

PLURISTEM THERAPEUTICS INC
Form 10-K
September 11, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2014

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from [] to []

Commission file number 001-31392

PLURISTEM THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada 98-0351734
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

MATAM Advanced Technology Park,
Building No. 5, Haifa, Israel 31905
(Address of principal executive offices) (Zip Code)

Registrant's telephone number 011-972-74-7108759

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value \$0.00001	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:

None.

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer
Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

\$214,202,402

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

69,278,512 as of September 2, 2014

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Our financial statements are stated in thousands United States Dollars (US\$) and are prepared in accordance with United States Generally Accepted Accounting Principles (U.S. GAAP).

In this annual report, unless otherwise specified, all dollar amounts are expressed in United States dollars.

As used in this annual report, the terms "we", "us", "our", "the Company", and "Pluristem" mean Pluristem Therapeutics Inc. and our wholly owned Israeli subsidiary, unless otherwise indicated or required by the context.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Annual Report on Form 10-K (Annual Report) that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Such forward-looking statements may be identified by, among other things, the use of forward-looking terminology such as "believes," "intends," "plans," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, and similar expressions are intended to identify forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements appear in Item 1 – "Business" and Item 7 – "Management's discussion and Analysis of Financial Condition and Results of Operations," (especially in the section titled "Outlook") as well as elsewhere in this Annual Report and include, among other statements, statements regarding the following:

- the expected development and potential benefits from our products in treating various medical conditions;
- the exclusive license agreements we entered into with United Therapeutics Corporation (United) and CHA Bio&DioStech (CHA) and clinical trials to be conducted according to such agreements;
- the prospects of entering into additional license agreements, or other forms of cooperation with other companies and medical institutions;
- our pre-clinical and clinical trials plans, including timing of conclusion of trials;
- our belief that PLX cells may be effective in supporting bone marrow transplantation and in treating bone marrow suppression from radiation and chemotherapy;
- achieving regulatory approvals;
- developing capabilities for new clinical indications of placenta expanded cells (PLX);
- our expectation to compete based upon our intellectual property portfolio, our in-house manufacturing efficiencies and the efficacy of our products;
- the potential market demand for our products;
- our expectation that in the upcoming years our research and development expenses, net, will continue to be our major operating expense;

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- our expectations regarding our short- and long-term capital requirements;
 - our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses; and
 - information with respect to any other plans and strategies for our business.
-

The factors discussed herein, including those risks described in Item 1A. "Risk Factors", and expressed from time to time in our filings with the Securities and Exchange Commission (SEC) could cause actual results and developments to be materially different from those expressed in or implied by such statements. In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this Annual Report would be interpreted differently in light of additional research, clinical and preclinical trials results. The forward-looking statements are made only as of the date of this filing, and except as required by law we undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

PART I

Item 1. Business.

Our Current Business

We are a bio-therapeutics company developing off-the-shelf allogeneic cell therapy products for the treatment of multiple ischemic and inflammatory conditions, with our lead indications focusing on cardiovascular, orthopedic, pulmonary, hematological, and women's health diseases. Our patented PLX (PLacental eXpanded) cells function as a platform that releases a number of therapeutic proteins in response to various local and systemic inflammatory and ischemic signals, generated by the patient's own body. PLX cells are grown using our proprietary 3D micro-environment technology that produces a product that requires no tissue matching prior to administration.

We were incorporated as a Nevada corporation in 2001. We have a wholly owned subsidiary in Israel called Pluristem Ltd. We operate in one segment and our operations are focused on the research, development, clinical trials and manufacturing of cell therapeutics and related technologies.

Our strategy is to develop and produce cell therapy products for the treatment of multiple disorders using several methods of administration, such as intravenous and intramuscular injections. We plan to execute this strategy independently, using our own personnel, and through relationships with research and clinical institutions or in collaboration with other companies, such as United Therapeutics Corporation (United) and CHA Bio&Diostech (CHA). We have built a Good Manufacturing Practices (GMP) grade facility and we are planning to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

Scientific Background

Cell therapy is an emerging and promising field within the regenerative medicine area. The characteristics and properties of cells vary as a function of tissue source and growth conditions. The human placenta from which our PLX cells are derived provides an uncontroversial source of non-embryonic, adult cells and represents a new approach in the cell therapy field. The different factors that PLX cells release suggest that the cells can be used therapeutically for a variety of ischemic, inflammatory, autoimmune and hematological disorders.

PLX cells do not require tissue matching prior to administration. This allows for the development of ready-to-use allogeneic "off-the-shelf" products.

Our Technology

We develop and intend to commercialize cell therapy production technologies and products that are derived from the human placenta. Our PLX cells are adherent stromal cells (ASCs) that are expanded using a proprietary three dimensional (3D) process.

This system utilizes a synthetic scaffold to create an artificial 3D environment where placental-derived stromal cells can grow. Our 3D process enables the large scale production of reproducible, high quality cell products, and is capable of manufacturing large numbers of PLX doses originating from different placentas. Additionally, our manufacturing process has demonstrated batch-to-batch consistency, an important manufacturing challenge for biological products.

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Product Candidates

Our primary objective is to be the leading provider of allogeneic cell therapy products that are true off the shelf products that do not require any matching prior to administration. From the physician and patient's perspective, our PLX products are delivered in a vial and are administered using a standard needle and syringe. Our PLX products are in clinical stage development for multiple indications such as cardiovascular, orthopedic, pulmonary, and women's health diseases.

Our business model for commercialization and revenue generation includes, but is not limited, to the following activities that we may conduct with both pharmaceutical and medical device companies: partnerships, licensing deals, and joint ventures. To date, we have two strategic relationships, one with United for the licensing of PLX cells for the Pulmonary Arterial Hypertension (PAH), and a second strategic partnership with CHA in South Korea for both Intermittent Claudication (IC) and Critical Limb Ischemia (CLI). CHA is planning to conduct PLX clinical studies in South Korea, and, following regulatory approval, a joint venture equally owned with us will be established to market PLX products in South Korea. Currently, Pluristem's PLX cells are being used in a United-sponsored PAH trial in Australia, and in South Korean sites participating in our international IC study through our partnership with CHA.

