Pluristem Therapeutics Inc.

Inspired by Life

# 2019 ANNUAL REPORT

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

## FORM 10-K

(Mark One)

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

For the fiscal year ended **June 30, 2019**

[ ] 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** | **3508409** |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number **011-972-74-7108600**

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

| Title of each class | Trading Symbol | | Name of each exchange on which registered |
|---|---|---|---|
| **Common Stock, par value $0.00001** | **PSTI** | | **Nasdaq Capital Market** |

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

**None.**

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐
Smaller reporting company ☒ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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.

$85,199,084

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

15,547,621 as of September 4, 2019

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

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

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

All information in this Annual Report on Form 10-K or Annual Report, relating to shares or price per share reflects the 1-for-10 reverse stock split effected by us on July 25, 2019.

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The statements contained in this 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;
- our plan to execute our strategy independently, using our own personnel, and through relationships with research and clinical institutions or in collaboration with other companies;
- our entering into certain contracts with third parties;
- the prospects of entering into additional license agreements, or other forms of cooperation with other companies and medical institutions;
- our pre-clinical and clinical trials plans, including timing of initiation, enrollment and conclusion of trials;
- the expected timing of the release of data from our various studies;
- achieving regulatory approvals, including under accelerated paths;
- receipt of future funding from the Israel Innovation Authority, or IIA, the European Union's Horizon 2020 program, the Biomedical Advanced Research and Development Authority, or BARDA, as well as grants from other independent third parties;

- our marketing plans, including timing of marketing our product candidates, PLX-PAD and PLX-R18, and the filing of any requests for marketing authorization;
- developing capabilities for new clinical indications of placenta expanded (PLX) cells and new products;
- the timing and development of our PLX-Immune product candidate;
- the potential manufacturing of cannabinoid-producing cells in our 3D bioreactors systems;
- our estimations regarding the size of the global market for our product candidates;
- our expectations regarding our production capacity, including the use of our serum-free formulation;
- our expectation to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity;
- 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, or CLI, muscle recovery following surgery for hip fracture, and acute radiation syndrome, or ARS. Each of these indications is a severe unmet medical need. 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.

PLX cells are derived from a class of placental cells that are harvested from donated placenta at the time of full term healthy delivery of a 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 the European, Japanese, Israeli, South Korean and U.S. Food and Drug Administration, or FDA's, current Good Manufacturing Practice requirements and has been approved by the European and Israeli regulators for production of PLX-PAD for late stage trials. In December 2017, after an audit of our facilities, we were granted manufacturer/importer authorization and Good Manufacturing Practice Certification by Israel's Ministry of Health. If we obtain FDA and other regulatory approvals to market PLX cells, we expect to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

Our goal is to make significant progress with our clinical pipeline and our clinical pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We expect to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity. Our business model for commercialization and revenue generation includes, but is not limited to, direct sale of our products, partnerships, licensing deals, and joint ventures with pharmaceutical companies.

We aim to shorten the time to commercialization of our product candidates by leveraging unique accelerated regulatory pathways that exist in the United States, Europe and other territories to bring innovative products that address life-threatening diseases to the market efficiently. We believe that these accelerated pathways create substantial opportunities for us and for the cell therapy industry as a whole.

We have determined to invest our resources primarily on the PLX-PAD Phase III clinical trials relating to CLI and muscle recovery following surgery for hip fracture, and focus on finalizing the clinical trials in the United States, Europe and Israel while we prepare for the marketing phase, with the initiation of such marketing phase subject to regulatory approval, in these territories.

Two pivotal, Phase III multinational clinical trials are currently being conducted with our PLX-PAD product candidate: one in CLI, and the other in muscle recovery following surgery for hip fracture. In April 2019, we successfully enrolled over 50% of patients in our Phase III study in CLI, which allows for an interim analysis of efficacy after a one-year follow-up period under the European Medicines Agency's, or EMA, Adaptive Pathways pilot project, or the Adaptive Pathways Project, in which PLX-PAD was selected to participate. Based on our current patient enrollment progress, we expect to complete the follow up of our Phase III study in CLI in the first half of 2020 with respect to Europe, and in the first half of 2021 with respect to the United States. In addition, based on our current patient enrollment progress, we expect to complete the efficacy follow up of our Phase III study in muscle recovery following surgery for hip fracture in the second half of 2020. We expect to release the clinical trial results shortly after the conclusion of the follow ups.

Our PLX-PAD cell program in CLI had been selected for the EMA's Adaptive Pathways Project, Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, accelerated pathway, the FDA Fast Track Designation and FDA Expanded Access Program, or EAP, in the United States. The CLI program in the European Union was awarded a Euro 7,600,000 (approximately $8,700,000) grant as part of the European Union's Horizon 2020 program and to date we have received a portion of such grant.

Our PLX-PAD cell program in muscle recovery following surgery for hip fracture was also selected for the EMA's Adaptive Pathways Project and was awarded a Euro 7,400,000 (approximately $8,400,000) grant as part of the European Union's Horizon 2020 program and to date we have received a portion of such grant.

Our second product candidate, PLX-R18, is under development in the United States for ARS via the FDA Animal Rule regulatory pathway, and, based on our assessment, is expected to advance to a pivotal trial, which may also result in approval without the prior performance of human efficacy trials. The National Institutes of Health's National Institute of Allergy and Infectious Diseases has completed a dose selection trial with our PLX-R18 product candidate in the hematologic component of ARS.

We are targeting to submit a proposal for a contract with the U.S. government in the second half of 2019 to fund an additional non-human primates, or NHPs study. We are also targeting to receive funding from BARDA for the full cost of the ARS pivotal trial during 2020.

PLX-R18 is also under development in the United States and Israel for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation, or HCT. In March 2019, we announced that we had fully enrolled the second cohort of six patients in our ongoing Phase I clinical trial in HCT, and received data and safety monitoring board approval to continue to the final cohort of the trial. In September 2018, we announced that the FDA granted orphan drug designation to our PLX cell therapy for the treatment of graft failure and incomplete hematopoietic recovery following HCT.

**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 a large number 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 placenta based 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, we believe that 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.

Our first product candidate, PLX-PAD, is currently in a Phase III multinational clinical trial in CLI, and in a Phase III multinational clinical trial in recovery following surgery for hip fracture. We have also completed Phase II multinational clinical trial in intermittent claudication, or IC, and a Phase I/II is currently conducted with our PLX-PAD by Tel Aviv Sourasky Medical Center (Ichilov Hospital) for the treatment of Steroid-Refractory Chronic Graft-Versus-Host-Disease.

Our second product candidate, PLX-R18, is under development in the United States for ARS via the FDA Animal Rule regulatory pathway, as well as in a Phase I trial in the United States and Israel for incomplete hematopoietic recovery following HCT.

Our third product candidate, PLX-Immune is under pre-clinical development for treatment of certain types of human cancer.

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 additional PLX cell therapy products and indications.

**Our Clinical Development Product Candidates**

**Peripheral and Cardiovascular Diseases –** We are investigating the use of PLX-PAD cells for the treatment of various stages of peripheral arterial disease, or PAD, from early stage IC to advanced CLI.

In May 2015, our CLI clinical development program was selected for the EMA's Adaptive Pathways Project. The goal of the project is to improve timely access for patients to new medicines. During our fiscal year ended June 30, 2017, the FDA and several EU regulatory agencies cleared our application to begin the pivotal Phase III trial of PLX-PAD cells in the treatment of CLI for patients with minor tissue loss (Rutherford Category 5) who are unsuitable for revascularization. This multinational Phase III trial is being conducted in the United States, Europe and Israel. In September 2017, we announced that the FDA granted a fast track designation to our ongoing Phase III study of PLX-PAD for the treatment of CLI. The FDA's fast track designation is a process designed to facilitate the development and expedite the review of drug to treat serious conditions and unmet medical needs. With fast track designation, there is an increased possibility for a priority review by the FDA of PLX-PAD cells for the treatment of CLI.

Our intention is to file a request for marketing authorization in the United States and in Europe following a successful completion of this 246-patient trial. In April 2019, we successfully enrolled over 50% of patients in our Phase III study in CLI, which allows for an interim analysis of efficacy after a one-year follow-up period. If the interim analysis yields positive results, it could lead to early conditional marketing approval in Europe.

