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

TABLE OF CONTENTS

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.

3

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.

4

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	International (PCT) Application	

TREATMENT OF GRAFT-VERSUS-HOST DISEASE PCT/IB2014/059706	
ADHERENT CELLS FROM ADIPOSE OR PLACENTA TISSUES AND USE THEREOF IN THERAPY PCT/IB2014/062963	International (PCT) Application

Research and Development

Our research and development expenses were $23,416,000, $24,938,000 and $19,906,000 in fiscal years 2015, 2014 and 2013, respectively, before deducting the participation by the Office of the Chief Scientist, or 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 ensuing 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, or 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, or 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 have used the services of Hadassah to conduct pre-clinical trials from 2011 through 2013, mainly in the field of radiation-induced hematopoietic failure. We have no current or ongoing obligations to Hadassah.

On June 19, 2011, we entered into an exclusive license agreement, or 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 several 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 related to any non-cancellable commitments made by us prior to the date of termination and cease all activities in connection with the United Agreement.

On June 26, 2013, we entered into an exclusive out-licensing and commercialization agreement, or 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. 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 is a Phase II trial in IC. This study is part of our multination phase II study. The Korean arm study was approved in November 2013 by South Korea's MFDS.

Upon the first regulatory approval for a PLX product in South Korea, if granted, 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 a 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 that the parties do not reach an agreement upon a 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 manufactured in the new, efficient and improved manufacturing processes.

We obtain 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 the product for marketing. 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, or GCP, to establish the safety and efficacy of the product for its intended indication;

- The manufacture of the product according to GMP 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 are sovereign decisions of states, made by national, or, in case of the European Union, international regulatory competent authorities.

The 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, or IRBs, of research institutions or other clinical sites to introduce the drug candidate into humans in clinical trials;

- Submission to the FDA of a Biologics License Application, or 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.

The 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 via 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;

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Obtaining approval of affiliated Ethics Committees of research institutions or other clinical sites to introduce the 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. The EMA is expected to review and approve the Marketing Authorization Application.

In April 2015, the EMA designated PLX-PAD as a somatic cell therapy medicinal product and as a tissue-engineered product.

In April 2015, the Pediatric Committee of the EMA granted PLX-PAD a waiver for the requirement to submit a pediatric investigational plan for all indications falling under "treatment of peripheral atherosclerosis", including IC and CLI.

In May 2015, we were selected by EMA for development of PLX-PAD cells via the Adaptive Pathways approach, with the potential to reach the market several years faster than the traditional regulatory approval pathway.

Other Regulations

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. In Japan, we have initiated regulatory interactions with the PMDA in the framework of the new regulations for regenerative therapy effective in November 2014, which promote expedited approval for regenerative therapies that are being developed for seriously debilitating/life-threatening indications. We intend to develop PLX-PAD for CLI using this regulatory approach, with the potential to reach the market via conditional approval after a Phase I/II study.

In general, the approval procedure varies among countries, and may involve additional preclinical testing and clinical trials. The requirements and time required may differ from those required for FDA or EMA approval. Each country may impose certain procedures and requirements of its own. Most countries other than the United States, the European Union and Japan are willing to consider requests for marketing approval only after the product had been approved for marketing by either the FDA, the EMA or the PMDA. The decision regarding marketing approval is made following the submission of a dossier that is thoroughly assessed and critically addressed.

Clinical trials

Typically, in the United States and the European Union as well as in Japan , 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 in cases of ethical issues with using healthy volunteers, 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 a homogenous group of patients afflicted with the specific target 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 a heterogeneous group of patients afflicted with the target disease, in order to provide statistically valid proof of efficacy, as well as safety and potency. The Phase III trials represent the trials that are considered for confirmation of efficacy and safety and are the most important ones for the approval. In some circumstances, a regulatory agency 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.

12

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, and also to submit in an expedited manner any individual serious adverse events that are suspected to be related to the tested drug,. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the clinical study based upon the data that 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 based on the advancements made in clinical trials and due to the new favorable regenerative medicine legislation in certain regions. 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 Athersys, Inc., Capricor Therapeutics, Inc., Celgene Corporation, and Mesoblast LTD. 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, the EMA, the PMDA 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, Europe, Japan, , 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 ,the EMA and the PMDA 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, the EMA or the PMDA 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, the EMA or the PMDA 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, PMDA 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 a clinical hold notification, or the Clinical Hold, 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, the EMA or the PMDA 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, PMDA or MFDS 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, PMDA 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, the EMA, the PMDA or other applicable 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 in 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 large 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.

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, the PMDA 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. Despite our eligibility for certain accelerated pathways, this could 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 current GMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these raw materials to current GMP 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 current GMP-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.

We may not be able to take advantage of the new regulatory pathways in Europe and Japan to shorten our time to market of our products

Recent regulatory pathways in Europe and Japan may allow for early commercialization of our products and reducing the time to market of our products. The purpose of Europe's Adaptive Pathways is to shorten the time it takes for innovative medicines to reach patients with serious conditions that lack adequate treatment options. After a therapy is selected for the program, the Adaptive Pathways group conducts high level discussions and provides guidance to the applicant regarding the formal regulatory processes that precede a trial targeting early approval and further expansion of the indications. In Japan, a new law regarding regenerative therapies, including cell therapies, came into effect. The new law allows for conditional, time-limited approval of products for marketing after limited proof of efficacy.

In May 2015, the EMA selected our PLX cell program in CLI for its Adaptive Pathway project. In addition, the PMDA approved the proposed quality and large-scale manufacturing methods for PLX-PAD and has recently cleared our PLX-PAD cells for use in clinical trials in Japan. However, since these new regulatory pathways are relatively new, we may eventually not be able to meet the regulatory requirements and as a result would not benefit from early access to the market.

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, or 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.

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, or COO, President, and Chief Financial Officer, or CFO. 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, or 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 2015, we entered into forward contracts and other derivative instruments to hedge against some of the risk of changes in future cash flows from payments of payroll and related expenses and costs of operations 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, 2015. 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.