These relationships are intended to leverage our expertise in manufacturing high quality, adult, placenta-derived cells, using our proprietary, scalable, efficient 3D cell manufacturing platform that supports the cost-effective mass production of PLX cells. Our policy for these partnerships is to retain control of the manufacturing of PLX cell products and their associated intellectual property.

We believe that using the placenta as a unique cell source, combined with our innovative research, development and high quality manufacturing capabilities, will be the "engine" that drives this platform technology towards the successful development of many PLX cell therapy products.

Our Clinical Development Product Candidates

Peripheral and Cardiovascular Diseases – We are investigating using PLX-PAD cells for treatments for multiple types of peripheral arterial disease from early stage IC to CLI.

We have completed two Phase I safety/dose-finding clinical trials for CLI, one in the United States and one in Germany. These CLI trials demonstrated that no blood or genetic matching is required and that the administration of PLX-PAD cells is safe, even if two doses are administered to patients from the same placental source. In addition, PLX-PAD cells are potentially effective in reducing amputation in CLI patients. Generally, the U.S. Food and Drug Administration (FDA) and the European Medicines Agencies (EMA) require the primary endpoint for pivotal CLI clinical trials to be Amputation Free Survival (AFS) at one year. The two studies we conducted suggest an AFS one-year rate of 85% versus the 66% as published for patients treated with currently approved methods of treatment.

Following our successful Phase I trials in CLI, a large international Phase II, double-blind, randomized, placebo-controlled, 4 arms trial was initiated in the United States, Germany, Israel and South Korea to assess the safety and efficacy of PLX-PAD in 150 patients suffering from IC. Similar to the Phase I studies in CLI, PLX-PAD cells are administered intramuscularly into the patient's affected leg. The primary efficacy endpoint for the study is the patient's maximal walking distance on a treadmill. In June 2013, the study was put on hold by the FDA (but subsequently lifted), following the occurrence of a serious hypersensitivity reaction in a patient participating in the study. We suspended the study in the other countries that were part of the study at the time of the clinical hold imposed by the FDA in June 2013 (Clinical Hold) (i.e., Germany and Israel), and provided the competent authorities from the different countries a comprehensive analysis of the hypersensitivity reactions that occurred with PLX-PAD in completed and ongoing studies. Following information submitted to the FDA, the FDA, the Paul Ehrlich Institute

(PEI) and the Israeli Ministry of Health (MOH) lifted the Clinical Hold during September and October 2013.

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Orthopedic Diseases – A Phase I/II, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of intramuscular injections of allogeneic PLX-PAD cells for the regeneration of injured gluteal musculature (GM) after total hip replacement is being conducted in Germany under the approval of the PEI. In this study, PLX-PAD cells or placebo were injected into the traumatized gluteal muscle during the total hip replacement. On July 11, 2013, we announced that enrollment for this clinical trial was completed. On January 21, 2014, we announced that the study met its primary efficacy endpoint, namely the change in maximal voluntary isometric contraction force of the gluteal muscle at six months after total hip replacement patients treated with PLX-PAD had a greater improved change of maximal voluntary muscle contraction force than the placebo group ($p=0.0067$). The one-year safety follow-up of all the patients was completed at the beginning of July 2014. The study is expected to be concluded with second year safety follow up expected in July 2015.

Pulmonary Diseases – We have out-licensed to United PLX-PAD for the treatment of PAH. A Phase I study was initiated in Australia in patients suffering from PAH during the second quarter of 2013.

Acute Radiation Syndrome (ARS) – Following positive data from the use of PLX-RAD cells in animals in stimulating hematopoiesis in diseased or injured bone marrow, we intend to pursue the development of PLX- RAD, for enhancing the engraftment of hematopoietic stem cells after bone marrow transplant. Additionally, on July 26, 2012 we received an invitation from the National Institute of Allergy and Infectious Diseases (NIAID), Department of Health and Human Services, to submit our PLX cells to the agency for evaluation in models of ARS. Through today we have conducted with the NIAID multiple animal research using PLX-RAD cells for the treatment of ARS.

Pre-eclampsia - Following promising results in a pre-clinical model of pre-eclampsia, we decided to engage in studies in preeclampsia with severe features. We applied to the FDA for an orphan drug designation and we are discussing with the FDA to evaluate the requirements to initiate a clinical trial of our PLX product for this indication.

Rotator-cuff Repair - Following promising results of a pre-clinical model of tendon injury, we have decided to conduct a multinational study in patients undergoing surgical repair of the rotator-cuff. We are working on the regulatory requirements to initiate this study.

Regulatory and Clinical Affairs Strategy

Our cell therapy development strategy is to hold open discussions with regulators at all stages of development from preclinical trials to more advanced regulatory stages. We utilize this strategy in working with the FDA as well as the EMA, Germany's PEI and the MOH, and working with the Ministry of Food and Drug Safety (MFDS) of South Korea and the Australian regulatory authorities via our collaborators.

Intellectual Property

We understand that our success will depend, in part, on maintaining our intellectual property, and therefore we are committed to protecting our technology and product candidates with patents and other methods described below.

We are the sole owner of 30 issued patents and more than 120 patent applications in the U.S., Europe, China and Japan, as well as in additional countries worldwide, including in the Far East, Israel and South America.

Based on the well-established understanding that the characteristics and therapeutic potential of a cell product are largely determined by the source of the cells and by the methods and conditions used during their culturing, our patent portfolio includes different types of claims that protect the various unique aspects of our technology.

Our multi-national portfolio of patent and patent applications include the following claims:

- Our proprietary expansion methods and devices for 3D stromal cells;
 - Composition of matter claims on the cells;
- The therapeutic use of PLX cells for the treatment of a variety of medical conditions; and
 - Cell-culture devices.

Through our experience with ASC-based product development, we have developed expertise and know-how in this field and have established procedures for manufacturing clinical-grade PLX cells in our facilities. Certain aspects of our manufacturing process are covered by patents and patent applications. In addition, specific aspects of our technology are retained as know-how and trade secrets that are protected by our confidentiality agreements with our employees, consultants, contractors, manufacturers and advisors. These agreements generally provide for protection of confidential information, restrictions on the use of materials, and assignment to Pluristem of inventions conceived during the course of performing services for us.

