PLURISTEM THERAPEUTICS INC
Form 10-K
September 09, 2015

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

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2015

o 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 011-972-74-7108607

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 o No x

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 o No x

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 x No o

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 x No o

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. x

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 o	Accelerated filer x	Non-accelerated filer o
Smaller reporting company o		

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

Yes o No x

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.

$164,533,166

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

79,106,381 as of September 2, 2015

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

In this annual report, unless otherwise specified, all dollar amounts are expressed in U.S. 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, or 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, or United, and CHA Biotech Co. Ltd., or 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 placenta expanded, or PLX, cells may be effective in supporting bone marrow transplantation and in treating bone marrow suppression from radiation and chemotherapy;
- achieving regulatory approvals, including under accelerated paths;
- our marketing plans, including timing of marketing our first product, PLX-PAD;
- developing capabilities for new clinical indications of PLX and new products;
- 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;
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our expectation that in the upcoming years our research and development expenses, net, will continue to be our major operating expense;

- 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, or 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 placenta expanded, or PLX, cells are intended to function as a platform that releases a number of therapeutic proteins in response to various local and systemic inflammatory and ischemic signals that are generated by the patient's own body. PLX cells are grown using our proprietary three-dimensional, or 3D, micro environment technology which 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 routes 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. We have built a facility that complies with current Good Manufacturing Practice requirements, or GMPs, and we are planning to have in-house production capacity to grow clinical grade PLX cells in commercial quantities.

Our focus is to make significant progress in our clinical pipeline and shorten the time to market of our first product, PLX-PAD, in Europe and Japan, in parallel to our clinical trials in the United States. We intend to leverage the new regulatory environments in Europe and Japan that now offer unique opportunities for accelerated paths to bring new products to the market. We believe that these new pathways create substantial opportunities for us and for the cell therapy industry as a whole. We will explore these accelerated pathways for several of our current clinical indications, such as critical limb ischemia, or CLI, as well as for carefully selected hematologic indications which represent substantial unmet needs that we hope to address with our second product, PLX-R18. In May 2015, we announced that the PLX cell program in CLI had been selected for the Adaptive Pathways pilot project of the European Medicines

Agency, or EMA. In addition, we reported that Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, approved the proposed quality and large-scale manufacturing methods for PLX-PAD for use in clinical trials in Japan. In August 2015, we announced that the PMDA has cleared our PLX-PAD cells for use in clinical trials in Japan. We plan to continue frequent discussions with these regulators in order to initiate clinical studies using the accelerated paths. Our intention is to initiate the CLI studies during calendar year 2016 with the aim of obtaining initial approval in calendar year 2018.

We plan to continue developing multiple placenta-derived cell therapy products that we anticipate will lead to significant improvement in the lives of patients, and expect to demonstrate the real-world impact and value of our pipeline, technology platform and commercial-scale manufacturing capacity. We made progress in our Phase II intermittent claudication, or IC, trial, a randomized, double blind, placebo controlled, multinational clinical trial. We currently have active clinical sites in the United States, Israel, Germany and South Korea. We also anticipate that United Therapeutics Corporation, or United, will complete an ongoing Phase I clinical trial of PLX-PAD cells in pulmonary arterial hypertension in Australia, which will potentially lay the groundwork for a Phase II clinical trial.

We plan to initiate a Phase I/II incomplete engraftment study in the United States, and we are currently in discussions with the Food and Drug Administration, or the FDA, before submitting an investigational new drug, or IND, application. Currently, we plan to continue working in partnership with the National Institutes of Health, or NIH, in developing PLX-R18 as a potential treatment for Acute Radiation Syndrome, or ARS. In the upcoming months, we expect to receive FDA guidance on the additional animal studies that would be required to approve PLX-R18 for use in ARS under the Animal Rule regulatory pathway, which does not require human efficacy trials.

We plan to evaluate in the upcoming months the timing to initiate our advanced orthopedic indications, based on potential partnering interest as well as regulatory approvals for early access to the market.

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 an innovative 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 / "off-the-shelf" allogeneic 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, or ASCs, that are expanded using a proprietary 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.

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’s and patient’s perspective, our PLX products are delivered in a vial and do not require any additional manipulation. Our PLX products 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.

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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 worldwide licensing of PLX cells for the Pulmonary Arterial Hypertension, or PAH, and a second strategic partnership with CHA Biotech Co. Ltd., or CHA, in South Korea for both IC and CLI for the Korean market only. United is currently running a Phase I PAH trial in Australia. CHA is currently conducting PLX clinical studies in South Korea, and, following regulatory approval, if received, we contemplate forming a joint venture equally owned by us and CHA to market PLX products in South Korea.