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 marketable securities include our investment in CHA shares as part of the license agreement signed with CHA in June 2013 We may be exposed to fluctuations in the market values of the shares, as well as to fluctuations in the KRW exchange rate to U.S. dollar.

As part of the CHA Agreement, in June 2013 the parties invested in each other's equity. As of June 30, 2015, we held 400,368 CHA shares valued at $6.0 million. The shares are listed on the KOSDAQ and the shares' price is denominated in KRW. We are exposed to changes in the market price of CHA shares, as well as to exchange rates fluctuations in the KRW currency compared to the U.S. dollar.

Although our internal control over financial reporting was considered effective as of June 30, 2015, there is no assurance that our internal control over financial reporting will continue to be effective in the future, which could result in our financial statements being unreliable, government investigations or loss of investor confidence in our financial reports.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish an annual report by our management assessing the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. In addition, our independent registered public accounting firm must annually provide an opinion on the effectiveness of our internal control over financial reporting. Management's report as of the end of fiscal year 2015 concluded that our internal control over financial reporting was effective. In addition, our registered independent public accounting firm provided an opinion that our internal control over financial reporting was effective as of the end of fiscal year 2015. There is, however, no assurance that we will be able to maintain such effective internal control over financial reporting in the future. Ineffective internal control over financial reporting can result in errors or other problems in our financial statements. In the future, if we or our registered independent public accounting firm are unable to assert that our internal controls are effective, our investors could lose confidence in the accuracy and completeness of our financial reports, which in turn could cause our stock price to decline. Failure to maintain effective internal control over financial reporting could also result in investigation or sanctions by regulatory authorities.

Because substantially all of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against the management for misconduct and may not be able to enforce judgment and civil liabilities against our officers, directors, experts and agents.

Substantially all of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for you to enforce within the United States any judgments obtained against our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state.

Because we do not intend to pay any dividends on our common stock, investors seeking dividend income should not purchase shares of our common stock.

We have not declared or paid any dividends on our common stock since our inception, and we do not anticipate paying any such dividends for the foreseeable future. Investors seeking dividend income should not invest in our common stock.

Item 1B. Unresolved Staff Comments.

Not Applicable.

26

Item 2. Properties.

Our principal executive, new manufacturing and research and development offices are located at MATAM Advanced Technology Park, Building No. 5, Haifa, Israel 31905, where we occupy approximately 4,390 square meters. Our monthly rent payment for these leased facilities as of July 2015 was 177,000 NIS (approximately $47,000). For the fiscal year ended June 30, 2015, we paid $457,450 for rent for such facilities. In addition, we rent a facility that is located at MATAM Advanced Technology Park, Building No. 20, Haifa, Israel 31905, where we occupy approximately 1,280 square meters. Our monthly rent payment for the leased facilities in Building No. 20 as of July 2015 was 77,000 NIS (approximately $20,500). For the fiscal year ended June 30, 2015, we paid $246,600 for rent for such facilities. We believe that the current space we have, including our current improvement plans, is adequate to meet our current and near future needs.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our shares trade on the NASDAQ Capital Market under the symbol PSTI and in the Tel Aviv Stock Exchange under the ticker symbol PLTR.

The following table sets forth, for the periods indicated, the high and low sales prices of our common stock, as reported on NASDAQ website and may not necessarily represent actual transactions.

Quarter Ended	High	Low
Fiscal Year Ended June 30, 2014		
September 30, 2013	$ 3.48	$ 2.93
December 31, 2013	$ 3.70	$ 3.19
March 31, 2014	$ 4.47	$ 3.58
June 30, 2014	$ 3.90	$ 3.11
Fiscal Year Ended June 30, 2015		
September 30, 2014	$ 3.15	2.58
December 31, 2014	$ 3.37	$ 2.32
March 31, 2015	$ 3.78	$ 2.54
June 30, 2015	$ 2.97	$ 2.48

On September 1, 2015, the per share closing price of our common stock, as reported on NASDAQ website, was $1.90. As of September 1, 2015, there were 110 holders of record, and 79,106,381 of our common shares were issued and outstanding.

American Stock Transfer and Trust Company, LLC is the registrar and transfer agent for our common shares. Their address is 6201 15th Avenue, 2nd Floor, Brooklyn, NY 11219, telephone: (718) 921-8261, (800) 937-5449.

27

Comparative Stock Performance Graph

The following graph shows how an initial investment of $100 in our common stock would have compared to an equal investment in the Nasdaq Composite Index and to a peer group index (comprised of: Athersys, Inc.; Cytori Therapeutics, Inc.; Capricor Therapeutics, Inc. and Mesoblast, Ltd.) during the period from July 1, 2010 through June 30, 2015. The performance shown is not necessarily indicative of future price performance.

Dividend Policy

We have not paid any cash dividends on our common stock and have no present intention of doing so. Our current policy is to retain earnings, if any, for use in our operations and in the development of our business. Our future dividend policy will be determined from time to time by our Board of Directors.

Recent Sales of Unregistered Securities

In May 2015, we issued 300,000 shares of common stock to an investor. We also granted 2,200 restricted stock units to IR consultants and 5,500 restricted stock units to clinical consultants.

In June 2015, we granted 31,100 restricted stock units to IR consultants for services rendered.

The above issuance was exempt under Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 6. Selected Financial Data.

The selected data presented below under the captions "Statements of Operations Data," "Statements of Cash Flows Data" and "Balance Sheet Data" for, and as of the end of, each of the fiscal years in the five-year period ended June 30, 2015, are derived from, and should be read in conjunction with, our audited consolidated financial statements.