The following table provides a description of our key patents and patent applications and is not intended to represent an assessment of claims, limitations or scope. There is a risk that our patents will be invalidated, and that our pending patent applications will not result in issued patents. We also cannot be certain that we will not infringe on any patents that may be issued to others. See "Risk Factors - We must further protect and develop our technology and products in order to become a profitable company". The expiration dates of these patents, based on filing dates, range from 2019 to 2033. Actual expiration dates will be determined according to extensions received based on the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), commonly known as the "Hatch-Waxman" Act, that permits extensions of pharmaceutical patents to reflect regulatory delays encountered in obtaining FDA market approval. The Hatch-Waxman Act is based on a U.S. federal law and therefore only relevant to U.S. patents.

Pluristem's Patent Portfolio

Patent Name	Pending Jurisdictions	Granted Jurisdictions
METHOD AND APPARATUS FOR MAINTENANCE AND EXPANSION OF HAEMATOPOIETIC STEM CELLS AND/OR PROGENITOR CELLS	United States, Europe, Mexico	United States, Japan, Europe, Mexico, Australia, South Africa, Israel, Russia, New Zealand, India, China, Hong Kong, Canada
METHODS FOR CELL EXPANSION AND USES OF CELLS AND CONDITIONED MEDIA PRODUCED THEREBY FOR THERAPY	United States, Japan, Europe, Mexico, Israel, China, Hong Kong, Canada, Brazil, Korea, Singapore	Russia, South Africa, Australia, India
ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY	United States, Europe, Mexico, Australia, Israel, India, China, Hong Kong, Canada, Brazil, Singapore, Russia	United States, South Africa
ADHERENT CELLS FROM ADIPOSE OR PLACENTA TISSUES AND USE THEREOF IN THERAPY	United States, Japan, Europe, Mexico, Australia, Israel, India, China, Canada, Korea, Brazil, Russia, Hong Kong,	Europe, United States, Hong Kong, Singapore, South Africa, Australia,

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METHODS OF TREATING INFLAMMATORY COLON DISEASES	United States, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel	Russia, South Africa
METHODS OF SELECTION OF CELLS FOR TRANSPLANTATION	United States, Europe, Israel, Hong Kong	
ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY	United States, Europe, Israel, Hong Kong	
ADHERENT STROMAL CELLS DERIVED FROM PLACENTAS OF MULTIPLE DONORS AND USES THEREOF	United States, Europe, Israel, Hong Kong	
ADHERENT CELLS FROM PLACENTA AND USE OF SAME IN DISEASE TREATMENT	United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Mexico, New-Zealand	South Africa
METHODS AND SYSTEMS FOR HARVESTING ADHERENT STROMAL CELLS	United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Korea, Mexico, Singapore, South Africa	
METHODS FOR TREATING RADIATION OR CHEMICAL INJURY	United States, Europe, Hong Kong, Israel, Korea, Japan	
SKELETAL MUSCLE REGENERATION USING MESENCHYMAL STEM CELLS	United States, Europe, Israel, Hong Kong	

A comment to the table: In some cases, a jurisdiction is listed as both pending and granted for a single patent family. This is due to pending continuation or divisional applications of the granted case.

Research and Development

Our research and development expenses were \$24,938,000, \$19,906,000 and \$12,685,000 in fiscal years 2014, 2013 and 2012, respectively, before deducting the participation by the Office of the Chief Scientist (OCS) and grants by third parties.

Foundational Research

Our initial technology, the PluriX™ Bioreactor system, was invented at the Technion - Israel Institute of Technology's Rappaport Faculty of Medicine, in collaboration with researchers from the Weizmann Institute of Science. This technology has been further significantly developed by our research and development teams over the years.

Ongoing Research and Development Plans

In July 2007, we entered into a five year collaborative research agreement with the Berlin-Brandenburg Center for Regenerative Therapies at Charité - University Medicine Berlin (Charité). In August 2012, we extended our collaborative research agreement with Charité for a period of five years through 2017. We and Charité are collaborating on a variety of indications utilizing PLX cells. According to the agreement, we will be the exclusive owner of the technology and any products produced as a result of the collaboration. The Charité will receive up to 1% royalties from new developments that have been achieved during the joint development.

In recent years we have also engaged in research and development projects with other leading research institutions such as Hadassah University Medical Center (Hadassah) in Jerusalem, Israel and the Texas A&M Health Science Center (Texas A&M) in Round Rock, Texas.

We use the services of Texas A&M for conducting a pre-clinical trial with PLX cells in a mice model of pre-eclampsia. We have no current or ongoing obligations to Texas A&M.

We used the services of Hadassah to conduct pre-clinical trials from 2011 through 2013, mainly in the field of radiation. We have no current or ongoing obligations to Hadassah.

On June 19, 2011, we entered into an exclusive license agreement (the United Agreement) with United for the use of our PLX cells to develop and commercialize a cell-based product for the treatment of PAH. The United Agreement provides that United will receive exclusive worldwide license rights for the development and commercialization of our PLX cell-based product to treat PAH. The United Agreement further provides for the following consideration payable to us: (i) an upfront payment of \$7 million paid in August 2011, which includes a \$5 million non-refundable upfront payment and a \$2 million advance payment on the development ; (ii) up to \$37.5 million upon reaching certain regulatory milestones with respect to the development of a product to treat PAH; (iii) reimbursement of up to \$10 million of certain of our expenses if we establish a GMP manufacturing facility in North America; (iv) reimbursement of certain costs in connection with the development of the product; and (v) following commercialization of the product, royalties at a mid-single digit percent and the purchase of commercial supplies of the developed product from us at a specified margin over our cost.

The United Agreement became effective on August 2, 2011, and will continue until the later of a few events, including termination of all patents relating to the collaboration, upon certain government action or if the parties do not develop any product under the United Agreement. United may unilaterally terminate the United Agreement at any time and without cause. In such event, United shall pay us certain costs and expenses of winding down any non-cancellable commitments made by us prior to the date of termination and cease all development activities in connection with the United Agreement.