In January 2018, we announced that the FDA cleared our EAP for the use of our PLX-PAD cell treatment in patients with CLI. In October 2018, we announced that the FDA approved cost recovery for our PLX-PAD under an EAP held by Wide Trial, Inc., or Wide Trial, a privately-held third-party sponsor. In April 2019, we announced the initiation of our FDA approved EAP, with several site initiations in the United States. Under the terms of the EAP, an initial cohort of 100 Rutherford-5 CLI patients who are ineligible for inclusion under our ongoing Phase III study protocol can be enrolled and treated.

We have completed two Phase I safety/dose-escalating 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 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 66% in patients from placebo arms in other CLI trials.

In June 2018, we announced the results from our 172 patients, randomized, double blind, placebo controlled, and multinational Phase II clinical trial in IC. Analysis of the Phase II IC data, which was announced on November 2018, confirmed the optimal dosing regimen of PLX-PAD in the treatment of PAD - two administrations of 300 million cells, each originating from a different donor. This is also the treatment regimen being administered to patients in the Company's ongoing multinational Phase III study in CLI, a more severe stage of PAD. PLX-PAD treated patients showed a good safety profile in the study.

In April 2015, Japan's PMDA approved our large-scale manufacturing methods and quality for PLX-PAD cells for use in clinical trials. In August 2015, the PMDA granted safety clearance to PLX-PAD cells for use in clinical trials in Japan, and in December 2015 we reached an agreement with the PMDA on the design of the final trial needed to apply for conditional marketing approval of PLX-PAD cells in the treatment of CLI. Currently, as part of our strategy to focus on our active clinical trials and marketing readiness, we have not initiated clinical trial activities in Japan.

**Orthopedic Diseases –** In April 2018, we announced that the FDA cleared our Investigational New Drug, or IND, for our Phase III trial for recovery following surgery for hip fracture. This multinational Phase III trial is being conducted in the United States, Europe and Israel. The EMA confirmed that recovery following surgery for hip fracture is eligible for the Adaptive Pathways Project as well.

Our Phase III trial protocol and design was based on our phase I/II, randomized, double-blind, placebo-controlled study (n=20) 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 PEI. In this study, PLX-PAD cells or placebo were administered into the traumatized gluteal muscle during total hip replacement surgery. The study results met its primary efficacy endpoint, 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). In addition, the study demonstrated that PLX-PAD was safe and well tolerated by the patients.

**Recovery Following HCT –** In March 2015, we reported positive data from three independent preclinical trials 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 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. In February 2018, we announced that a peer-reviewed journal published key animal findings from a study of PLX-R18 that demonstrate the cells' efficacy in improving human hematopoietic engraftment. 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.

PLX-R18 is under development in a Phase I clinical trial in the United States and Israel for incomplete hematopoietic recovery following HCT, which was initiated in fiscal year 2017.

**ARS –** We have conducted several animal studies for the evaluation of PLX-R18 for the treatment of ARS, in collaboration with the NIAID. The U.S. National Institutes of Health, or NIH, funded and conducted a pilot study in NHPs to evaluate the therapeutic effect of PLX-R18 on hematological aspects of ARS. In May 2017, we announced results of the NHPs pilot study for PLX-R18 as a treatment for ARS. Although study size was not designed to show significance, results showed a trend toward improved survival of PLX-R18 treated animals compared to control, placebo treated animals. The study, conducted and funded by the NIAID, was designed to assess the safety and efficacy of PLX-R18 following intramuscular injection into irradiated and non-irradiated NHPs. Efficacy measures included survival as well as hematological parameters which are affected by exposure to high levels of radiation as may occur in a nuclear accident or attack. These data will help the design of a pivotal study to fulfill the requirements for a Biologics License Application submission under the FDA's Animal Rule regulatory pathway.

We plan to continue the discussions with the different government agencies with the goal of receiving their support for pivotal studies in large animals as well as conducting the safety studies required in order to file BLA for this indication.

In October 2017, we announced that the FDA granted us an orphan drug designation for our PLX-R18 cell therapy for the prevention and treatment of ARS.

In April 2018, we announced that the FDA approved our IND application for PLX-R18 cell therapy in the treatment of ARS. The IND allows us to treat victims who may have been acutely exposed to high dose radiation due to nuclear attack or accident.

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. In June 2018, we reported positive animal data from studies conducted in collaboration with Fukushima Medical University evaluating PLX-R18 cells as a treatment for radiation damage to the gastrointestinal, or GI, tract and bone marrow. Data from these studies showed that PLX-R18 cells significantly increased survival rates, preserved GI stem cells activity that enhance the recovery of the GI system and prevented severe damage to the intestinal lining, suggesting PLX-R18 potential as a multi-organ therapy for ARS.

In July 2019, we presented positive results from a series of studies of our PLX-R18 cell therapy product conducted by the U.S. Department of Defense's, or DoD, Armed Forces Radiobiology Research Institute, part of the Uniformed Services University of Health Sciences. The studies were designed to evaluate PLX-R18 as a potential prophylactic countermeasure against ARS administered prior to radiation exposure. These animal studies demonstrate that PLX-R18, administered 24 hours before radiation exposure, and again 72 hours after exposure, resulted in a significant increase in survival rates, from 4% survival rate in the placebo group to 74% in the treated group. In addition, the data show an increase in recovery of blood lineages and a favorable safety profile. Furthermore, histopathological analysis and hematopoietic progenitor clonogenic assay of tissues collected show a significant increase in bone marrow cell numbers and improved regenerative capability into all blood lineages.

**Other Indications** – In September 2017, we signed an agreement with Tel Aviv Sourasky Medical Center (Ichilov Hospital) to conduct a clinical Phase I/II trial of PLX-PAD cell therapy for the treatment of Steroid-Refractory Chronic Graft-Versus-Host-Disease. This trial is an investigator initiated study. As such, Tel Aviv Sourasky Medical Center supports the study and is responsible for its design and implementation.

In January 2018, we announced the publication of a peer-reviewed article in a journal which examined the effect of PLX-Immune cells on the proliferation of over 50 lines of human cancerous cells. Data showed that the PLX-Immune cells exhibited an anti-proliferative effect on a wide range of human cancer cell types, with a strong inhibitory effect on various lines of breast, colorectal, kidney, liver, lung, muscle and skin cancers. We have also conducted a pre-clinical trial of female mice harboring human triple negative breast cancer. In this study, the results showed a statistically significant reduction in tumor size as well as complete tumor remission in 30% of treated recipients.

In June 2018, we announced that we entered into collaboration with the U.S. DoD and its United States Army Medical Research Institute of Chemical Defense to study PLX-R18 in the treatment of long term lung injuries following exposure to mustard gas. These non-clinical trials will be funded by the NIH.

In January 2019, we announced a successful one-year follow up of a compassionate use treatment in a Buerger's disease patient treated with our PLX-PAD cell therapy.

**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, Germany's PEI as well as other European national competent authorities, the Israeli Minister of Health, or MOH and Japan's PMDA, 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 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 Project's 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. We have applied early to this program and have been selected for it.

In September 2017, we announced that the FDA granted "Fast Track" designation for PLX-PAD in CLI. The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and unmet medical needs. With Fast Track designation, there is an increased possibility for a priority review by the FDA of PLX-PAD cells for the treatment of CLI.

In January 2018, we announced that the FDA cleared our EAP for the use of our PLX-PAD cell treatment in patients with CLI. In October 2018, we announced that the FDA approved cost recovery for our PLX-PAD under an EAP held by Wide Trial, a privately-held third-party sponsor. EAP allows the use of an investigational medical product outside of clinical trials and is usually granted in cases where patients are unsuitable for inclusion under the study protocol and the patient's condition is life-threatening with an unmet medical need. As part of the EAP, our PLX-PAD cell therapy is available to a limited number of CLI patients in the United States who are unsuitable for revascularization and cannot take part in the our ongoing Phase III clinical trial.

***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 139 issued patents and 89 pending 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.

In February 2017, the Subsidiary signed an agreement with founders of a certain patent for a five year option to purchase the certain patent for an amount of 1 million Euro. The agreement includes yearly payments of Euro 75,000, 75,000 and 100,000 in February 2017, 2018 and 2019, respectively, which have been paid. We are entitled to terminate the agreement for convenience upon providing the founders 30 days prior notice.

In May 2019, we filed a U.S. provisional patent application titled "Methods and Compositions for Producing Cannabinoids," which covers the use of our state-of-the-art, proprietary 3-D cell culturing technology for the potential manufacturing of cannabinoid-producing cells.

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 2036.

