

PLURISTEM THERAPEUTICS INC

Form FWP

October 30, 2017

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Issuer Free Writing Prospectus

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Registration No. 333-218916

October 30, 2017

COMPANY PRESENTATION October 2017

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This presentation 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, we are using forward-looking statements when we discuss the expected timing of obtaining regulatory approval for our various patient trials and clinical data readout, proposed trials that may occur in the future, the timing and implementation of our collaborations with various partners and the execution of definitive agreements relating to such collaborations and the potential benefits and impact our products could have on improving patient health care. These forward-looking statements and their implications are based on the current expectations of our management 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 clinical 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 our actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, we undertake 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 us, reference is made to our reports filed from time to time with the Securities and Exchange Commission Forward looking Statement \*

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Cell therapy company using off the shelf placenta-derived cell products Entering late-stage trials in 3 indications Multifactorial therapy releasing a range of therapeutic proteins in response to signals from patient's body First in class 3D cell culturing technology allowing for efficient, controlled production of different cell products in commercial quantities CORPORATE OVERVIEW \*

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FINANCIAL GLANCE \* Pluristem Therapeutics Inc. NASDAQ: PSTITASE: PSTI Stock Price (As of 10/27/2017) \$1.97 Market Capitalization ~\$192 million Cash and Marketable Securities (As of 6/30/2017) \$26.7 million Debt \$0 Employees 180 Intellectual Property Ownership 115+ granted~100 pending

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\* PLURISTEM in one slide

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The PLX Platform Technology \*

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Best In Class GMP Facility \*

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3D Manufacturing, In-house Cell Production Potential capability to manufacture up to 150,000 doses annually \*

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Manufacturing CMC\* approved by \* \* Chemistry, Manufacturing, and Controls

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\* Placenta Derived Cells Ethically accepted Rich & Diverse Highly potent Pro-angiogenic Immunoregulatory Young donors Unlimited source & Easy to collect Over 25,000 Doses of 300 million cells per placenta The Placenta Project was Launched by the US National Institutes of Health (NIH) to further explore the role of the placenta in health and disease <http://www.the-scientist.com/?articles.view/articleNo/43618/title/The-Prescient-Placenta/>

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From The Miracle of Birth to Therapeutics for All \*

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Indication Critical Limb Ischemia (CLI) Intermittent Claudication (IC) Hip Fracture\*\*\* Acute Radiation Syndrome (ARS) Location U.S. Europe\* Japan\*\* U.S., Europe S. Korea, Israel U.S. Europe U.S. Late-stage trials Company Pipeline Pre-Clinical Phase 2 Phase 1 Phase 3 Product PLX-PAD PLX-PAD PLX-PAD PLX-R18 Single pivotal study \* One Multinational trial- U.S- phase 3, Europe- via adaptive pathway potentially allowing early marketing approval\*\* Via PMDA's accelerated regulatory pathway for regenerative therapies\*\*\* Pending FDA/EMA approval Pivotal study via FDA Animal Rule \* Funding

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A CHANGE IN REGULATORY ENVIRONMENT \*

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Regulatory Status CLI (PLX-PAD) Fast track approvalSingle pivotal study (n=246) Adaptive regulatory pathwaySingle pivotal study (n=246)Potential conditional approval on interim report (n=123) Accelerated regulatory pathwaySingle pivotal study (n=75) Hip fracture (PLX-PAD) Pivotal study Subject to FDA approval Adaptive regulatory pathwaySingle pivotal study ARS (PLX-R18) Animal rule pathwayOpen communication, unlimited pre-IND 14 FDA EMA PMDA

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Reduces inflammation Stimulates growth of collateral blood vessels Stimulates repair of damaged muscle PLX-PAD Peripheral Arterial Diseases Orthopedic Injuries \*

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PLX-PAD Mechanism of Action \*

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Two completed Phase I studies in Critical limb ischemia (CLI) in U.S. and Germany, N=27 Good safety profile Trends of efficacy (pain reduction and increase in tissue perfusion) Ongoing multinational Phase II study in Intermittent claudication (IC) in U.S., Germany, South Korea and Israel, N=172 Enrollment completed Data readouts expected in H1 2018 Completed Phase II study in muscle injury following total hip replacement in Germany, N=20 Good safety profile Strong efficacy (increase in muscle volume and muscle force) Completed and Ongoing Clinical Studies with PLX-PAD \*

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Ongoing multinational Phase III study In Critical Limb Ischemia (CLI) in U.S., Europe, N=246 Fast track designation from FDA Adaptive regulatory pathway from EMA Support from EU Horizon 2020 program Planned multinational Phase III study In Hip Fracture in U.S., Europe Adaptive regulatory pathway from EMA Support from EU Horizon 2020 program Planned Pivotal study in CLI in Japan, N=75 PMDA's accelerated regulatory pathway for regenerative therapies Form joint venture Completed and Ongoing Clinical Studies with PLX-PAD \* Pre-Treatment 8 Weeks posttreatment

