

PLURISTEM THERAPEUTICS INC
Form 10-K
September 07, 2016

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

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2016

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 No

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

Yes No

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

Yes No

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

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

Yes No

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

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

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

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

Yes No

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

\$84,296,685

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

80,723,647 as of August 31, 2016

2

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I</u>	2
<u>Item 1. Business.</u>	2
<u>Item 1A. Risk Factors.</u>	14
<u>Item 1B. Unresolved Staff Comments.</u>	28
<u>Item 2. Properties.</u>	29
<u>Item 3. Legal Proceedings.</u>	29
<u>Item 4. Mine Safety Disclosures.</u>	29
<u>PART II</u>	29
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	29
<u>Item 6. Selected financial data.</u>	30
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	31
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk.</u>	40
<u>Item 8. Financial Statements and Supplementary Data.</u>	41
<u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	42
<u>Item 9A. Controls and Procedures.</u>	42
<u>Item 9B. Other Information.</u>	43
<u>PART III</u>	44
<u>Item 10. Directors, Executive Officers and Corporate Governance.</u>	44
<u>Item 11. Executive Compensation.</u>	49
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters.</u>	57
<u>Item 13. Certain Relationships and Related Transactions and Director Independence.</u>	59
<u>Item 14. Principal Accounting Fees and Services.</u>	59
<u>PART IV</u>	61
<u>Item 15. Exhibits.</u>	61

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 CHA Biotech Co. Ltd., or CHA, and clinical trials to be conducted according to such agreement;
- the prospects of entering into additional license agreements, or other forms of cooperation with other companies and medical institutions;
- the Memorandum of Understanding we entered into with Fukushima Medical University, Fukushima Global Medical Science Center and the potential for the development of our PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients;
- our belief that PLX-PAD may be effective in treating critical limb ischemia and femoral neck fracture;
- our belief that PLX R18 may be effective in treating Acute Radiation Syndrome (ARS); our belief that we may obtain orphan drug status for some of our products;
 - the potential for the accelerated approvals of some of our products with the European Medicines Agency and Japan's Pharmaceuticals and Medical Devices Agency;
- the prospects of having in-house production capacity to grow clinical-grade PLX cells in commercial quantities;
- 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;
 - 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

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. Our lead indications are critical limb ischemia, recovery after surgery for femoral neck fracture, and acute radiation syndrome. Pivotal, multinational clinical trials are planned for our PLX-PAD product in critical limb ischemia and femoral neck fracture, and the National Institutes of Health's, or NIH, National Institute of Allergy and Infectious Diseases, or NIAID, is currently conducting a dose selection trial with PLX-R18 in the hematologic component of acute radiation syndrome. Each of these indications is a severe unmet medical need. Together, these treatments could address a multibillion dollar global market.

PLX cells are derived from a class of placental cells that are harvested from donated placentas at the time of full term delivery of a live baby. PLX cell products require no tissue matching prior to administration. They are produced using our proprietary three-dimensional expansion technology. Our manufacturing facility complies with current Good Manufacturing Practice requirements and has been approved by the U.S. Food and Drug Administration, or FDA, and the European, Japanese and Israeli regulatory authorities for production of PLX-PAD for late stage trials and marketing. We expect to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

We were incorporated in Nevada in 2001, and have a wholly owned subsidiary in Israel called Pluristem Ltd., or the Subsidiary. 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 goal is to make significant progress with our robust clinical pipeline and our anticipated pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We intend to shorten the time to commercialization of our first product, PLX-PAD, by leveraging the unique accelerated regulatory pathways that exist in Europe and Japan to bring innovative products to the market efficiently, in order to address life-threatening diseases. We believe that these accelerated pathways create substantial opportunities for us and for the cell therapy industry as a whole. We are pursuing these accelerated pathways for PLX-PAD in critical limb ischemia and femoral neck fracture. Our second product, PLX R18, is under development in the United States for ARS via the animal rule regulatory pathway, which requires no human efficacy trials for approval. We expect to demonstrate the real-world impact and value of our pipeline, technology platform, and commercial-scale manufacturing capacity.

In May 2015, we announced that the PLX-PAD cell program in CLI had been selected for the Adaptive Pathways pilot project of the European Medicines Agency (EMA). In addition, we reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on the design of the final trial needed to apply for conditional approval of PLX-PAD cells in the treatment of CLI. The approval of the protocol for the 75-patient trial was part of a larger agreement on the development of PLX-PAD via Japan's new accelerated regulatory pathway for regenerative medicine. In August 2016, we received a positive FDA response to our pivotal Phase III protocol for PLX-PAD in CLI. Our intention is to initiate these CLI studies in early 2017, and obtain initial approval in the coming two to three years.

In July 2016, we announced our intent to conduct a Phase III trial assessing our PLX-PAD cells in recovery following surgery for femoral neck fracture in the United States and Europe. In addition, the EMA confirmed that this indication would also be eligible for the Adaptive Pathways project.

In February 2016, we announced that the NIAID, a part of the NIH, will initiate studies in large animals to select the appropriate doses for PLX-R18 as a medical counter measure in the treatment of the hematologic component of Acute Radiation Syndrome, or ARS. These studies have been initiated. Once the optimal dose is determined in large animals, a pivotal trial could be conducted, the results of which may be used to support a Biologics License Application for PLX-R18 for this indication under the Animal Rule regulatory pathway. The NIAID supports and collaborates on the dosing studies, and Pluristem supplies the PLX-R18 cells. In December 2015, we also signed a Memorandum of Understanding for a collaboration with Fukushima Medical University, Fukushima Global Medical Science Center. The purpose of the collaboration is to develop our PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients.

We made progress in our Phase II intermittent claudication (IC) trial, a randomized, double blind, placebo controlled, multinational clinical study. We have enrolled 160 patients to date and have expanded the clinical trial to include a total of 170 patients, with enrollment completion expected in 2016. We currently have active clinical sites in the United States, Israel, Germany, and South Korea.

The FDA cleared our Investigational New Drug application to begin a Phase I trial of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT. We plan to initiate the clinical trial in the United States in calendar 2016.

In December 2015, the FDA granted our PLX-PAD cells Orphan Drug Designation in the treatment of severe preeclampsia. We are currently conducting additional pre-clinical studies in order to advance towards a Phase I trial.

On December 8, 2015, we received a notice from United Therapeutics Corporation, or United, terminating our exclusive license agreement, or the United Agreement. Pursuant to the United Agreement termination clause, we

regained full rights to PLX in the field of Pulmonary Arterial Hypertension, or PAH, as well as all clinical data and regulatory submissions. We may continue the development of this indication subject to interest of potential licensing partners in the U.S. and Japan.

Scientific Background

Cell therapy is an emerging 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 monitored and controlled 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 or additional manipulation prior to administration. From the physician's and patient's perspective, our PLX products are comparable to any other product delivered in a vial. 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.

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 a strategic partnership with CHA Biotech Co. Ltd., or CHA, in South Korea for both IC and CLI for the Korean market only. 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.

The relationship with CHA is intended to leverage our expertise in manufacturing high quality, 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 this partnership 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 various stages of peripheral arterial disease, from early stage IC to advanced 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 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. The initial sample size was 150 and we expanded the IC trial to enroll an additional 20 patients to be randomized in order to preserve the study's original design to administer two injections to each of 150 patients. Twenty of the 150 patients originally enrolled did not complete the trial with two injections. Previous findings in clinical and preclinical studies of PLX cells demonstrated the superior efficacy of two injections vs. a single injection in certain indications.

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 received clearance for the clinical study and agreed with the PMDA on the terms for conditional marketing approval in December 2015. The next step consists of submitting a clinical trial notification to the PMDA to enable us to potentially start a Phase II study of PLX-PAD in CLI in late 2016.

Additionally, in May 2015, the PLX-PAD clinical development program was selected for the EMA's Adaptive Pathways pilot project and one of only 6 companies that successfully passed through the different stages of the 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 due to an expected increase in diabetic patients and aging population. 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. Pluristem has conducted a parallel scientific advice with EMA and European health technology assessment bodies in March 2016, under the Adaptive Pathways project, in order to discuss the clinical development plan in CLI. In addition we have had a pre-IND interaction with FDA on the same protocol in July 2016. As an outcome of these interactions, we plan to conduct a Phase III study in CLI in 2017 in the United States and EU, subject to the clearance of our applications.

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.

In July 2016, we announced our intention to conduct a Phase III trial assessing our PLX-PAD cells in recovery following surgery for femoral neck fracture in the United States and Europe. In addition, the EMA confirmed that this indication would be eligible for the Adaptive Pathway regulatory approval. We are currently in discussions with respect to the FDA submission of the Phase III protocol. In addition, we submitted this protocol to the EMA following consultation with the Adaptive Pathways Project Group.

Recovery following Hematopoietic cell transplantation ("HCT") – Following positive data from the use of PLX-R18 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 recovery following HCT.

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 NIAID, 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 HCT. We received IND approval in January 2016. We anticipate initiating the Phase I trial in the United States in late 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.

NIH continues to support us and a pilot study in large animals has been initiated to determine the most appropriate dose of PLX-R18 for recovery of patients with hematopoietic syndrome of ARS.

Regulatory and Clinical Affairs Strategy

Our cell therapy development strategy is to hold open and frequent 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 we are also working with the Ministry of Food and Drug Safety, or MFDS, of South Korea authority via our collaborator CHA.

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.

6

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 76 issued patents and 135 patent applications in the United States, Europe, China and Japan, as well as in additional countries worldwide, including Israel, countries in the Far East and South America (in calculating the number of issued patents, each European patent validated in multiple jurisdictions was counted as a single patent). In April 2016, the Subsidiary entered into a licensing agreement with TES Holdings Co., Ltd., a venture company derived from the University of Tokyo, to obtain a key patent in Japan to cover the treatment of ischemic diseases with placental cell therapy. This license is subject to future single low-digit royalties from sales of our product for treatment in the field of ischemic diseases in Japan, until expiry of the patent in 2023. This license follows the grant of two key patents to us by the Japanese Patent Office, which address three dimensional methods for expanding placental and adipose cells, and specified cell therapies produced from placental tissue using these methods.

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, harvest, and thawing 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 2020 to 2035. 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	Expiry Date
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	February 4, 2020
METHODS FOR CELL EXPANSION AND USES OF CELLS AND CONDITIONED MEDIA PRODUCED THEREBY FOR THERAPY PCT/IL2007/000380	United States, Europe, Israel, China, Hong Kong, Canada, Brazil, Korea	Japan, Europe, Israel, Singapore, Russia, South Africa, Australia, India, Korea, Mexico, Hong Kong, China	March 23, 2027
ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2008/001185	United States, Europe, Korea, Israel, China, Hong Kong, Canada, Brazil, Russia, Japan	United States, Europe, Singapore, Australia, Hong Kong, South Africa India, Mexico, Japan	September 2, 2028
METHODS OF TREATING INFLAMMATORY COLON DISEASES PCT/IL2009/000527	United States, Brazil, Canada, China, Europe, Hong Kong, Israel	Russia, South Africa	May 26, 2029
METHODS OF SELECTION OF CELLS FOR TRANSPLANTATION PCT/IL2009/000844	United States, Europe, Israel, Hong Kong		September 1, 2029
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, Europe	September 1, 2029
ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000845	Israel	United States, Europe	September 1, 2029
ADHERENT STROMAL CELLS DERIVED FROM PLACENTAS OF MULTIPLE DONORS AND USES THEREOF PCT/IB2011/001413	United States, Israel, Hong Kong	Europe	April 21, 2031
ADHERENT CELLS FROM PLACENTA AND USE OF SAME IN DISEASE TREATMENT PCT/IB2010/003219	United States, Canada, China, Europe, Hong Kong, Israel, India	United States, Europe, China, Australia, New Zealand, South Africa, Hong-Kong, Mexico	November 29, 2030

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	April 15, 2032
METHODS FOR TREATING RADIATION OR CHEMICAL INJURY PCT/IB2012/000664	United States, Europe, Hong Kong, Israel, Korea, Japan		March 22, 2032
SKELETAL MUSCLE REGENERATION USING MESENCHYMAL STEM CELLS PCT/EP2011/058730	United States, Israel, Hong Kong	Europe	May 27, 2031
GENE AND PROTEIN EXPRESSION PROPERTIES OF ADHERENT STROMAL CELLS CULTURED IN 3D PCT/IB2014/059114	United States, Israel		February 20, 2034
DEVICES AND METHODS FOR CULTURE OF CELLS PCT/IB2013/058184	United States, Europe, China, Korea, Brazil, Hong Kong, India, Mexico, Russia	Europe, Canada, China, Europe, Israel, Japan, Singapore	August 31, 2033
METHODS FOR PREVENTION AND TREATMENT OF PREECLAMPSIA PCT/IB2013/058186	United States, Europe, China, Japan, Korea, Canada, Israel, Singapore, Australia, Hong Kong	South Africa	August 31, 2033
METHOD AND DEVICE FOR THAWING BIOLOGICAL MATERIAL PCT/IB2013/059808	United States, Europe, China, Japan, Korea, Canada, Brazil, Israel, India, Russia, Singapore, Australia, Hong Kong		October 31, 2033
SYSTEMS AND METHODS FOR GROWING AND HARVESTING CELLS PCT/IB2015/051559	International (PCT) Application Taiwan		March 3, 2035
DRUG CONTAINING HUMAN PLACENTA-ORIGIN MESENCHYMAL CELLS AND PROCESS FOR PRODUCING VEGF USING THE CELLS		Japan	March 28, 2023

Research and Development

Our research and development expenses were \$22,856,000, \$23,416,000 and \$24,938,000 in fiscal years 2016, 2015 and 2014, respectively, before deducting the participation by the Israel Innovation Authority, or IIA (previously the Office of the Chief Scientist, or IIA), 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. Charité will receive between 1% to 2% 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. In addition, we also signed a memorandum of understanding (MOU) for a collaboration with Fukushima Medical University.

We used 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 are currently performing additional studies with Hadassah furthering our understanding of the mechanism of action of the PLX-R18 product. We have no current or ongoing obligations to Hadassah.

We are performing proof of concept studies in conjunction with the Israeli Duchenne Association, or ADI, to assess the utility of PLX-PAD in alleviating symptoms of Duchenne muscular dystrophy.

We signed an MOU with for a collaboration with Fukushima Medical University, Fukushima Global Medical Science Center. The purpose of the collaboration is to develop Pluristem's PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients. The collaboration will proceed alongside research supported by the NIH, which is studying PLX-R18 as a potential treatment for the hematologic component of ARS.

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 multinational 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 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, PMDA and the Israeli MOH. Our second product, PLX R18, was cleared by the FDA and the Israeli Ministry of Health for clinical use. Furthermore, the site was inspected and approved by an EU qualified person (European accreditation body), approving that the site and production processes meet the current GMP for the purpose of manufacturing clinical grade products. 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 like Japan, Israel and South Korea. 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, or, if approved, will be reimbursed by public and private health insurance.

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 (Voluntary Harmonisation procedure), which makes it possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries;

Obtaining approval of affiliated ethics committees of clinical sites to test the investigational product into humans in clinical trials;

Adequate and well-controlled clinical trials to establish the safety and efficacy of the investigational 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

In Japan, we have completed the required regulatory interactions with the PMDA, prior to the submission of clinical trial notification, 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, 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.

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 169 full-time employees and 8 part-time employees, of whom 154 full-time employees and 8 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 based in the United States, Europe, Japan, Korea, and Australia such as Athersys, Inc., Capricor Therapeutics, Inc., Celgene Corporation, ReNeuron Group plc, Tigenix NV, SanBio Inc., Healios K.K., Cytori Therapeutics, Green Cross Cell Corp. 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 & Media" 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.

14

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 two Phase I clinical trials 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. 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.

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, 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 agreement with 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 a strategic partnership 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. Our PLX cells are also being used in South 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 and other regulatory authorities 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 HCT. 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 for PLX-PAD have received approval from the FDA, EMA, Germany's PEI, the Korean MFDS and the PMDA. 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 our products.

Recent regulatory pathways in Europe and Japan may allow for early commercialization of our products and reducing the time to market 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 cleared our PLX-PAD cells for use in clinical trials in Japan. However, since these new regulatory pathways are relatively new, we may 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 Israel Innovation Authority, or IIA, we are subject to on-going restrictions.

We have received royalty-bearing grants from the IIA, for research and development programs that meet specified criteria. The terms of the IIA'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 IIA and to undertake to observe the law governing the grant programs of the IIA, 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”.

20

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, which was terminated in December 2015, 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 a 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.

If we fail to obtain or maintain orphan drug exclusivity for our products, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Our business strategy focuses on the development of drugs that are eligible for FDA and European Union orphan drug designation. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union Community. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even with orphan drug exclusivity, if a third party were to prepare or market a product which infringes upon our intellectual property, we may need to initiate litigation, which may be costly, to enforce our rights against such party. After an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation on its own neither shortens the development time or regulatory review time for a drug.

While orphan drug products are typically sold at a high price relative to other medications, the market may not be receptive to high pricing of our products.

We develop our product candidates to treat rare and ultra-rare diseases, a space where medications are usually sold at high prices compared with other medications. Accordingly, even if regulatory authorities approve our product candidates, the market may not be receptive to, and it may be difficult for us to achieve, a per-patient per-year price high enough to allow us to realize a return on our investment.

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.

If we do not complete the development of our technology and products in development by the time our patents expire, create additional sufficient layers of patents or other intellectual property rights, 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.

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.

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 New Israeli Shekel, or NIS, and the Euro, 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 2016, 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, 2016. 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, 2016, we held 400,368 CHA shares valued at \$5.4 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, 2016, 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 2016 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 2016. 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 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.

We may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business.

We are subject to the Foreign Corrupt Practice Act, or FCPA, and other laws that prohibit U.S. companies or their agents and employees from providing anything of value to a foreign official or political party for the purposes of influencing any act or decision of these individuals in their official capacity to help obtain or retain business, direct business to any person or corporate entity or obtain any unfair advantage. We have operations and agreements with third parties. Our international activities create the risk of unauthorized and illegal payments or offers of payments by our employees or consultants, even though they may not always be subject to our control. We discourage these practices by our employees and consultants. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees or consultants, may engage in conduct for which we might be held responsible for. Any failure by us to adopt appropriate compliance procedures and ensure that our employees and consultants comply with the FCPA and applicable laws and regulations in foreign jurisdictions could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions.

Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the U.S. government may seek to hold our Company liable for successor liability FCPA violations committed by companies in which we invest or that we acquire.

Failure in our information technology systems, including by cybersecurity attacks or other data security incidents, could significantly disrupt our operations.

Our operations depend, in part, on the continued performance of our information technology systems. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Failure of our information technology systems could adversely affect our business, profitability and financial condition. Although we have information technology security systems, a successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is possible that a cybersecurity attack might not be noticed for some period of time. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our shareholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third-parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

Item 1B. Unresolved Staff Comments.

Not Applicable.

Item 2. Properties.

Our principal executive, manufacturing and research and development offices are located at MATAM Advanced Technology Park, Building No. 5, Haifa, Israel 31905, where we occupy approximately 4,389 square meters. Our monthly rent payment for these leased facilities as of July 2016 was 258,000 NIS (approximately \$67,500), exclude MTM - Scientific Industries Center Haifa, Ltd., or MTM, participation as described at Item 7. For the fiscal year ended June 30, 2016, we paid \$728,000, net, for rent for such facilities, which was offset by MATAM participation of \$188,000. 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 2016 was 77,000 NIS (approximately \$20,200). For the fiscal year ended June 30, 2016, we paid \$240,000 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, 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
Fiscal Year Ended June 30, 2016		
September 30, 2015	\$2.54	\$1.80
December 31, 2015	\$1.86	\$0.98
March 31, 2016	\$1.72	\$0.71
June 30, 2016	\$1.85	\$1.20

On August 31, 2016, the per share closing price of our common stock, as reported on NASDAQ website, was \$1.65. As of September 1, 2016, there were 108 holders of record, and 80,723,647 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.

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, 2011 through June 30, 2016. 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 April 2016, we issued 6,667 shares of common stock to 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, 2016, are derived from, and should be read in conjunction with, our audited consolidated financial statements.

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

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):

	2016	2015	2014	2013	2012
Statements of Operations Data:					
Revenues	\$2,847	\$379	\$379	\$679	\$716
Cost of revenues	100	13	11	20	21
Gross profit	2,747	366	368	659	695
Research and development expenses	22,856	23,416	24,938	19,906	12,685
Participation by the IIA and other parties	3,276	4,243	5,396	2,673	3,527
Research and development expenses, net	19,580	19,173	19,542	17,233	9,158
General and administrative expenses	6,486	6,460	8,676	5,649	6,568
Operating loss	23,319	25,267	27,850	22,223	15,031
Financial income (expenses), net	73	590	918	1,068	237
Net loss for the period	\$23,246	\$24,677	\$26,932	\$21,155	\$14,794
Basic and diluted net loss per share	\$0.29	\$0.35	\$0.42	\$0.38	\$0.34
Weighted average number of shares used in computing basic and diluted net loss per share					
	79,547,989	70,284,337	63,514,405	55,481,357	44,031,866
Statements of Cash Flows Data:					
Net cash used in operating activities	\$18,522	\$20,605	\$19,121	\$16,887	\$3,275
Net cash provided by (used in) investing activities	1,312	21,537	1,983	(19,799)	(30,797)
Net cash provided by financing activities	807	17,201	12,624	36,304	632
Net increase (decrease) in cash	(16,403)	18,133	(4,514)	(382)	(33,440)
Cash and cash equivalents at beginning of year	22,626	4,493	9,007	9,389	42,829
Cash and cash equivalents at end of year	\$6,223	\$22,626	\$4,493	\$9,007	\$9,389
Balance Sheet Data:					
Cash, cash equivalents, short-term bank deposits, restricted cash and short-term deposits, and marketable securities	\$32,750	\$53,119	\$58,819	\$54,213	\$37,809
Current assets	35,596	56,868	61,987	55,085	38,192
Long-term assets	10,941	11,287	12,036	13,231	9,228
Total assets	45,835	68,155	74,023	68,316	47,420
Current liabilities	5,775	6,183	7,397	5,921	5,522
Long-term liabilities	2,010	3,829	4,503	4,929	4,156
Stockholders' equity	38,156	58,143	62,123	57,466	37,742

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

We are a leading developer of placenta-based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. Our lead indications are critical limb ischemia, recovery after surgery for femoral neck fracture, and acute radiation syndrome. Pivotal, multinational clinical trials are planned for our PLX-PAD product in critical limb ischemia and femoral neck fracture, and the NIH's NIAID is currently conducting a dose selection trial with PLX-R18 in the hematologic component of acute radiation syndrome. Each of these indications is a severe unmet medical need. Together, these treatments could address a multibillion dollar global

market.

PLX cells are derived from a class of placental cells that are harvested from donated placentas at the time of full term delivery of a live baby. PLX cell products require no tissue matching prior to administration. They are produced using our proprietary three-dimensional expansion technology. Our manufacturing facility complies with current Good Manufacturing Practice requirements and has been approved by the FDA and the European, Japanese and Israeli regulatory authorities for production of PLX-PAD for late stage trials and marketing. We expect to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

31

We were incorporated in Nevada in 2001, and 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 goal is to make significant progress with our robust clinical pipeline and our anticipated pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We intend to shorten the time to commercialization of our first product, PLX-PAD, by leveraging the unique accelerated regulatory pathways that exist in Europe and Japan to bring innovative products to the market efficiently, in order to address life-threatening diseases. We believe that these accelerated pathways create substantial opportunities for us and for the cell therapy industry as a whole. We are pursuing these accelerated pathways for PLX-PAD in critical limb ischemia and femoral neck fracture. Our second product, PLX R18, is under development in the United States for ARS via the animal rule regulatory pathway, which requires no human efficacy trials for approval. We expect to demonstrate the real-world impact and value of our pipeline, technology platform, and commercial-scale manufacturing capacity.

In May 2015, we announced that the PLX-PAD cell program in CLI had been selected for the Adaptive Pathways pilot project of the EMA. In addition, we reached an agreement with Japan's PMDA on the design of the final trial needed to apply for conditional approval of PLX-PAD cells in the treatment of CLI. The approval of the protocol for the 75-patient trial was part of a larger agreement on the development of PLX-PAD via Japan's new accelerated regulatory pathway for regenerative medicine. In August 2016, we received a positive FDA response to our pivotal Phase III protocol for PLX-PAD in CLI. Our intention is to initiate these CLI studies in early 2017, and obtain initial approval in the coming two to three years.

In July 2016, we announced our intent to conduct a Phase III trial assessing our PLX-PAD cells in recovery following surgery for femoral neck fracture in the United States and Europe. In addition, the EMA confirmed that this indication would also be eligible for the Adaptive Pathways project.

In February 2016, we announced that the NIAID, a part of the NIH, will initiate studies in large animals to select the appropriate doses for PLX-R18 as a medical counter measure in the treatment of the hematologic component of ARS. These studies have been initiated. Once the optimal dose is determined in large animals, a pivotal trial could be conducted, the results of which may be used to support a Biologics License Application for PLX-R18 for this indication under the Animal Rule regulatory pathway. The NIAID supports and collaborates on the dosing studies, and Pluristem supplies the PLX-R18 cells. In December 2015, we also signed a Memorandum of Understanding for a collaboration with Fukushima Medical University, Fukushima Global Medical Science Center. The purpose of the collaboration is to develop our PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients.

We made progress in our Phase II intermittent claudication (IC) trial, a randomized, double blind, placebo controlled, multinational clinical study. We have enrolled 160 patients to date and have expanded the clinical trial to include a total of 170 patients, with enrollment completion expected in 2016. We currently have active clinical sites in the United States, Israel, Germany, and South Korea.

The FDA cleared our IND application to begin a Phase I trial of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT. We plan to initiate the clinical trial in the United States in calendar 2016.

In December 2015, the FDA granted our PLX-PAD cells Orphan Drug Designation in the treatment of severe preeclampsia. We are currently conducting additional pre-clinical studies in order to advance towards a Phase I trial.

On December 8, 2015, we received a notice from United Therapeutics Corporation, or United, terminating our exclusive license agreement. Pursuant to the United Agreement termination clause, we regained full rights to PLX in the field of PAH as well as all clinical data and regulatory submissions. We may continue the development of this indication subject to interest of potential licensing partners in the U.S. and Japan.

RESULTS OF OPERATIONS – YEAR ENDED JUNE 30, 2016 COMPARED TO YEAR ENDED JUNE 30, 2015 AND YEAR ENDED JUNE 30, 2015 COMPARED TO YEAR ENDED JUNE 30, 2014.

Revenues

Revenues for each of the years ended June 30, 2016 and June 30, 2015 were \$2,847,000 and \$379,000, respectively. All such revenues were derived from the United Agreement.

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.

On December 8, 2015, we received a notice from United terminating the United Agreement, effective immediately. As we have no further obligations towards United, we recognized the remaining upfront payment received in August 2011 as revenues during the year ended June 30, 2016.

Cost of revenues

Cost of revenues increased from \$13,000 for the year ended June 30, 2015 to \$100,000 for the year ended June 30, 2016. This increase is related to the royalties we are obligated to pay to the IIA, which reflects 3.5% of the revenues derived from the United Agreement in fiscal 2016 and fiscal 2015.

Cost of revenues increased by 18% 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 IIA, 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.

Research and Development net

Research and development net costs (costs less participation and grants by the IIA and other parties) for the year ended June 30, 2016 increased by 2% to \$19,580,000 from \$19,173,000 for the year ended June 30, 2015.

This increase is attributed to a lower participation of the IIA in fiscal 2016 compared to fiscal 2015 (\$4,200,000 was approved in calendar year 2014 compared to \$2,900,000 that was approved in calendar year 2015 and \$3,300,000 that was approved in calendar year 2016). The reduced IIA participation was offset by a decrease in stock-based compensation expenses due to the decrease in the market value of our common stock on the day of the grant.

Research and development net costs (costs less participation and grants by the IIA and other parties) for the year ended June 30, 2015 decreased by 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 IIA participation. The decrease in the IIA participation is attributable to a delay in the approval of the IIA grant for 2013 with resulted a higher participation in 2014 and a lower grant approved by the IIA 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.

General and Administrative

General and administrative expenses increased by 0.4% from \$6,460,000 for the year ended June 30, 2015 to \$6,486,000 for the year ended June 30, 2016. This increase is related to corporate activities, offset by a decrease in stock-based compensation expenses related to our directors and officers and attributable to the timing of the grants under the option plan and the market value of our common stock on the day of the grant.

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.

Financial Income, net

Financial income decreased from \$590,000 for the year ended June 30, 2015 to \$73,000 for the year ended June 30, 2016. This decrease is mainly attributable to lower income related to our marketable securities (such as net gains related to sales of the marketable securities, interest and dividend income and accretion of discount, amortization of premium), and a decrease in income related to derivatives, offset by a decrease in exchange rates expenses, related to the strength of the U.S. dollar against the NIS in the year ended June 30, 2016 compared to year ended June 30, 2015.

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.

Net Loss

Net loss for the year ended June 30, 2016 was \$23,246,000 as compared to a net loss of \$24,677,000 for the year ended June 30, 2015. Net loss per share for the year ended June 30, 2016 was \$0.29, as compared to \$0.35 for the year ended June 30, 2015. 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 2016.

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.

Liquidity and Capital Resources

As of June 30, 2016, our total current assets were \$35,596,000 and our total current liabilities were \$5,775,000. On June 30, 2016, we had a working capital surplus of \$29,821,000 and an accumulated deficit of \$161,757,000.

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.

Our cash and cash equivalents as of June 30, 2016 amounted to \$6,223,000. This is a decrease of \$16,403,000 from the \$22,626,000 reported as of June 30, 2015. Cash balances decreased in the year ended June 30, 2016 for the reasons presented below:

Operating activities used cash of \$18,522,000 in the year ended June 30, 2016. Cash used by operating activities in the year ended June 30, 2016 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 IIA grant. During the year ended June 30, 2016, operating activities were also offset by the participation of MTM in the cost of constructing additional office space. In October 2015, MTM, participated in the cost of constructing additional office space for us by contributing an amount of NIS 3,683,000 (approximately \$944,000) toward the cost of construction. Such participation was made pursuant to our lease agreement with MTM, and is recognized by rateably deducting from our monthly rent payment over the rent period. We recognized participation of \$188,000 in Fiscal 2016.

Investing activities provided cash of \$1,312,000 in the year ended June 30, 2016. The investing activities consisted primarily of proceeds of \$8,093,000 from the sale and redemption of marketable securities, offset by investing \$4,215,000 in marketable securities and the purchase of property and equipment for \$1,750,000.

Financing activities generated cash in the amount of \$807,000 during the year ended June 30, 2016. The financing activities are primarily attributable to proceeds received from shares issued in a private placement in May 2015 as described below and exercises of warrants and options by shareholders.

From October 2014 through May 2015, we issued shares of common stock in private placements to an investor. In October 2014, we issued 200,000 shares of common stock to an investor for aggregate cash consideration of \$528,000. In February 2015, we issued an additional 200,000 shares of common stock to an investor for aggregate cash consideration of \$586,000. In May 2015, we issued an additional 300,000 shares of common stock to an investor for consideration in the amount of \$790,000, which was received from the investor during September 2015.

In February 2015, we entered into an agreement with a contractor for the construction of our new laboratories facility for consideration of approximately NIS 3.3 million (approximately \$841,000). Under the terms of the agreement, we paid part of the NIS 3.3 million consideration using 100,004 restricted shares of common stock of the Company, linked to performance milestones with respect to the new laboratories construction and which serve as a guarantee. These restricted shares were issued in December 2014 and were released to the contractor upon the successful completion of the construction.

In May 2015, we entered into an addendum to the agreement with the contractor for the design and construction of additional office space renovations in our leased facility for additional consideration of approximately NIS 4 million (approximately \$1,032,000), which is comprised of NIS 3 million (approximately \$774,000) in cash and 90,000 restricted shares, which were issued to the contractor in February 2016, upon the successful completion of the construction by the contractor.

The construction work was initiated in June 2015. On October 30, 2015, the contractor completed the agreed construction milestones. We have issued a total of 190,004 restricted shares of common stock to the contractor. As a result, we recognized the fair value of the share-based payments awards, using the fair value of the Company's shares on October 30, 2015, totaling approximately \$302,000 as share-based payment to the contractor in "additional paid-in capital" with a corresponding amount included in "property and equipment, net".

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 IIA 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.

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.

During the years that ended June 30, 2016, 2015 and 2014 we received approximately \$2,526,000, \$4,405,000 and \$3,243,000, respectively, from the IIA towards our research and development expenses.

According to the IIA 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 IIA 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, 2016, we paid royalties to the IIA in the aggregate amount of \$106,240 in cash. The IIA may impose certain conditions on any arrangement under which the IIA 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 February 2013, MTM, our landlord, participated by contributing an amount of NIS 2,990,000 (approximately \$816,000) toward the cost of constructing our new facility.

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 was presented as "Financial income, net" in fiscal 2015.

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, 2016 is \$5,369,000, and other comprehensive income includes unrealized gains of \$243,000 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 options contracts in order to hedge our exposures to NIS.

Outlook

We have accumulated a deficit of \$161,757,000 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. 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 IIA grants and other research grants, sales of our common stock or sales of the marketable securities we hold.

The IIA has supported our activity in the past eleven years. Our last program, for the eleventh year, was approved by the IIA in May 2016 and relates to an approximately \$3,300,000 grant. The grant will be used to cover research and development expenses for the period January 1, 2016 to December 31, 2016.

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.

In August 2016, our CLI program in the European Union was awarded a Euro 7,600,000 (approximately \$8,400,000) grant. The grant is part of the European Union's Horizon 2020 program. The Phase III study of PLX-PAD in CLI will be a collaborative project carried out by an international consortium led by the Berlin-Brandenburg Center for Regenerative Therapies together with the Company and with participation of additional third parties. The grant will cover a significant portion of the CLI program costs. An amount of Euro 1,900,000 (approximately \$2,100,000) is a direct grant allocated to us, and the Company also expects to benefit from cost savings resulting from grant amounts allocated to the other consortium members.

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 were subject to the achievement of certain regulatory milestones by United.

Since the deliverables in the United Agreement did not have stand-alone value, none of them qualify as a separate unit of accounting. Accordingly, the non-refundable upfront license fee of \$5,000,000 was deferred and was recognized on a straight line basis over the related performance period which was the development period in accordance with Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition".

We also received an advance payment for the development of \$2,000,000 that was deductible against development expenses as it accrued.

On December 8, 2015, we received a notice from United terminating the United Agreement, effective immediately. Pursuant to the United Agreement termination clause, we regained full rights to PLX in the field of PAH, as well as all clinical data and regulatory submissions. As we have no further obligations towards United, we recognized the remaining upfront payment received in August 2011 as revenues during the year ended June 30, 2016.

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 2016, we recorded stock-based compensation expenses related to restricted stock and restricted stock units in the amount of \$3,049,000.

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 2016 and 2015 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.

38

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.

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 recognized an impairment charge of \$38,000 on outstanding securities during the year ended June 30, 2016.