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, Mexico, New Zealand | February 4, 2020 |
| **METHODS FOR CELL EXPANSION AND USES OF CELLS AND CONDITIONED MEDIA PRODUCED THEREBY FOR THERAPY PCT/IL2007/000380** | United States, China, Hong Kong, Canada, Brazil | Japan, Europe, Israel, Singapore, Russia, South Africa, Australia, India, South Korea, Mexico, Hong Kong, China | March 23, 2027 |
| **ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY** | United States, Europe, Israel, China, Hong Kong, | United States, Europe, Singapore, Australia, Hong | September 2, 2028 |

| | | | |
|---|---|---|---|
| **PCT/IL2008/001185** | Brazil, Russia | Kong, South Africa, India, Mexico, Japan, South Korea, Canada, China, Israel | |
| **METHODS OF TREATING INFLAMMATORY COLON DISEASES PCT/IL2009/000527** | United States | United States, Israel, Russia, South Africa | May 26, 2029 |
| **METHODS OF SELECTION OF CELLS FOR TRANSPLANTATION PCT/IL2009/000844** | | Europe, Israel | September 1, 2029 |
| **ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000846** | Hong Kong, China | United States, Russia, Australia, South Africa, Mexico, Europe, Canada, Singapore, Hong Kong, Israel, India | September 1, 2029 |
| **ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000845** | | United States, Europe, Israel | September 1, 2029 |
| **ADHERENT STROMAL CELLS DERIVED FROM PLANCENTAS OF MULTIPLE DONORS AND USES THEREOF PCT/IB2011/001413** | United States | Israel, Europe, Hong Kong | April 21, 2031 |
| **ADHERENT CELLS FROM PLACENTA AND USE OF SAME IN DISEASE TREATMENT PCT/IB2010/003219** | United States, China, Israel, India | United States, Europe, China, Canada, Australia, New Zealand, South Africa, Hong-Kong, Mexico, Israel | November 29, 2030 |
| **METHODS AND SYSTEMS FOR HARVESTING ADHERENT STROMAL CELLS PCT/IB2012/000933** | United States, China, Europe, Hong Kong, Israel, India | United States, Canada, Israel, Australia, Mexico, Singapore, South Africa, South Korea | April 15, 2032 |
| **METHODS FOR TREATING RADIATION OR CHEMICAL INJURY PCT/IB2012/000664** | United States, Hong Kong, Israel | Europe, Japan, South Korea, Israel, Hong Kong, Israel | March 22, 2032 |
| **SKELETAL MUSCLE REGENERATION USING MESENCHYMAL STEM CELLS** | | United States, Europe, Israel, Hong Kong | May 27, 2031 |

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| **PCT/EP2011/058730** | | | |
| **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** | India | United States, Canada, China, Israel, Japan, Singapore, Australia, Hong Kong, South Korea, Russia, Mexico | August 31, 2033 |
| **METHODS FOR PREVENTION AND TREATMENT OF PREECLAMPSIA PCT/IB2013/058186** | Israel, Singapore, Hong Kong | United States, Europe, China, Australia, South Africa, Japan, Korea, | August 31, 2033 |
| **METHOD AND DEVICE FOR THAWING BIOLOGICAL MATERIAL PCT/IB2013/059808** | Europe, China, South Korea, Canada, Israel, Hong Kong | United States, Australia, Singapore, Japan, India, Russia | October 31, 2033 |
| **SYSTEMS AND METHODS FOR GROWING AND HARVESTING CELLS PCT/IB2015/051559** | Europe, Israel | United States | March 3, 2035 |
| **METHODS AND COMPOSITIONS FOR TREATING AND PREVENTING MUSCLE WASTING DISORDERS PCT/IB2015/059763** | Israel | United States | December 18, 2035 |
| **USE OF ADHERENT STROMAL CELLS FOR ENHANCING HEMATOPOIESIS IN A SUBJECT IN NEED THEREOF PCT/IB2016/051585** | United States, China, Israel | | March 21, 2036 |
| **ALTERED ADHERENT STROMAL CELLS AND METHODS OF PRODUCING AND USING SAME PCT/IB2016/053310** | United States, Europe, China, Israel | | June 6, 2036 |
| **METHODS AND COMPOSITIONS FOR** | United States, Europe, Japan, | | February 16, 2037 |

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| **TREATING CANCERS AND NEOPLASMS PCT/IB2017/050868** | Canada, Australia, Israel | | |
| **METHODS AND COMPOSITIONS FOR TREATING NEUROLOGICAL DISORDERS PCT/IB2018/052806** | Patent Cooperation Treaty | | |
| **METHODS AND COMPOSITIONS FOR TUMOR ASSESSMENT PCT/IB2018/050984** | United States, Israel | | |
| **METHODS AND COMPOSITIONS FOR TREATING ADDICTIONS PCT/IB2018/055473** | Patent Cooperation Treaty | | |
| **METHODS AND COMPOSITIONS FOR DETACHING ADHERENT CELLS US 16/026,199** | United States, Israel, Germany | | |
| **DRUG CONTAINING HUMAN PLACENTA-ORIGIN MESENCHYMAL CELLS AND PROCESS FOR PRODUCING VEGF USING THE CELLS JP20030579842** | | Japan | March 28, 2023 |
| **METHODS AND COMPOSITIONS FOR PRODUCING CANNABINOIDS** | United States (provisional) | | (Not yet determined) |

***Research and Development***

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.

Collaborations and Ongoing Research and Development Plans

Charité Agreement

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. In June 2017, we extended our collaborative research agreement with Charité for a period of additional five 5 years, through June 2022. 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.

Fukushima Medical University

We signed an MOU 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. The MOU for a collaboration with Fukushima will be renewed automatically on a yearly basis. Each party is entitled to terminate the agreement for convenience upon providing the other party 30 days prior notice.

CHA Agreement

On June 26, 2013, we entered into an exclusive out-licensing and commercialization agreement, or the CHA Agreement, with CHA Biotech Co. Ltd., or 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 trial that was performed as part of the CHA Agreement was a Phase II trial in IC. 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 with the purpose of commercializing 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.

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.

Horizon 2020

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 the participation of additional third parties.

Our Phase III study of PLX-PAD cell therapy in the treatment of muscle recovery following surgery for hip fracture will be a collaborative project carried out by an international consortium led by Charité, together with us and with the participation of additional third parties.

In October 2017, we entered into a collaborative project, the nTRACK, carried out by an international consortium led by Leitat. The aim of this project is to examine gold nano particles labeling of stem cells to enable assessment of cells' in vivo persistence and distribution in correlation to biological efficacy. Under the project, PLX cells, labeled and non-labeled will be characterized and examined in animal models for muscle injury.

Indiana University

In April 2018, NIAID awarded a $2.5 million grant to Indiana University to conduct, together with us, studies of our PLX-R18 cell therapy in the treatment of ARS. The goal of this project is to extend the PLX-R18 ARS studies to include examination of survival in pediatric and geriatric populations as well as the ability of PLX-R18 to alleviate delayed effects of radiation in survivors.

Thermo Fisher

In July 2018, we entered into a strategic collaboration agreement with Thermo Fisher Scientific Inc., or Thermo Fisher, with the aim of advancing the fundamental knowledge of cell therapy industrialization and to improve quality control of the end-to-end supply chain. The collaboration will combine Thermo Fisher's experience in cell therapy development and bioproduction scaleup with our expertise in cell therapy manufacturing, clinical development and quality control.

Chart Industries

In November 2018, we entered into a license agreement with a subsidiary of Chart Industries, Inc., or Chart, regarding our thawing device for cell-based therapies. Pursuant to the terms of the agreement, Chart obtained the exclusive rights to manufacture and market the thawing device in all territories worldwide, excluding Greater China, and we are to receive royalties from sales of the product and supply of an agreed upon number of thawing devices. Royalties shall commence on the date of Chart's first commercial sale of the thawing device.

Burn injuries joint grant

In January 2019, we announced the receipt of a joint grant awarded by the Israeli Ministry of Defense and the IIA for the pre-clinical development of our PLX cells for the treatment of burn injuries. We have decided to suspend this current collaboration in the near term, as we focus our attention on our on-going Phase III clinical trials.

NASA

In February 2019, we entered into a collaboration with NASA's Ames Research Center to evaluate the potential of our PLX cell therapies in preventing and treating medical conditions caused during space missions.