On June 26, 2013, we entered into an exclusive out-license and commercialization agreement (the CHA Agreement) with CHA, for conducting clinical trials and commercialization of our PLX-PAD product in South Korea in connection with two indications: the treatment of CLI and IC. Under the terms of the CHA Agreement, CHA will bear the costs of conducting the clinical trials for the agreed upon indications, and we will continue to retain rights to our proprietary manufacturing technology and cell-related intellectual property.

The first clinical study to be performed as part of the CHA Agreement will be a Phase II trial in IC. This study was approved in November 2013 by South Korea's MFDS.

Upon the first regulatory approval for a PLX product in South Korea, for the specified indications, we and CHA will establish an equally owned joint venture. The purpose of the joint venture will be to commercialize PLX cell products in South Korea. Additionally, we will be able to use the data generated by CHA to pursue the development of PLX product candidates outside of South Korea.

In addition, and as contemplated by the CHA Agreement, in December 2013, we and CHA executed the mutual investment pursuant to which we issued 2,500,000 shares of our common stock in consideration for 1,011,504 shares of CHA, which reflects total consideration to each of us and CHA of approximately \$10,414,000.

The term of the CHA Agreement extends from June 24, 2013 until the later of the expiration, lapse, cancellation, abandonment or invalidation of the last valid patent claim covering the development of the product indications. The CHA Agreement contains customary termination provisions, including in the event the parties do not reach an agreement upon development plan for conducting the clinical trials.

Upon termination of the CHA Agreement, the license granted thereunder will terminate and all rights included therein will revert to us, whereupon we will be free to enter into agreements with any other third parties for the granting of a license in or outside South Korea or to deal in any other manner with such rights as it shall see fit in our sole discretion.

We plan to continue to collaborate with universities and academic institutions and corporate partners worldwide to fully leverage our expertise and explore the use of our cells in other indications.

In-House Clinical Manufacturing

We have the in-house capability to perform clinical cell manufacturing. Our new state-of-the-art GMP grade manufacturing facility in Haifa has been in use since February 2013 for the main purpose of clinical grade large scale manufacturing. The facility's new automated manufacturing process and products were approved for production of PLX-PAD for clinical use by the FDA, PEI, Korean MFDS and the Israeli MOH after submission of a comprehensive comparability study. Furthermore, the site was inspected and approved by a qualified person representing PEI, approving that the site and production processes meet the current GMP for the purpose of manufacturing PLX-PAD. Following the clinical approval of the facility, we are moving forward with our planned clinical trials based on cells coming from the new, efficient and improved manufacturing processes.

We receive the human placentas used for our research and manufacturing activities from various hospitals in Israel after receiving a written informed consent by the mother and pathogen clearance. Any medical waste related to the use of placentas is treated in compliance with local environmental laws and standards.

Government Regulation

The development, manufacturing, and marketing of our cell therapy product candidates are subject to the laws and regulations of governmental authorities in the United States and the European Union as well as other countries in which our products will be marketed in the future. Specifically, the FDA in the United States and the EMA in Europe must approve new drug and cell therapy products before they may be marketed. Furthermore, various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and record keeping related to such products and their marketing. Governments in other countries have similar requirements for testing and marketing.

The process of obtaining these approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time, resources and money. There can be no assurance that our product candidates will ultimately receive marketing approval.

There are several stages every drug has to go through during its development process. Among these are:

- Performance of nonclinical laboratory and animal studies to assess a drug's biological activity and to identify potential safety problems, and to characterize and document the product's chemistry, manufacturing controls, formulation, and stability. In accordance with regulatory requirements nonclinical safety and toxicity studies are conducted under Good Laboratory Practice requirements to ensure their quality and reliability.
- Conducting adequate and well-controlled human clinical trials in compliance with Good Clinical Practice (GCP) to establish the safety and efficacy of the product for its intended indication;
 - The manufacture of the product according to cGMP regulations and standards; and
- Potential post-marketing clinical testing and surveillance of the product after marketing approval, which can result in additional conditions on the approvals or suspension of clinical use.

Approval of a drug for clinical studies in humans and approval of marketing is a sovereign decision of states, delegated to national, or, in case of the European Union, international regulatory competent authorities.

Regulatory Process in the United States

In the United States, our product candidates are subject to regulation as a biological product under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. The FDA, regulating the approval of clinical trials and marketing applications in the United States, generally requires the following steps prior to approving a new biological product either for clinical studies or for commercial sale:

- Submission of an Investigational New Drug Application, which must become effective before clinical testing in humans can begin;
- Obtaining approval of Institutional Review Boards (IRBs) of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials;

- Submission to the FDA of a Biologics License Application (BLA) for marketing authorization of the product which must include adequate results of pre-clinical testing and clinical trials;

- FDA review of the BLA in order to determine, among other things, whether the product is safe and effective for its intended uses; and
- FDA inspection and approval of the product manufacturing facility at which the product will be manufactured.

Regulatory Process in Europe

In the European Union, our investigational cellular products are regulated under the Advanced Therapy Medicinal Product regulation, a regulation specific to cell and tissue products. This European Union regulation requires:

- Filing a Clinical Trial Application with the various member states or a centralized procedure (a Voluntary Harmonisation), which makes it possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries;
- Obtaining approval of affiliated Ethic Committees of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials;
- Adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; and
- Since our investigational cellular products are regulated under the Advanced Therapy Medicinal Product regulation, the application for marketing authorization to the EMA is mandatory within the 28 member states of the EU. EMA is expected to review and approve the Marketing Authorization Application.

Other Regulation

We expect to have to obtain approval for clinical studies and ultimately for marketing of each of our products from regulatory authorities in countries outside the United States and the European Union, prior to the commencement of marketing of the product in those countries. The approval procedure varies among countries, and may involve additional preclinical testing and clinical trials. The requirements and time required may differ from that required for FDA or EMA approval. Each country may impose certain procedures and requirements of its own. In most other countries outside the United States and the European Union, they are willing to consider requests for marketing approval only after the product had been approved for marketing by either the FDA or the EMA. The decision regarding marketing approval is made following the submission of a dossier that is thoroughly assessed and critically addressed.

