



Pluristem Reports Fourth Quarter and Fiscal 2017 Corporate and Financial Highlights

- ***Company steps up its clinical platform with pipeline of three late-stage clinical indications***
- ***All late-stage programs are supported and funded by 3rd parties with over \$19 million in non-dilutive funding awarded to PLX programs***
- ***PLX-R18 advances towards pivotal trial in Acute Radiation Syndrome (ARS) with the NIH and with U.S. Department of Defense***
- ***Multinational pivotal phase III CLI trial actively enrolling patients, phase III study in hip fracture to follow***

HAIFA, Israel, September 11, 2017- Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, today reported financial results and corporate developments for its fourth quarter and fiscal year ended June 30, 2017.

“Fiscal 2017 has marked a significant advancement in our clinical development pipeline,” stated Pluristem Chairman and Co-CEO Zami Aberman. “We have completed patient enrollment in our Phase II Trial of PLX-PAD in Intermittent Claudication (IC) and expect clinical data from this study in the first half of 2018. We are currently in Phase III trials, with an ongoing pivotal Phase III study in Critical Limb Ischemia (CLI), and another Phase III planned for hip fracture. Our pipeline has been awarded non-dilutive funding of over \$19 million, which we believe will cover significant portion of the costs of these studies. Our PLX-R18 development has had significant progress and is heading towards a pivotal trial as a countermeasure for Acute Radiation Syndrome (ARS) as the U.S. National Institutes of Health (NIH) concludes a successful Phase II equivalent animal dosing study, enabling the selection of optimal dosage for the Pivotal study. The NIH’s promising results have led to an additional agreement with the U.S. Department of Defense (DOD) to evaluate PLX-R18 based on the scope needed for the U.S. armed forces, thereby broadening PLX-R18’s potential to protect troops and civilians before and after a nuclear incident.”

Pluristem Co-CEO and President Yaky Yanay commented, “Looking ahead to fiscal 2018, we look forward to meeting our enrollment target for our Phase III CLI trial, which may put us in a position to apply for conditional marketing approval of PLX-PAD for the treatment of CLI in Europe through the Adaptive Pathways project. We intend to continue our work with U.S. agencies on PLX-R18, including the NIH and DOD, towards approval that would qualify PLX-R18 for stockpiling. Pluristem has worked diligently throughout the fiscal year to bring the benefits of cell therapies closer to the patients and healthcare systems that need them.”

Clinical and Corporate Highlights Include:

PLX-R18 Advances Towards Pivotal Trial in Treatment of ARS; Investigated by the NIH and DOD as ARS Antidote Both Before and After Radiation Exposure- During fiscal 2017, the U.S. NIH released data from a successful large animal study that evaluated PLX-R18 as an antidote for ARS when administered 24 hours after exposure to radiation. Study results showed that all three doses of PLX-R18 demonstrated improved survival rates compared to placebo. The PLX-R18-treated groups also showed better and faster recovery of blood lineages, a major component of recovery after radiation-induced damage to bone marrow. Safety data showed that PLX-R18 cells can be safely administered without determining an individual's level of exposure to radiation and without any matching or blood tests, offering a significant and time-critical advantage when treating a mass casualty disaster.

In August 2017, we announced that the U.S. DOD will examine whether PLX-R18 administered prior to, or within the first 24 hours of, exposure to radiation will mitigate ARS. The DOD studies will be conducted in parallel with the NIH studies, allowing for a broader understanding of the potential therapeutic effects of PLX-R18 as a novel medical countermeasure for ARS. This announcement enjoyed broad media coverage, including features in media outlets such as [CNN](#), [124 News](#) and more.

Additional Regulatory Approvals for Pivotal Phase III CLI Trial; Actively Enrolling Patients with Goal of 40 Active Sites Worldwide by the End of 2017- Pluristem's multinational Phase III study of PLX-PAD cells in the treatment of CLI is currently enrolling in the U.S., U.K., Germany and Austria. An interim efficacy analysis is planned based on data from the first 125 patients. Positive results are expected to lead to early conditional marketing approval in Europe via the Adaptive Pathways project. Following completion of the study, data from all 250 patients will be submitted to the U.S. Food and Drug Administration (FDA) and the European Medicine Agency (EMA) for full marketing approval.

Total of \$19 million in Non-Dilutive Funding Awarded to PLX Programs- Pluristem's planned Phase III study to support recovery following surgery for hip fracture was awarded an \$8.7 million non-dilutive grant from the European Union's Horizon 2020 program. Previously, Horizon 2020 awarded \$8 million for Pluristem's Phase III study in the treatment of CLI. The two grants are expected to cover a significant portion of the costs of these Phase III studies.

Pluristem also received approval for a \$1.5 million grant from the Israel Innovation Authority within the Israeli Ministry of Economy to support its PLX-PAD program and was also awarded a "Smart Money" grant from Israel's Ministry of Economy and Industry to advance its product candidates towards marketing in China-Hong Kong markets.

The PLX-R18 Program also received \$900,000 in funding from the Israel-U.S. Binational Industrial Research and Development Foundation (BIRD) for a collaborative study with the New York Blood Center on umbilical cord blood transplantation.

Financial Update:

As of June 30, 2017, Pluristem had \$26.7 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. During the fiscal year, Pluristem conducted a public offering for aggregate net proceeds of \$15.7 million. The Company's net cash used for operating activities for the quarter ended June 30, 2017 was \$6.4 million and \$21.6 million during the fiscal year.

"Throughout our history, Company management has evaluated financing opportunities and market conditions in the best interest of our shareholders to ensure that we are able to execute on our business strategy. This year, we enjoyed major successes as our PLX programs were awarded \$19 million through non-dilutive grants, most recently in the amount of \$8.7 million by the E.U. to support our Phase III hip fracture trial. We continue to evaluate additional financing options available also through strategic and licensing opportunities," stated Yaky Yanay, Pluristem President and Co-CEO.

Goals for the Coming 12 Months

"We expect to meet significant milestones in the coming 12 months that will position Pluristem as a global leading cell therapy company," stated Zami Aberman and Yaky Yanay. "These milestones include completion of a partnership deal in Asia, continued development of our ARS project including 3rd party funding of pivotal studies from the U.S. government, expected data readouts from several clinical trials, launch of our phase III study for hip fracture, preparations for Biological License Application (BLA) submission in ARS and meeting enrollment goals for our CLI study. We look forward to leveraging our PLX platform technology for new and exciting business partnerships and opportunities, strengthening our balance sheet and bringing significant value to our shareholders. Over the past 12 months, we've made significant progress building our pipeline and technology platform. This year's upcoming milestones will enable us to monetize our capabilities for the benefit of the company and its shareholders."

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cell products release a range of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has a strong intellectual property position; Company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses that it expects clinical data from its Phase II trial of PLX-PAD in IC during the first half of 2018, when it discusses its planned Phase III trial in hip fractures, when it discusses its goal of having 40 active sites worldwide by the end of 2017 for its Phase III CLI trial, the expected recruitment plan in its Phase III CLI trial and possibly being in a position to apply for conditional marketing approval of PLX-PAD for the treatment of CLI in Europe through the Adaptive Pathways project, that the DOD studies relating to PLX-R18 as a treatment for ARS will be conducted in parallel with the NIH studies and that data from all 250 participants planned for the study will be submitted to the FDA and the EMA for full marketing approval and that the two grants provided by the Horizon 2020 program are expected to cover significant portion of the costs of these Phase III studies. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; 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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