U.S. DoD

In August 2017, we announced that a pilot study of our PLX-R18 cell therapy was initiated by the U.S. DoD. The study is examining the effectiveness of PLX-R18 as a treatment for ARS prior to, and within the first 24 hours of exposure to radiation. In July 2019, we presented positive results from a series of studies of our PLX-R18 cell therapy product conducted by the U.S. DoD.

Israeli Duchenne Association

We have performed proof of concept studies from April 2015 to December 2016 in conjunction with the Israeli Duchenne Association to assess the utility of PLX-PAD in alleviating symptoms of Duchenne muscular dystrophy.

RESTORE

In February 2019, we announced that the large-scale research initiative, the RESTORE project, of which we are a member, has received funding of Euro 1,000,000 (approximately $1,100,000) from the European Union's Horizon 2020 research and innovation program, to submit a full grant application for the development and advancement of transformative therapeutics. We expect the members of the RESTORE project to collectively submit the grant application in the first quarter of the 2020 calendar year.

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, EMA, 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.

The site was also inspected and approved by Israel's Ministry of Health and we received a GMP certification and manufacturer-importer authorization. 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.

In June 2019, we announced that we developed a serum-free formulation to support the manufacturing of cell therapy products. This serum-free formulation was developed using our deep understanding in cell therapy industrial scale production standards, and the quality methods designed to support implementation in Phase III development and marketing. Achieving this significant technological challenge is expected to provide us with large-scale, highly-consistent production capacity with operational independency from third party suppliers for standard serum, an expensive and quantity limited product. PLX-R18 is the first product candidate that we intend to manufacture using the serum-free media, which is expected to be followed by PLX-PAD.

**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. In addition, the manufacturing conditions are specifically inspected by the Israeli Ministry of Health.

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 trials 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 trials 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;

- FDA may grant approval for EAP prior to the completion of clinical trials, in order to allow access for the investigational drug, for patients that are excluded from the study.

- FDA may grant priority review status, in order to expedite the Biologics License Application, or BLA, review process. Obtaining of a Fast Track designation allows access for the request of priority review.

- Submission to the FDA of a BLA for marketing authorization of the product, which must include adequate results of pre-clinical testing and clinical trials;

- Submission of BLA with a proof of efficacy that is based only on animal studies, where human efficacy studies cannot be conducted because the conduct of such trials is unethical and field trials after an accidental or deliberate exposure are not feasible.

- 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 via a centralized 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 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 EMA Adaptive Pathways Project, with the potential to reach the market several years faster than the traditional regulatory approval pathway. Representatives of the Adaptive Pathways Project at the EMA are advising us with respect to the clinical development of PLX-PAD in CLI and in recovery following surgery for hip fracture.

Other Regulations

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.

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.

Clinical Trials

Typically, in the United States, as well as in the European Union, clinical testing involves a three-phase process, although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers, or patients 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 trial based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

***Employees***

We presently employ a total of 160 full-time employees and 5 part-time employees, of whom 131 full-time employees and 5 part-time employees are engaged in research and development, 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.

While there are hundreds of companies in the regenerative medicine space globally, 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., Celularity – a spin-off of Celgene Corporation, Tigenix NV (acquired by Takeda), SanBio Inc., Healios K.K., Cytori Therapeutics, Cesca. and Mesoblast LTD. Among other things, we expect to compete based upon our intellectual property portfolio, our in-house manufacturing efficiencies and capabilities, and the efficacy of our products. Our ability to compete successfully will depend on our continued ability to attract and retain experienced and skilled executives, 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 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 on the SEC’s 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 independent registered public accounting firm's report states that there is a substantial doubt that we will be able to continue as a going concern.***

We anticipate that our principal sources of liquidity as of June 30, 2019, together with the funds received under the Open Market Sales Agreement[SM], or the Sales Agreement, with Jefferies LLC, or Jefferies, as agent, during July and August 2019, will only be sufficient to fund our activities into the first quarter of the Company's fiscal year 2021. As of June 30, 2019, we had cash and cash equivalents, short-term bank deposits and restricted cash and long-term bank deposits of $24.8 million.

We need to obtain additional funding by the first quarter of our fiscal year 2021 in order to continue to fund our operations, and we cannot provide any assurance that we will be successful in doing so. Our independent registered public accounting firm, Kost Forer, Gabbay & Kassierer, a Member of Ernst & Young Global, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended June 30, 2019, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

***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, enter into collaborations and licensing deals 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.

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

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

***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 one Phase I/II clinical trial of Gluteal Musculature rehabilitation after total hip arthroplasty (efficacy, ongoing for safety), two Phase I clinical trials for CLI, and one Phase II clinical trial in IC. 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, 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, 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 or the EMA (or, if we seek to conduct development efforts in Japan, 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 other regulatory bodies 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, MOH 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 MOH 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, MOH 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, MOH and other regulatory authorities.

***The results of our clinical trials may not support our product candidates claims or any additional claims we may seek for our product candidates and our clinical trials may result in the discovery of adverse side effects.***

Even if any clinical trial that we need to undertake is completed as planned, or if interim results from existing clinical trials are released, we cannot be certain that such results will support our product candidates claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

***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 one 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.

***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.

***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.

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

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

***There are very few drugs and limited therapies that the FDA or EMA 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, muscle recovery following surgery for hip fracture 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.

***The clinical manufacturing process for cell therapy products is complex and requires meeting high regulatory standards. Any delay or problem in the clinical manufacturing of PLX may result in a material adverse effect on our business.***

Our manufacturing process, controls, equipment and quality system 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.

***Because we received grants from the 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".

***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 commercializing cell production technology. Until we entered into the United Agreement, which was terminated in December 2015, we did not generate any revenues. While we generated minimal revenue for the year ended June 30, 2018 and 2019, it is not clear when we will generate additional revenues or whether we will experience further delays in recognizing revenues such as if we experienced 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.

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

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

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

***The 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 effect 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.

***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, subcontractors and material suppliers, fees for consultants and lease payments on our facilities. During the year ended June 30, 2019, or fiscal year 2019, we entered into options contracts 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 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.

***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 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 and cash equivalents and bank deposits. 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, 2019. Currently, we hold part of our current assets in bank deposits. 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.

***Although our internal control over financial reporting was considered effective as of June 30, 2019, there is no assurance that our internal control over financial reporting will continue to be effective in the future, which could result in our financial statements being unreliable, government investigations or loss of investor confidence in our financial reports.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish an annual report by our management assessing the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. In addition, our independent registered public accounting firm must annually provide an opinion on the effectiveness of our internal control over financial reporting. Management's report as of the end of fiscal year 2019 concluded that our internal control over financial reporting was effective. In addition, our registered independent public accounting firm provided an opinion that our internal control over financial reporting was effective as of the end of fiscal year 2019. 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 most 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.***

Most 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 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 intend to decrease our dependency in third-party suppliers for raw materials. To that effect we have developed a serum-free formulation which is expected to support the manufacturing of cell therapy products. This serum-free formulation was developed using our deep understanding in cell therapy industrial scale production standards, and the quality methods designed to support implementation in Phase III development and marketing. Achieving this significant technological challenge is expected to provide us with large-scale, highly consistent production with operational independency from third party suppliers for standard serum, an expensive and quantity limited product. There can be no guarantee that we will successfully implement the use of our serum-free formulation to support the manufacturing of cell therapy products or any other future product candidates, if any, that we seek to produce using such formulation, or that such implementation of the serum-free formulation will decrease our dependency on third-party suppliers for raw materials.

***We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We depend and will depend upon independent investigators and collaborators, such as universities, medical institutions, CROs, vendors and strategic partners to conduct our pre-clinical and clinical trials under agreements with us. We negotiate budgets and contracts with CROs, vendors and study sites which may result in delays to our development timelines and increased costs. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, any Phase III clinical trials which we may conduct must be conducted with biologic product produced under cGMP and may require a large number of test patients. Biologic products for commercial purposes must also be produced under cGMP. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws and regulations.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, which in some instances may be limited, we cannot control whether or not they devote sufficient time and resources to our ongoing pre-clinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf.

If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

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

Recent regulatory pathways in United States, Europe and Japan may allow for early commercialization of our products and reducing the time to market our products.

The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and unmet medical needs. The FDA granted PLX-PAD with "Fast Track" designation for the treatment of CLI.

The EAP allows the use of an investigational medical product outside of clinical trials and is usually granted in cases where patients are unsuitable for inclusion under the study protocol and the patient's condition is life-threatening with an unmet medical need. The FDA has cleared PLX-PAD EAP, for the treatment of patients with CLI. As part of the EAP, our PLX-PAD cell therapy will be made available to a limited number of CLI patients in the United States who are unsuitable for revascularization and cannot take part in the our ongoing Phase III clinical trial.