Clinical trials

Typically, both in the United States and the European Union, clinical testing involves a three-phase process although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers or patients and are designed to provide information about product safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. Phase III clinical trials are generally large-scale, multi-center, controlled trials conducted with patients afflicted with a target disease in order to provide statistically valid proof of efficacy, as well as safety and potency. In some circumstances, the FDA or the EMA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators to minimize risks. The sponsor of a clinical trial is required to submit an annual safety report to the relevant regulatory agencies, in which serious adverse events must be reported. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

Employees

We presently employ a total of 160 full-time employees and 9 part-time employees, of whom 142 full-time employees and 9 part-time employees are engaged in research, manufacturing and clinical trials.

Competition

The regenerative medicine field is characterized by intense competition as global pharma players are becoming more engaged in the cell therapy field. The cellular therapeutics industry is subject to technological changes that can be rapid and important. We face competition from both allogeneic and autologous cell therapy companies, academic, commercial and research institutions, pharmaceutical companies, biopharmaceutical companies, and governmental agencies. Some of the clinical indications we currently have under development are also being investigated in preclinical and clinical programs by others.

There are multiple participants in the cell therapy field such as Aastrom Biosciences Inc., Athersys Inc., Capricor Therapeutics, Inc., Cytori Therapeutics, Inc., Mesoblast LTD, Tigenix NV, and Celgene Corporation. Among other things, we expect to compete based upon our intellectual property portfolio, our in-house manufacturing efficiencies and the efficacy of our products. Our ability to compete successfully will depend on our continued ability to attract and retain experienced and skilled executive, scientific and clinical development personnel to identify and develop viable cellular therapeutic candidates and exploit these products commercially. Given the magnitude of the potential opportunity for stem cell therapy, we expect competition in this area to intensify.

Available Information

Additional information about us is contained on our Internet website at www.pluristem.com. Information on our website is not incorporated by reference into this report. Under the "SEC Filings" and "Financial Information" sections, under the "Investors" section of our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended (Exchange Act), as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our reports filed with the SEC are also made available to read and copy at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. You may obtain information about the Public Reference Room by calling the SEC at 1-800-SEC-0330. Reports filed with the SEC are also made available on its website at www.sec.gov. The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics, and the Charters for each of the Committees of our Board of Directors.

Item 1A. Risk Factors.

The following risk factors, among others, could affect our actual results of operations and could cause our actual results to differ materially from those expressed in forward-looking statements made by us. These forward-looking statements are based on current expectations and except as required by law we assume no obligation to update this information. You should carefully consider the risks described below and elsewhere in this Annual Report before making an investment decision. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Our common stock is considered speculative and the trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The following risk factors are not the only risk factors facing our Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business.

Our likelihood of profitability depends on our ability to license and/or develop and commercialize products based on our cell production technology, which is currently in the development stage. If we are unable to complete the development and commercialization of our cell therapy products successfully, our likelihood of profitability will be limited severely.

We are engaged in the business of developing cell therapy products. We have not realized a profit from our operations to date and there is little likelihood that we will realize any profits in the short or medium term. Any profitability in the future from our business will be dependent upon successful commercialization of our potential cell therapy products and/or licensing of our products, which will require significant additional research and development as well as substantial clinical trials.

If we are not able to successfully license and/or develop and commercialize our cell therapy product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations.

So far, the products we are developing have completed only one Phase I/II clinical trial of Gluteal Musculature rehabilitation after total hip arthroplasty (efficacy, ongoing for safety) and one Phase I clinical trial for CLI. Our early stage cell therapy product candidates may fail to perform as we expect. Moreover, even if our cell therapy product candidates successfully perform as expected, in later stages of development they may fail to show the desired safety and efficacy traits despite having progressed successfully through pre-clinical or initial clinical testing. We will need to devote significant additional research and development, financial resources and personnel to develop commercially viable products and obtain the necessary regulatory approvals.

If our cell therapy product candidates do not prove to be safe and effective in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations.

Even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to regulate marketed products, manufacturers and manufacturing facilities, which may create additional regulatory barriers and burdens. Later discovery of previously unknown problems with a product, manufacturer or facility, may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

We cannot market and sell our cell therapy product candidates in the United States or Europe or in other countries if we fail to obtain the necessary regulatory approvals or licensure.

We cannot sell our cell therapy product candidates until regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain. It is likely to take at least several years to obtain the required regulatory approvals for our cell therapy product candidates, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly.

To obtain marketing approvals in the United States and Europe for cell therapy product candidates we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA and the EMA that the cell therapy product candidates is safe and effective for each disease for which we seek approval. So far, we have successfully conducted Phase I/II and Phase I clinical trials for our PLX-PAD product, which currently is our only product that is the subject of clinical trials. Several factors could prevent completion or

cause significant delay of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that cell therapy product candidates are safe and effective for use in humans. Negative or inconclusive results from or adverse medical events during a clinical trial could cause the clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful. The FDA or the EMA can place a clinical trial on hold if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury. If safety concerns develop, we, the FDA, or the EMA could stop our trials before completion.

Future sales of our shares may cause the prevailing market price of our shares to decrease.

Future sales of our common stock, or the perception that such sales may occur, could cause immediate dilution and adversely affect the market price of our common stock.

If we are not able to conduct our clinical trials properly and on schedule, marketing approval by FDA, EMA and other regulatory authorities may be delayed or denied.

The completion of our clinical trials may be delayed or terminated for many reasons. For instance, in June 2013, we received the Clinical Hold notification with respect to our United States Phase II IC study due to a serious allergic reaction in a case which required hospitalization. This Clinical Hold, which was lifted in September 2013, resulted in delays in our clinical trials plan for IC in the United States, Europe and Israel as well as the extension of the development period for which we received funds from United from 6.5 years to 11.5 years. Our clinical trials may be delayed or terminated due to other reasons, such as:

- The FDA or the EMA does not grant permission to proceed or places additional trials on clinical hold;
 - Subjects do not enroll in our trials at the rate we expect;
 - The regulators may ask to increase subject's population in the clinical trials;
 - Subjects experience an unacceptable rate or severity of adverse side effects;
- Third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- Inspections of clinical trial sites by the FDA, EMA, KFDA and other regulatory authorities find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or
- One or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial.

Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the FDA, EMA and other regulatory authorities.

We may need to raise additional financing to support the research, development and manufacturing of our cell therapy products and our products in the future but we cannot be sure we will be able to obtain additional financing on terms favorable to us when needed. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.

It is highly likely that we will need to raise significant additional capital in the future. Although we were successful in raising capital in the past, our current financial resources are limited and may not be sufficient to finance our operations until we become profitable, if that ever happens. It is likely that we will need to raise additional funds in the near future in order to satisfy our working capital and capital expenditure requirements. Therefore, we are dependent on our ability to sell our common stock for funds, receive grants or to otherwise raise capital. There can be no assurance that we will be able to obtain financing. Any sale of our common stock in the future will result in

dilution to existing stockholders and could adversely affect the market price of our common stock. Also, we may not be able to borrow or raise additional capital in the future to meet our needs or to otherwise provide the capital necessary to conduct the development and commercialization of our potential cell therapy products, which could result in the loss of some or all of one's investment in our common stock.

Favorable results from compassionate use treatment or initial interim results from a clinical trial do not ensure that later clinical trials will be successful and success in early stage clinical trials does not ensure success in later-stage clinical trials.

PLX cells have been administered as part of compassionate use treatments, which permit the administration of the PLX cells outside of clinical trials. No assurance can be given that any positive results are attributable to the PLX cells, or that administration of PLX cells to other patients will have positive results. Compassionate use is a term that is used to refer to the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. Regulators often allow compassionate use on a case-by-case basis for an individual patient or for defined groups of patients with similar treatment needs.

There is no assurance that we will obtain regulatory approval for PLX cells. We will only obtain regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable non-U.S. regulatory authorities, in well-designed and conducted clinical trials, that the product candidate is safe and effective and that the product candidate, including the cell production methodology, otherwise meets the appropriate standards required for approval. Clinical trials can be lengthy, complex and extremely expensive processes with uncertain results. A failure of one or more clinical trials may occur at any stage of testing.

Success in early clinical trials does not ensure that later clinical trials will be successful, and initial results from a clinical trial do not necessarily predict final results. While results from treating patients through compassionate use have in certain cases been successful, we cannot be assured that further trials will ultimately be successful. Results of further clinical trials may be disappointing.

Even if early stage clinical trials are successful, we may need to conduct additional clinical trials for product candidates with patients receiving the drug for longer periods before we are able to seek approvals to market and sell these product candidates from the FDA and regulatory authorities outside the United States. Even if we are able to obtain approval for our product candidates through an accelerated approval review program, we may still be required to conduct clinical trials after such an approval. If we are not successful in commercializing any of our lead product candidates, or are significantly delayed in doing so, our business will be materially harmed.

We may not successfully maintain our existing exclusive out-licensing agreements with United and CHA, or establish new collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize our product candidates.

One of the elements of our business strategy is to license our technology to other companies. Our business strategy includes establishing collaborations and licensing agreements with one or more pharmaceutical or biotechnology companies. To date, we have two strategic relationships, one with United for the licensing of PLX cells for the PAH indication. The second strategic partnership is with CHA for both the IC and CLI indications in Korea. CHA will conduct PLX clinical studies in South Korea, and, following approval, a joint venture equally owned by both parties will be established to market PLX products in South Korea. Currently, our PLX cells are being used in a United sponsored PAH trial in Australia, and our PLX cells are also being used in Korean sites participating to our International IC study through our partnership with CHA. Notwithstanding, we may not be able to further establish or maintain such licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

Our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of certain product candidates, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of centers experienced with cell therapy product candidates heightens our dependence on such research institutions. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

We have limited experience in conducting and managing human trials. If we fail in the conduct of such trials, our business will be materially harmed.

Even though we conducted Phase I/II and Phase I trials for our PLX-PAD product and have recruited employees who are experienced in managing and conducting clinical trials, we have limited experience in this area. We will need to expand our experience and rely on consultants in order to obtain regulatory approvals for our therapeutic product candidates. The failure to successfully conduct clinical trials could materially harm our business.

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies having greater financial resources and technical discovery capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic product candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation.

This trend may adversely affect our ability to enter into license agreements or agreements for the development and commercialization of our product candidates, and as a result may materially harm our business.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regards to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA, the EMA and other countries' regulatory authorities have relatively limited experience with cell therapies. Very few cell therapy products have been approved by regulatory authorities to date for commercial sale, and the pathway to regulatory approval for our cell therapy product candidates may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

There are very few drugs and limited therapies that the FDA or EMA have approved as treatments for some of the disease indications we are pursuing. This could complicate and delay FDA, EMA or other countries' regulatory authorities approval of our biologic drug candidates.

There are very few drugs and limited therapies currently approved for treatment of CLI, IC, ARS or PH. As a result, the clinical efficacy endpoints, or the criteria to measure the intended results of treatment may be difficult to determine. This will increase the difficulty of our obtaining FDA, EMA or other countries' regulatory authorities approval to market our products.

Our cell therapy drug candidates represent new classes of therapy that the marketplace may not understand or accept.

Even if we successfully develop and obtain regulatory approval for our cell therapy candidates, the market may not understand or accept them. We are developing cell therapy product candidates that represent novel treatments and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our developed and potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our cell therapy drug candidates and their perceived advantage over alternative treatment methods, if any;
- adverse events involving our cell therapy product candidates or the products or product candidates of others that are cell-based; and
- the cost of our products and the reimbursement policies of government and private third-party payers.

If the health care community does not accept our potential products for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations.

If our processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects would be adversely affected.

If our processing and storage facility, our clinical manufacturing facilities or the equipment in such facilities were to be damaged or destroyed, the loss of some or all of the stored units of our cell therapy drug candidates would force us to delay or halt our clinical trial processes. We have two clinical manufacturing facilities located in Haifa, Israel. If these facilities or the equipment in them are significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity.

The clinical manufacturing process for cell therapy products is complex and requires meeting high regulatory standards; We have limited manufacturing experience and know-how. Any delay or problem in the clinical manufacturing of PLX may result in a material adverse effect on our business.

