study protocol to several national authorities for PLX-PAD cells in CLI and submission for Phase I/II study protocol to the PMDA, or when we discuss timing for receipt of preliminary data from the Phase I trial in pulmonary arterial hypertension. 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. In addition, historic results of scientific research do not guarantee that the conclusions of future research would not suggest different conclusions or that historic results referred to in this letter would not be interpreted differently in light of additional research or otherwise. Also, while the company's program was selected for the European Medicines Agency's Adaptive Pathways pilot project, as well as recognized by the PMDA, these agencies are not bound by these communications and accordingly may change their position in the future due to reasons within or outside the control of Pluristem. 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.