The purpose of the EMA's Adaptive Pathways Project 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 discussion group that oversees a given project entering into the EMA's Adaptive Pathways Project 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. The EMA selected our PLX-PAD cell program in CLI and in recovery following surgery for hip fracture for its Adaptive Pathways 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.

***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 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 trials 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.

***Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.***

We rely on and utilize services provided by third parties in connection with our clinical trials, which services involve the collection, use, storage and analysis of personal health information.

While we receive assurances from these vendors that their services are compliant with the Health Insurance Portability and Accountability Act, or HIPAA, and other applicable privacy laws, there can be no assurance that such third parties will comply with applicable laws or regulations. Non-compliance by such vendors may result in liability for us which would have a material adverse effect on our business, financial conditions and results of operations.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While, to our knowledge, we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

***Unsuccessful compliance with certain European privacy regulations could have an adverse effect on our business and reputation.***

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GPDR also extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles and creates new obligations for companies and new rights for individuals. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. There may be circumstances under which a failure to comply with GDPR, or the exercise of individual rights under the GDPR, would limit our ability to utilize clinical trial data collected on certain subjects. The GDPR regulations impose additional responsibility and liability in relation to personal data that we process and we intend to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. Changes to these European privacy regulations and unsuccessful compliance may be onerous and adversely affect our business, financial condition, prospects, results of operations and reputation.

***We have limited experience in conducting Phase III trials. If we fail in the conduct of such trials, our business will be materially harmed.***

Even though we conducted Phase I and Phase II trials and we are currently conducting Phase III for our PLX-PAD product, and Phase I for our PLX-R18 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.

***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.

***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.

***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.

***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.

***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.

**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, where we occupy approximately 4,389 square meters. Our monthly rent payment for these leased facilities as of July 2019 was 258,000 NIS (approximately $71,000), excluding MTM - Scientific Industries Center Haifa, Ltd., or MTM, participation as described at Item 7. For the fiscal year ended June 30, 2019, we recognized an expense of $854,000, net, for rent of Building No. 5, which was offset by MATAM participation of $239,000 due to renovations made in Building No. 5.

We believe that the current space we have 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.

As of September 4, 2019, there were 111 holders of record, and 15,547,621 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) 921-8300, (800) 937-5449.

**Item 6. Selected Financial Data**

Not applicable.

**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 CLI, recovery following surgery for hip fracture and ARS. Each of these indications is a severe unmet medical need.

PLX cells are derived from a class of placental cells that are harvested from donated placenta at the time of full term healthy delivery of a 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 the European, Japanese, Israeli and FDA’s current Good Manufacturing Practice requirements and has been approved by the European and Israeli regulators for production of PLX-PAD for late stage trials and marketing. In December 2017, after an audit of our facilities, we were granted manufacturer/importer authorization and Good Manufacturing Practice Certification by Israel’s Ministry of Health. If we obtain FDA and other regulatory approvals to market PLX cells, we expect to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

Our goal is to make significant progress with our clinical pipeline and our clinical pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We expect to demonstrate a real-world impact and value from our clinical pipeline, technology platform and commercial-scale manufacturing capacity. Our business model for commercialization and revenue generation includes, but is not limited to, direct sale of our products, partnerships, licensing deals, and joint ventures with pharmaceutical companies.

We aim to shorten the time to commercialization of our product candidates, by leveraging unique accelerated regulatory pathways that exist in the United States, Europe and other territories to bring innovative products that address life-threatening diseases to the market efficiently.

We have determined to invest our resources primarily on the PLX-PAD Phase III clinical trials relating to CLI and muscle recovery following surgery for hip fracture, and focus on finalizing the clinical trials in the United States, Europe and Israel while we prepare for the marketing phase, with the initiation of such marketing phase subject to regulatory approval, in these territories.

Two pivotal, Phase III multinational clinical trials are currently conducted with our PLX-PAD product candidate: one in CLI, and the other in recovery following surgery for hip fracture.

Our second product candidate, PLX-R18, is under development in the United States for ARS via the FDA Animal Rule regulatory pathway, which may result in approval under the Animal Rule, without the performance of human efficacy trials.

*RESULTS OF OPERATIONS – YEAR ENDED JUNE 30, 2019 COMPARED TO YEAR ENDED JUNE 30, 2018.*

**Revenues**

Revenues for the year ended June 30, 2019 were $54,000 and revenues for the year ended June 30, 2018 were $50,000. All revenues in the years ended June 30, 2019 and June 30, 2018 were related to the sale of our PLX cells for research use.

**Cost of revenues**

Cost of revenues for the year ended June 30, 2019 and June 30, 2018 were $2,000. All cost of revenues are related to the royalties we are obligated to pay to the IIA.

**Research and Development net**

Research and development net costs (costs less participation and grants by the IIA, Horizon 2020 and other parties) for the year ended June 30, 2019 increased by 17% to $26,427,000 from $22,629,000 for the year ended June 30, 2018. The increase is mainly attributed to: (1) an increase in subcontractor expenses related to some of our clinical trials, (2) an increase in materials consumption due to high volume of production of our products for clinical trials, (3) a decrease in IIA participation (approximately $900,000 was approved in calendar year 2018 compared to approximately $500,000 that was approved in calendar year 2019), and (4) an increase in stock-based compensation expenses due to the amount of restricted stock units, or RSUs, and options granted. The increase was partially offset due to grants received from the Israel-United States Binational Industrial Research and Development Foundation, or BIRD, and from Indiana University, and due to a decrease in payroll expenses related to differences in exchange rates.

**General and Administrative**

General and administrative expenses decreased by 18% from $11,193,000 for the year ended June 30, 2018 to $9,157,000 for the year ended June 30, 2019.

This decrease is attributed to a decrease in stock-based compensation expenses related to the amount of RSUs granted and their vesting schedules, a decrease in corporate activities expenses and a decrease in payroll expenses related to differences in exchange rates.

**Financial Income, net**

Financial income decreased from $7,605,000 for the year ended June 30, 2018 to $225 for the year ended June 30, 2019. This decrease is mainly due to the sale of our investments in marketable securities which occurred in the year ended June 30, 2018 that resulted a net gain of $7,606,000.

**Net Loss**

Net loss for the year ended June 30, 2019 was $35,307,000 as compared to a net loss of $26,126,000 for the year ended June 30, 2018. The changes were mainly due to a decrease in financial income, net, and increases in research and development expenses for the reasons mentioned above. Net loss per share for the year ended June 30, 2019 was $2.90, as compared to $2.50 for the year ended June 30, 2018. The net loss per share increased mainly as a result of an increase in the net loss, offset by an increase in our weighted average number of shares due to the issuance of additional shares during fiscal year 2019.

**Liquidity and Capital Resources**

As of June 30, 2019, our total current assets were $26,371,000 and our total current liabilities were $8,158,000. On June 30, 2019, we had a working capital surplus of $18,213,000 and an accumulated deficit of $251,004,000.

As of June 30, 2018, our total current assets were $32,036,000 and our total current liabilities were $8,548,000. On June 30, 2018, we had a working capital surplus of $23,488,000 and an accumulated deficit of $215,697,000.

Our cash and cash equivalents and restricted cash as of June 30, 2019 amounted to $5,186,000. This is a decrease of $4,701,000 from the $9,887,000 reported as of June 30, 2018. Cash balances decreased in the year ended June 30, 2019 for the reasons presented below.

Operating activities used cash of $29,453,000 in the year ended June 30, 2019. Cash used by operating activities in the year ended June 30, 2019 primarily consisted of payments to subcontractors, suppliers, and professional services providers primarily related to our ongoing Phase III clinical trials and payments of salaries to our employees, offset by participation of the IIA, Horizon 2020 and other grants.

Investing activities provided cash of $1,170,000 in the year ended June 30, 2019. The investing activities in the year ended June 30, 2019 consisted primarily of cash provided from repayment of short term deposits of $1,415,000, offset by payments of $239,000 related to investments in property and equipment and Investment in restricted bank deposits of $6,000.