The information contained in this table should also be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto included elsewhere in this report (in thousands of dollars except share and per share data):

	2015	2014	2013	2012	2011
Statements of Operations Data:					
Revenues	$379	$379	$679	$716	$-
Cost of revenues	13	11	20	21	-
Gross profit	366	368	659	695	-
Research and development expenses	23,416	24,938	19,906	12,685	8,311
Participation by the OCS and other parties	4,243	5,396	2,673	3,527	1,682
Research and development expenses, net	19,173	19,542	17,233	9,158	6,629
General and administrative expenses	6,460	8,676	5,649	6,568	4,485
Operating loss	25,267	27,850	22,223	15,031	11,114
Financial income (expenses), net	590	918	1,068	237	266
Net loss for the period	$24,677	$26,932	$21,155	$14,794	$10,848
Basic and diluted net loss per share	$0.35	$0.42	$0.38	$0.34	$0.35
Weighted average number of shares used in computing basic and diluted net loss per share	70,284,337	63,514,405	55,481,357	44,031,866	31,198,825
Statements of Cash Flows Data:					
Net cash used in operating activities	$20,605	$19,121	$16,887	$3,275	$5,755
Net cash provided by (used in) investing activities	21,537	1,983	(19,799)	(30,797)	(36)
Net cash provided by financing activities	17,201	12,624	36,304	632	47,037
Net increase (decrease) in cash	18,133	(4,514)	(382)	(33,440)	41,246
Cash and cash equivalents at beginning of year	4,493	9,007	9,389	42,829	1,583
Cash and cash equivalents at end of year	$22,626	$4,493	$9,007	$9,389	$42,829
Balance Sheet Data:					
Cash, cash equivalents, short-term bank deposits, restricted cash and short-term deposits, and marketable securities	$53,119	$58,819	$54,213	$37,809	$42,829
Current assets	56,868	61,987	55,085	38,192	43,297
Long-term assets	11,287	12,036	13,231	9,228	2,719
Total assets	68,155	74,023	68,316	47,420	46,016
Current liabilities	6,183	7,397	5,921	5,522	2,018
Long-term liabilities	3,829	4,503	4,929	4,156	576
Stockholders’ equity	58,143	62,123	57,466	37,742	43,422

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 FDA before submitting an IND application. Currently, we plan to continue working in partnership with the 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 coming 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.

RESULTS OF OPERATIONS – YEAR ENDED JUNE 30, 2015 COMPARED TO YEAR ENDED JUNE 30, 2014 AND YEAR ENDED JUNE 30, 2014 COMPARED TO YEAR ENDED JUNE 30, 2013.

Revenues

Revenues for each of the years ended June 30, 2015 and June 30, 2014 were $379,000. All such revenues were derived from the United Agreement.

Revenues decreased by 44% from $679,000 for the year ended June 30, 2013 to $379,000 for the year ended June 30, 2014. All such revenues were derived from the United Agreement.

The reduction from the year ended June 30, 2013 to 2014 is due to a re-evaluation we did for the development period under the United Agreement in light of the Clinical Hold. In June 2013, we received notification from the FDA that our United States Phase II IC study had been placed on Clinical Hold due to a serious allergic reaction in a case which required hospitalization. In September 2013, the FDA lifted the Clinical Hold. In June 2013, following the Clinical Hold, we extended the development period for which we received funds from United from 6.5 years to 11.5 years. The license fee will be recognized on a straight line basis as revenue over the estimated development period.

30

We estimated the remaining performance period of the development to be approximately 7.5 years as of June 30, 2015. The license fee will continue to be recognized on a straight-line basis as revenue over the estimated remaining development period.

Cost of revenues

Cost of revenues increased by 17% from $11,000 for the year ended June 30, 2014 to $13,000 for the year ended June 30, 2015. This increase is related to the royalties we are obligated to pay to the OCS, which reflects 3.5% of the revenues derived from the United Agreement in fiscal 2015 compared to 3% of the revenues derived from the United Agreement in fiscal 2014.

Cost of revenues decreased by 45% from $20,000 for the year ended June 30, 2013 to $11,000 for the year ended June 30, 2014.

The reductions in the years ended June 30, 2013 and 2014 are a result of the re-evaluation we did for the development period under the United Agreement. As described above, following the Clinical Hold we extended the development period for which we received funds from United from 6.5 years to 11.5 years.

Research and Development net

Research and development net costs (costs less participation and grants by the OCS and other parties) for the year ended June 30, 2015 decreased in 2% to $19,173,000 from $19,542,000 for the year ended June 30, 2014.

This decrease is attributed to improved planning of our production process, which resulted in a decrease in materials consumption, offset by an increase in subcontractors and consultants fees which related to regulatory and preclinical activities, and a decrease in the OCS participation. The decrease in the OCS participation is attributable to a delay in the approval of the OCS grant for 2013 with resulted a higher participation in 2014, and a lower grant approved by the OCS in 2015 compared to 2014.

The decrease in research and development expenses, net, is also attributed to the fluctuations in the exchange rates of the U.S. dollar and the NIS. The average exchange rate during the year ended June 30, 2014 was 3.518 while the average exchange rate during the year ended June 30, 2015 was 3.778. The strength of the U.S. dollar against the NIS during the year ended June 30, 2015 caused lower expenses in U.S. dollars, for the same amount of expenses that are dominated in NIS.

Research and development net costs (costs less participation and grants by the OCS and other parties), for the year ended June 30, 2014 increased by 13% to $19,542,000 from $17,233,000 for the year ended June 30, 2013. This increase is attributed to the material increase in our in-house research and development activity, increase in our salaries due to, among other things, an increase of 45 employees as compared to the average number of employees in the year ended June 30, 2013, an increase in our depreciation expenses and an increase in our rent and maintenance expenses, offset by an increase in OCS participation. This increase in OCS participation is attributable to the fact that due to a delay in the approval of the OCS grant for 2013, we recognized $5,396,000 in fiscal year 2014 compared to $2,673,000 in fiscal year 2013.

General and Administrative

General and administrative expenses decreased by 26% from $8,676,000 for the year ended June 30, 2014 to $6,460,000 for the year ended June 30, 2015. This is primarily driven by a decrease in stock-based compensation expenses related to our directors and officers and attributable to the timing of the grant of restricted stock units, or RSUs.

General and administrative expenses increased by 54% from $5,649,000 for the year ended June 30, 2013 to $8,676,000 for the year ended June 30, 2014. This is primarily driven by an increase in stock-based compensation expenses related to our employees and directors, due to timing of grants made to directors, and an increase in our salaries due to, among other things, an increase of 6 employees as compared to the average number of employees in the year ended June 2013.