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 2014 through 2016 (in thousands of dollars):

	Year ended June 30,		
	2014	2015	2016
Clinical trials expenses	\$2,440	\$2,540	\$3,048
Consultants and subcontractor expenses	2,108	2,863	1,734
Payroll and related expenses	7,846	7,785	7,945
Materials expenses	5,624	3,835	3,799
Stock based compensation expenses	1,260	1,601	1,021
Depreciation expenses	1,785	1,942	2,006
Rent and maintenance expenses	1,808	1,610	1,515
Patent expenses	572	650	640
Other R&D expenses	1,495	3,130	1,149
Total expenses	24,938	23,416	22,856
Less: IIA and others participation	(5,396)	(4,243)	(3,276)
Research and Development Expenses, Net	\$19,542	\$19,173	\$19,580

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 2014, 2015 and 2016. 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, 2016, and the effect such obligations could have on our liquidity and cash flow in future periods:

Contractual Obligations	Total	Payments due by period			More than 5 years
		Less than 1 year	1-3 years	3-5 years	
Operating lease obligations	\$6,064,000	\$1,202,000	\$3,270,000	\$1,592,000	
Minimum purchase requirements	\$151,000	\$151,000			
Accrued Severance Pay, net	\$144,000				\$144,000
Total	\$6,359,000	\$1,353,000	\$3,270,000	\$1,592,000	\$144,000

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, 2016, we had \$6.2 million in cash and cash equivalents, \$9.1 million in short-term bank deposits and restricted deposits and \$17.4 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. During the fiscal year ended June 30, 2016 we also used forward contracts in order to hedge our exposures to 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, 2016, we own net balances in NIS of approximately \$2,244,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate gain of approximately \$250,000, while assuming a 10% devaluation of the NIS against the U.S. dollars, we would experience an exchange rate loss of approximately \$204,000, 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,		
	2014	2015	2016
Average rate for period	3.518	3.788	3.862
Rate at period-end	3.438	3.769	3.846

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

As of June 30, 2016, 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, 2016, our net loss 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 was \$205,000.

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 7, 2016.

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.

41

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2016

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2016

U.S. DOLLARS IN THOUSANDS

INDEX

	Page
<u>Reports of Independent Registered Public Accounting Firm</u>	F-2 - F-3
<u>Consolidated Balance Sheets</u>	F-4 - F-5
<u>Consolidated Statements of Operations</u>	F-6
<u>Consolidated Statements of Comprehensive Loss</u>	F-7
<u>Statements of Changes in Shareholders' Equity</u>	F-8 - F-10
<u>Consolidated Statements of Cash Flows</u>	F-11 - F-12
<u>Notes to Consolidated Financial Statements</u>	F-13 - F-36

Kost Forer Gabbay & Kasierer
2 Pal-Yam Ave.
Haifa 330905, Israel

Tel: 972 (4)8654021
Fax: 972(3) 5633439
www.ey.com

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, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended June 30, 2016. 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, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2016, 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, 2016, 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 7, 2016, expressed an unqualified opinion thereon.

Haifa, Israel /s/ Kost Forer Gabbay & Kasierer
September 7, 2016 A Member of Ernst & Young Global

Kost Forer Gabbay & Kasierer
2 Pal-Yam Ave.
Haifa 330905, Israel

Tel: 972 (4)8654021
Fax: 972(3) 5633439
www.ey.com

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, 2016, 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, 2016, based on the COSO criteria.

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

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, 2016 and 2015 and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended June 30, 2016 of Pluristem Therapeutics Inc. and its subsidiary and our report dated September 7, 2016, expressed an unqualified opinion thereon.

Haifa, Israel /s/ Kost Forer Gabbay & Kasierer
September 7, 2016 A Member of Ernst & Young Global

F - 3

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

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

	Note	June 30, 2016	2015
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$6,223	\$22,626
Short-term bank deposits		8,570	7,167
Restricted cash and short term-bank deposits	2f	542	1,076
Marketable securities	3	17,415	22,250
Accounts receivable from the Israel Innovation Authority		2,228	1,691
Other current assets	5	618	2,058
<u>Total</u> current assets		35,596	56,868
LONG-TERM ASSETS:			
Long-term deposits and restricted bank deposits	2g	363	360
Severance pay fund		766	753
Property and equipment, net	6	9,216	10,173
Other long-term assets		-	1
<u>Total</u> long-term assets		10,345	11,287
<u>Total</u> assets		\$45,941	\$68,155

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, 2016	2015
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		\$2,705	\$3,268
Accrued expenses		1,369	910
Deferred revenues	1c, 2i	-	379
Advance payment from United	1c, 2i	-	93
Other accounts payable	7	1,701	1,533
<u>Total</u> current liabilities		5,775	6,183
LONG-TERM LIABILITIES			
Deferred revenues	1c, 2i	-	2,468
Accrued severance pay		910	859
Other long-term liabilities		1,100	502
<u>Total</u> long-term liabilities		2,010	3,829
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: 80,268,999 shares as of June 30, 2016: 78,771,905 shares			
as of June 30, 2015;		1	1
Additional paid-in capital		198,432	195,303
Accumulated deficit		(161,757)	(138,511)
Receivables on account of shares		-	(790)
Other comprehensive income		1,480	2,140
		38,156	58,143
		\$45,941	\$68,155

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

F - 5

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,		
		2016	2015	2014
Revenues	1c, 2i	\$2,847	\$379	\$379
Cost of revenues		(100)	(13)	(11)
Gross profit		2,747	366	368
Research and development expenses		(22,856)	(23,416)	(24,938)
Less participation by the Israel Innovation Authority and other parties		3,276	4,243	5,396
Research and development expenses, net		(19,580)	(19,173)	(19,542)
General and administrative expenses		(6,486)	(6,460)	(8,676)
Operating loss		(23,319)	(25,267)	(27,850)
Financial income, net	10	73	590	918
Net loss		\$(23,246)	\$(24,677)	\$(26,932)
Loss per share:				
Basic and diluted net loss per share		\$(0.29)	\$(0.35)	\$(0.42)
Weighted average number of shares used in computing basic and diluted net loss per share		79,547,989	70,284,337	63,514,405

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

F - 6

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. Dollars in thousands

	Year ended June 30,		
	2016	2015	2014
Net loss	\$(23,246)	\$(24,677)	\$(26,932)
Other comprehensive income (loss), net:			
Unrealized gain (loss) on derivative instruments	-	285	(25)
Unrealized gain (loss) on available-for-sale marketable securities, net	(1,071)	(1,132)	3,404
Reclassification adjustment of derivative instruments gains (losses) realized in net loss, net	(46)	(262)	48
Reclassification adjustment of available-for-sale marketable securities gains (losses) realized in net loss, net	457	290	(727)
Other comprehensive income (loss)	(660)	(819)	2,700
Total comprehensive loss	\$(23,906)	\$(25,496)	\$(24,232)

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

F - 7

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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 9d)	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 1c)	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.

F - 8

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN SHAREHOLDERS' 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
	Shares	Amount	Capital	of shares	(Loss)	Deficit	Stockholders' 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 9f)	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 9e)	700,000	(*)	1,904	(790)	-	-	1,114
Stock based compensation to contractor (Note 9g)	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.

F - 9

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in	Receivables on account of shares	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Capital				
Balance as of July 1, 2015	78,771,905	\$ 1	\$ 195,303	\$ (790)	\$ 2,140	\$(138,511)	\$ 58,143
Exercise of options by employees and non-employee consultants	28,000	(*)	17	-	-	-	17
Stock-based compensation to employees, directors and non-employee consultants	1,379,094	(*)	3,073	-	-	-	3,073
Proceeds related to issuance of common stock in a private placement (Note 9e)	-	-	-	790	-	-	790
Stock-based compensation to contractor (Note 9g)	90,000	(*)	39	-	-	-	39
Other comprehensive loss, net	-	-	-	-	(660)	-	(660)
Net loss	-	-	-	-	-	(23,246)	(23,246)
Balance as of June 30, 2016	80,268,999	\$ 1	\$ 198,432	\$ -	\$ 1,480	\$(161,757)	\$ 38,156

(*) Less than \$1

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

F - 10

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. Dollars in thousands

	Year ended June 30,		
	2016	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(23,246)	\$(24,677)	\$(26,932)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,150	2,074	1,902
Loss on property and equipment	82	20	85
Accretion of discount, amortization of premium and changes in accrued interest of marketable securities	(114)	213	1,282
Loss (gain) from sale of investments of available-for-sale marketable securities	419	290	(727)
Other-than-temporary loss of available-for-sale marketable securities	38	-	-
Stock-based compensation to employees, directors and non-employees consultants	3,073	4,052	5,851
Decrease (increase) in Accounts receivable from the Israel Innovation Authority	(537)	572	(1,990)
Decrease (increase) in other current assets and other long-term assets	1,395	(1,129)	(251)
Increase (decrease) in trade payables	(77)	(566)	1,257
Increase (decrease) in other accounts payable, accrued expenses and other long-term liabilities	1,225	(949)	902
Decrease in deferred revenues	(2,847)	(379)	(379)
Decrease in advance payment from United	(93)	(154)	(146)
Decrease (increase) in interest receivable on short-term deposits	(25)	35	(36)
Linkage differences and interest on short and long-term deposits and restricted bank deposits	(3)	54	12
Accrued severance pay, net	38	(61)	49
Net cash used in operating activities	\$(18,522)	\$(20,605)	\$(19,121)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	\$(1,750)	\$(831)	\$(1,573)
Proceeds from sale of property and equipment	28	19	-
Repayment of (investment in) short-term deposits	(849)	16,061	7,421
Repayment of (investment in) long-term deposits and restricted bank deposits	5	(78)	119
Proceeds from sale of available-for-sale marketable securities	6,999	10,635	6,113
Proceeds from redemption of available-for-sale marketable securities	1,094	634	754
Investment in available-for-sale marketable securities	(4,215)	(4,903)	(10,851)
Net cash provided by (used in) investing activities	\$1,312	\$21,537	\$1,983

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,		
	2016	2015	2014
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds related to issuance of common stock and warrants, net of issuance costs	\$790	\$16,914	\$10,644
Exercise of warrants and options	17	287	1,980
Net cash provided by financing activities	\$807	\$17,201	\$12,624
Increase (decrease) in cash and cash equivalents	(16,403)	18,133	(4,514)
Cash and cash equivalents at the beginning of the period	22,626	4,493	9,007
Cash and cash equivalents at the end of the period	\$6,223	\$22,626	\$4,493
(a) Supplemental disclosure of cash flow activities:			
Cash paid during the period for:			
Taxes paid due to non-deductible expenses	\$66	\$54	\$48
(b) Supplemental disclosure of non-cash activities:			
Purchase of property and equipment in credit	\$126	\$612	\$243
Share consideration to constructor	\$39	\$263	\$-
Issuance of common stock under CHA Agreement (Note 1c)	\$-	\$-	\$10,414
Receivables on account of shares	\$-	\$790	\$-

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

F - 12

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 1:-GENERAL

Pluristem Therapeutics Inc., a Nevada corporation, was incorporated on May 11, 2001. Pluristem Therapeutics Inc. a. has a wholly owned subsidiary, Pluristem Ltd. (the “Subsidiary”), which is incorporated under the laws of the State of Israel. Pluristem Therapeutics Inc. and the Subsidiary are referred to as the “Company” or “Pluristem”.

The Company’s shares of common stock are traded on the NASDAQ Capital Market under the symbol “PSTI”, and on the Tel-Aviv Stock Exchange under the symbol “PLTR”.

The Company is a bio-therapeutics company developing placenta-based cell therapy product candidates for the treatment of multiple ischemic and inflammatory conditions. The Company has sustained operating losses and b. expects such losses to continue in the foreseeable future. The Company's accumulated losses aggregated to \$161,757 through June 30, 2016 and incurred a net loss of \$23,246 for the year ended June 30, 2016.

As of June 30, 2016, the Company's cash position (cash and cash equivalents, short-term bank deposits and marketable securities) totaled approximately \$32,208. The Company plans to continue to finance its operations with sales of equity securities, entering into licensing technology agreements (see Note 1c) and from grants to support its research and development activity. Management believes that these funds, together with its existing operating plan, are sufficient for the Company to meet its obligation as they come due at least for a period of twelve months from the date of the consolidated financial statement. In the longer term, the Company plans to finance its operations from revenues from sales of products.

c. License Agreements:

United Therapeutics Corporation ("United") Agreement

On June 19, 2011, the Company entered into an exclusive license agreement (the “United Agreement”) with United for the use of the Company's PLX cells to develop and commercialize a cell-based product for the treatment of Pulmonary Hypertension (“PAH”). The United Agreement provided that United would receive exclusive worldwide license rights for the development and commercialization of the Company's PLX cell-based product to treat PAH.

Under the United Agreement the Company received an upfront payment of \$7,000 paid in August 2011, which included a \$5,000 non-refundable upfront payment and a \$2,000 advance payment on development.

On December 8, 2015, the Company received a notice from United terminating the United Agreement, effective immediately. Pursuant to the United Agreement termination clause, Pluristem regained full rights to PLX in the field of PAH, as well as all clinical data and regulatory submissions. As the Company has no further obligations towards United, the Company recognized the remaining upfront payment received in August 2011 as revenues during the year ended June 30, 2016.

CHA Biotech Co. Ltd. (“CHA”) Agreement

On June 26, 2013, Pluristem entered into an exclusive license and commercialization agreement (the “CHA Agreement”) with CHA, for conducting clinical trials and commercialization of Pluristem's PLX-PAD product in South Korea in connection with two indications: the treatment of Critical Limb Ischemia and Intermediate Claudication (the

“Indications”). Under the terms of the CHA Agreement, CHA will receive exclusive rights in South Korea for conducting clinical trials with respect to the Indications, and the Company will continue to retain rights to its proprietary manufacturing technology and cell-related intellectual property.

The first clinical study as part of the CHA Agreement is a Phase II trial in Intermittent Claudication. South Korea’s Ministry of Food and Drug Safety approved this study in November 2013.

F - 13

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 1:-GENERAL (CONT.)

Upon the first regulatory approval for a PLX product in South Korea, for the specified indications, Pluristem 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.

Pluristem will be able to use the data generated by CHA to pursue the development of PLX product candidates outside of South Korea.

The CHA Agreement contains customary termination provisions, including in the event the parties do not reach an agreement upon development plan for conducting the clinical trials. Upon termination of this CHA Agreement, the license granted thereunder will terminate and all rights included therein will revert to the Company, whereupon the Company 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 at its sole discretion.

In addition, and as contemplated by the CHA Agreement, in December 2013, Pluristem and CHA executed the mutual investment pursuant to which Pluristem issued 2,500,000 shares of its common stock in consideration for 1,011,504 shares of CHA, which reflects total consideration to each of Pluristem and CHA of approximately \$10,414. The parties also agreed to give an irrevocable proxy to the other party's management with respect to the voting power of the shares issued.

During March 2015, the Company sold a portion of the CHA shares received in December 2013.

The remaining investment in CHA shares is presented as "Marketable Securities" and classified as available-for-sale in accordance with Accounting Standards Codification (the "ASC") 320, "Investments - Debt and Equity Securities". The fair value of the remaining investment as of June 30, 2016, is \$5,369.

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") applied on consistent basis.

a. Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates, judgments, and assumptions that are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

b. Functional currency of the Subsidiary

The Subsidiary's revenues are generated and determined in U.S. Dollars ("dollars"). In addition, most of the financing of the Subsidiary's operations has been made in dollars. The Company's management believes that the Dollar is the primary currency of the economic environment in which the Subsidiary operates. Thus, management believes that the functional currency of the Subsidiary is the dollar. Accordingly, monetary accounts maintained in currencies other than the dollar are remeasured into dollars in accordance with ASC 830, "Foreign Currency Matters". All transaction

gains and losses from the remeasurement of monetary balance sheet items are reflected in the statement of operations as financial income or expenses, as appropriate.

c. Principles of consolidation

The consolidated financial statements include the accounts of Pluristem Therapeutics Inc. and its Subsidiary. Intercompany transactions and balances have been eliminated upon consolidation.

F - 14

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

d. Cash and cash equivalents

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with maturities of three months or less at the date acquired.

e. Short-term bank deposit

Bank deposits with original maturities of more than three months but less than one year are presented as part of short-term investments. Deposits are presented at their cost which approximates market values including accrued interest. Interest on deposits is recorded as financial income.

f. Restricted cash and short-term deposits

Short-term restricted deposits and restricted cash used to secure derivative and hedging transactions and the Company's credit line. The restricted cash and short-term deposits are presented at cost which approximates market values including accrued interest.

g. Long-term restricted deposits

Long-term restricted deposits with maturities of more than one year used to secure operating lease agreement are presented at cost which approximates market values including accrued interest.

h. Marketable Securities

The Company accounts for its investments in marketable securities in accordance with ASC 320, "Investments – Debt and Equity Securities". The Company determines the classification of marketable securities at the time of purchase and re-evaluates such designations as of each balance sheet date. The Company classifies all of its marketable securities as available-for-sale. Available-for-sale marketable securities are carried at fair value, with the unrealized gain and loss reported at "Accumulated other comprehensive income (loss)" in the statement of changes in shareholders' equity.

Realized gain and loss on sales of marketable securities are included in the Company's "Financial income, net" and are derived using the specific identification basis for determining the cost of marketable securities. The amortized cost of available for sale marketable securities is adjusted for amortization of premiums and accretion of discount to maturity. Such amortization, together with interest on available for sale marketable securities, is included in the "Financial income, net".

The Company recognizes an impairment charge when a decline in the fair value of its available-for-sale marketable securities below the cost basis is judged to be other-than-temporary. The Company considers various factors in determining whether to recognize an impairment charge, including the length of time the investment has been in a loss position, the extent to which the fair value has been less than the Company's cost basis, the investment's financial condition and the near-term prospects of the issuer. ASC 320-10-35, "Investments - Debt and Equity Securities", requires another-than-temporary impairment for debt securities to be separated into (a) the amount representing the credit loss and (b) the amount related to all other factors (provided that the Company does not intend to sell the

security and it is not more likely than not that it will be required to sell it before recovery). For securities that are deemed other-than-temporarily impaired, the amount of impairment is recognized in "financial income, net", in the statement of operations and is limited to the amount related to credit loss, while impairment related to other factors is recognized in other comprehensive income (loss).

During 2016, the Company recognized an other-than-temporary impairment loss of \$38. During 2015 and 2014, no impairment losses have been identified (see Note 3).

F - 15

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

i. Revenue Recognition from the license Agreement with United

The Company recognized 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.

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

Since the deliverables in the United Agreement did not have stand-alone value, none of them qualified as a separate unit of accounting. Accordingly, the non-refundable upfront license fee of \$5,000 was deferred and recognized on a straight line basis over the related performance period which was the development period in accordance with Staff Accounting Bulletin ("SAB") 104, "Revenue Recognition".