Financing activities generated cash in the amount of $23,582,000 during the year ended June 30, 2019. The cash generated in the year ended June 30, 2019 from financing activities is related to net proceeds of $19,464,000 from issuing shares of our common stock in a public offering we conducted in April 2019, net proceeds of $4,003,000 from issuing shares of our common stock under our At Market Sales Agreement, or the ATM Agreement, with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc., and the Sales Agreement, proceeds of $107,000 related to a grant received from BIRD and net proceeds of $8,000 from the exercise of options.

In July 2017, we entered into the ATM Agreement with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc., each an Agent, which provided that, upon the terms and subject to the conditions and limitations set forth in the ATM Agreement, we could elect, from time to time, to issue and sell shares of common stock having an aggregate offering price of up to $80,000,000 through any of the Agents.

We were not obligated to make any sales of common stock under the ATM Agreement. From July 2017 through February 4, 2019, we sold an aggregate of 530,541 shares of common stock pursuant to the ATM Agreement at an average price of $13.70 per share. On February 4, 2019, we notified the Agents of the termination of the ATM Agreement.

On February 6, 2019, we entered into a Sales Agreement with Jefferies LLC, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time through Jefferies. We are not obligated to make any sales of common stock under the Sales Agreement. From February 6, 2019 through June 30, 2019, we sold an aggregate of 236,800 shares of common stock pursuant to the Sales Agreement at an average price of $9.70 per share.

On April 8, 2019, we sold, pursuant to an underwriting agreement relating to a firm commitment public offering, or the Public Offering, an aggregate of 2,857,143 shares of common stock and warrants to purchase up to 2,857,143 shares of common stock, inclusive of the underwriter's over-allotment option which was exercised in full, for aggregate gross proceeds of $20,000,000. The warrants issued in the Public Offering are exercisable for a period of five years from issuance and have an exercise price of $7.00 per share. In addition, on April 8, 2019, we sold, pursuant to a subscription agreement with a certain investor in a registered direct offering, or the Registered Direct Offering, 142,857 shares of common stock, for aggregate gross proceeds of $1,000,000. The net proceeds from the Public Offering and the Registered Direct Offering, after deducting underwriting commissions and discounts, and other offering expenses, were $19,464,000.

During the year ended June 30, 2019, we received cash of approximately $54,000 from third parties from the sale of our PLX cells for research use.

Our cash and cash equivalents as of June 30, 2018 amounted to $8,821,000. This is an increase of $4,114,000 from the $4,707,000 reported as of June 30, 2017. Cash balances increased in the year ended June 30, 2018 for the reasons presented below.

Operating activities used cash of $21,380,000 in the year ended June 30, 2018. Cash used by operating activities in the year ended June 30, 2018 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 trials, offset by IIA and Horizon 2020 grants.

Investing activities provided cash of $5,573,000 in the year ended June 30, 2018. The investing activities in the year ended June 30, 2018 consisted primarily of cash provided from the sale and the redemption of marketable securities of $21,890,000, offset by investments in short term deposits of $14,829,000, investment of $1,146,000 in marketable securities and payments of $342,000 related to investments in property and equipment.

Financing activities generated cash in the amount of $19,921,000 during the year ended June 30, 2018. The financing activities are primarily attributable to net proceeds of $13,646,000 from issuing shares of our common stock in a public offering we conducted in Israel in October 2017, net proceeds of $1,202,000 from issuing shares of our common stock from the exercise of warrants and options, net proceeds of $4,985,000 from issuing shares of our common stock under the ATM Agreement and proceeds of $88,000 related to a grant received from BIRD.

As of June 30, 2018, we had sold 359,941 shares of common stock under the ATM Agreement, at an average price of $14.30 per share.

On October 31, 2017, we completed a public offering in Israel, pursuant to our existing shelf registration statement in the United States and a shelf registration statement filed in Israel, pursuant to which we raised aggregate gross proceeds of $15,051,000 through the sale of 900,000 shares of our common stock at a purchase price of NIS 59 (approximately $16.70 per share). The net proceeds, after deducting fees and expenses related to the offering, were $13,646,000.

During the year ended June 30, 2018, we received cash of approximately $50,000 from a third party from the sale of our PLX cells for research use.

During the year ended June 30, 2018, we were awarded approximately $43,000 (NIS 150,000) by the Israeli Ministry of Labor, Social Affairs and Social Services related to an "Equal Employment" program which aims to reward and honor Israeli employers who demonstrate and promote gender equality in employment.

During the years ended June 30, 2019 and 2018, we received approximately $550,000 and $2,328,000, respectively, in cash 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% 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, 2019, we paid $2,000 of royalties to the IIA. 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.

During the years ended June 30, 2019 and 2018, we received total cash grants of approximately $1,374,000 and $2,265,000, respectively, from the European Union research and development consortiums relating to the Horizon 2020 program.

In accordance with the CHA Agreement, in December 2013, we issued to CHA 250,000 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. 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.

During January 2018, we sold the remainder of our holdings in CHA, consisting of 400,368 shares of CHA, on the open market for aggregate net proceeds of approximately $10,500,000, representing a net gain of $6,200,000 presented in "Financial income, net".

*Non-dilutive grants*

The IIA has supported our activity in the past fourteen years. Our last program, for the fourteenth year, was approved by the IIA in 2019 and relates to a grant of approximately $500,000. The grant will be used to cover research and development expenses for the period January 1, 2019 to December 31, 2019.

In July 2018, we were awarded a marketing grant of approximately $52,000 under the "Shalav" program of the Israeli Ministry of Economy and Industry. The grant is intended to facilitate certain marketing and business development activities with respect to our advanced cell therapy products in the U.S. market.

In July 2017, we were awarded an additional Smart Money grant of approximately $229,000 from Israel's Ministry of Economy. The Israeli government granted us budget resources that we intend to use to advance our product candidate towards marketing in China-Hong Kong markets. We will also receive close support from Israel's trade representatives stationed in China, including Hong Kong, along with experts appointed by the Smart Money program.

In August 2016, our CLI program in the European Union was awarded a Euro 7,600,000 (approximately $8,700,000) 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 $2,200,000) 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. In July 2017, the consortium amended the consortium agreement, pursuant to which the original grant allocation was amended such that we will receive an additional direct grant of Euro 1,000,000 (approximately $1,100,000). The additional direct grant was allocated to us from the total amount of the original grant.

In September 2017, our Phase III study of PLX-PAD cell therapy in the treatment of muscle injury following surgery for hip fracture was awarded a Euro 7,400,000 (approximately $8,400,000) grant, as part of the European Union's Horizon 2020 program. This Phase III study will be a collaborative project carried out by an international consortium led by Charité, together with us, and with participation of additional third parties. The grant will cover a significant portion of the project costs. An amount of Euro 2,550,000 (approximately $2,900,000) is a direct grant allocated to us for manufacturing and other costs, and we also expect to have a direct benefit from cost savings resulting from grant amounts allocated to the other consortium members.

In October 2017, the nTRACK, a collaborative project carried out by an international consortium led by Leitat was awarded a Euro 6,800,000 (approximately $7,700,000) non-royalty bearing grant. An amount of Euro 500,000 (approximately $570,000) is a direct grant allocated to us. We also expect to benefit from cost savings resulting from grant amounts allocated to the other consortium members.

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 other low risk instruments. 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 $251,004,000 since our inception in May 2001. We do not expect to generate any significant revenues from sales of products in the next twelve months. It is possible that 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. We will be required to obtain additional liquidity resources in order to support the commercialization of our products and maintain our research and development and clinical trials activities.

As of June 30, 2019, our cash position (cash and cash equivalents, short-term bank deposits and restricted cash and long-term bank deposits) totaled approximately $24,795,000. We are addressing our liquidity issues by implementing initiatives to allow the continuation of our activities. Our current operating plan includes various assumptions concerning the level and timing of cash outflows for operating activities and capital expenditures.

Our ability to successfully carry out our business plan, which includes a cost-reduction plan should we be unable to raise sufficient additional capital, is primarily dependent upon our ability to (1) obtain sufficient additional capital, (2) entering into license agreements to use or commercialize our products and (3) receive other sources of funding, including non-diluting sources such as the IIA grants, the Horizon 2020 grants and other grants. There are no assurances, however, that we will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of our products.

According to our management's estimates, liquidity resources as of June 30, 2019, together with the funds received under the Sales Agreement during July and August 2019, will be sufficient to maintain our operations into the first quarter of fiscal year 2021. Our inability to raise funds to carry out our business plan will have a severe negative impact on its ability to remain a viable company. These conditions raise substantial doubt about our ability to continue as a going concern.