Financial Income, net

Financial income decreased from $918,000 for the year ended June 30, 2014 to $590,000 for the year ended June 30, 2015. This decrease is mainly attributable to an increase in exchange rates expenses, related to the strength of the U.S. dollar against the NIS in the year ended June 30, 2015. The exchange rates expenses' increase was offset by an increase in gains related to our sale of our marketable securities and the sale of a portion of CHA shares, as well as increase in gains from derivatives and fair value hedge derivatives.

Financial income decreased from $1,068,000 for the year ended June 30, 2013 to $918,000 for the year ended June 30, 2014. The decrease is mainly due to a decrease in gains from hedging instruments and interest income on deposits over fiscal 2014, offset by an increase in our gain from marketable securities.

Net Loss

Net loss for the year ended June 30, 2015 was $24,677,000 as compared to a net loss of $26,932,000 for the year ended June 30, 2014. Net loss per share for the year ended June 30, 2015 was $0.35, as compared to $0.42 for the year ended June 30, 2014. The net loss per share decreased as a result of the decrease in our net loss, and an increase in our weighted average number of shares due to the issuance of additional shares during fiscal 2015.

Net loss for the year ended June 30, 2014 was $26,932,000 as compared to a net loss of $21,155,000 for the year ended June 30, 2013. Net loss per share for the year ended June 30, 2014 was $0.42, as compared to $0.38 for the year ended June 30, 2013. The net loss per share increased as a result of the increase in our net loss, offset by the increase in our weighted average number of shares due to the issuance of additional shares, mainly the shares issued to CHA in December 2013 and the shares issued under an At Market Issuance Sales Agreement, or ATM Agreement.

Liquidity and Capital Resources

As of June 30, 2015, our total current assets were $56,868,000 and our total current liabilities were $6,183,000. On June 30, 2015, we had a working capital surplus of $50,685,000 and an accumulated deficit of $138,511,000.

As of June 30, 2014, our total current assets were $61,987,000 and our total current liabilities were $7,397,000. On June 30, 2014, we had a working capital surplus of $54,590,000 and an accumulated deficit of $113,834,000.

Our cash and cash equivalents as of June 30, 2015 amounted to $22,626,000. This is an increase of $18,133,000 from the $4,493,000 reported as of June 30, 2014. Cash balances increased in the year ended June 30, 2015 for the reasons presented below:

Operating activities used cash of $20,605,000 in the year ended June 30, 2015. Cash used by operating activities in the year ended June 30, 2015 primarily consisted of payments of salaries to our employees, and payments of fees to our consultants, suppliers, subcontractors, and professional services providers including the costs of clinical studies, offset by an OCS grant.

Investing activities provided cash of $21,537,000 in the year ended June 30, 2015. The investing activities consisted primarily of withdrawal of $16,061,000 of short-term deposits and proceeds of $11,269,000 from the sale and redemption of marketable securities, offset by investing $4,903,000 in marketable securities and the purchase of property and equipment for $831,000.

Financing activities generated cash in the amount of $17,201,000 during the year ended June 30, 2015. The financing activities are primarily attributable to net proceeds of $16,914,000 from issuing shares of our common stock in the offering we closed in June 2015 and stock issuances in private placements in October 2014 and February 2015, and $287,000 from exercises of warrants and options by employees and investors.

On June 25, 2015, we entered into definitive agreements to sell 6,800,000 shares of common stock and warrants to purchase up to 4,080,000 shares of common stock at a combined price of $2.50 per share and related warrants. The gross proceeds from the offering were $17 million. The warrants have an exercise price of $2.85 per share of common stock, are immediately exercisable and expire 5 years from the closing of this offering. The offering was closed on June 30, 2015.

In October 2014, we issued 200,000 shares of common stock to an investor, in a private placement. The aggregate cash consideration received was $528,000. In February 2015, we issued an additional 200,000 shares of common stock to an investor, in a private placement. The aggregate cash consideration received was $586,000. In May 2015, the Company issued an additional 300,000 shares of common stock to an investor, in a private placement. As of June 30, 2015, the Company received the par value of the 300,000 shares, and the remaining consideration of $790,000 is presented as “receivables on account of shares”. The Company expects to receive the consideration by the end of September 2015.

From July 2014 through June 2015, a total of 2,081,303 warrants were exercised via “cashless” exercise, resulting in the issuance of 963,876 shares of common stock to our investors. In addition, 170,167 warrants were exercised for cash and resulted in the issuance of 170,167 shares of common stock to investors of the Company. The aggregate cash consideration received was $276,000.

Our cash and cash equivalents as of June 30, 2014 amounted to $4,493,000. This is a decrease of $4,514,000 from the $9,007,000 reported as of June 30, 2013. Cash balances decreased in the year ended June 30, 2014 for the reasons presented below:

Operating activities used cash of $19,121,000 in the year ended June 30, 2014. Cash used by operating activities in the year ended June 30, 2014 primarily consisted of payments of salaries to our employees, and payments of fees to our consultants, suppliers, subcontractors, and professional services providers including the costs of clinical studies, offset by an OCS grant.

Investing activities provided cash of $1,983,000 in the year ended June 30, 2014. The investing activities consisted primarily of withdrawal of $7,421,000 of short-term deposits and proceeds of $6,867,000 from the sale and redemption of marketable securities, offset by investing $10,851,000 in marketable securities and the purchase of property and equipment for $1,573,000.

Financing activities generated cash in the amount of $12,624,000 during the year ended June 30, 2014. The financing activities are primarily attributable to net proceeds of $10,644,000 from issuing shares of our common stock under the ATM Agreement as described below, and from exercises of warrants by shareholders.

From July 1, 2013 through June 30, 2014, a total of 2,517,907 warrants were exercised via “cashless” exercise, resulting in the issuance of 1,469,584 shares of common stock to investors of the Company. In addition, 1,432,584 warrants were exercised for cash and resulted in the issuance of 1,432,584 shares of common stock to investors of the Company. The aggregate cash consideration received was $1,968,000. From July 1, 2013 through June 30, 2014, a total of 65,000 warrants were exercised via a “cashless” exercise, resulting in the issuance of 36,970 shares of common stock to our consultants.