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 type or human leukocyte antigen matching is required, and that the administration of PLX-PAD cells is safe, even if two doses are administered to a patient from the same placental source on two different occasions. In addition, PLX-PAD cells are potentially effective in reducing the frequency of amputations in CLI patients. Generally, the FDA and the EMA require the primary endpoint for pivotal CLI clinical trials to be Amputation Free Survival, or AFS, at one year. The pooled data from the two studies we conducted suggest an AFS rate at one year of 86% in PLX-treated patients versus an AFS ranging between 48% to 81% in patients from placebo arms in other trials.

Following our promising Phase I trials in CLI, a large, international, Phase II, double-blind, randomized, placebo-controlled, 4-arm 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 April 2015, Japan’s PMDA approved the proposed quality and large-scale manufacturing methods for PLX-PAD cells for use in clinical trials. This approval is an important milestone for initiation of a Phase I/II study in CLI, and we plan to submit an application for conditional, time-limited approval for marketing of PLX-PAD cells for treatment of CLI through Japan’s Accelerated Pathway for Regenerative Medicine. The new regulatory pathway could potentially significantly reduce time to market for cell therapies such as PLX-PAD cells. Two additional consultation meetings were held at the end of July 2015 to discuss with the PMDA the safety of PLX-PAD and the design of a proposed study in CLI patients to be conducted in Japan. In August 2015, the PMDA granted safety clearance to PLX-PAD cells for use in clinical trials. We expect to talk with the PDMA during the last quarter of 2015, and are anticipating that we will receive permission to begin the trial by the end of 2015. This approval would enable us to potentially start a Phase II study of PLX-PAD in CLI in early 2016.

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Additionally, in May 2015, the PLX-PAD clinical development program was selected for the EMA's Adaptive Pathways pilot project. The goal of the project is to improve timely access for patients to new medicines. It allows for early marketing authorization of a therapy in a restricted patient population, followed by additional assessments and the possibility of later approval for use in broader patient populations. Our first indication to be developed through this new regulatory approach is CLI. It is estimated that there are 500 to 1,000 new cases of CLI per a one million population per year in the United States and Europe, and the prevalence is expected to increase significantly in the coming decades. CLI therefore represents a major commercial opportunity. Acceptance of our cells for the treatment of CLI into the Adaptive Pathways could significantly curtail the time and investment needed to bring this product to market. Additional indications have the potential for accelerated approval through the Adaptive Pathways project, including orthopedic indications and muscle wasting associated with chronic disease.

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 after total hip replacement has been conducted in Germany under the approval of the Paul Ehrlich Institute, or PEI. In this study, PLX-PAD cells or a placebo were injected into the traumatized gluteal muscle during total hip replacement surgery. In July 2013, we announced that enrollment for this clinical trial was completed. In January 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 significantly greater improvement 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 was concluded with two year safety follow up in July 2015. At two years of follow-up no case of new cancer was reported.

We are currently considering other orthopedic indications or indications that include the need for improvement of muscle volume and strength, as we have demonstrated a significant effect on those parameters. The indications with the highest likelihood to be developed are total hip fracture and muscle wasting associated with most chronic diseases or occurring after stroke or burns. We plan to initiate the study in the United States and in Europe. In our discussions with the EMA, we presented several indications for potential development through the Adaptive Pathways project, including muscle wasting and hip fracture.

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

Bone Marrow Failure – Following positive data from the use of PLX-R18 (previously PLX-RAD) cells in animals in stimulating hematopoiesis in injured bone marrow and following bone marrow transplantation, we intend to pursue the development of PLX-R18 in the treatment of bone marrow failure from various causes.

In March 2015, we reported positive data from three independent preclinical studies of PLX-R18. Results from these trials, as well as those from nineteen prior studies conducted by the National Institute of Allergy and Infectious Diseases, or NIAID, at the NIH, Case Western University, Cleveland, Ohio, and Hadassah Medical Center, Jerusalem, Israel, collectively suggest that PLX-R18 is safe and may significantly improve outcomes after bone marrow failure and/or support hematopoietic cell transplantation. Data collected on the mechanism of action show that PLX-R18 acts by enhancing production of platelets and white and red blood cells in cases of severely damaged bone marrow, and may also accelerate engraftment of transplanted hematopoietic cells. With these capabilities, PLX-R18 could potentially treat a broad range of indications related to bone marrow function which, taken together, constitute a substantial global market.

We met with FDA representatives to discuss the initiation of a Phase I first-in-human clinical study of PLX-R18 for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation. We anticipate initiating the Phase I trial in the United States in early 2016.