The Company also received an advanced payment for the development, of \$2,000 that was deductible against development expenses as it was incurred. The upfront payment which was received was included in the balance sheet as advance payment. The Company deducted the payments from its research and development expenses in accordance with ASC 730-20, "Research and Development Agreements".

On December 8, 2015, the Company received a notice from United terminating the United Agreement, effective immediately. Pursuant to the United Agreement termination clause, Pluristem regained full rights to PLX in the field of PAH, as well as all clinical data and regulatory submissions. As the Company had no further obligations towards United, the Company recognized the remaining upfront payment received in 2011 as revenues during the year ended June 30, 2016.

j. Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful lives of the assets, at the following annual rates:

	%
Laboratory equipment	10-15
Computers and peripheral equipment	33
Office furniture and equipment	15
Vehicles	15
Leasehold improvements	The shorter of the expected useful life

or the
reasonable
assumed
term of the
lease.

F - 16

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

k. Impairment of long-lived assets

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360, "Property, Plant and Equipment", whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During 2016, 2015 and 2014, no impairment losses were identified.

l. Accounting for stock-based compensation

The Company accounts for stock-based compensation in accordance with ASC 718- "Compensation-Stock Compensation" ("ASC 718") and ASC 505-50 -"Equity-Based Payments to Non-Employees" ("ASC505-50"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model. The Company accounts for employee's share-based payment awards classified as equity awards (restricted stocks or restricted stock units) using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. The Company estimates forfeitures based on historical experience and anticipated future conditions. The Company elected to recognize compensation cost for an award with service conditions and goals achievement that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

During fiscal years 2016, 2015 and 2014, there were no options granted to employees or directors.

The assumptions below are relevant to restricted stock and restricted stock units granted in 2016, 2015 and 2014:

In accordance with ASC 718, restricted stock and restricted stock units are measured at their fair value. All restricted stock and restricted stock units to employees, directors and non-employees granted in 2016, 2015 and 2014 were granted for no consideration; therefore, their fair value was equal to the share price at the date of grant.

The fair value of all restricted stock and restricted stock units was determined based on the close trading price of the Company's shares known at the grant date. The weighted average grant date fair value of shares granted during 2016, 2015 and 2014 was \$1.13, \$2.70 and \$3.53, respectively.

m. Research and Development expenses and grants

Research and development expenses, net of participations, are charged to the statement of operations as incurred.

Research and development grants from the government of Israel and other parties for funding approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the cost incurred and applied as a deduction from research and development costs.

n. Loss per share

Basic and dilutive net loss per share is computed based on the weighted average number of shares of common stock outstanding during each year. All outstanding stock options and unvested restricted stock units have been excluded from the calculation of the diluted loss per common share because all such securities are anti-dilutive for each of the periods presented.

F - 17

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Income taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"). This Topic prescribes the use of the liability method, whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value.

ASC 740 establishes a single model to address accounting for uncertain tax positions. ASC 740 clarified the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements.

p. Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term deposits, long-term deposits, restricted deposits and marketable securities.

The majority of the Company's cash and cash equivalents and short-term and long-term deposits are invested in dollar instruments of major banks in Israel and in the United States. Generally, these deposits may be redeemed upon demand and therefore bear minimal risk.

The Company invests its surplus cash in cash deposits and marketable securities in financial institutions and has established guidelines, approved by the Company's Investment Committee, relating to diversification and maturities to maintain safety and liquidity of the investments.

The Company holds an investment portfolio consisting of corporate bonds, government bonds, stocks and index linked notes. The Company intends, and has the ability, to hold such investments until recovery of temporary declines in market value or maturity. However, the Company can provide no assurance that it will recover declines in the market value of its investments.

The Company utilizes forward and options contracts to protect against the risk of overall changes in exchange rates. The derivative instruments hedge a portion of the Company's non-dollar currency exposure. Counterparties to the Company's derivative instruments are all major financial institutions.

q. Severance pay

Majority of the Company's agreements with employees in Israel, are subject to Section 14 of the Israeli Severance Pay Law, 1963 ("Severance Pay Law"). The Company's contributions for severance pay have replaced its severance obligation. Upon contribution of the full amount of the employee's monthly salary for each year of employment, no additional calculations are conducted between the parties regarding the matter of severance pay and no additional payments are made by the Company to the employee. Further, the related obligation and amounts deposited on behalf of the employee for such obligation are not stated on the balance sheet, as the Company is legally released from the obligation to employees once the deposit amounts have been paid.

For some employees, which their agreement is not subject to Section 14 of the Severance Pay Law, the Subsidiary's liability for severance pay is calculated pursuant to Israeli Severance Pay Law, based on the most recent salary of the employees multiplied by the number of years of employment, as of the balance sheet date. Employees are entitled to one month's salary for each year of employment or a portion thereof.

The Company's liability for all of its employees is fully provided by monthly deposits with insurance policies and by an accrual. The value of these policies is recorded as an asset in the Company's balance sheet. The deposited funds include profits or losses accumulated up to the balance sheet date. The deposited funds may be withdrawn only upon the fulfillment of the obligation pursuant to the Severance Pay Law or labor agreements. The value of the deposited funds is based on the cash surrendered value of these policies, and includes immaterial profits or losses.

F - 18

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Severance expenses for the years ended June 30, 2016, 2015 and 2014, were \$556, \$441 and \$534, respectively.

r. Fair value of financial instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, short-term and restricted bank deposits, trade payable and other accounts payable and accrued liabilities, approximate fair value because of their generally short term maturities.

The Company measures its investments in marketable securities and derivative instruments at fair value under ASC 820, "Fair Value Measurements and Disclosures". Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 - Unobservable inputs for the asset or liability.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company categorized each of its fair value measurements in one of these three levels of hierarchy.

s. Derivative financial instruments

The Company uses options strategies and forward contracts ("derivative instruments") primarily to manage exposure to foreign currency. The Company accounts for derivatives and hedging based on ASC 815, "Derivatives and Hedging" ("ASC 815"). ASC 815 requires the Company to recognize all derivative instruments as either assets or liabilities on the balance sheet at fair value. The accounting for changes in the fair value (i.e., gains or losses) of derivative instruments depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must designate the hedging instrument, based upon the exposure being hedged, as a fair value hedge, cash flow hedge, or a hedge of a net investment in a foreign operation.

If the derivative instruments meet the definition of a hedge and are so designated, depending on the nature of the hedge, changes in the fair value of such derivatives will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings, or recognized in other comprehensive income until the hedged item is recognized in the statement of operations. The ineffective portion of a derivative's change in fair value is recognized in the statement of operations.

Cash Flow Hedges. The Company entered into forward and option contracts to hedge against the risk of overall changes in future cash flow from payments of payroll and related expenses denominated in New Israeli Shekels ("NIS").

The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2). The gain or loss on the effective portion of a cash flow hedge is initially reported as a component of accumulated other comprehensive income and subsequently reclassified into operating expenses in the same period or periods in which the payroll and related expenses are recognized, or reclassified into "Financial income, net", if the hedged transaction becomes probable of not occurring. Any gain or loss after a hedge is no longer designated, because it is no longer probable of occurring or it is related to an ineffective portion of a cash flow hedge is recognized in the statement of operations immediately.

F - 19

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The net gain (loss) realized in statement of operations during the year ended June 30, 2016, 2015 and 2014 resulting from the cash flow hedge transactions, amounted to approximately \$7, (\$269) and \$48, respectively.

Other Derivatives. Other derivatives that are non-designated consist primarily of options strategies to minimize the risk associated with the foreign exchange effects of monetary assets and liabilities denominated in NIS. The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2). The fair value of approximately \$65 presented in "other current assets" and the net gains (losses) recognized in "Financial income, net" during the year ended June 30, 2016, 2015 and 2014 were (\$205), \$248 and (\$70), respectively.

t. Comprehensive income (loss):

The Company accounts for comprehensive income (loss) in accordance with ASC 220, "Comprehensive Income". Comprehensive income generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders'. The Company determined that its items of other comprehensive income (loss) relate to gains and losses on cash flow hedging derivative instruments and unrealized gains and losses on available for sale marketable securities.

The following table summarizes the changes in accumulated balances of other comprehensive income for the year ended June 30, 2016:

	Year ended June 30, 2016		
	Unrealized gains (losses) on marketable securities	Unrealized gains (losses) on cash flow hedges	Total
Beginning balance	\$2,094	\$ 46	\$2,140
Other comprehensive income before reclassifications	(1,071)	-	(1,071)
Amounts reclassified from accumulated other comprehensive loss	457	(46)	411
Net current-period other comprehensive income (loss)	(614)	(46)	(660)
Ending balance	\$1,480	\$ (-)	\$1,480

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES (CONT.)

u. Recent Accounting Pronouncement

ASU 2014-15 - Presentation of Financial Statements-Going Concern (Subtopic 205-40):

In August 2014, the Financial Accounting Standards Board (“the FASB”) issued Accounting Standards Update (the “ASU”) 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", which defines management’s responsibility to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

ASU 2016-02 - Leases (Topic 842):

In February 2016, the FASB issued guidance on the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a manner similar to the accounting under existing guidance for operating leases today. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840, "Leases". The guidance is effective for the interim and annual periods beginning on or after December 15, 2018 (early adoption is permitted). The Company is currently evaluating the potential effect of the guidance on its consolidated financial statements.

ASU 2014-09 - Revenue from Contracts with Customers (Topic 606):

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity’s contracts with customers. In April 2016, the FASB issued ASU 2016-10, which clarifies the implementation guidance on identifying promised goods or services and on determining whether an entity's promise to grant a license with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). The guidance is effective for the interim and annual periods beginning on or after December 15, 2017, or July 1, 2018 for the Company (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The guidance permits the use of either a retrospective or cumulative effect transition method. The Company is currently evaluating the impact of the guidance on its

consolidated financial statements.

F - 21

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES (CONT.)

ASU 2016-09 - Stock Compensation (Topic 718):

In March 2016, the FASB issued ASU 2016-9, "Stock Compensation (Topic 718) – Improvements to Employee Share-Based Payment Accounting." This guidance simplifies various aspects related to how share-based payments are accounted for and presented in the financial statements. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

NOTE 3:- MARKETABLE SECURITIES

As of June 30, 2016 and 2015, all of the Company's marketable securities were classified as available-for-sale.

	June 30, 2016					June 30, 2015				
	Amortized cost / cost	Gross unrealized gain	Gross unrealized loss	Other-than- temporary impairment	Temporary value	Amortized cost / cost	Gross unrealized gain	Gross unrealized loss	Fair value	
Available-for-sale - matures within one year:										
Stock and index linked notes	\$11,599	\$1,594	\$(208)	\$(38)	\$12,947	\$12,305	\$2,083	\$(72)	\$14,316	
Government debentures – fixed interest rate	786	12	-	-	798	287	1	(10)	278	
Corporate debentures – fixed interest rate	439	7	-	-	446	939	26	(52)	913	
	\$12,824	\$1,613	\$(208)	\$(38)	\$14,191	\$13,531	\$2,110	\$(134)	\$15,507	
Available-for-sale - matures after one year through five years:										
Government debentures – fixed interest rate	717	27	-	-	744	2,033	40	(9)	2,064	
Corporate debentures – fixed interest rate	2,403	47	-	-	2,450	4,436	97	(17)	4,516	
	\$3,120	\$74	\$-	\$-	\$3,194	\$6,469	\$137	\$(26)	\$6,580	
Available-for-sale - matures after five years through ten years:										
Corporate debentures – fixed interest rate	29	1	-	-	30	156	8	(1)	163	
	\$29	\$1	\$-	\$-	\$30	\$156	\$8	\$(1)	\$163	
Total	\$15,973	\$1,688	\$(208)	\$(38)	\$17,415	\$20,156	\$2,255	\$(161)	\$22,250	

The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of June 30, 2016 and June 30, 2015, and the length of time that those investments have been in a

continuous loss position:

	12 months or less		Greater than 12 months	
	Fair Value	Gross unrealized loss	Fair Value	Gross unrealized loss
As of June 30, 2016	\$1,258	\$ (143)	\$563	\$ (65)
As of June 30, 2015	\$2,535	\$ (107)	\$524	\$ (54)

The Company typically invests in highly-rated securities. When evaluating the investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's amortized cost basis.

F - 22

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 3:- MARKETABLE SECURITIES (CONT.)

Based on the above factors, the Company concluded that unrealized losses in the amount of \$208 on available-for-sale securities were not other-than-temporary and no credit loss was present for any of its investments. The Company recognized other-than-temporary impairment loss on outstanding securities during the year ended June 30, 2016, of \$38.

As of June 30, 2016 and 2015, interest receivable amounted to \$28 and \$105, respectively.

NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

	June 30, 2016		June 30, 2015	
	Level		Level	
	Level 1	2	Level 1	2
Marketable securities	\$ 11,228	\$ 6,187	\$ 12,650	\$ 9,600
Foreign currency derivative instruments	-	65	-	322
Total financial assets	\$ 11,228	\$ 6,252	\$ 12,650	\$ 9,922

	June 30, 2016 Balance Sheet presentation	Fair Value	June 30, 2015 Balance Sheet presentation	Fair Value
Derivatives not designated as hedge instruments	Other current assets	\$ 65	Other current assets	\$ 270
Total		\$ 65		\$ 322

NOTE 5:-OTHER CURRENT ASSETS

	June 30,	
	2016	2015
Prepaid expenses	\$300	\$919
Accounts receivable from the Ministry of Economy	23	44
Derivatives designated as cash flow hedge instruments	-	52
Derivatives not designated as hedge instruments	65	270
VAT receivables	167	152
Other receivables	63	621
Total	\$618	\$2,058

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6:-PROPERTY AND EQUIPMENT, NET

	June 30,	
	2016	2015
Cost:		
Laboratory equipment	\$6,000	\$6,096
Computers and peripheral equipment	1,024	933
Office furniture and equipment	715	617
Leasehold improvements	9,349	8,514
Vehicles	95	95
Total Cost	17,183	16,255
Accumulated depreciation:		
Laboratory equipment	3,401	2,805
Computers and peripheral equipment	802	617
Office furniture and equipment	353	262
Leasehold improvements	3,374	2,375
Vehicles	37	23
Total accumulated depreciation	7,967	6,082
Property and equipment, net	\$9,216	\$10,173

Depreciation expenses amounted to \$2,150, \$2,074 and \$1,902 for the years ended June 30, 2016, 2015 and 2014, respectively.

NOTE 7:-OTHER ACCOUNTS PAYABLE

	June 30,	
	2016	2015
Accrued payroll	\$421	\$395
Payroll institutions	309	293
Accrued vacation	720	748
Other payables	251	97
Total	\$1,701	\$1,533

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 8:-COMMITMENTS AND CONTINGENCIES

In February 2015, the Company signed an addendum to its facility operating lease agreement (the “Addendum”) with
a. the lessor, which extended the rent period to December 2021.

The lessor paid a non-refundable leasehold improvement participation payment, of approximately \$947 in October 2015, in addition to the non-refundable payment of approximately \$816 received in January 2013.

The payments are deductible against lease expenses as they are incurred. The lessor upfront payment is included in the balance sheet as advance payment and recognized as a deduction from lease expenses over the lease term. The Company recognizes rent expense, net of lessor participation, under such arrangements, on a straight-line basis over the lease term.

As of June 30, 2016, aggregate minimum lease commitments under the operating lease agreements are as follows:

Year ending June 30,	
2017	1,044
2018	1,044
2019	1,044
2020	1,052
2021 and thereafter	1,592
Total	\$5,776

Lease expenses, net of lessor participation amounted to \$824, \$704 and \$720 for the years ended June 30, 2016, 2015 and 2014, respectively. The Subsidiary issued a bank guarantee in favor of the lessors in the amount of approximately \$360.

The Subsidiary leases several motor vehicles under operating lease agreements, which expire in various dates during
b. years 2016 through June 2019.

As of June 30, 2016, future aggregate minimum lease commitments under non-cancelable operating lease agreements are as follows:

Year ending June 30,	
2017	\$ 158
2018	102
2019	28
Total	\$288

Lease expenses amounted to \$210, \$218 and \$244 for the years ended June 30, 2016, 2015 and 2014, respectively.

An amount of \$542 of cash and deposits was pledged by the Subsidiary to secure the derivatives and hedging
c. transactions, credit line and bank guarantees.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 8:-COMMITMENTS AND CONTINGENCIES (CONT.)

Under the Law for the Encouragement of Industrial Research and Development, 1984, (the “Research Law”), research and development programs that meet specified criteria and are approved by the Israel Innovation Authority (“IIA”) are eligible for grants of up to 50% of the project’s expenditures, as determined by the research committee, in exchange for the payment of royalties from the sale of products developed under the program. Regulations under the Research Law generally provide for the payment of royalties to the IIA of 3% to 4% on sales of products and services derived d. from a technology developed using these grants until 100% of the dollar-linked grant is repaid. The Company’s obligation to pay these royalties is contingent on its actual sale of such products and services. In the absence of such sales, no payment is required. Outstanding balance of the grants will be subject to interest at a rate equal to the 12 month LIBOR applicable to dollar deposits that is published on the first business day of each calendar year. Following the full repayment of the grant, there is no further liability for royalties.

Through June 30, 2016, total grants obtained aggregated to approximately \$21,183. Through June 30, 2016, total royalties paid and accrued amounted to \$166. As of June 30, 2016, the Company’s contingent liability in respect to royalties to the IIA amounted \$21,017, not including LIBOR interest as described above.

NOTE 9: - STOCKHOLDERS' EQUITY

The Company's authorized common stock consists of 200,000,000 shares with a par value of \$0.00001 per share. All shares have equal voting rights and are entitled to one vote per share in all matters to be voted upon by stockholders. The shares have no pre-emptive, subscription, conversion or redemption rights and may be issued only as fully paid and non-assessable shares. Holders of the common stock are entitled to equal ratable rights to dividends and distributions with respect to the common stock, as may be declared by the Board of Directors out of funds legally available.