33

During the years that ended June 30, 2015, 2014 and 2013 we received approximately $4,405,000, $3,243,000 and $1,452,000, respectively, from the OCS towards our research and development expenses.

According to the OCS grant terms, we are required to pay royalties at a rate of 3% - 4% on sales of products and services derived from technology developed using this and other OCS grants until 100% of the dollar-linked grants amount plus interest are repaid. In the absence of such sales, no payment is required. During the year ended June 30, 2015, we paid royalties to the OCS in the aggregate amount of $12,000 in cash. The OCS may impose certain conditions on any arrangement under which the OCS permits the Company to transfer technology or development out of Israel or outsource manufacturing out of Israel. While the grant is given to the Company over a certain period of time (usually a year), the requirements and restrictions under the Israeli Law for the Encouragement of Industrial Research and Development, 1984 continue and do not have a set expiration period, except for the royalties, which requirement to pay them expires after payment in full.

In addition, the European authorities approved a research grant under the European Commission's Seventh Framework Program (FP7) in the amount of approximately €92,955 for a period of 5 years which began on January 1, 2011.

In December 2012, we entered into the ATM Agreement with MLV & Co. LLC, or MLV, which provides that, upon the terms and subject to the conditions and limitations set forth in the ATM Agreement, we may elect, from time to time, to issue and sell shares of common stock having an aggregate offering price of up to $95 million through MLV as a sales agent. We are not obligated to make any sales of common stock under the ATM Agreement.

During the year ended June 30, 2014, we issued 2,596,032 shares of common stock and raised approximately $10,644,000, net of issuance expenses of $195,000, under the ATM Agreement. On September 11, 2014, we notified MLV of the termination of the ATM Agreement.

In February 2013, MTM – Scientific Industries Center Haifa Ltd., or MTM, our landlord, participated by contributing an amount of NIS 2,990,000 (approximately $816,000) toward the cost of constructing our new facility. Such participation is being made pursuant to our lease agreement with MTM, and is recognized by ratably deducting from our monthly rent payment over the rent period. We recognized participation of $85,000 in fiscal year 2015.

In accordance with the CHA Agreement, in December, 2013, we issued to CHA 2,500,000 shares of our common stock in consideration for the issuance to us of 1,011,504 common shares of CHA, which reflected total consideration of approximately $10,414,000 to each of us and CHA. Each of us and CHA agreed not to sell the other party's shares for at least one year. The parties also agreed to give an irrevocable proxy to the other party's management with respect to the shares issued.

During March 2015, we sold a portion of the CHA shares received in December 2013, resulting in net proceeds of $5,717,000. The net gain was $282,000 and is presented as "Financial income, net".

The remaining investment in CHA shares is presented as "Marketable Securities" and classified as available-for-sale in accordance with ASC 320, "Investments - Debt and Equity Securities". The fair value of the remaining investment as of June 30, 2015 is $5,982,000, and other comprehensive income includes unrealized gains of $857,000 related to the increase in the fair value of CHA shares. If we decide to sell our investment in CHA shares, we will reclassify the unrealized gains or losses in our statement of operations.

We adhere to an investment policy set by our investment committee which aims to preserve our financial assets, maintain adequate liquidity and maximize return while minimizing exposure to the NIS. Such policy further provides that we should hold most of our current assets in bank deposits and the remainder of our current assets is to be invested in government bonds and a combination of corporate bonds and relatively low risk stocks. As of today, the

currency of our financial portfolio is mainly in U.S. dollars and we use forward and options contracts in order to hedge our exposures to NIS.

Outlook

We have accumulated a deficit of $138,511,000 since our inception in May 2001. We do not expect to generate any revenues from sales of products in the next twelve months. Our cash needs will increase in the foreseeable future. We expect to generate revenues, which in the short and medium terms will unlikely exceed our costs of operations, from the sale of licenses to use our technology or products, as we have in the United Agreement. Our management believes that we may need to raise additional funds before we have cash flow from operations that can materially decrease our dependence on our existing cash and other liquidity resources. We are continually looking for sources of funding, including non-diluting sources such as the OCS grants, other sales of our common stock or sales of the marketable securities we hold.

The OCS has supported our activity in the past ten years. Our last program, for the tenth year, was approved by the OCS in June 2015 and relates to an approximately $2,871,000 grant. The grant will be used to cover research and development expenses for the period January 1, 2015 to December 31, 2015.

In addition, the European authorities approved a research grant under the FP7 in the amount of approximately €92,955 for a period of 5 years which began on January 1, 2011.

In June 2015, we were awarded a “Smart Money” grant of approximately $117,559 from Israel’s Ministry of Economy. The program’s aim is to assist companies to extend their activities in international markets. The Israeli government granted us budget and resources for the marketing of our advanced cell therapy products in Japan and for regulatory activities there. We will also receive assistance from Israel’s trade attachés stationed in Japan, and from experts appointed especially by the "Smart Money" program.

We believe that we have sufficient cash to fund our operations for at least the next 12 months.

Application of Critical Accounting Policies

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing in this Annual Report. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition from the United Agreement

We recognize revenue pursuant to the License Agreement with United in accordance with ASC 605-25, "Revenue Recognition, Multiple-Element Arrangements".

Pursuant to ASC 605-25, each deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has “stand-alone value” to the customer. The arrangement’s consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods

or services are delivered, limited to the consideration that is not contingent upon future deliverables.

We received an up-front, non-refundable license payment of $5,000,000. Additional payments totaling $37,500,000 are subject to the achievement of certain regulatory milestones by United.

Since the deliverables in the United Agreement do not have stand-alone value, none of them qualifies as a separate unit of accounting. Accordingly, the non-refundable upfront license fee of $5,000,000 is deferred and recognized on a straight line basis over the related performance period which is the development period in accordance with Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition". We assessed the remaining performance period under the United Agreement at 7.5 years as of June 30, 2015.

The additional regulatory milestones payments will be recognized upon the achievement of futures events by United, in accordance with ASC 450-30-25, “Gain Contingencies". As of June 30, 2015, no regulatory milestones were achieved.