**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.

**Stock-based compensation**

Stock-based compensation is considered critical accounting policy due to the significant expenses of RSUs which were granted to our employees, directors and consultants. In fiscal year 2019, we recorded stock-based compensation expenses related to options, restricted stock and RSUs in the amount of $5,146,000.

In accordance with ASC 718, "Compensation-Stock Compensation", or ASC 718, restricted share units granted to employees and directors are measured at their fair value on the grant date. All restricted shares units granted in 2019 and 2018 were granted for no consideration; therefore their fair value was equal to the share price at the date of grant, based on the close trading price of our shares known at the grant date. The restricted shares units to non-employees consultants are remeasured in any future vesting period for the unvested portion of the grants.

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

**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 2017 through 2019 (in thousands of dollars):

| | Year ended June 30, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Payroll and related expenses | $9,752 | $9,915 | $8,341 |
| Materials expenses | 5,871 | 4,521 | 3,145 |
| Clinical trials expenses | 5,774 | 4,370 | 4,461 |
| Depreciation expenses | 1,841 | 1,893 | 2,029 |
| Consultants and subcontractor expenses | 2,028 | 1,469 | 1,485 |
| Rent and maintenance expenses | 1,473 | 1,429 | 1,567 |
| Stock-based compensation expenses | 1,616 | 1,423 | 1,584 |
| Patent expenses | 482 | 426 | 461 |
| Other Research and Development expenses | 1,045 | 925 | 928 |
| Total expenses | 29,882 | 26,371 | 24,001 |
| Less: Research and Development participation grants | (3,455) | (3,742) | (2,909) |
| Research and Development Expenses, Net | $26,427 | $22,629 | $21,092 |

We invest heavily in research and development. Research and development expenses, net, were our major operating expenses, representing 74%, 67% and 75% of the total operating expenses for each of our fiscal years 2019, 2018 and 2017, respectively. 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, 2019, and the effect such obligations could have on our liquidity and cash flow in future periods:

| | | Payments due by period | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **Less than 1 year** | **1-3 years** | **3-5 years** | **More than 5 years** |
| Operating lease obligations | $2,641,000 | $1,110,000 | $1,531,000 | - | - |
| Minimum purchase requirements | $312,200 | $312,200 | - | - | - |
| Accrued severance pay, net | $257,000 | - | - | - | $257,000 |
| **Total** | $3,210,200 | $1,422,200 | $1,531,000 | - | $257,000 |

**Off Balance Sheet Arrangements**

We have 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 and inflation.

As of June 30, 2019, we had $4.1 million in cash and cash equivalents and $20.7 million in short-term bank deposits and restricted deposits.

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 low risk instruments. 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 currencies other than the U.S. dollar.

**Interest Rate Risk**

We invest a major portion of our cash surplus in bank deposits in banks in Israel. Since the bank deposits typically carry fixed interest rates, financial income over the holding period is not sensitive to changes in interest rates. However, our interest gains from future deposits may decline in the future as a result of changes in the financial markets. In 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, materials, consultants' fees and facility 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, 2019, we own net financial balances in NIS of approximately ($2,569,000).

Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate loss of approximately $234,000, while assuming a 10% devaluation of the NIS against the U.S. dollars, we would experience an exchange rate gain of approximately $285,000, 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, | | |
|---|---|---|---|
| | **2017** | **2018** | **2019** |
| Average rate for period | 3.741 | 3.529 | 3.647 |
| Rate at period-end | 3.496 | 3.650 | 3.566 |

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

For the year ended June 30, 2019, our net realized loss from hedging transactions that are non-designated and consist primarily of options strategies and also forward contracts to minimize the risk associated with the foreign exchange effects of monetary assets and liabilities denominated in NIS was $373,000.

**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 12, 2019.

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.

# PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## CONSOLIDATED FINANCIAL STATEMENTS

**As of June 30, 2019**

**PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY**
**CONSOLIDATED FINANCIAL STATEMENTS**

**As of June 30, 2019**

**U.S. DOLLARS IN THOUSANDS**

## INDEX

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# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
## To The Board of Directors and Stockholders Of
## PLURISTEM THERAPEUTICS INC.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Pluristem Therapeutics Inc. and its subsidiary (the "Company") as of June 30, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended June 30, 2019 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2019, 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) (PCAOB), the Company's internal control over financial reporting as of June 30, 2019, 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 12, 2019 expressed an unqualified opinion thereon.

**The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company has suffered recurring losses from operations, has limited liquidity resources and has stated that substantial doubt exists about its ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans in regard to these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company‘s auditor since 2003.
Haifa, Israel
September 12, 2019

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# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
## To The Board of Directors and Stockholders Of
## PLURISTEM THERAPEUTICS INC.

**Opinion on Internal Control over Financial Reporting**

We have audited Pluristem Therapeutics Inc. and its subsidiary's (the "Company") internal control over financial reporting as of June 30, 2019, 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"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Pluristem Therapeutics Inc. and its subsidiary as of June 30, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended June 30, 2019, and the related notes and our report dated September 12, 2019 expressed an unqualified opinion thereon.

**Basis for Opinion**

The Company'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 Annual 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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

**Definition and Limitations of Internal Control Over Financial Reporting**

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.

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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.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

Haifa, Israel
September 12, 2019

**CONSOLIDATED BALANCE SHEETS**

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

| | Note | June 30, 2019 | June 30, 2018 |
|---|---|---|---|
| **ASSETS** | | | |
| CURRENT ASSETS: | | | |
| Cash and cash equivalents | | $ 4,106 | $ 8,821 |
| Short-term bank deposits | | 19,599 | 21,079 |
| Restricted cash and short-term bank deposits | 2f | 692 | 687 |
| Other current assets | 5,2n | 1,974 | 1,449 |
| Total current assets | | 26,371 | 32,036 |
| LONG-TERM ASSETS: | | | |
| Long-term deposits and restricted bank deposits | 2g | 398 | 383 |
| Severance pay fund | | 693 | 846 |
| Property and equipment, net | 6 | 3,838 | 5,678 |
| Other long-term assets | | 10 | 17 |
| Total long-term assets | | 4,939 | 6,924 |
| Total assets | | $ 31,310 | $ 38,960 |

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

## CONSOLIDATED BALANCE SHEETS

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

| | Note | June 30, 2019 | June 30, 2018 |
|---|---|---|---|
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | | |
| CURRENT LIABILITIES | | | |
| Trade payables | | $ 2,281 | $ 3,261 |
| Accrued expenses | | 3,744 | 2,266 |
| Other accounts payable | 7 | 2,133 | 3,021 |
| Total current liabilities | | 8,158 | 8,548 |
| LONG-TERM LIABILITIES | | | |
| Accrued severance pay | | 950 | 1,127 |
| Other long-term liabilities | | 381 | 778 |
| Total long-term liabilities | | 1,331 | 1,905 |
| COMMITMENTS AND CONTINGENCIES | 8 | | |
| STOCKHOLDERS' EQUITY | | | |
| Share capital: | 9 | | |
| Common stock $0.00001 par value per share: Authorized: 30,000,000 shares Issued and outstanding: 15,082,852 shares as of June 30, 2019; 11,356,579 shares as of June 30, 2018 | | 1 | 1 |
| Additional paid-in capital | | 272,824 | 244,203 |
| Accumulated deficit | | (251,004) | (215,697) |
| Total stockholders' equity | | 21,821 | 28,507 |
| Total liabilities and stockholders' equity | | $ 31,310 | $ 38,960 |

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

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

| | Note | Year ended June 30, 2019 | 2018 | 2017 |
|---|---|---|---|---|
| Revenues | 2i | 54 | 50 | - |
| Cost of revenues | | (2) | (2) | - |
| Gross profit | | 52 | 48 | - |
| Operating Expenses: | | | | |
| Research and development expenses | | (29,882) | (26,371) | (24,001) |
| Less: participation grants by the IIA, Horizon 2020 and other parties | | 3,455 | 3,742 | 2,909 |
| Research and development expenses, net | | (26,427) | (22,629) | (21,092) |
| General and administrative expenses, net | | (9,157) | (11,193) | (6,927) |
| Other income | 10 | - | 43 | - |
| Total operating loss | | (35,532) | (33,731) | (28,019) |
| Financial income, net | 11 | 225 | 7,605 | 205 |
| Net loss for the period | | $ (35,307) | $ (26,126) | $ (27,814) |
| Loss per share: Basic and diluted net loss per share | | $ (2.90) | $ (2.50) | $ (3.20) |
| Weighted average number of shares used in computing basic and diluted net loss per share | | 12,332,912 | 10,587,677 | 8,742,621 |