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Peripheral Arterial Disease (PAD) \*Source: Sage Group- (link, link, link)\*\*Source: European Society for Vascular Surgery (link) \* Build up of fatty substances in the wall of the artery

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Primary endpoint is time to event (amputation or death); other measures of efficacy include AFS, quality of life, TcPO<sub>2</sub>, and pain score Dosing regimen: two doses of 300 million cells, two months apart (n=144), placebo (n=72) No HLA matching or immunosuppression required Follow-up of 12-36 months increases the study's power allowing for a smaller trial CLI Phase III Study -U.S./ Europe (N=246) \* Accelerated regulatory pathways in U.S. (Fast Track), Europe (Adaptive regulatory pathway) & Japan) accelerated regulatory pathway for regenerative therapies (An interim analysis (N=123) of efficacy will be performed in support of an application to the EMA for Conditional Marketing Authorization (CMA) Interim analysis could lead to CMA based on the success of either the primary or one of the key secondary endpoints, or a composite endpoint that includes death, major amputation, and certain measures of severity of wounds and gangrene \$8 million grant from the EU Horizon 2020 program to support Phase III trial

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Clinical Development of CLI in Japan Accepted to the PMDA's accelerated regulatory pathway for regenerative therapiesA single 75 patient study may lead to early conditional marketing approval and reimbursementBinding term sheet with Sosei CVC to establish joint venture for the clinical development and commercialization of PLX-PAD for CLI in Japan \*

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Injured (operated) Contralateral (non-operated) Improvement of 4000% P=0.012 Improvement of 500% P=0.0067 \* Muscle Regeneration- clinical data Muscle injury following total hip replacement (N=20)

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Muscle Injury following Total Hip Replacement (N=20) Change in Volume from Day 0 Improvement of 300%P=0.004 \* Muscle Regeneration- clinical data

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Phase III Hip Fracture Study Femoral neck fracture is the most common form of hip fracture Annual treatment costs in the U.S. are estimated to be between \$10 to \$15 billion, and are expected to rise due to the aging population, with mortality rates of up to 36%\*Positive feedback from FDA and EMA on the proposed study design and endpoints of Phase III trial in treatment for muscle recovery following arthroplasty for hip fracturePLX-PAD program in hip fracture might be eligible for Breakthrough Therapy designation and benefit from the 21st Century Cures Act as well as the EMA's Adaptive Pathways pilot project \* \* Source: Simran Mundi, Bharadwaj Pindiprolu, Nicole Simunovic, Mohit Bhandari \$8.7 million grant from the EU Horizon 2020 program to support this Phase III trial

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\* Stimulates regeneration of damaged bone marrow to produce blood cells (white, red and platelets) Acute Radiation Syndrome (ARS) Hematologic Indications PLX-R18

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PLX-R18 Mechanism of Action \*

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Acute Radiation Syndrome (ARS) In Preparations for pivotal study \* PLX-R18 Programs Bone Marrow  
Failure Following or in support of a transplant of hematopoietic stem cells (HCT) Ongoing Phase I study in U.S and  
Israel Hematological Disorders Autoimmune diseases, Genetic disorders, Chemotherapy, Radiation therapy, Side  
effects from treatments Covered by patent

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\* ARS occurs following acute exposure to very high levels of radiation, and involves severe, potentially lethal injury to the bone marrow as well as to other organs and systems within the body High doses of radiation can destroy the bone marrow's ability to produce white cells, red cells and platelets; without these cells patients are at high risk of death Acute Radiation Syndrome ARS

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Late Post Exposure Department of Defense (DOD)Warfighter and Immediate Response Department of Health and Human Services (DHHS)First Responders and Hospitals Armed Forces Radiobiology Research Institute NIAID/NIH Chronic Phase (Months-Years) Response Phase Exposure Timeline ResearchInstitutes & Agencies Governmental Departments Initial Response (hours) Clinical Syndrome 24h Pre-exposure Acute Phase (Days-Weeks) DEARE (Months-Years) ARS (Hours-Weeks) Early Post Exposure Collaboration on ARS with U.S. Government

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\* Studies are conducted and funded by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) and U.S the department of defense Collaboration on ARS with U.S. Government

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\* PLX-R18 Data- Phase I equivalent study (FDA animal rule) Survival Weight