We also received an advance payment for the development of $2,000,000 that will be deductible against development expenses as it accrued. The upfront payment which was received and has not yet fully recognized in the statement of operations, is included in the balance sheet as advance payment. Part of the expenses related to the development, on a cost basis, shall be repaid to the Company by United according to the applicable license agreement. We are deducting the payments from research and development expenses in accordance with ASC 730-20, "Research and Development Agreements". As of June 30, 2015, we deducted an amount of approximately $1,907,000.

Stock-based compensation

Stock-based compensation is considered critical accounting policy due to the significant expenses of restricted stock units which were granted to our employees, directors and consultants. In fiscal year 2015, we recorded stock-based compensation expenses related to restricted stock units in the amount of $4,050,000.

In accordance with ASC 718, "Compensation-Stock Compensation", or ASC 718, restricted shares units to employees and directors are measured at their fair value on the grant date. All restricted shares units granted in 2015 and 2014 were granted for no consideration; therefore their fair value was equal to the share price at the date of grant, based on the close trading price of our shares known at the grant date. The restricted shares units to non-employees consultants are remeasured in any future vesting period for the unvested portion of the grants.

The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in our consolidated statements of operations. We have graded vesting based on the accelerated method over the requisite service period of each of the awards. The expected pre-vesting forfeiture rate affects the number of the shares. Based on our historical experience, the pre-vesting forfeiture rate per grant is 7% for the shares granted to employees and 0% for the shares granted to our directors, officers and non-employees consultants.

Marketable Securities

Marketable securities consist of corporate bonds, government bonds and stocks. We determine the appropriate classification of marketable securities at the time of purchase and re-evaluate such designation at each balance sheet date. In accordance with ASC No. 320, "Investment Debt and Equity Securities," we classify marketable securities as available-for-sale. Available-for-sale securities are stated at fair value, with unrealized gains and losses reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity. Realized gains and losses on sales of marketable securities, as determined on a specific identification basis, are included in financial income. The amortized cost of marketable securities is adjusted for amortization of premium and accretion of discount to maturity, both of which, together with interest, are included in financial income.

36

Marketable securities are classified within Level 1 or Level 2 because marketable securities are valued using quoted market prices or alternative pricing sources and models utilizing market observable inputs.

We recognize an impairment charge when a decline in the fair value of our investments is below the cost basis and is judged to be other-than-temporary. Factors considered in making such a determination include the duration and severity of the impairment, the reason for the decline in value, the potential recovery period and our intent to sell, including whether it is more likely than not that we will be required to sell the investment before recovery of cost basis. As such, we did not recognize any impairment charges on outstanding securities during the year ended June 30, 2015.

Research and Development Expenses, Net

We expect our research and development expenses to remain our primary expense in the near future as we continue to develop our product candidates. Our research and development expenses consist primarily of clinical trials expenses, consultant and subcontractor expenses, payroll and related expenses, lab material expenses, stock based compensation expenses, rent and maintenance expenses and patent expenses. The following table provides a breakdown of the related costs for fiscal years 2013 through 2015 (in thousands of dollars):

	Year ended June 30,		
	2013	2014	2015
Clinical trials expenses	$ 1,900	$ 2,440	$ 2,540
Consultants and subcontractor expenses	3,562	2,108	2,863
Payroll and related expenses	5,672	7,846	7,785
Materials expenses	3,824	5,624	3,835
Stock based compensation expenses	993	1,260	1,601
Depreciation expenses	955	1,785	1,942
Rent and maintenance expenses	1,362	1,808	1,610
Patent expenses	673	572	650
Other R&D expenses	965	1,495	3,130
Total expenses	19,906	24,938	23,416
Less: OCS and others participation	(2,673)	(5,396)	(4,243)
Research and Development Expenses, Net	$ 17,233	$ 19,542	$ 19,173

We invest heavily in research and development. Research and development expenses, net, were our major operating expenses, representing between 70% - 77% of the total operating expenses for each of our fiscal years 2013, 2014 and 2015. We expect that in the upcoming years our research and development expenses, net, will continue to be our major operating expense.

Contractual Obligations

The following summarizes our contractual obligations and other commitments on June 30, 2015, and the effect such obligations could have on our liquidity and cash flow in future periods:

		Payments due by period			
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$7,236,000	$1,094,000	$3,265,000	$2,101,000	$776,000
Minimum purchase requirements	759,000	759,000			
Accrued Severance Pay, net	106,000				106,000
Total	$8,101,000	$1,853,000	$3,265,000	$2,101,000	$882,000

Off Balance Sheet Arrangements

Our Company has no off balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to a variety of risks, including changes in interest rates, foreign currency exchange rates, changes in the value of our marketable securities and inflation.

As of June 30, 2015, we had $22.6 million in cash and cash equivalents, $8.5 million in short-term bank deposits and restricted deposits and $22.2 million in marketable securities.

We adhere to an investment policy set by our investment committee, which aims to preserve our financial assets, maintain adequate liquidity and maximize return while minimizing exposure to the NIS. Such policy further provides that we should hold most of our current assets in bank deposits and the remainder of our current assets should be invested in government bonds and a combination of corporate bonds and relatively low risk stocks. As of today, the currency of our financial portfolio is mainly in U.S. dollars and we use forward and options contracts in order to hedge our exposures to currencies other than the U.S. dollar.

Interest Rate Risk

We invest a major portion of our cash surplus in bank deposits in banks in Israel. Since the bank deposits typically carry fixed interest rates, financial income over the holding period is not sensitive to changes in interest rates. However, our interest gains from future deposits may decline in the future as a result of changes in the financial markets. In addition, our income from marketable securities is exposed to market risks resulting from changes in interest rates. In any event, given the historic low levels of the interest rate, we estimate that a further decline in the interest rate we are receiving will not result in a material adverse effect to our business.