ARS – We have conducted several in-vivo studies for the evaluation of PLX-R18 for the treatment of ARS, in cooperation with the NIAID.

We anticipate that the NIH will continue to support and conduct animal studies to determine if PLX-R18 can bring about the recovery of patients with acute radiation syndrome.

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, the EMA, Japan's PMDA, Germany's PEI and the Israeli Minister of Health, or MOH, and working with the Ministry of Food and Drug Safety, or MFDS, of South Korea and the Australian regulatory authorities via our collaborators.

The Adaptive Pathways pilot project is part of the EMA's efforts to improve timely access for patients to new therapies. It targets treatments with the potential to heal serious conditions with an unmet medical need, and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups. The pilot is open to clinical programs in early stages of development only. After a therapy is selected for the program, the Adaptive Pathways Discussion Group provides detailed guidance to the applicant regarding the formal regulatory processes that precede a trial targeting early approval and further expansion of the indications.

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 45 issued patents and 149 patent applications in the U.S., Europe, China and Japan, as well as in additional countries worldwide, including Israel and countries in the Far East, South America (in calculating the number of issued patents, each European patent validated in multiple jurisdictions was counted as a single patent).

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 includes the following claims:

- Our proprietary expansion methods for 3D stromal cells;
- Composition of matter claims covering 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 an obligation to assign to us 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. 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.

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.

Our Patent Portfolio

Patent Name/ Int. App. No.	Pending Jurisdictions	Granted Jurisdictions
METHOD AND APPARATUS FOR MAINTENANCE AND EXPANSION OF HAEMATOPOIETIC STEM CELLS AND/OR PROGENITOR CELLS PCT/US2000/02688	United States, Europe	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 PCT/IL2007/000380	United States, Japan, Europe, Mexico, Israel, China, Hong Kong, Canada, Brazil, Korea	Japan, Europe, Israel, Singapore, Russia, South Africa, Australia, India, Korea
ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2008/001185	United States, Europe, Mexico, Korea, Australia, Israel, India, China, Hong Kong, Canada, Brazil, Russia, Mexico	United States, Europe, Singapore, Australia, Hong Kong, South Africa
METHODS OF TREATING INFLAMMATORY COLON DISEASES PCT/IL2009/000527	United States, Brazil, Canada, China, Europe, Hong Kong, Israel	Russia, South Africa
METHODS OF SELECTION OF CELLS FOR TRANSPLANTATION PCT/IL2009/000844	United States, Europe, Israel, Hong Kong	

ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000846	United States, Europe, Israel, India, Singapore, Hong Kong, Canada, China, Brazil	United States, Russia, Australia, South Africa, Mexico
ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000845	United States, Europe, Israel, Hong Kong	
ADHERENT STROMAL CELLS DERIVED FROM PLANCENTAS OF MULTIPLE DONORS AND USES THEREOF PCT/IB2011/001413	United States, Europe, Israel, Hong Kong	

ADHERENT CELLS FROM PLACENTA AND USE OF SAME IN DISEASE TREATMENT PCT/IB2010/003219	United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Mexico	China, Australia, New Zealand, South Africa
METHODS AND SYSTEMS FOR HARVESTING ADHERENT STROMAL CELLS PCT/IB2012/000933	United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Korea, Mexico, Singapore	South Africa
METHODS FOR TREATING RADIATION OR CHEMICAL INJURY PCT/IB2012/000664	United States, Europe, Hong Kong, Israel, Korea, Japan	
SKELETAL MUSCLE REGENERATION USING MESENCHYMAL STEM CELLS PCT/EP2011/058730	United States, Europe, Israel, Hong Kong	
GENE AND PROTEIN EXPRESSION PROPERTIES OF ADHERENT STROMAL CELLS CULTURED IN 3D PCT/IB2014/059114	United States, Israel	
DEVICES AND METHODS FOR CULTURE OF CELLS PCT/IB2013/058184	United States, Europe, China, Japan, Korea, Canada, Brazil, Hong Kong, Israel, India, Mexico, New Zealand, Russia, Singapore	Europe
METHODS FOR PREVENTION AND TREATMENT OF PREECLAMPSIA PCT/IB2013/058186	United States, Europe, China, Japan, Korea, Canada, Israel, Singapore	
METHOD AND DEVICE FOR THAWING BIOLOGICAL MATERIAL PCT/IB2013/059808	United States, Europe, China, Japan, Korea, Canada, Brazil, Israel, India, Russia, Singapore	
METHODS FOR PREVENTION AND		

TREATMENT OF
GRAFT-VERSUS-HOST
DISEASE
PCT/IB2014/059706