Our facility and its commercial scale manufacturing process have received approval from the FDA, EMA, Germany's PEI, and the Korean MFDS. However, the clinical manufacturing process is complex and we have no experience in manufacturing our product candidates at a commercial level. There can be no guarantee that we will be able to successfully develop and manufacture our product candidates in a manner that is cost-effective or commercially viable, or that our development and manufacturing capabilities might not take much longer than currently anticipated to be ready for the market. In addition, if we fail to maintain regulatory approvals for our manufacturing facilities, we may suffer delays in our ability to manufacture our product candidates. This may result in a material adverse effect on our business.

We are dependent upon third-party suppliers for raw materials needed to manufacture PLX; if any of these third parties fails or is unable to perform in a timely manner, our ability to manufacture and deliver will be compromised.

In addition to the placenta used in the clinical manufacturing process of PLX we require certain raw materials. These items must be manufactured and supplied to us in sufficient quantities and in compliance with cGMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these raw materials to cGMP standards. Our requirements for these items are expected to increase if and when we transition to the manufacture of commercial quantities of our cell-based drug candidates.

In addition, as we proceed with our clinical trial efforts, we must be able to continuously demonstrate to the FDA, EMA and other regulatory authorities that we can manufacture our cell therapy product candidates with consistent characteristics. Accordingly, we are materially dependent on these suppliers for supply of cGMP-grade materials of consistent quality. Our ability to complete ongoing clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical materials.

If we encounter problems or delays in the research and development of our potential cell therapy products, we may not be able to raise sufficient capital to finance our operations during the period required to resolve such problems or delays.

Our cell therapy products are currently in the development stage and we anticipate that we will continue to incur substantial operating expenses and incur net losses until we have successfully completed all necessary research and clinical trials. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technology. Our research and development programs may not be successful, and our cell culture technology may not facilitate the production of cells outside the human body with the expected result. Our cell therapy products may not prove to be safe and efficacious in clinical trials. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue. Accordingly, we may be forced to discontinue or suspend our operations.

Existing government programs and tax benefits may be terminated.

We have received certain Israeli government approvals under certain programs and may in the future utilize certain tax benefits in Israel by virtue of these programs. To remain eligible for such tax benefits, we must continue to meet certain conditions. If we fail to comply with these conditions in the future, the benefits we receive could be canceled and have to pay additional taxes. We cannot guarantee that these programs and tax benefits will be continued in the future, at their current levels or at all. If these programs and tax benefits are ended, our business, financial condition and results of operations could be materially adversely affected.

Because we received grants from the OCS, we are subject to on-going restrictions.

We have received royalty-bearing grants from the OCS, for research and development programs that meet specified criteria. The terms of the OCS's grants limit our ability to transfer know-how developed under an approved research and development program outside of Israel, regardless of whether the royalties are fully paid. Any non-Israeli citizen, resident or entity that, among other things, becomes a holder of 5% or more of our share capital or voting rights, is entitled to appoint one or more of our directors or our Chief Executive Officer (CEO), serves as a director of our Company or as our CEO is generally required to notify the same to the OCS and to undertake to observe the law governing the grant programs of the OCS, the principal restrictions of which are the transferability limits described above. For more information, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources".

We have limited operating history, which raises doubts with respect to our ability to generate revenues in the future.

We have a limited operating history in our business of developing and commercializing cell production technology. Until we entered into the United Agreement, we did not generate any revenues. It is not clear when we will generate additional revenues or whether we will experience further delays in recognizing revenues such as resulted from the Clinical Hold. Our primary source of funds has been the sale of our common stock and government grants. We cannot give assurances that we will be able to generate any significant revenues or income in the future. There is no assurance that we will ever be profitable.

If we do not keep pace with our competitors and with technological and market changes, our technology and products may become obsolete and our business may suffer.

The cellular therapeutics industry, of which we are a part, is very competitive and is subject to technological changes that can be rapid and intense. We have faced, and will continue to face, intense competition from biotechnology, pharmaceutical and biopharmaceutical companies, academic and research institutions and governmental agencies engaged in cellular therapeutic and drug discovery activities or funding, both in the United States and internationally. Some of these competitors are pursuing the development of cellular therapeutics, drugs and other therapies that target the same diseases and conditions that we target in our clinical and pre-clinical programs.

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Many of our competitors have greater resources, more product candidates and have developed product candidates and processes that directly compete with our products. Our competitors may have developed, or could develop in the future, new products that compete with our products or even render our products obsolete.

We depend to a significant extent on certain key personnel, the loss of any of whom may materially and adversely affect our Company.

Our success depends to a significant extent on the continued services of certain highly qualified scientific and management personnel, in particular, Zami Aberman, our CEO and Chairman, and Yaky Yanay, our Chief Operating Officer (COO) and President. We face competition for qualified personnel from numerous industry sources, and there can be no assurance that we will be able to attract and retain qualified personnel on acceptable terms. The loss of service of any of our key personnel could have a material adverse effect on our operations or financial condition. In the event of the loss of services of such personnel, no assurance can be given that we will be able to obtain the services of adequate replacement personnel. We do not maintain key person insurance on the lives of any of our officers or employees.

The patent approval process is complex and we cannot be sure that our pending patent applications or future patent applications will be approved.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and any future licensors' patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States and we may not be able to obtain meaningful patent protection for any of our commercial products either in or outside the United States.

No assurance can be given that the scope of any patent protection granted will exclude competitors or provide us with competitive advantages, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or products or design around any patents that have been or may be issued to us or any future licensors. Since patent applications in the United States and in Europe are not publicly disclosed until patents are issued, there can be no assurance that others did not first file applications for products covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We have yet to conduct comprehensive freedom-to-operate searches to determine whether our proposed business activities or use of certain of the patent rights owned by us would infringe patents issued to third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be

required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. For example, we are aware of issued third party patents directed to placental stem cells and their use for therapy and in treating various diseases. We may need to seek a license for one or more of these patents. No assurances can be given that such a license will be available on commercially reasonable terms, if at all. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors are able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

The market for our products will be heavily dependent on third party reimbursement policies.

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, as well as private health insurers, health maintenance organizations and other third party payers will pay for our products and related treatments.