Foreign Currency Exchange Risk and Inflation

A significant portion of our expenditures, including salaries, lab materials, consultants' fees and office expenses relate to our operations in Israel. The cost of those Israeli operations, as expressed in U.S. dollars, is influenced by the extent to which any increase in the rate of inflation in Israel is not offset (or is offset on a lagging basis) by a devaluation of the NIS in relation to the U.S. dollar. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. In addition, as of June 30, 2015, we own net balances in NIS of approximately $3,871,000, Assuming a 10% appreciation of the NIS against the U.S. dollar, we would

experience exchange rate gain of approximately $430,000, while assuming a 10% devaluation of the NIS against the U.S. dollars, we would experience an exchange rate loss of approximately $352,000, in both cases excluding the effect of our hedging transactions (as described below).

The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Year Ended June 30,		
	2013	2014	2015
Average rate for period	3.794	3.518	3.788
Rate at period-end	3.618	3.438	3.769

We use currency hedging transactions of options and forwards to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS.

Since November 2013, we have entered into forward contracts to hedge against the risk of overall changes in future cash flow from payments of payroll and related expenses denominated in NIS. As of June 30, 2015, we had forward contracts in place to hedge future payroll and related expenses in NIS in the notional principal amount of approximately $1,560,000, with a fair value of approximately $52,000, which is presented in “other current assets” on our consolidated balance sheets. The net unrealized gain on the effective portion of these cash flow hedges was $23,000. The forward contracts on our future NIS payroll and related expenses will settle by October 2015.

As of June 30, 2015, we own 400,368 common shares of CHA, which are presented in our financial statements as marketable securities. The shares are listed on the KOSDAQ and the shares' price is denominated in KRW. We are exposed to changes in the market price of CHA shares, as well as to exchange rates fluctuations in the KRW currency compared to the U.S dollar. In February 2014, we entered into a forward contract with a notional principal of $11 million, to hedge against the foreign currency risk between the KRW and the U.S. dollar. The forward contract expired on December 26, 2014, resulting in a net gain of $59,000.

For the year ended June 30, 2015, our net gain from hedging transactions that are non-designated and consist primarily of options strategies to minimize the risk associated with the foreign exchange effects of monetary assets and liabilities denominated in NIS were $248,000.

Item 8. Financial Statements and Supplementary Data.

Our financial statements are stated in thousands United States dollars (US$) and are prepared in accordance with U.S. GAAP.

The following audited consolidated financial statements are filed as part of this Annual Report:

Reports of Independent Registered Public Accounting Firm, dated September 9, 2015.

Consolidated Balance Sheets.

Consolidated Statements of Operations.

Consolidated Statements of Comprehensive Loss.

Statements of Changes in Equity.

Consolidated Statements of Cash Flows.

Notes to the Consolidated Financial Statements.

39

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2015

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2015

U.S. DOLLARS IN THOUSANDS

INDEX

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and Stockholders Of

PLURISTEM THERAPEUTICS INC.

We have audited the accompanying consolidated balance sheets of Pluristem Therapeutics Inc. and its subsidiary (the "Company") as of June 30, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended June 30, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of June 30, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of June 30, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework and our report dated September 9, 2015, expressed an unqualified opinion thereon.

Haifa, Israel
September 9, 2015

/s/ Kost Forer Gabbay & Kasierer
Kost Forer Gabbay & Kasierer
A Member of Ernst & Young Global

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and Stockholders Of

PLURISTEM THERAPEUTICS INC.

We have audited Pluristem Therapeutics Inc. internal control over financial reporting as of June 30, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework (the COSO criteria). Pluristem Therapeutics Inc. and its subsidiary's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Pluristem Therapeutics Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Pluristem Therapeutics Inc. and its subsidiary as of June 30, 2015 and 2014 and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended June 30, 2015 of Pluristem Therapeutics Inc. and its subsidiary and our report dated September 9, 2015 expressed an unqualified opinion thereon.

Haifa, Israel
September 9, 2015

/s/ Kost Forer Gabbay & Kasierer
Kost Forer Gabbay & Kasierer
A Member of Ernst & Young Global

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEET

U.S. Dollars in thousands (except share and per share data)

	Note	June 30, 2015	2014
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		$22,626	$4,493
Short-term bank deposits		7,167	19,451
Restricted cash and short term bank deposits	2f	1,076	4,914
Marketable securities	3	22,250	29,961
Accounts receivable from OCS		1,691	2,263
Other current assets	5	2,058	905
Total current assets		56,868	61,987
LONG-TERM ASSETS:			
Long-term deposits and restricted bank deposits	2g	360	304
Severance pay fund		753	901
Property and equipment, net	6	10,173	10,823
Other long term assets		1	8
Total long-term assets		11,287	12,036
Total assets		$68,155	$74,023

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEETS
U.S. Dollars in thousands (except share and per share data)

	Note	June 30, 2015	2014
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		$3,268	$3,465
Accrued expenses		910	915
Deferred revenues	1d, 2i	379	379
Advance payment from United	1d, 2i	93	247
Other accounts payable	7	1,533	2,391
Total current liabilities		6,183	7,397
LONG-TERM LIABILITIES			
Deferred revenues	1d, 2i	2,468	2,847
Accrued severance pay		859	1,068
Other long term liabilities		502	588
Total long term liabilities		3,829	4,503
COMMITMENTS AND CONTINGENCIES	8		
STOCKHOLDERS' EQUITY			
Share capital:	9		
Common stock $0.00001 par value per share: Authorized: 200,000,000 shares Issued and outstanding: 78,771,905 shares as of June 30, 2015: 68,601,452 shares as of June 30, 2014;		1	- (*)
Additional paid-in capital		195,303	172,998
Accumulated deficit		(138,511)	(113,834)
Receivables on account of shares		(790)	-
Other comprehensive income		2,140	2,959
		58,143	62,123
		$68,155	$74,023

(*) Less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. Dollars in thousands (except share and per share data)

	Note	Year ended June 30, 2015	2014	2013
Revenues	1d, 2i	$ 379	$ 379	$ 679
Cost of revenues		(13)	(11)	(20)
Gross profit		366	368	659
Research and development expenses		(23,416)	(24,938)	(19,906)
Less participation by the Office of the Chief Scientist and other parties		4,243	5,396	2,673
Research and development expenses, net		(19,173)	(19,542)	(17,233)
General and administrative expenses		(6,460)	(8,676)	(5,649)
Operating loss		(25,267)	(27,850)	(22,223)
Financial income, net	10	590	918	1,068
Net loss		$ (24,677)	$ (26,932)	$ (21,155)
Loss per share:				
Basic and diluted net loss per share		$ (0.35)	$ (0.42)	$ (0.38)
Weighted average number of shares used in computing basic and diluted net loss per share		70,284,337	63,514,405	55,481,357