The Company's authorized preferred stock consists of 10,000,000 shares of preferred stock, par value \$0.00001 per share, with series, rights, preferences, privileges and restrictions as may be designated from time to time by the Company’s Board of Directors. No shares of preferred stock have been issued.

From July 2013 through June 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 a. Company. The aggregate cash consideration received was \$1,968. From July 2013 through June 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 a consultant of the Company.

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 investors of the Company. In addition, 170,167 warrants were b. 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.

In December 2013, as part of the CHA Agreement, Pluristem and CHA executed the mutual investment pursuant to c. which Pluristem issued 2,500,000 shares of its common stock in consideration for 1,011,504 shares of CHA, which reflects total consideration to each of Pluristem and CHA of approximately \$10,414 (see Note 1c).

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)

Following a shelf registration on Form S-3 filed and declared effective in October 2011, the Company entered in d. December 2012 into an At Market Issuance Sales Agreement (“ATM Agreement”) with an underwriter, which provides that, upon the terms and subject to the conditions and limitations set forth in the ATM

Agreement, the Company may elect, from time to time, to issue and sell shares of common stock having an aggregate offering price of up to \$95,000 through the underwriter as a sales agent. The Company was not obligated to make any sales of common stock under the ATM Agreement.

During the year ended June 30, 2014, the Company issued 2,596,032 shares of common stock for aggregate consideration of approximately \$ 10,644, net of issuance costs of \$195, under the ATM Agreement.

On September 11, 2014, the Company notified the underwriter of the termination of the ATM Agreement.

From October 2014 through May 2015 the Company issued shares of common stock in private placements to an investor. In October 2014, the Company issued 200,000 shares of common stock to an investor for an aggregate cash consideration received of \$528. In February 2015, the Company issued additional 200,000 shares of common e. stock to an investor for an aggregate cash consideration received of \$586. In May 2015, the Company issued an additional 300,000 shares of common stock to an investor, for which the consideration in the amount of \$790 was received from the investor in September 2015.

On June 25, 2015, the Company 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 f. warrants (the "Offering"). The gross proceeds from the Offering were \$17,000. Issuance costs amounted to \$1,200. 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 the Offering. The Offering was closed on June 30, 2015.

In February 2015, the Subsidiary entered into an agreement with a contractor for the construction of its new laboratories facility for a consideration of approximately NIS 3.3 million (approximately \$841). Under the terms of the agreement, the Subsidiary will pay part of the NIS 3.3 million consideration using g. 100,004 restricted shares of common stock of the Company, linked to performance milestones with respect to the new laboratories construction and which serve as a guarantee. The restricted shares were issued in December 2014 and released to the contractor upon the successful completion of the construction.

In May 2015, the Subsidiary entered into an addendum to the agreement with the contractor for the design and construction of additional office space renovations in the Subsidiary leased facility for additional consideration of approximately NIS 4 million (approximately \$1,032) which is comprised of NIS 3 million (approximately \$774) in cash and 90,000 restricted shares which were issued to the contractor in February 2016.

The Company accounted for the abovementioned stock-based payment awards to the contractor in accordance with ASC 505-50, “Equity based payments to non-employees”. As performance by the contractor is not complete if the awards are forfeitable (or not issued) in the event performance not completed, the Company measured the fair value of the awards at each reporting period through the performance completion date (until completion of the construction work).

The construction work was initiated in June 2015. On October 30, 2015, the contractor completed the agreed construction milestones. As a result, the Company recognized the fair value of the stock-based payments awards, using the fair value of the Company's shares on October 30, 2015, totaling approximately \$302 as stock-based payment to the contractor in "Additional paid-in capital" with a corresponding amount included in "Property and equipment, net".

F - 27

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)

h. Options, warrants and restricted stock units to employees, directors and consultants:

The Company has approved incentive option plan from 2005 (the "2005 Plan"). Under the Plan, options, restricted stock and restricted stock units (the "Awards") may be granted to the Company's officers, directors, employees and consultants. Any Awards that are cancelled or forfeited before expiration become available for future grants.

In addition, at the Company's annual meeting of its stockholders, held on May 31, 2016, the Company's stockholders approved the 2016 Equity Compensation Plan (the "2016 Plan"). Under the 2016 Plan, options, restricted stock ("RS") and restricted stocks units ("RSUs") may be granted to the Company's officers, directors, employees and consultants or the officers, directors, employees and consultants of our subsidiary.

As of June 30, 2016, the number of shares of common stock authorized for issuance under the 2005 Plan amounted to 15,451,297. As of June 30, 2016, 474,806 shares are available for future grant under the 2005 Plan.

As of June 30, 2016, the number of shares of common stock authorized for issuance under the 2016 Plan amounted to 2,614,197 for calendar year 2016. No awards were granted under the 2016 Plan as of June 30 2016.

(1) Options to employees and directors:

The Company accounted for its options to employees and directors under the fair value method in accordance with ASC 718. A summary of the Company's share option activity for options granted to employees and directors under the 2005 plan is as follows:

	Year ended June 30, 2016			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value
Options outstanding at beginning of period	1,836,900	\$ 3.72		
Options exercised	(28,000)	\$ 0.62		
Options forfeited	(37,200)	\$ 4.40		
Options outstanding at end of the period	1,771,700	\$ 3.76	1.16	\$ 260
Options exercisable at the end of the period	1,771,700	\$ 3.76	1.16	\$ 260
Options vested	1,771,700	\$ 3.76	1.16	\$ 260

Intrinsic value of exercisable options (the difference between the Company's closing stock price on the last trading day in the period and the exercise price, multiplied by the number of in-the-money options) represents the amount that would have been received by the employees and directors option holders had all option holders exercised their options on June 30, 2016. This amount changes based on the fair market value of the Company's common stock.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)

(2) Options and warrants to non-employees:

A summary of the Company's activity related to options and warrants to consultants is as follows:

	Year ended June 30, 2016			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options and warrants outstanding at beginning of period	228,000	\$ 5.73		
Options granted	15,300	\$ 0.00		
Options and warrants exercised	(6,000)	\$ 4.40		
Options and warrants outstanding at end of the period	237,300	\$ 5.40	1.93	\$ 123
Options and warrants exercisable at the end of the period	233,438	\$ 5.49	1.82	121
Options and warrants vested and expected to vest	237,300	\$ 5.40	1.93	\$ 123

Compensation expenses related to options and warrants granted to consultants were recorded as follows:

	Year ended June 30,		
	2016	2015	2014
Research and development expenses	\$22	\$ 1	\$ 11
General and administrative expenses	2	1	
	\$24	\$ 2	\$ 11

(3) Restricted stock units to employees and directors:

The following table summarizes the activities for unvested restricted stock units granted to employees and directors for the year ended June 30, 2016:

	Number
Unvested at the beginning of period	1,732,383
Granted	1,461,431
Forfeited	(103,211)
Vested	(1,183,984)
Unvested at the end of the period	1,906,619
Expected to vest after June 30, 2016	1,837,036

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)

(3) Restricted stock units to employees and directors (cont.):

Compensation expenses related to restricted stock units granted to employees and directors were recorded as follows:

	Year ended June 30,		
	2016	2015	2014
Research and development expenses	\$1,905	\$1,469	\$1,172
General and administrative expenses	960	2,277	4,390
	\$2,865	\$3,746	\$5,562

Future expenses related to restricted stock units granted to employees and directors for an average time of approximately 1.6 years is \$1,006.

(4) Restricted stock units to consultants:

The following table summarizes the activities for unvested restricted stock units and restricted stock granted to consultants for the year ended June 30, 2016:

	Number
Unvested at the beginning of period	28,385
Granted	192,725
Vested	(195,110)
Unvested at the end of the period	26,000

Compensation expenses related to restricted stock units granted to consultants were recorded as follows:

	Year ended June 30,		
	2016	2015	2014
Research and development expenses	\$39	\$131	\$201
General and administrative expenses	145	173	77
	\$184	\$304	\$278

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)

i. Summary of warrants and options:

	Exercise Price per Share	Options and Warrants for Common Stock	Options and Warrants Exercisable	Weighted Average Remaining Contractual Terms (in years)
Warrants / Options				
Warrants:	\$ 2.85	4,080,000	4,080,000	4.00
	\$ 4.20	5,060,000	5,060,000	0.09
	\$ 5.00	3,219,983	3,219,983	1.22
Total warrants		12,359,983	12,359,983	
Options:	\$ 0.00	92,300	88,438	4.69
	\$ 0.62	361,500	361,500	2.29
	\$ 1.04	25,000	25,000	2.16
	\$ 2.97	20,000	20,000	1.86
	\$ 3.50	900,000	900,000	0.58
	\$ 3.72	15,000	15,000	0.49
	\$ 3.80	16,050	16,050	0.53
	\$ 4.00	42,500	42,500	0.30
	\$ 4.38	372,500	372,500	1.47
	\$ 4.40	400	400	1.14
	\$ 6.80	36,250	36,250	1.37
	\$ 8.20	20,000	20,000	1.16
	\$ 20.00	107,500	107,500	0.88
Total options		2,009,000	2,005,138	
Total warrants and options		14,368,983	14,365,121	

This summary does not include 1,932,619 restricted stocks and restricted stock units and that are not vested as of June 30, 2016.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 10:-FINANCIAL INCOME, NET

	Year ended June 30,		
	2016	2015	2014
Foreign currency translation differences, net	\$(174)	\$(1,109)	\$407
Bank and broker commissions	(85)	(37)	(36)
Interest income on deposits	149	112	246
Gain related to marketable securities, net	190	1,229	384
Gain (loss) from derivatives and fair value hedge derivatives	(30)	395	(83)
Other financial income	23	-	-
	\$73	\$590	\$918

NOTE 11:-TAXES ON INCOME

A. Tax laws applicable to the companies:

1. Pluristem Therapeutics Inc. is taxed under U.S. tax laws.
2. Pluristem Ltd. is taxed under Israeli tax laws.

B. Tax assessments:

The Subsidiary has not received final tax assessments since its incorporation; however, the assessments of the Subsidiary are deemed final through 2011.

C. Tax rates applicable to the Company:-

1. Pluristem Therapeutics Inc.:

The tax rates applicable to Pluristem Therapeutics Inc., a Nevada corporation, are corporate (progressive) tax at the rate of up to 35%, excluding state tax and local tax if any, which rates depend on the state and city in which Pluristem Therapeutics Inc. conducts its business.

2. The Subsidiary:

Taxable income of Israeli companies is subject to tax at the rate of 25% in year 2016, and 26.5% in 2015 and 2014.

Under the Foreign Exchange Regulations, The Subsidiary calculates its tax liability in U.S. Dollars according to certain orders. The tax liability, as calculated in U.S. Dollars is translated into New Israeli Shekels according to the exchange rate as of June 30 of each year.

Tax Benefits Under the Law for Encouragement of Capital Investments.

According to the Law for Encouragement of Capital Investments, 1959 (the "Encouragement Law"), the Subsidiary is entitled to various tax benefits due to "Beneficiary Enterprise" status granted to its enterprise, as implied by the Encouragement Law. The principal benefits by virtue of the Encouragement Law are:

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 11:-TAXES ON INCOME (CONT.)

Tax benefits and reduced tax rates:

On July 7, 2010, the Subsidiary has received a letter of approval (the "Ruling") from the Israeli Tax Authority. According to the Ruling, the Subsidiary's expansion program of its plant was granted the status of a "Beneficiary Enterprise" under the "Alternative Track" (the "2007 Program"). The Subsidiary chose the year 2007 as the election year of the 2007 Program.

Under the 2007 Program "Alternative Track", the Subsidiary, which was located in a National Priority Zone "B" with respect to the year 2007, is tax exempt in the first six years of the benefit period and subject to tax at the reduced rate of 10%-25% for a period of one to four years for the remaining benefit period (dependent on the level of foreign investments).

On June 6, 2013, the Subsidiary informed the Israeli Tax Authority that it has chosen the year 2012 as an election year to the expansion of its "Beneficiary Enterprise" program (the "2012 Program").

Under the 2012 Program, the Subsidiary, which was located in the "Other National Priority Zone" with respect to the year 2012, would be tax exempt in the first two years of the benefit period and subject to tax at the reduced rate of 10%-25% for a period of five to eight years for the remaining benefit period (dependent on the level of foreign investments).

Following the enactment of Amendment No. 60 to the Encouragement Law, subsequent to April 1, 2005, companies whose election year entitled them to a Beneficiary Enterprise status are required, among others, to make a minimum qualifying investment. This condition requires an investment in the acquisition of productive assets such as machinery and equipment, which must be carried out within three years. The minimum qualifying investment required for setting up a plant is NIS 300,000, linked to the Israeli CPI in accordance with the guidelines of the Israeli tax authorities. As for plant expansion, the minimum qualifying investment is the higher of NIS 300,000, linked to the Israeli CPI as stated above, and an amount equivalent to the "qualifying percentage" of the value of the productive assets. Productive assets that are used by the plant but not owned by it will also be viewed as productive assets.

The qualifying percentage of the value of the productive assets is as follows:

The value of productive assets before the expansion (NIS in millions)	The new proportion that the required investment bears to the value of productive assets
Up to NIS 140	12%
NIS 140 - NIS 500	7%
More than NIS 500	5%

C. Tax rates applicable to the Company: (cont. :)

The income qualifying for tax benefits under the alternative track is the taxable income of a "beneficiary company" that has met certain conditions as determined by the Encouragement Law, and which is derived from an industrial enterprise. The Encouragement Law specifies the types of qualifying income that is entitled to tax benefits under the

alternative track both in respect of an industrial enterprise and of a hotel, whereby income from an industrial enterprise includes, among others, revenues from the production and development of software products and revenues from industrial research and development activities performed for a foreign resident (and approved by the Head of the Administration of Industrial Research and Development).

F - 33

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 11:-TAXES ON INCOME (CONT.)

As stated above, the Subsidiary's 2007 Program and 2012 Program were granted the status of a "Beneficiary Enterprise", in accordance with the Encouragement Law, under the alternative benefits track. Accordingly, income derived from the Beneficiary Enterprise is subject to the benefits and conditions stated above.

In respect of expansion programs pursuant to Amendment No. 60 to the Encouragement Law, the benefit period starts at the later of the election year and the first year the Company earns taxable income provided that 12 years have not passed since the beginning of the election year and for companies in National Priority Zone

A - 14 years since the beginning of the election year. The benefit period for the Subsidiary's 2007 Program will expire in 2018 (12 years since the beginning of the election year– 2007).The benefit period for the Subsidiary's 2012 Program would expire in 2023 (12 years since the beginning of the election year – 2012).

If a dividend is distributed out of tax exempt profits, as detailed above, the Subsidiary will become liable for tax at the rate applicable to its profits from the Beneficiary Enterprise in the year in which the income was earned, (tax at the rate of 10- 25%, dependent on the level of foreign investments) and to a withholding tax rate of 15% (or lower, under an applicable tax treaty).

As for "Beneficiary Enterprises" pursuant to Amendment No. 60 to the Encouragement Law, the basic condition for receiving the benefits under this track is that the enterprise contributes to Israeli economic growth and is a competitive factor for the gross domestic product. In order to comply with this condition, the Encouragement Law prescribes various requirements regarding industrial enterprises.

As for industrial enterprises, in each tax year during the benefit period, one of the following conditions must be met:

1. The industrial enterprise's main field of activity is biotechnology or nanotechnology as approved by the Head of the Administration of Industrial Research and Development, prior to the approval of the relevant program.
2. The industrial enterprise's sales revenues in a specific market during the tax year do not exceed 75% of its total sales for that tax year. A "market" is defined as a separate country or customs territory.
3. At least 25% of the industrial enterprise's overall revenues during the tax year were generated from the enterprise's sales in a specific market with a population of at least 12 million.

Accelerated depreciation:

The Subsidiary is eligible for deduction of accelerated depreciation on buildings, machinery and equipment used by the "Beneficiary Enterprise" at a rate of 200% (or 400% for buildings) from the first year of the assets operation.

Conditions for the entitlement to the benefits:

The abovementioned benefits are conditional upon the fulfillment of the conditions stipulated by the Encouragement Law, regulations promulgated thereunder, and the Ruling with respect to the beneficiary enterprise. Non-compliance with the conditions may cancel all or part of the benefits and refund of the amount of the benefits, including interest. The management believes that the Subsidiary is meeting the aforementioned conditions.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 11:-TAXES ON INCOME (CONT.)

Amendment to the Encouragement Law:

Effective January 2011, the Knesset (Israeli parliament) enacted a reform to the Encouragement Law. According to the reform a flat rate tax would apply to companies eligible for the "Preferred Enterprise" status. In order to be eligible for a "Preferred Enterprise" status, a company must meet minimum requirements to establish that it contributes to the country's economic growth and is a competitive factor for the Gross Domestic Product (a competitive enterprise).

Israeli companies which currently benefit from an Approved or Privileged Enterprise status and meet the criteria for qualification as a "Preferred Enterprise" can elect to apply the new "Preferred Enterprise" benefits by waiving their benefits under the "Approved" and "Beneficiary Enterprise" status.

Benefits granted to a "Preferred Enterprise" include reduced tax rates. Following the enactment of the National Priorities Law, effective January 1, 2014, the reduced tax rate is 9% in the Development Area A regions and 16% in other regions. "Preferred Enterprises" in peripheral regions are also eligible for Israeli government Investment Center grants, as well as the applicable reduced tax rates.

A distribution from a "Preferred Enterprise" out of the "Preferred Income" through December 31, 2013, was subject to 15% withholding tax for Israeli-resident individuals and non-Israeli residents (subject to applicable treaty rates) and effective January 1, 2014, subject to 20% withholding tax for Israeli-resident individuals and non-Israeli residents (subject to applicable treaty rates).

A distribution from a "Preferred Enterprise" out of the "Preferred Income" would be exempt from withholding tax for an Israeli-resident company.

The Subsidiary did not apply the Amendment to the Encouragement Law with respect to the Privileged Enterprise status, but may choose to apply the Amendment in the future.

D. Carryforward losses for tax purposes

As of June 30, 2016, the Company had U.S. federal net operating loss carryforward for income tax purposes in the amount of approximately \$29, 172. Net operating loss carryforward arising in taxable years, can be carried forward and offset against taxable income for 20 years and expiring between 2023 and 2036.