Reimbursement by third party payers depends on a number of factors, including the payer's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement from third party payers may reduce the demand for, or negatively affect the price of, our products. The lack of reimbursement for these procedures by insurance payers has negatively affected the market for our products in this indication in the past.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and of foreign governments. In addition, third party payers are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, third party payers may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

Our success depends in large part on our ability to develop and protect our technology and our cell therapy products. If our patents and proprietary rights agreements do not provide sufficient protection for our technology and our cell therapy products, our business and competitive position will suffer.

Our success will also depend in part on our ability to develop our technology and commercialize cell therapy products without infringing the proprietary rights of others. We have not conducted full freedom of use patent searches and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to develop our technology or maintain our competitive position with respect to our potential cell therapy products. If our technology components, devices, designs, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology or products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed

products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development of our technology and the commercialization our potential cell therapy products.

We have built the ability to manufacture clinical grade ASCs in-house. Through our experience with ASC-based product development, we have developed expertise and know-how in this field. To protect these expertise and know-how, our policies require confidentiality agreements with our employees, consultants, contractors, manufacturers and advisors. These agreements generally provide for protection of confidential information, restrictions on the use of materials and assignment of inventions conceived during the course of performance for us. These agreements might not effectively prevent disclosure of our confidential information.

We must further protect and develop our technology and products in order to become a profitable company.

The initial patent underlying our technology will expire in approximately 2019. If we do not complete the development of our technology and products in development by then, or create additional sufficient layers of patents or other intellectual property right, other companies may use the technology to develop competing products. If this happens, we may lose our competitive position and our business would likely suffer.

Furthermore, the scope of our patents may not be sufficiently broad to offer meaningful protection. In addition, our patents could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. We also intend to seek patent protection for any of our potential cell therapy products once we have completed their development.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

The price of our common stock may fluctuate significantly.

The market for our shares of common stock may fluctuate significantly. A number of events and factors may have an adverse impact on the market price of our common stock, such as:

- results of our clinical trials or adverse events associated with our products;
- the amount of our cash resources and our ability to obtain additional funding;
- changes in our revenues, expense levels or operating results;
- entering into or terminating strategic relationships;
- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;
- changes in laws and governmental regulations, including changes in tax, healthcare, competition and patent laws;
- disputes concerning patents or proprietary rights;

- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;
 - patent or proprietary rights developments;
 - regulatory actions that may impact our products;
 - disruptions in our manufacturing processes; and
- competition.

In addition, a market downturn in general and/or in the biopharmaceutical sector in particular, may adversely affect the market price of our securities, which may not necessarily reflect the actual or perceived value of our Company.

We are exposed to fluctuations in currency exchange rates.

A significant portion of our business is conducted outside the United States. Therefore, we are exposed to currency exchange fluctuations in other currencies such as the Euro and the New Israeli Shekel (NIS) because a portion of our expenses in Israel and Europe are paid in NIS and Euros, respectively, which subjects us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, fees for consultants and subcontractors and lease payments on our Israeli facilities. During 2014, we entered into forward contracts to hedge against some of the risk of changes in future cash flows from payments of payroll and related expenses denominated in NIS.

The dollar cost of our operations in Israel will increase to the extent increases in the rate of inflation in Israel are not offset by a devaluation of the NIS in relation to the dollar, which would harm our results of operations.

Since a considerable portion of our expenses such as employees' salaries are linked to an extent to the rate of inflation in Israel, the dollar cost of our operations is influenced by the extent to which any increase in the rate of inflation in Israel is or is not offset by the devaluation of the NIS in relation to the dollar. As a result, we are exposed to the risk that the NIS, after adjustment for inflation in Israel, will appreciate in relation to the dollar. In that event, the dollar cost of our operations in Israel will increase and our dollar-measured results of operations will be adversely affected. We cannot predict whether the NIS will appreciate against the dollar or vice versa in the future. Any increase in the rate of inflation in Israel, unless the increase is offset on a timely basis by a devaluation of the NIS in relation to the dollar, will increase labor and other costs, which will increase the dollar cost of our operations in Israel and harm our results of operations.

Potential product liability claims could adversely affect our future earnings and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the use of our products results in adverse effects. We may not be able to maintain adequate levels of insurance for these liabilities at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition.

Our principal research and development and manufacturing facilities are located in Israel and the unstable military and political conditions of Israel may cause interruption or suspension of our business operations without warning.

Our principal research and development and manufacturing facilities are located in Israel. As a result, we are directly influenced by the political, economic and military conditions affecting Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. During July and August 2014 and November 2012, Israel was engaged in an armed conflict with a militia group and political party which controls the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel.

In addition, Israeli-based companies and companies doing business with Israel, have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel's establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, we cannot predict whether or in what manner these problems will be resolved. Wars and acts of terrorism have resulted in significant damage to the Israeli economy, including reducing the level of foreign and local investment.

Furthermore, certain of our officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and are subject to being called up for active military duty at any time. All Israeli male citizens who have served in the army are subject to an obligation to perform reserve duty until they are between 40 and 49 years old, depending upon the nature of their military service.

Our cash may be subject to a risk of loss and we may be exposed to fluctuations in the market values of our portfolio investments and in interest rates.

Our assets include a significant component of cash. We adhere to an investment policy set by our investment committee which aims to preserve our financial assets, maintain adequate liquidity and maximize returns. We believe that our cash is held in institutions whose credit risk is minimal and that the value and liquidity of our deposits are accurately reflected in our consolidated financial statements as of June 30, 2014. Currently, we hold part of our current assets in bank deposits and part is invested in bonds, government bonds and a combination of corporate bonds and relatively low risk stocks. However, nearly all of our cash and bank deposits are not insured by the Federal Deposit Insurance Corporation, or the FDIC, or similar governmental deposit insurance outside the United States. Therefore, our cash and any bank deposits that we now hold or may acquire in the future may be subject to risks, including the risk of loss or of reduced value or liquidity, particularly in light of the increased volatility and worldwide pressures in the financial and banking sectors. In the future, should we determine that there is a decline in value of any of our portfolio securities which is not temporary in nature, this would result in a loss being recognized in our consolidated statements of operations.