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Placebo - 50% 20M/Kg - 67% 4/10M/Kg - 83/86% Non irradiated and low radiation -  
100% Group Females Males Females and Males Total 04+10 only NR-00 3/3 = 100% 3/3 = 100% 6/6 =  
100% 6/6 = 100% NR-04 3/3 = 100% 3/3 = 100% 6/6 = 100% 18/18 = 100% NR-10 3/3 = 100% 3/3 =  
100% 6/6 = 100% 18/18 = 100% NR-20 3/3 = 100% 3/3 = 100% 6/6 = 100% 18/18 = 100% R-00 1/3 =  
33% 2/3 = 67% 3/6 = 50% 3/6 = 50% R-04 2/3 = 67% 3/3 = 100% 5/6 = 83% 15/19 = 79% 11/13=  
85% R-10 3/4 = 75% 3/3 = 100% 6/7 = 86% 15/19 = 79% 11/13= 85% R-10 3/4 = 75% 3/3 = 100% 6/7 =  
86% 15/19 = 79% R-20 2/3 = 67% 2/3 = 67% 4/6 = 67% 15/19 = 79% R-Id-00 - 3/3 = 100% 3/3 =  
100% R-Id-04 - 3/3 = 100% 3/3 = 100% R-Id-10 - 3/3 = 100% 3/3 = 100% R-Id-20 - 3/3 = 100% 3/3 =  
100% Legend:R : RadiatedR-ID: Low RadiationNR : Non-Radiated R-00 : Not TreatedR-04 : 4 million cells per  
kgR-10 : 10 million cells per kgR-20 : 20 million cells per kg PLX-R18 Data- Phase II equivalent study (N=62) (FDA  
animal rule)

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Allogeneic, ready to use as an off the shelf product  
Easy IM administration  
Beneficial when administered even 48 hrs. following exposure to radiation  
No need for prescreening – no effect if injected to those who were not exposed to radiation  
Supports recovery of all three blood lineages (red and white cells and platelets)  
Long shelf life  
Showed increased survival rates In irradiated non-human primates (NHPs) \* PLX-R18- Treatment of ARS

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PLX-R18 Hematological Program \*

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Out-licensing commercialization deals with partners Direct sales of indications with small patients population & high market price Direct sales of our PLX-R18 product for Acute Radiation Syndrome (governments) Commercialization Strategy \*

Out-licensing commercialization deals with partners Direct sales of indications with small patients population & high market price Direct sales of our PLX-R18 product for Acute Radiation Syndrome (governments) Commercialization Strategy 38

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Partner Indication Deal structure IC, CLISouth Korea only Joint Venture following marketing authorization by the South Korean authorities Acute Radiation Syndrome U.S. National Institutes of Health (NIH) to examine the effectiveness of PLX-R18 as a treatment for ARS following 24 hours from exposure Acute Radiation Syndrome U.S. Department of Defense to examine the effectiveness of PLX-R18 prior to, and within the first 24 hours of exposure to radiation Acute Radiation Syndrome Pluristem will contribute cells and scientific knowledge, FMU will conduct the studies and provide the required resources. Acute Radiation Syndrome Conducting trials to test PLX-R18 cells in the treatment of ARS and understanding of MOA CLI, Immunology, Cardiovascular, Orthopedic Research to test the unique immunology of the placenta and cells MOA Umbilical Cord Blood Transplantation Evaluating PLX-R18 as an Adjuvant Therapy to Umbilical Cord Blood Transplantation Pluristem keeps IP and manufacturing rights in all collaborations Collaborations 39

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Investment Highlights Publicly traded on the Nasdaq and Tel Aviv Stock Exchange [PSTI] Late-stage pipeline with products advancing towards commercialization and 3rd parties fundingAdvanced regulatory pathways that could shorten time to commercialization Expected near-term data readouts“Off the shelf” product, no HLA-matching requiredUnique multifactorial MoA with a vast scientific background Major technological competitive advantagesStrong collaborations and partnerships \*

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Initiate pivotal trials  
Critical limb ischemia (CLI) – U.S., Europe (Japan yet to start)  
Hip fracture – U.S., Europe  
ARS  
Clinical data readout Phase II Intermittent Claudication (IC) Phase I incomplete engraftment of hematopoietic cell transplantation – open label  
Pivotal study in ARS  
Business development U.S. – Advance discussions with U.S. government regarding stockpiling of PLX-R18 for ARS  
Japan- Finalize joint venture  
Asia – Licensing/ joint venture with partner for Asian market  
Upcoming Milestones – 12 Months \*

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Zami Aberman Chairman & Co-CEO Efrat Livne-Hadass VP Human Resources Racheli Ofir, Ph.D. VP Research & Intellectual Property Sagi Moran VP Operations Erez Egozi CFO Karine Kleinhaus, M.D., MPH Divisional VP, North America Esther Lukasiewicz Hagai, M.D., Ph.D. VP Clinical & Medical Affairs Lior Raviv VP Development Yaky Yanay President & Co-CEO Orly Amiran VP Quality Assurance Management team \*

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