Utilization of U.S. net operating losses may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

The Subsidiary in Israel has accumulated losses for tax purposes as of June 30, 2016, in the amount of approximately \$88,419, which may be carried forward and offset against taxable business income and business capital gain in the future for an indefinite period.

Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

F - 35

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 11:-TAXES ON INCOME (CONT.)

	June 30,	
	2016	2015
Deferred tax assets:		
U.S. net operating loss carryforward	\$10,210	\$9,132
Israeli net operating loss carryforward	22,105	19,880
Allowances and reserves	216	226
Total deferred tax assets before valuation allowance	32,531	29,238
Valuation allowance	(32,531)	(29,238)
Net deferred tax asset	\$-	\$-

As of June 30, 2016 and 2015, the Company has provided full valuation allowances in respect of deferred tax assets resulting from tax loss carryforward and other temporary differences, since they have a history of operating losses and current uncertainty concerning its ability to realize these deferred tax assets in the future.

The Company accounts for its income tax uncertainties in accordance with ASC 740 which clarifies the accounting for uncertainties in income taxes recognized in a Company's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

As of June 30, 2016 and 2015, there were no unrecognized tax benefits that if recognized would affect the annual effective tax rate.

Reconciliation of the theoretical tax expense (benefit) to the actual tax expense (benefit):

In 2016, 2015 and 2014, the main reconciling item of the statutory tax rate of the Company (25% to 35% in 2016, 2015 and 2014) to the effective tax rate (0%) is tax loss carryforwards, stock-based compensation and other deferred tax assets for which a full valuation allowance was provided.

NOTE 12:-SUBSEQUENT EVENTS

In August 2016, the Company's Critical Limb Ischemia ("CLI") program in the European Union has been awarded a Euro 7,600 thousands (approximately \$8,400) grant. The grant is part of the European Union's Horizon 2020 program. The Phase III study of PLX-PAD in CLI will be a collaborative project carried out by an international consortium led by the Berlin-Brandenburg Center for Regenerative Therapies together with the Company and with participation of additional third parties. The grant will cover a significant portion of the CLI program costs. An amount of Euro 1,900 thousands (approximately \$2,100) is a direct grant allocated to the Company, and the Company also expect to benefit from cost savings resulting from grant amounts allocated to the other consortium members.

Quarterly Information (unaudited)

The following unaudited quarterly financial information includes, in management's opinion, all the normal and recurring adjustments necessary to fairly state the results of operations and related information for the periods presented (in thousands of dollars except share and per share data).

	September 30, 2015	December 31, 2015	March 31, 2016	June 30, 2016
Revenues	\$ 95	\$ 2,752	\$-	\$-
Gross profit	92	2,655	-	-
Operating expenses	5,615	6,883	7,395	6,173
Operating loss	5,523	4,228	7,395	6,173
Net loss	5,876	3,962	7,203	6,205
Basic and diluted net loss per share	0.07	0.05	0.09	0.08

	September 30, 2014	December 31, 2014	March 31, 2015	June 30, 2015
Revenues	\$ 95	\$ 95	\$95	\$94
Gross profit	92	91	92	91
Operating expenses	5,715	6,392	7,621	5,905
Operating loss	5,623	6,301	7,529	5,814
Net loss	5,911	6,245	7,226	5,295
Basic and diluted net loss per share	0.09	0.09	0.10	0.07

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation under the supervision of our CEO and CFO (our principal executive officer and principal financial officer, respectively), regarding the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2016. Based on the aforementioned evaluation, management has concluded that our disclosure controls and procedures were effective as of June 30, 2016.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting has been 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 generally accepted in the United States of America.

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of our assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures are being made only in accordance with authorization of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Management assessed the effectiveness of our internal control over financial reporting on June 30, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework, or COSO, in Internal Control—Integrated Framework. Based on that assessment under those criteria, management has determined that, as of June 30, 2016, our internal control over financial reporting was effective.

Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm, who audited our consolidated financial statements included elsewhere in this Annual Report, has also issued an attestation report on our internal control over financial reporting, which is included elsewhere in this Annual Report.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of Fiscal 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Given the timing of the event, the following information is included in this Form 10-K pursuant to Item 5.03 “Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year” of Form 8-K in lieu of filing a Form 8-K.

On September 7, 2016, our Board of Directors approved Amended and Restated By-Laws of the Company, or the Amended Bylaws. The Amended Bylaws revised Section 1 of the bylaws to remove a provision which permitted shareholders of at least 5% of the outstanding shares of the Company, and who attends a meeting of the shareholders, to bring up a subject for discussion at such meeting. Additionally, the Amended Bylaws amended Section 2 of the bylaws to increase the threshold by which a shareholder could call a special meeting of the shareholders from 10% to 33.34%.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

As of June 30, 2016, our directors and executive officers, their ages, positions held, and duration of such, are as follows:

Name	Position Held With Company	Age	Date First Elected or Appointed
Zami Aberman	-President (until February 2014)		September 26, 2005
	-CEO and Director	62	November 21, 2005
	-Chairman of the Board of Directors		April 3, 2006
Yaky Yanay	-CFO and Secretary (until February 2014)		November 1, 2006
	-Executive Vice President (until February 2014)	45	March 17, 2013
	-President and COO		February 4, 2014
	-CFO and Director		February 5, 2015
Nachum Rosman	Director	70	October 9, 2007
Doron Shorrer	Director	63	October 2, 2003
Hava Meretzki	Director	47	October 2, 2003
Isaac Braun	Director	64	July 6, 2005
Israel Ben-Yoram	Director	56	January 26, 2005
Mark Germain	Director	66	May 17, 2007
Moria Kwiat	Director	37	May 15, 2012

Business Experience

The following is a brief account of the education and business experience of each director and executive officer during at least the past five years, indicating each person's principal occupation during the period, and the name and principal business of the organization by which they were employed.

Zami Aberman

Mr. Aberman joined the Company in September 2005 and has served since then as Chief Executive Officer, or CEO, and until February 2014 as President of the Company. He changed the Company's strategy towards cellular therapeutics. Mr. Aberman's vision to use the maternal section of the Placenta (Decidua) as a source for cell therapy, combined with the Company's 3D culturing technology, led to the development of our products. Since November 2005, Mr. Aberman has served as a director of the Company, and since April 2006, as Chairman of the Board. He has 25 years of experience in marketing and management in the high technology industry. Mr. Aberman has held positions of CEO and Chairman positions in companies in Israel, the United States, Europe, Japan and Korea. Mr. Aberman operated within high-tech global companies in the fields of automatic optical inspection, network security, video over IP, software, chip design and robotics. He serves as the chairman of Rose Hitech Ltd., a private investment company. He served in the past as the chairman of VLScom Ltd., a private company specializing in video compression for HDTV and video over IP and as a director of Ori Software Ltd., a company involved in data management. Prior to that, Mr. Aberman served as the President and CEO of Elbit Vision System Ltd. (EVS.NF.OB), a company engaged in automatic optical inspection. Prior to his service with the Company, Mr. Aberman served as President and CEO of Netect Ltd., specializing in the field of internet security software and was the Co-Founder, President and CEO of Associative Computing Ltd., which developed an associative parallel processor for real-time video processing. He also served as Chairman of Display Inspection Systems Inc., specializing in laser based inspection machines and as

President and CEO of Robomatix Technologies Ltd.

44

In 1992, Mr. Aberman was awarded the Rothschild Prize for excellence in his field from the President of the State of Israel. Mr. Aberman holds a B.Sc. in Mechanical Engineering from Ben Gurion University in Israel.

We believe that Mr. Aberman's qualifications to sit on our Board include his unique multidisciplinary innovative approach, years of experience in the financial markets in Israel and globally, as well as his experience in serving as the CEO of publicly traded entities.

Yaky Yanay

Mr. Yaky Yanay was re-appointed as our CFO in February 2015, and as President and Chief Operating Officer, or COO, in February 2014. Until February 2014, he served as our CFO and Secretary since November 2006, and Executive Vice President since March 2013. Prior to joining us, Mr. Yanay was the CFO of Elbit Vision Systems Ltd., a public company. Prior to that Mr. Yanay served as manager of audit groups of the technology sector at Ernst & Young Israel. Since September 2015, Mr. Yanay has served as Co-Chairman of Israel Advanced Technology Industries (IATI), the largest umbrella organization representing Israel's high tech and life science industries. Mr. Yanay is representing Israel's life sciences industry and has served on the Board of Directors of IATI for three years before he was appointed as Co-Chairman. Mr. Yanay serves as a director of Elbit Vision System Ltd., and he also founded and served as Chairman of the "The Life Science Forum".

Mr. Yanay holds a bachelor's degree with honors in business administration and accounting from the College of Management Academic Studies of Rishon LeZion and is a Certified Public Accountant in Israel.

We believe that Mr. Yanay's qualifications to sit on our Board include his years of experience in the medical technology industry, his vast skill and expertise in accounting and economics, as well as his knowledge and familiarity with corporate finance.

Nachum Rosman

Mr. Rosman became a director of the Company in October 2007. He provides management and consulting services to startup companies in the financial, organizational and human resource aspects of their operations. Mr. Rosman also serves as the CEO of Simba Ltd. and as a director at several privately held companies. Throughout his career, Mr. Rosman held CEO and CFO positions in Israel, the United States and England. In these positions he was responsible, among other things, for finance management, fund raising, acquisitions and technology sales.

Mr. Rosman holds a B.Sc. in Management Engineering and an M.Sc. in Operations Research from the Technion, Haifa, Israel. Mr. Rosman also participated in a Ph.D. program in Investments and Financing at the Tel Aviv University, Israel.

We believe that Mr. Rosman's qualifications to sit on our Board of Directors include his years of experience in the high-tech industry, as well as his knowledge and familiarity with corporate finance.

Doron Shorrer

Mr. Shorrer became a director of the Company in October 2003. Mr. Shorrer was one of the Company's founders and served as its first Chairman until 2006. Since 1998, Mr. Shorrer has served as the Chairman and CEO of Shorrer International Ltd., an investment and financial consulting company. Mr. Shorrer also serves as a director of other companies: Provident Fund for employees of the Israel Electric Company Ltd. and for Hebrew University employees, and Massad Bank from the International Bank group. Between 1999 and 2004 he was Chairman of the Boards of Phoenix Insurance Company, one of the largest insurance companies in Israel, and of Mivtachim Pension Funds Group, the largest pension fund in Israel. Prior to serving in these positions, Mr. Shorrer held senior positions that included Arbitrator at the Claims Resolution Tribunal for Dormant Accounts in Switzerland; Economic and Financial

Advisor, Commissioner of Insurance and Capital Markets for the State of Israel; Member of the board of directors of “Nechasim” of the State of Israel; Member Committee for the Examination of Structural Changes in the Capital Market (The Brodet Committee); General Director of the Ministry of Transport; Founder and managing partner of an accounting firm with offices in Jerusalem, Tel-Aviv and Haifa; Member of the Lecture Staff of the Hebrew University Business Administration School; Chairman of Amal School Chain; Chairman of a Public Committee for Telecommunications; and Economic Consultant to the Ministry of Energy. Among many areas of expertise, Mr. Shorrer formulates implements and administers business planning in the private and institutional sector in addition to consulting on economic, accounting and taxation issues to a large audience ranging from private concerns to government ministries.

Mr. Shorrer holds a B.A. in Economics and Accounting and an M.A. in Business Administration (specialization in finance and banking) from the Hebrew University of Jerusalem and is a Certified Public Accountant in Israel.

We believe that Mr. Shorrer's qualifications to sit on our Board of Directors include his years of experience in the high-tech industry, his vast skill and expertise in accounting and economics, as well as his knowledge and familiarity with corporate finance.

Hava Meretzki

Ms. Meretzki became a director of the Company in October 2003. Ms. Meretzki is an attorney and is a partner in Meretzki law firm in Haifa, Israel. Ms. Meretzki specializes in civil, trade and labor law, and is presently the Chairman of the National Council of the Israel Bar Association. Ms. Meretzki received a Bachelor's Degree in Law from the Hebrew University in 1991 and was admitted to the Israel Bar Association in 1993.

We believe that Ms. Meretzki's qualifications to sit on our Board include her years of experience with legal and corporate governance matters.

Isaac Braun

Mr. Braun became a director of the Company in July 2005. Mr. Braun is a business veteran with entrepreneurial, industrial and manufacturing experience. He is a co-founder and has been a board member of several hi-tech start-ups in the areas of e-commerce, security, messaging, search engines and biotechnology. Mr. Braun is involved with advising private companies on raising capital and business development.

We believe that Mr. Braun's qualifications to sit on our Board include his years of experience in the high-tech industry, as well as his knowledge and familiarity with corporate finance.

Israel Ben-Yoram

Mr. Ben-Yoram became a director of the Company in January 2005. He has been a director and partner in the accounting firm of Mor, Ben-Yoram and Partners in Israel since 1985. In addition, since 1992, Mr. Ben-Yoram has been a shareholder and has served as the head director of Mor, Ben-Yoram Ltd., a private company in Israel in parallel to the operation of Mor, Ben-Yoram and Partners. This company provides management services, economic consulting services and other professional services to businesses. Furthermore, Mr. Ben-Yoram is the founder, owner and CEO of SBY Group (Eshed Dash Ltd., Zonbit Ltd. and Eshed Yuvalim Ltd.). During 2003 to 2004 Mr. Ben-Yoram served as a director of Brainstorm Cell Therapeutics Inc. (BCLI) and Smart Energy solutions, Inc. (SMGY), both of which were traded on the NASDAQ. Mr. Ben-Yoram is also a member of STEP (Society of Trust and Estate Practitioners).

Mr. Ben-Yoram received a B.A. in accounting from the University of Tel Aviv, an M.A. in Economics from the Hebrew University of Jerusalem, an LL.B. and an MBA from Tel Aviv University and an LL.M. from Bar Ilan University. In addition, Mr. Ben-Yoram is a Certified Public Accountant in Israel and is qualified in arbitration and in mediation.

We believe that Mr. Ben-Yoram's qualifications to sit on our Board include his years of experience in the high-tech industry, his experience serving as a director of NASDAQ companies, as well as his knowledge and familiarity with corporate finance and accounting.

Mark Germain

Mr. Germain became a director of the Company in May 2007. Between May 2007 and February 2009, Mr. Germain served as Co-Chairman of our Board. For more than five years, Mr. Germain has been a merchant banker serving primarily the biotech and life sciences industries. He has been involved as a founder, director, chairman of the board of, and/or investor in, over twenty companies in the biotech field, and assisted many of them in arranging corporate partnerships, acquiring technology, entering into mergers and acquisitions, and executing financings and going public transactions. He graduated from New York University School of Law in 1975, Order of the Coif, and was a partner in a New York law firm practicing corporate and securities law before leaving in 1986. Since then, and until he entered the biotech field in 1991, he served in senior executive capacities, including as president of a public company, which was sold in 1991. In addition to being a director of the Company, Mr. Germain is a director of ChromaDex Corp. (CDXB.OB), a publicly traded company. Mr Germain also serves or served as a director of the following companies that were reporting companies in the past: Stem Cell Innovations, Inc., Omnimmune Corp. and Collexis Holdings, Inc. He is also a co-founder and director of a number of private companies in and outside the biotechnology field.

We believe that Mr. Germain's qualifications to sit on our Board include his years of experience in the biotech industry, his experience serving as a director of public companies, as well as his knowledge and familiarity with corporate finance.

Moria Kwiat

Dr. Kwiat became a director of the Company in May 2012. Dr. Kwiat is a research associate in the Department of Materials and NanoSciences, Faculty of Chemistry at Tel Aviv University. During her studies she has gained broad scientific experience in inter-disciplinary fields, with special expertise on the development and application of new technologies for biosensors based on nano-materials. Dr. Kwiat holds a B.Sc. and M.Sc. in Biotechnology from the Department of Molecular Microbiology and Biotechnology at Tel Aviv University, and a Ph.D. in Chemistry from the Faculty of Exact Sciences at Tel Aviv University.

We believe that Dr. Kwiat's qualifications to sit on our Board of Directors include her knowledge and experience as a scientist and a researcher in the fields of biotechnology, microbiology and nanotechnology.

There are no family relationships between any of the directors or officers named above.

Audit Committee and Audit Committee Financial Expert

The members of our Audit Committee are Doron Shorrer, Nachum Rosman and Israel Ben-Yoram. Doron Shorrer is the Chairman of the Audit Committee, and our Board of Directors has determined that Israel Ben-Yoram is an "Audit Committee financial expert" and that all members of the Audit Committee are "independent" as defined by the rules of the SEC and the NASDAQ rules and regulations. The Audit Committee operates under a written charter that is posted on our website at www.pluristem.com. The information on our website is not incorporated by reference into this Annual Report. The primary responsibilities of our Audit Committee include:

·Appointing, compensating and retaining our registered independent public accounting firm;

·Overseeing the work performed by any outside accounting firm;

·Assisting the Board in fulfilling its responsibilities by reviewing: (i) the financial reports provided by us to the SEC, our stockholders or to the general public, and (ii) our internal financial and accounting controls; and

·Recommending, establishing and monitoring procedures designed to improve the quality and reliability of the disclosure of our financial condition and results of operations.

Our Audit Committee held five meetings from July 1, 2015 through June 30, 2016 (Fiscal 2016).

Compensation Committee

The members of our Compensation Committee are Doron Shorrer, Nachum Rosman and Israel Ben-Yoram. The Board has determined that all of the members of the Compensation Committee are "independent" as defined by the rules of the SEC and NASDAQ rules and regulations. The Compensation Committee operates under a written charter that is posted on our website at www.pluristem.com. The information on our website is not incorporated by reference into this Annual Report. The primary responsibilities of our Compensation Committee include:

·Reviewing and recommending to our Board of the annual base compensation, the annual incentive bonus, equity compensation, employment agreements and any other benefits of our executive officers;

·Administering our equity based plans and making recommendations to our Board with respect to our incentive-compensation plans and equity-based plans; and

·Annually reviewing and making recommendations to our Board with respect to the compensation policy for such other officers as directed by our Board.