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. Dollars in thousands

	Year ended June 30,		
	2015	2014	2013
Net loss	$(24,677)	$(26,932)	$(21,155)
Other comprehensive income (loss), net:			
Unrealized gain (loss) on derivative instruments	285	(25)	-
Unrealized gain (loss) on available-for-sale marketable securities, net	(1,132)	3,404	415
Reclassification adjustment of derivative instruments gains (losses) realized in net loss, net	(262)	48	-
Reclassification adjustment of available-for-sale marketable securities gains (losses) realized in net loss, net	290	(727)	(26)
Total comprehensive loss	$(25,496)	$(24,232)	$(20,766)

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN EQUITY
U.S. Dollars in thousands (except share and per share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance as of July 1, 2012	46,448,051	$(*)	$103,619	$ (130)	$ (65,747)	$ 37,742
Issuance of common stock and warrants related to September 2012 public offering, net of issuance costs of $2,694 (Note 9e)	9,200,000	(*)	34,106	-	-	34,106
Exercise of options and warrants by employees and consultants	176,867	(*)	176	-	-	176
Exercise of warrants by investors and finders	1,621,359	(*)	2,009	-	-	2,009
Stock based compensation to employees, directors and non-employee consultants	1,750,340	(*)	2,799	-	-	2,799
Stock based compensation to contractor	-	-	1,400	-	-	1,400
Other comprehensive income	-	-	-	389	-	389
Net loss for the period	-	-	-	-	(21,155)	(21,155)
Balance as of June 30, 2013	59,196,617	$(*)	$144,109	$ 259	$ (86,902)	$ 57,466

(*) Less than $1

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN EQUITY
U.S. Dollars in thousands (except share and per share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive		Total Stockholders'
	Shares	Amount	Capital	Income	Accumulated Deficit	Equity
Balance as of July 1, 2013	59,196,617	$(*)	$144,109	$ 259	$ (86,902)	$ 57,466
Issuance of common stock under ATM Agreement, net of issuance costs of $195 (Note 9f)	2,596,032	(*)	10,644	-	-	10,644
Exercise of options and warrants by employees and non-employee consultants	53,470	(*)	12	-	-	12
Exercise of warrants by investors and finders	2,902,168	(*)	1,968	-	-	1,968
Stock based compensation to employees, directors and non-employee consultants	1,353,165	(*)	5,851	-	-	5,851
Issuance of common stock under CHA Agreement (Note 1d)	2,500,000	(*)	10,414	-	-	10,414
Other comprehensive income, net	-	-	-	2,700	-	2,700
Net loss	-	-	-	-	(26,932)	(26,932)
Balance as of June 30, 2014	68,601,452	$(*)	$172,998	$ 2,959	$ (113,834)	$ 62,123

(*) Less than $1

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN EQUITY
U.S. Dollars in thousands (except share and per share data)

	Common Stock		Additional Paid-in	Receivables on account	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Capital	of shares	(Loss)	Deficit	Equity
Balance as of July 1, 2014	68,601,452	$ (*)	$ 172,998	-	$ 2,959	$ (113,834)	$ 62,123
Issuance of common stock and warrants related to June 2015 offering, net of issuance costs of $1,200 (Note 9h)	6,800,000	1	15,799				15,800
Exercise of options by employees and non-employee consultants	39,000	(*)	11	-	-	-	11
Exercise of warrants by investors and finders	1,134,043	(*)	276	-	-	-	276
Stock based compensation to employees, directors and non-employee consultants	1,397,406	(*)	4,052	-	-	-	4,052
Issuance of common stock in a private placement (Note 9g)	700,000	(*)	1,904	(790)	-	-	1,114
Stock based compensation to contractor (Note 9i)	100,004	(*)	263		-	-	263
Other comprehensive loss, net	-	-	-	-	(819)	-	(819)
Net loss	-	-	-	-	-	(24,677)	(24,677)
Balance as of June 30, 2015	78,711,905	$ 1	$ 195,303	$ (790)	$ 2,140	$ (138,511)	$ 58,143

(*) Less than $1

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. Dollars in thousands

	Year ended June 30,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(24,677)	$(26,932)	$(21,155)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,074	1,902	1,033
Loss on property and equipment	20	85	-
Accretion of discount, amortization of premium and changes in accrued interest of marketable securities	213	1,282	154
Loss (gain)from sale of investments of available-for-sale marketable securities	290	(727)	(26)
Stock-based compensation to employees, directors and non-employees consultants	4,052	5,851	2,799
Decrease (increase) in OCS receivables	572	(1,990)	(70)
Increase in other current assets and other long-term assets	(1,129)	(251)	(470)
Increase (decrease) in trade payables	(566)	1,257	1,335
Increase (decrease) in other accounts payable, accrued expenses and other long-term liabilities	(949)	902	1,556
Decrease in deferred revenues	(379)	(379)	(679)
Decrease in advance payment from United	(154)	(146)	(1,183)
Decrease (increase) in interest receivable on short-term deposits	35	(36)	(140)
Linkage differences and interest on short and long-term deposits and restricted bank deposits	54	12	(30)
Accrued severance pay, net	(61)	49	(11)
Net cash used in operating activities	$(20,605)	$(19,121)	$(16,887)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	$(831)	$(1,573)	$(4,309)
Proceeds from sale of property and equipment	19	-	-
Repayment of (investment in) short-term deposits	16,061	7,421	(10,202)
Repayment of (investment in) long-term deposits and restricted bank deposits	(78)	119	869
Proceeds from sale of available-for-sale marketable securities	10,635	6,113	1,848
Proceeds from redemption of available-for-sale marketable securities	634	754	529
Investment in available-for-sale marketable securities	(4,903)	(10,851)	(8,534)
Net cash provided by (used in) investing activities	$21,537	$1,983	