Our Compensation Committee held six meetings during Fiscal 2016. The Compensation Committee did not receive advice from or retain any consultants during Fiscal 2016.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended June 30, 2016, Mr. Shorrer, Mr. Rosman, and Mr. Ben-Yoram served as the members of our Compensation Committee. None of the members of our Compensation Committee is, or has been, an officer or employee of ours or of our subsidiary.

During the last year, none of our executive officers served as: (1) a member of the compensation committee (or other committee of the board of directors performing equivalent functions or, in the absence of any such committee, the entire board of directors) of another entity, one of whose executive officers served on the compensation committee; (2) a director of another entity, one of whose executive officers served on the compensation committee; or (3) a member of the compensation committee (or other committee of the board of directors performing equivalent functions or, in the absence of any such committee, the entire board of directors) of another entity, one of whose executive officers served as a director on our Board of Directors.

Nominating/Corporate Governance; Director Candidates.

The Company does not have a Nominating Committee or Corporate Governance Committee or any committees of a similar nature, nor any charter governing the nomination process. Our Board does not believe that such committees are needed for a company our size. However, our independent directors will consider stockholder suggestions for additions to our Board.

Code of Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to, among other persons, members of our Board of Directors, our officers including our CEO (being our principal executive officer) and our CFO (being our principal financial and accounting officer) and our employees.

Our Code of Business Conduct and Ethics is posted on our Internet website at www.pluristem.com. The information on our website is not incorporated by reference into this Annual Report.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the SEC and to provide us with copies of those filings. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, except for (i) the Form 4s filed by Israel Ben Yoram on September 24, 2015 and (ii) the Form 4 filed by Doron Shorrer on June 6, 2016, we believe that during fiscal year ended June 30, 2016, all filing requirements applicable to our officers, directors and ten percent beneficial owners were complied with.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION AND RELATED INFORMATION

Compensation Discussion and Analysis

The Compensation Committee of our Board of Directors is comprised solely of independent directors as defined by NASDAQ, outside directors as defined by Section 162(m) of the Internal Revenue Code and non-employee directors as defined by Rule 16b-3 under the Exchange Act. The Compensation Committee has the authority and responsibility to review and make recommendations to the Board of Directors regarding the compensation of our CEO and other executive officers. Our named executive officers for Fiscal 2016 are those two individuals listed in the "2016 Summary Compensation Table" below. Other information concerning the structure, roles and responsibilities of our Compensation Committee is set forth in "Board Meetings and Committees—Compensation Committee" section of this Annual Report.

At our 2015 shareholders meeting, we provided our shareholders with the opportunity to cast an advisory vote on executive compensation. Over 67% of the votes cast on this "2015 say-on-pay vote" were voted in favor of the proposal. We have considered the 2015 say-on-pay vote and we believe that the support from our shareholders for the 2015 say-on-pay vote proposal indicates that our shareholders are supportive of our approach to executive compensation. At our 2013 shareholders meeting, our shareholders voted in favor of the proposal to hold say-on-pay votes every two years. We will continue to consider the outcome of our say-on-pay votes when making compensation decisions regarding our named executive officers.

A discussion of the policies and decisions that shape our executive compensation program, including the specific objectives and elements, is set forth below.

Executive Compensation Objectives and Philosophy

The objective of our executive compensation program is to attract, retain and motivate talented executives who are critical for our continued growth and success and to align the interests of these executives with those of our shareholders. To this end, our compensation programs for executive officers are designed to achieve the following objectives:

- attract, hire, and retain talented and experienced executives;
- motivate, reward and retain executives whose knowledge, skills and performance are critical to our success;

49

- ensure fairness among the executive management team by recognizing the contributions each executive makes to our success and the tenure of each team member as a factor in achieving such success;
- focus executive behavior on achievement of our corporate objectives and strategy;
- build a mechanism of "pay for performance"; and
- align the interests of management and shareholders by providing management with longer-term incentives through equity ownership.

The Compensation Committee reviews the allocation of compensation components regularly to ensure alignment with strategic and operating goals, competitive market practices and legislative changes. The Compensation Committee does not apply a specific formula to determine the allocation between cash and non-cash forms of compensation. Certain compensation components, such as base salaries, benefits and perquisites, are intended primarily to attract, hire, and retain well-qualified executives. Other compensation elements, such as long-term incentive opportunities, are designed to motivate and reward performance. Long-term incentives are intended to reward our long-term performance and executing our business strategy, and to strongly align named executive officers' interests with those of shareholders.

With respect to equity compensation, the Compensation Committee makes awards to executives under our stock option plans and other plans as approved by the Board of Directors. Executive compensation is paid or granted based on such matters as the Compensation Committee deems appropriate, including our financial and operating performance, the alignment of the interests of the executive officers and our shareholders, the performance of our common stock and our ability to attract and retain qualified individuals.

Elements of Executive Officer Compensation

Our executive officer compensation program is comprised of: (i) base salary or monthly compensation; (ii) performance based bonus; (iii) long-term equity incentive compensation in the form of periodic stock option and RSU grants; and (iv) benefits and perquisites.

In establishing overall executive compensation levels and making specific compensation decisions for our executive officers in 2016, the Compensation Committee considered a number of criteria, including the executive's position, scope of responsibilities, prior base salary and annual incentive awards and expected contribution.

Generally, our Compensation Committee reviews and, as appropriate, approves compensation arrangements for our named executive officers, from time to time but not less than once a year. The Compensation Committee also takes into consideration the CEO's recommendations for executive compensation of other named executive officers. The CEO generally presents these recommendations at the time of our Compensation Committee's review of executive compensation arrangements.

Base Salary

The Compensation Committee performs a review of base salaries / monthly compensation for our named executive officers from time to time as appropriate. In determining salaries, the Compensation Committee members also take into consideration their understanding of the compensation practices of comparable companies (based on size and stage of development), especially in Israel, where our named executive officers reside; independent third party market data such as compensation surveys to industry, including information relating to peer companies; individual experience and performance adjusted to reflect individual roles; and contribution to our clinical, regulatory, commercial and operational performance. None of the factors above has a dominant weight in determining the compensation of our executive officers, and our Compensation Committee considers the factors as a whole when considering such compensation. In addition, our Compensation Committee may, from time to time, use comparative data regarding compensation paid by peer companies in order to obtain a general understanding of current trends in

compensation practices and ranges of amounts being awarded by other public companies, and not as part of an analysis or a formula. We may also change the base salary / monthly compensation of an executive officer at other times due to market conditions. We believe that a competitive base salary / monthly compensation is a necessary element of any compensation program that is designed to attract and retain talented and experienced executives. We also believe that attractive base salaries can motivate and reward executives for their overall performance. Base salaries / monthly compensation are established in part based on the individual experience, skills and expected contributions of our executives and our executives' performance during the prior year. Compensation adjustments are made occasionally based on changes in an executive's level of responsibility, Company progress or on changed local and specific executive employment market conditions. In Fiscal 2016, our named executive officers' salaries and monthly compensation did not change from the previous year as we believe they do not deviate materially from the range of salaries received by our named executive officers' respective counterparts in companies in the biotechnology industry and other comparable companies in Israel. We did not conduct any analysis of salaries and monthly compensation received by our named executive officers' respective counterparts in companies in the biotechnology industry and other comparable companies in Israel in the fiscal year ended June 30, 2015 and Fiscal 2016.

Performance Based Bonus

Given the nature of our business, the determination of incentives for our executives is generally tied to success in promoting our Company's development. We are continually seeking non-dilutive sources of funding. In addition, a key component of our strategy is to develop and manufacture cell therapy products for the treatment of multiple disorders through collaboration with other companies and entering into licensing agreements with such companies, such as our agreement with CHA. Therefore, in order to reward our CEO and COO, each of them is entitled to a bonus calculated as a percentage of amounts received by us from non-dilutive funding received, among other things, from corporate partnering and strategic deals (e.g., the United Agreement). This is designed to support our business strategy to enter into multiple license agreements with pharmaceutical companies. The performance based bonus percentages are as follows: Mr. Zami Aberman – 1.5% of amounts received by us from non-dilutive funding and strategic deals, and Mr. Yaky Yanay – 1% of such amounts. The difference in the percentage of the performance based bonus was determined based on the Compensation Committee's assessment of the contribution and role of each of them in completing the licensing and strategic agreements. In addition, our executives may be entitled, from time to time, to a discretionary bonus that is in the Compensation Committee sole discretion. We paid no bonuses to our named executive officers in Fiscal 2016.

Long-term Equity Incentive Compensation

Long-term incentive compensation allows the executive officers to share in any appreciation in the value of our common stock. The Compensation Committee believes that stock participation aligns executive officers' interests with those of our shareholders. The amounts of the awards are designed to reward past performance and create incentives to meet long-term objectives. Awards are made at a level expected to be competitive within the biotechnology industry, as well as with Israeli based companies. We do not have a formula relating to, and did not conduct any analysis of, the level of awards that is competitive within the biotechnology industry and Israeli based companies. In determining the amount of each grant, the Compensation Committee also takes into account the number of shares held by the executive prior to the grant. Awards are made on a discretionary basis and not pursuant to specific criteria set out in advance.

RSU awards provide our executive officers with the right to purchase shares of our common stock at a par value of \$0.00001, subject to continued employment with our Company. In recent years we granted our executive officers RSU awards. We chose to grant RSU awards and not options because RSU awards, once vested, always have an immediate financial value to the holder thereof, unlike options where the exercise price might be below the current market price of the shares and therefore not have any intrinsic value to the holder thereof. In the past, due to the high volatility of our stock price, options we granted were out of the money, and many of them still are. In addition, because vested RSU awards always have financial value, as opposed to options, we were able to limit the number of securities issued to our executive officers and other employees, directors and consultants. RSUs generally vest over two years. Our currently serving named executive officers are entitled to acceleration of the vesting of their stock options and RSUs in the following circumstances: (1) if we terminate their employment, they will be entitled to acceleration of 100% of any unvested options and RSU and (2) if they resign, they will be entitled to acceleration of 50% of any unvested options and RSUs. In addition, our CEO is entitled to an acceleration of 100% of any unvested options and RSUs in the event of change in control. All grants are approved by our Board of Directors.

Benefits and Perquisites

Generally, benefits available to our named executive officers are available to all employees on similar terms and include welfare benefits, paid time-off, life and disability insurance and other customary or mandatory social benefits in Israel. We provide our named executive officers with a phone and a Company car which are customary benefits in Israel to managers and officers. Our named executive officers are also entitled to receive, once a year, a fixed sum equal to the amount of the monthly compensation to such executive officer.

In addition, in the event of termination of our CEO's consulting agreement, he will be entitled to receive an adjustment fee that equals the monthly consulting fees multiplied by 3 plus the number of years the Consulting Agreement is in force from the second year, but in any event no more than nine years in the aggregate. Our CFO/COO may be entitled to a severance payment that equals a month's compensation for each twelve-month period of employment or otherwise providing services to the Company.

We do not believe that the benefits and perquisites described above deviate materially from the customary practice for compensation of executive officers by other companies similar in size and stage of development in Israel. These benefits represent a relatively small portion of the executive officers' total compensation.

Compensation Committee Report

The Compensation Committee has reviewed and discussed the foregoing Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with our management and, based on such review and discussions, the Compensation Committee recommended to our Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K and in our proxy statement relating to our next annual meeting of stockholders.

Compensation Committee Members:

Doron Shorrer
Nachum Rosman
Israel Ben-Yoram

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

The following table shows the particulars of compensation paid to our named executive officers for the fiscal years ended June 30, 2016, 2015 and 2014. We do not currently have any other executive officers.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Fiscal Year	Salary (\$)(1)	Stock-based Awards (\$)(2)	All Other Compensation (\$)(3)	Total (\$)
Zami Aberman CEO	2016	519,050(4)	169,500	21,074	709,624
	2015	484,400(4)	512,000	18,813	1,015,213
	2014	524,200(4)	492,000	19,347	1,035,547
	2016	245,312	169,500	21,721	436,533
Yaky Yanay CFO and COO	2015	249,000	512,000	25,721	786,721
	2014	269,969	492,000	27,694	789,663

(1) Salary payments which were in NIS, were translated into US\$ at the then current exchange rate for each payment.

(2) The fair value recognized for the stock-based awards was determined as of the grant date in accordance with ASC 718. Assumptions used in the calculations for these amounts are included in Note 2(1) to our consolidated financial statements for Fiscal 2016 included elsewhere in this Annual Report.

(3) Represents cost to us in connection with car and a mobile phone expenses. The Company also pays the tax associated with this benefit, which is grossed up, and part of the amount in the Salary column in the table above.

(4) Includes \$18,910, \$19,054 and \$20,474 paid to Mr. Aberman as compensation for services as a director in fiscal 2016, 2015, and 2014, respectively and \$43,503 paid to Mr. Aberman as redemption in cash of 27.5 vacation Days in fiscal 2016.

We have the following written agreements and other arrangements concerning compensation with our named executive officers:

Mr. Aberman is engaged with us as a consultant and receives a monthly consulting fee of \$31,250. In addition, Mr. Aberman is entitled once a year to receive an additional amount that equals the monthly consulting fee. The U.S. (a) dollar rate will be not less than 4.35 NIS per \$. All amounts above are paid plus value added tax. Mr. Aberman is also entitled to one and a half percent (1.5%) from amounts received by us from non diluting funding and strategic deals.

Mr. Yanay's monthly salary is 53,125 NIS. In addition, Mr. Yanay is entitled once a year to receive an additional amount that equals his monthly salary. Mr. Yanay is provided with a cellular phone and a Company car pursuant to the terms of his agreement. Furthermore, Mr. Yanay is entitled to a bonus of one percent (1.0%) from amounts (b) received by us from non diluting funding and strategic deals. Since August 2011, Mr. Yanay has been engaged with us as a consultant, in addition to being an employee. For his services as a consultant he receives a monthly consulting fee. In addition, he continues to receive salary as an employee, but in an amount reduced by the consulting fee so the total cost to us did not change as a result of this change.

Potential Payments Upon Termination or Change-in-Control

We have no plans or arrangements in respect of remuneration received or that may be received by our executive officers to compensate such officers in the event of termination of employment (as a result of resignation, retirement,

change-in- control) or a change of responsibilities following a change-in-control, except for the following: (i) in the event of termination of Mr. Aberman's Consulting Agreement, he will be entitled to receive an adjustment fee that equals the monthly consulting fees multiplied by 3 plus the number of years the Consulting Agreement has been in force as of the second year, but in any event no more than nine years in the aggregate; (ii) Mr. Yanay may be entitled, under Israeli law and practice, to a severance payment that equals a month's salary for each twelve-month period of employment with the Company.

In addition, Mr. Aberman and Mr. Yanay are entitled to acceleration of the vesting of their stock options and restricted stock in the following circumstances: (1) if we terminate their employment, they will be entitled to acceleration of 100% of any unvested options and restricted stock and (2) if they resign, they will be entitled to acceleration of 50% of any unvested options and restricted stock. In addition, Mr. Aberman is entitled to acceleration of 100% of any unvested options and restricted stock in case of our change in control or merger into another company.

The following table displays the value of what our current named executive officers would have received from us had their employment been terminated, or a change in control of us happened on June 30, 2016.

Officer	Salary	Accelerated Vesting of Options and Restricted Stock Units (1)	Total
Zami Aberman			
Terminated due to officer resignation	\$ 317,529	\$ 166,250 (2)	\$ 483,779
Terminated due to discharge of officer	\$ 317,529	\$ 332,500 (3)	\$ 650,029
Change in control		\$ 332,500 (4)	\$ 332,500
Yaky Yanay			
Terminated due to officer resignation	\$ 78,119	\$ 166,250 (2)	\$ 244,369
Terminated due to discharge of officer	\$ 78,119	\$ 332,500 (3)	\$ 410,619

(1) Value shown represents the difference between the closing market price of our shares of common stock on June 30, 2016 of \$1.33 per share and the applicable exercise price of each grant.

(2) 50% of all unvested options and RSUs issued under the applicable equity incentive plans vest upon a termination without cause under the terms of those plans.

(3) All unvested options and RSUs issued under the applicable equity incentive plans vest upon a termination due to discharge.

(4) All unvested options and RSUs issued under the applicable equity incentive plans vest upon a change of control under the terms of those plans.

Pension, Retirement or Similar Benefit Plans

We have no arrangements or plans under which we provide pension, retirement or similar benefits for directors or executive officers. Our directors and executive officers may receive stock options, RSUs or restricted shares at the discretion of our Board in the future.

Grants of Plan-Based Awards

The following table shows grants of plan-based equity awards made to our named executive officers during the fiscal year ended June 30, 2016:

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units	Grant Date	Fair Value of Stock and Option Awards (\$)
Zami Aberman	01/05/16	150,000 (1)		169,500
Yaky Yanay	01/05/16	150,000 (1)		169,500

Grant of RSUs was made pursuant to our amended and restated 2005 stock option plan, or the 2005 Plan. The grant vests over a two-year period from the date of grant, as follows: 37,500 RSUs vest on July 5, 2016 and 112,500 (1) RSUs vest in six installments of 18,750 shares on each of October 5, 2016, January 5, 2017, April 5, 2017, July 5, 2017, October 5, 2017 and January 5, 2018.

Outstanding Equity Awards at the End of Fiscal 2016

The following table presents the outstanding equity awards held as of June 30, 2016 by our named executive officers:

Name	Number of Securities Underlying Unexercised				Stock Awards	
	Option Awards Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price(\$)	Option expiration date	Number of shares that have not vested (#)	Market value of shares that have not vested (\$)
Zami Aberman	30,000	-	4.00	10/30/2016	-	-
	250,000	-	3.50	1/23/2017	-	-
	105,000	-	4.38	12/25/2017	-	-
	110,000	-	0.62	10/30/2018	-	-
	-	-	-	-	100,000(1)	\$133,500
	-	-	-	-	150,000(2)	\$199,500
	62,500	-	4.38	12/25/2017	-	-
	12,500	-	4.00	9/17/2016	-	-
Yaky Yanay	50,000	-	3.50	1/23/2017	-	-
	55,000	-	0.62	10/30/2018	-	-
	-	-	-	-	100,000(1)	\$133,500
	-	-	-	-	150,000(2)	\$199,500
	-	-	-	-	-	-

(1) 100,000 RSUs vest in 4 installments of 25,000 shares on September 28, 2016, December 28, 2016, March 28, 2017 and June 28, 2017.

150,000 RSUs vest as follows: 37,500 RSUs vest on July 5, 2016 and 112,500 RSUs vest in six installments of (2) 18,750 shares on each of October 5, 2016, January 5, 2017, April 5, 2017, July 5, 2017, October 5, 2017 and January 5, 2018.

55

Option Exercises and Stock Vested Table

The following table presents the option exercises and stock vested awards during Fiscal 2016 by our named executive officers:

Name	Stock Awards	
	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (\$)
Zami Aberman	137,500	182,875
Yaky Yanay	137,500	182,875

Long-Term Incentive Plans-Awards in Last Fiscal Year

We have no long-term incentive plans, other than the stock option plans described below under Item 12.

Compensation of Directors

The following table provides information regarding compensation earned by, awarded or paid to each person for serving as a director who is not an executive officer during Fiscal 2016:

Name	Fees Earned or Paid		Total (\$)
	in Cash (\$)	Stock-based Awards (\$) ⁽¹⁾	
Mark Germain	16,915	54,240	71,155
Nachum Rosman	22,528	55,370	77,898
Doron Shorrer	22,941	55,370	78,311
Hava Meretzki	20,011	39,550	59,561
Isaac Braun	21,483	39,550	61,033
Israel Ben-Yoram	24,116	55,370	79,486
Moria Kwiat	21,558	39,550	61,108

The fair value recognized for the stock-based awards was determined as of the grant date in accordance with ASC (1)718. Assumptions used in the calculations for these amounts are included in Note 2(l) to our consolidated financial statements for Fiscal 2016 included elsewhere in this Annual Report.

We reimburse our directors for expenses incurred in connection with attending board meetings and provide the following compensation for directors: annual compensation of \$12,500; meeting participation fees of \$935 per in-person meeting; and for meeting participation by telephone, \$435 per meeting. The Board has determined that the dollar rate would be not less than 4.25 NIS per dollar. The directors are also entitled to two and a half percent (2.5%) in cash based on amounts received by us from non-diluting funding and strategic deals.

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

During Fiscal 2016 we paid a total of \$149,552 in cash to directors as compensation. This amount does not include compensation to Mr. Aberman in his capacity as a director, which is reflected in the Summary Compensation Table for Fiscal 2016 above. As of June 30, 2016, we granted our directors (not including the Chairman and our COO) 3,802,145 options, restricted shares and RSUs of which 2,865,880 were exercisable or vested, as the case may be, as follows:

Name	Total of Options, restricted shares and RSUs Granted	Total of Options, restricted shares and RSUs exercisable and vested
Mark Germain	805,708	628,636
Nachum Rosman	586,958	317,341
Doron Shorrer	679,964	606,333
Hava Meretzki	465,400	412,583
Isaac Braun	464,131	412,583
Israel Ben-Yoram	644,984	394,029
Moria Kwiat	155,000	94,375
Total	3,802,145	2,865,880

The vesting of directors' stock options, RSUs and restricted stock accelerates in the following circumstances: (1) termination of a director's position by the stockholders will result in the acceleration of 100% of any unvested options, RSUs and restricted stock and (2) termination of a director's position by resignation will result in the acceleration of 50% of any unvested options, RSUs and restricted stock.

Other than as described in the preceding four paragraphs, we have no present formal plan for compensating our directors for their service in their capacity as directors. Directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our Board. The Board may award special remuneration to any director undertaking any special services on our behalf other than services ordinarily required of a director. Other than indicated above, no director received and/or accrued any compensation for his or her services as a director, including committee participation and/or special assignments during Fiscal 2016.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters.

The following table sets forth certain information, to the best knowledge and belief of the Company, as of August 22, 2016 (unless provided herein otherwise), with respect to holdings of our common stock by (1) each person known by us to be the beneficial owner of more than 5% of the total number of shares of our common stock outstanding as of such date; (2) each of our directors; (3) each of our named executive officers; and (4) all of our directors and our executive officers as a group.

Name and Address of Beneficial Owner	Beneficial Number of Shares(1)	Percentage
<u>Directors and Named Executive Officers</u>		
Zami Aberman CEO, Chairman of the Board and Director	2,555,948(2)	3.1 %

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

Israel Ben-Yoram Director	443,302 (3)	*	
Isaac Braun Director	434,458 (4)	*	
Mark Germain Director	658,636 (5)	*	
Moria Kwiat Director	116,250	*	
Hava Meretzki Director	434,458 (6)	*	
Nachum Rosman Director	342,466 (7)	*	
Doron Shorrer Director	636,958 (8)	*	
Yaky Yanay Director, President, COO and CFO	1,516,865(9)	1.9	%
<u>Directors and Executive Officers as a group (9 persons)</u>	7,139,341(10)	8.7	%

* = less than 1%

(1) Based on 80,723,647 shares of common stock issued and outstanding as of August 22, 2016. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants or right to purchase or through the conversion of a security currently exercisable or convertible, or exercisable or convertible within 60 days, are reflected in the table above and are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants, but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(2) Includes options to acquire 495,000 shares.

(3) Includes options to acquire 63,000 shares.

(4) Includes options to acquire 90,500 shares.

(5) Includes options to acquire 307,500 shares.

(6) Includes options to acquire 90,500 shares.

(7) Includes options to acquire 63,750 shares.

(8) Includes options to acquire 110,500 shares.

(9) Includes options to acquire 167,500 shares.

(10) Includes options to acquire 1,388,250 shares.

Equity Compensation Plan Information

On November 25, 2003, our Board of Directors adopted the 2003 stock option plan. The 2003 stock option plan has expired, and we do not grant additional options under it.

On November 21, 2005, our Board of Directors adopted the 2005 Plan. Under the 2005 Plan, options may be granted to our officers, directors, employees and consultants or the officers, directors, employees and consultants of our subsidiary.

At our annual meeting of our stockholders held on January 21, 2009, our stockholders approved the adoption of the Amended and Restated 2005 Plan of the Company, amending the 2005 Plan in order to: (i) increase the number of shares of common stock authorized for issuance thereunder from 1,990,000 to be equal to 16% of the number of shares of common stock issued and outstanding on a fully diluted basis immediately prior to the grant of securities; (ii) allow the issuance of shares of common stock and units for such shares of common stock; and (iii) set the termination date of the 2005 Plan to December 31, 2018.

In addition, at our annual meeting of our stockholders held on May 31, 2016, our stockholders approved the 2016 Equity Compensation Plan, or the 2016 Plan. Under the 2016 Plan, options, restricted stock and RSUs may be granted to our officers, directors, employees and consultants or the officers, directors, employees and consultants of our subsidiary. Under the 2016 Plan, the plan administrator is authorized to grant awards to acquire shares of Common Stock, shares of restricted stock and restricted stock units, in each calendar year, in a number not exceeding two and three-quarters percent (2.75%) of the number of shares of our Common Stock issued and outstanding on a fully diluted basis on the immediately preceding December 31.

The following table summarizes certain information regarding our equity compensation plans as of June 30, 2016:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (2005 and 2016 Plan)
Equity compensation plan approved by security holders	2,009,000	\$ 3.95	3,089,003

Item 13. Certain Relationships and Related Transactions and Director Independence.

No director, executive officer, principal shareholder holding at least 5% of our common shares, or any family member thereof, had any material interest, direct or indirect, in any transaction, or proposed transaction, during Fiscal 2016, in which the amount involved in the transaction exceeded or exceeds \$120,000.

The Board of Directors has determined that Doron Shorrer, Nachum Rosman and Israel Ben-Yoram are "independent" as defined by the rules of the SEC and the NASDAQ rules and regulations.

Item 14. Principal Accounting Fees and Services

The fees for services provided by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, to the Company in the last two fiscal years were as follows:

Twelve months ended on	Twelve months ended on
------------------------	------------------------

	June 30, 2016	June 30, 2015
Audit Fees	\$103,000	\$155,000
Audit-Related Fees	None	None
Tax Fees	\$8,284	\$19,530
All Other Fees	\$16,747	\$14,982
Total Fees	\$128,031	\$189,512

Audit Fees. These fees were comprised of (i) professional services rendered in connection with the audit of our consolidated financial statements for our Annual Report on Form 10-K and internal control over financial reporting, (ii) the review of our quarterly consolidated financial statements for our quarterly reports on Form 10-Q, (iii) audit services provided in connection with other regulatory or statutory filings and (iv) fees related to the offering we closed in June 2015.

Tax Fees. These fees relate to our tax compliance and tax advisory projects.

All Other Fees. These fees were comprised of fees related to assistance in preparation of IIA applications as well as other incentive applications.

SEC rules require that before Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, is engaged by us to render any auditing or permitted non-audit related service, the engagement be:

1. pre-approved by our Audit Committee; or

2. entered into pursuant to pre-approval policies and procedures established by the Audit Committee, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service, and such policies and procedures do not include delegation of the Audit Committee's responsibilities to management.

The Audit Committee pre-approves all services provided by our independent registered public accounting firm. All of the above services and fees were reviewed and approved by the Audit Committee before the services were rendered.

The Audit Committee has considered the nature and amount of fees billed by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, and believes that the provision of services for activities unrelated to the audit is compatible with maintaining Kost Forer Gabbay & Kasierer's independence.

PART IV

Item 15. Exhibits.

3.1 Composite Copy of the Company's Articles of Incorporation as amended on May 22, 2014 (incorporated by reference to Exhibit 4.1 of our Registration Statement on Form S-8 filed June 5, 2014).

3.2* Amended and Restated By-laws.

3.3* Amended and Restated By-laws (marked copy).

4.1 Form of Common Stock Purchase Warrant dated October 18, 2010 (incorporated by reference to Exhibit 4.1 of our current report on Form 8-K filed on October 12, 2010).

4.2 Form of Warrant Agreement by and between Pluristem Therapeutics Inc. and American Stock Transfer & Trust Company, LLC (including the form of Warrant certificate) (incorporate by reference to Exhibit 4.2 of our quarterly report on Form 10-Q filed on February 9, 2011).

10.1 Consulting Agreement dated September 26, 2005 between Pluristem Ltd. and Rose High Tech Ltd. (incorporated by reference to Exhibit 10.25 of our quarterly report on Form 10-QSB filed February 9, 2006).+

10.2 Summary of Lease Agreement dated January 22, 2003, by and between Pluristem Ltd. and MTM – Scientific Industries Center Haifa Ltd., as supplemented on December 11, 2005, June 12, 2007 and July 19, 2011 (incorporated by reference to Exhibit 10.2 of our annual report on Form 10-K filed September 12, 2011).

10.3 Summary of Supplement to the Lease Agreement by and between Pluristem Ltd. and MTM – Scientific Industries Center Haifa Ltd dated July 31, 2012 (incorporated by reference to Exhibit 10.3 of our annual report on Form 10-K filed on September 11, 2013).

10.4 Summary of Supplement to the Lease Agreement by and between Pluristem Ltd. and MTM – Scientific Industries Center Haifa Ltd dated December 31, 2012 (incorporated by reference to Exhibit 10.4 of our annual report on Form 10-K filed on September 11, 2013).

10.5 Summary of Supplement to the Lease Agreement by and between Pluristem Ltd. and MTM – Scientific Industries Center Haifa Ltd dated February 3, 2015 (incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q filed on May 6, 2015).

10.6 Assignment Agreement dated May 15, 2007 between Pluristem Therapeutics Inc. and each of Technion Research and Development Foundation Ltd., Shai Meretzki, Dr. Shoshana Merchav (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on May 24, 2007).

10.7 Assignment Agreement dated May 15, 2007 between Pluristem Therapeutics Inc. and Yeda Research and Development Ltd. in (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on May 24, 2007).

10.8[^] Exclusive License Agreement dated June 19, 2011, between Pluristem Ltd. and United Therapeutics Corporation (incorporated by reference to Exhibit 10.5 of our annual report on Form 10-K filed on September 12, 2011).

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

- 10.9 Exclusive License and Commercialization Agreement dated June 26, 2013, between Pluristem Ltd. and CHA (incorporated by reference to Exhibit 10.8 of our annual report on Form 10-K filed on September 11, 2013).
- 10.10 Summary of Directors' Ongoing Compensation. (incorporated by reference to Exhibit 10.8 of our annual report on Form 10-K filed September 12, 2011). +
- 10.12 The Amended and Restated 2005 Stock Option Plan (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on January 23, 2009). +
- 10.13 2016 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 4, 2016). +
- 10.14 Form of Stock Option Agreement under the Amended and Restated 2005 Stock Option Plan. (incorporated by reference to Exhibit 10.4 of our annual report on Form 10-K filed on September 23, 2009). +
- 10.15 Form of Restricted Stock Agreement under the Amended and Restated 2005 Stock Option Plan. (incorporated by reference to Exhibit 10.16 of our annual report on Form 10-K filed on September 23, 2009). +
- 10.16 Form of Restricted Stock Agreement (Israeli directors and officers) under the Amended and Restated 2005 Stock Option Plan. (incorporated by reference to Exhibit 10.17 of our annual report on Form 10-K filed on September 23, 2009). +
- 10.17* Form of Stock Option Agreement under the 2016 Equity Compensation Plan.
- 10.18* Form of Restricted Stock Agreement under the 2016 Equity Compensation Plan.
- 10.19* Form of Restricted Stock Agreement (Israeli directors and officers) under the 2016 Equity Compensation Plan.
- 10.20 Letter of Approval Number 37245 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.16 of our annual report on Form 10-K filed on September 11, 2014).
- 10.21 Letter of Approval Number 38481 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.17 of our annual report on Form 10-K filed on September 11, 2014).
- 10.22 Letter of Approval Number 40100 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.18 of our annual report on Form 10-K filed on September 11, 2014).
- 10.23 Letter of Approval Number 41702 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.19 of our annual report on Form 10-K filed on September 11, 2014).
- 10.24 Letter of Approval Number 42075 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.20 of our annual report on Form 10-K filed on September 11, 2014).
- 10.25 Letter of Approval Number 43729 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.21 of our annual report on Form 10-K filed on September 11, 2014).

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-K

10.26 Letter of Approval Number 44056 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.22 of our annual report on Form 10-K filed on September 11, 2014).

10.27 Letter of Approval Number 45703 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.23 of our annual report on Form 10-K filed on September 11, 2014).

10.28 Letter of Approval Number 46927 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.24 of our annual report on Form 10-K filed on September 11, 2014).

10.29 Letter of Approval Number 47578 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.25 of our annual report on Form 10-K filed on September 11, 2014).

10.30 Letter of Approval Number 48070 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.26 of our annual report on Form 10-K filed on September 11, 2014).

10.31 Letter of Approval Number 49845 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.27 of our annual report on Form 10-K filed on September 11, 2014).

10.32 Letter of Approval Number 50435 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K filed on September 11, 2014).

10.33 Letter of Approval Number 52103 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K filed on September 11, 2014).

10.34 Letter of Approval Number 52802 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.30 of our annual report on Form 10-K filed on September 11, 2014).

10.35 Letter of Approval Number 54516 to Pluristem Ltd. from Israel's Office of the Chief Scientist (translation from Hebrew) (incorporated by reference to Exhibit 10.33 of our annual report on Form 10-K filed on September 9, 2015).

10.36* Letter of Approval Number 56904 to Pluristem Ltd. from the Israel Innovation Authority (previously the Office of the Chief Scientist) (translation from Hebrew).

10.37* Letter of Approval Number 57989 to Pluristem Ltd. from the Israel Innovation Authority (previously the Office of the Chief Scientist) (translation from Hebrew).

21.1 List of Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 of our annual report on Form 10-K filed on September 29, 2008).

23.1* Consent of Kost Forer Gabbay & Kasierer, A member of Ernst & Young Global.

31.1* Certification pursuant to Rule 13a-14(a)/15d-14(a) of Zami Aberman.

31.2* Certification pursuant to Rule 13a-14(a)/15d-14(a) of Yaky Yanay.

63

32.1** Certification pursuant to 18 U.S.C. Section 1350 of Zami Aberman.

32.2** Certification pursuant to 18 U.S.C. Section 1350 of Yaky Yanay.

The following materials from our Annual Report on Form 10-K for the fiscal year ended June 30, 2016 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Statements of Changes in Equity, (v) the Consolidated Statements of Cash Flows, and (vi) the Notes to the Consolidated Financial Statements, tagged as blocks of text and in detail.

* Filed herewith.

** Furnished herewith.

+ Management contract or compensation plan.

^ Confidential treatment granted as to certain portions.

64

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Pluristem Therapeutics Inc.

By: /s/ Zami Aberman
Zami Aberman, Chief Executive Officer

Dated: September 7, 2016

By: /s/ Yaky Yanay
Yaky Yanay, Chief Financial Officer, Chief Operating Officer and President

Dated: September 7, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ Zami Aberman
Zami Aberman, Chief Executive Officer
(Principal Executive Officer)
Chairman of the Board and Director
Dated: September 7, 2016

By: /s/ Israel Ben-Yoram
Israel Ben-Yoram, Director
Dated: September 7, 2016

By: /s/ Isaac Braun
Isaac Braun, Director
Dated: September 7, 2016

By: /s/ Mark Germain
Mark Germain, Director
Dated: September 7, 2016

By: /s/ Moria Kwiat
Moria Kwiat, Director
Dated: September 7, 2016

By: /s/ Hava Meretzki
Hava Meretzki, Director
Dated: September 7, 2016

By: /s/ Nachum Rosman
Nachum Rosman, Director
Dated: September 7, 2016

By: /s/ Doron Shorrer

Doron Shorrer, Director

Dated: September 7, 2016

By: /s/ Yaky Yanay

Yaky Yanay, Chief Financial Officer, Chief Operating Officer, President and Director
(Principal Financial and Accounting Officer)

Dated: September 7, 2016