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

## CONSOLIDATED BALANCE SHEETS

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

| | Year ended June 30, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Net loss | $ (35,307) | $ (26,126) | $ (27,814) |
| Other comprehensive income (loss), net: | | | |
| Unrealized gain (loss) on available-for-sale marketable securities, net | - | 6,441 | 924 |
| Reclassification adjustment of available-for-sale marketable securities losses (gains) realized in net loss, net | - | (8,440) | (405) |
| Other comprehensive income (loss) | - | (1,999) | 519 |
| Total comprehensive loss | $ (35,307) | $ (28,125) | $ (27,295) |

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

## STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

| | Common Stock | | Additional Paid-in | Accumulated Other Comprehensive | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|---|
| | Shares (**) | Amount | Capital | Income (Loss) | Deficit | Equity |
| **Balance as of July 1, 2016** | 8,026,900 | $ (*) | $ 198,433 | $ 1,480 | $ (161,757) | $ 38,156 |
| Exercise of options by employees and non-employee consultants | 1,790 | (*) | 10 | - | - | 10 |
| Stock-based compensation to employees, directors and non-employee consultants | 257,026 | (*) | 3,662 | - | - | 3,662 |
| Issuance of common stock and warrants related to January 2017 offering, net of issuance costs of $1,532 (Note 9b) | 1,408,163 | (*) | 15,718 | - | - | 15,718 |
| Other comprehensive income, net | - | - | - | 519 | - | 519 |
| Net loss | - | - | - | - | (27,814) | (27,814) |
| **Balance as of June 30, 2017** | 9,693,879 | $ (*) | $ 217,823 | $ 1,999 | $ (189,571) | $ 30,251 |

(*) Less than $1
(**) See note 1c for reverse stock split

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

## STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

| | Common Stock Shares (**) | Common Stock Amount | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| **Balance as of July 1, 2017** | 9,693,879 | $ (*) | $ 217,823 | $ 1,999 | $ (189,571) | $ 30,251 |
| Exercise of options by employees | 5,050 | (*) | 42 | - | - | 42 |
| Stock-based compensation to employees, directors and non-employee consultants | 314,838 | (*) | 6,548 | - | - | 6,548 |
| Issuance of common stock under At-The Market ("ATM") Agreement, net of issuance costs of $174 (Note 9d) | 359,941 | (*) | 4,985 | - | - | 4,985 |
| Issuance of common stock, net of issuance costs of $1,405 (Note 9e) | 900,000 | (*) | 13,646 | - | - | 13,646 |
| Exercise of warrants by investors (Note 9c) | 82,871 | (*) | 1,160 | - | - | 1,160 |
| Other comprehensive loss, net | - | - | - | (1,999) | - | (1,999) |
| Net loss | - | - | - | - | (26,126) | (26,126) |
| **Balance as of June 30, 2018** | 11,356,579 | $ (*) | $ 244,204 | $ - | $ (215,697) | $ 28,507 |

(*) Less than $1

(**) See note 1c for reverse stock split

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

## STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

| | Common Stock | | Additional Paid-in | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares (**) | Amount | Capital | Deficit | Equity |
| **Balance as of July 1, 2018** | 11,356,579 | $ (*) | $ 244,204 | $ (215,697) | $ 28,507 |
| Stock-based compensation to employees, directors and non-employee consultants | 317,023 | (*) | 5,146 | - | 5,146 |
| Issuance of common stock under At Market Issuance Sales Agreement, and Open Market Sales Agreement, net of aggregate issuance costs of $403 (Note 9d, 9f) | 407,400 | (*) | 4,003 | - | 4,003 |
| Issuance of common stock and warrants related to April 2019 offering, net of issuance costs of $1,536 (Note 9g) | 3,000,000 | (*) | 19,464 | - | 19,464 |
| Exercise of options by employees and non-employee consultants | 1,850 | (*) | 8 | - | 8 |
| Net loss | - | - | - | (35,307) | (35,307) |
| **Balance as of June 30, 2019** | 15,082,852 | $ (*) | $ 272,825 | $ (251,004) | $ 21,821 |

(*) Less than $1

(**) See note 1c for reverse stock split

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

## CONSOLIDATED STATEMENTS OF CASH FLOWS

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

| | Year ended June 30, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | | |
| Net loss | $ (35,307) | $ (26,126) | $ (27,814) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 1,962 | 2,018 | 2,177 |
| Loss from sale of property and equipment, net | - | 6 | 72 |
| Accretion of discount, amortization of premium and changes in accrued interest of marketable securities | - | 11 | 35 |
| Gain from sale of investments of available-for-sale marketable securities | - | (8,440) | (362) |
| Other-than-temporary loss of available-for-sale marketable securities | - | 850 | 767 |
| Stock-based compensation to employees, directors and non-employees consultants | 5,146 | 6,548 | 3,662 |
| Decrease (increase) in accounts receivable from the IIA | (121) | 978 | 1,192 |
| Increase in other current and other long-term assets | (397) | (59) | (731) |
| Increase (decrease) in trade payables | (863) | 1,212 | (701) |
| Increase in other accounts payable, accrued expenses, other long-term liabilities and other current liabilities | 86 | 1,600 | 138 |
| Decrease (increase) in interest receivable on short-term deposits | 68 | (128) | (24) |
| Linkage differences and interest on short and long-term deposits and restricted bank deposits | (3) | 5 | (14) |
| Accrued severance pay, net | (24) | 145 | (8) |
| Net cash used in operating activities | $ (29,453) | $ (21,380) | $ (21,611) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | | |
| Purchase of property and equipment | $ (239) | $ (342) | $ (378) |
| Proceeds from sale of property and equipment | - | - | 30 |
| Proceeds from (investment in) short-term deposits | 1,415 | (14,721) | 2,373 |
| Investment in Long-term deposits and restricted bank deposits | (6) | - | - |
| Proceeds from sale of available-for-sale marketable securities | - | 21,881 | 5,527 |
| Proceeds from redemption of available-for-sale marketable securities | - | 9 | 410 |
| Investment in available-for-sale marketable securities | - | (1,146) | (3,607) |
| Net cash provided by investing activities | $ 1,170 | $ 5,681 | $ 4,355 |

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

## CONSOLIDATED STATEMENTS OF CASH FLOWS

**U.S. Dollars in thousands**

| | Year ended June 30, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | | |
| Proceeds related to issuance of common stock and warrants, net of issuance costs | $ 23,467 | $ 18,631 | $ 15,718 |
| Proceeds with respect to Israel-United States Binational Industrial Research and Development Foundation | 107 | 88 | 69 |
| Exercise of options and warrants | 8 | 1,202 | 10 |
| Net cash provided by financing activities | $ 23,582 | $ 19,921 | $ 15,797 |
| Increase (decrease) in cash, cash equivalents and restricted cash | (4,701) | 4,222 | (1,459) |
| Cash, cash equivalents and restricted cash at the beginning of the period | 9,887 | 5,665 | 7,124 |
| Cash, cash equivalents and restricted cash at the end of the period | $ 5,186 | $ 9,887 | $ 5,665 |
| **(a) Supplemental disclosure of cash flow activities:** | | | |
| Cash paid during the period for: | | | |
| Taxes paid due to non-deductible expenses | $ 10 | $ 27 | $ 28 |
| **(b) Supplemental disclosure of non-cash activities:** | | | |
| Purchase of property and equipment on credit | $ 54 | $ 171 | $ 88 |

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**U.S. Dollars in thousands (except share and per share amounts)**

## NOTE 1:-GENERAL

a. Pluristem Therapeutics Inc., a Nevada corporation ("Pluristem Therapeutics"), was incorporated on May 11, 2001. Pluristem Therapeutics has a wholly owned subsidiary, Pluristem Ltd. (the "Subsidiary"), which is incorporated under the laws of the State of Israel. Pluristem Therapeutics 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".

b. The Company is a bio-therapeutics company developing placenta-based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. The Company has incurred an accumulated deficit of approximately $251,004 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of June 30, 2019, the Company's total stockholders' equity amounted to $21,821.

During the year ended June 30, 2019, the Company incurred operating losses of $35,532 and its negative cash flow from operating activities was $29,453. The Company will be required to identify additional liquidity resources in the near term in order to support the commercialization of its products and maintain its research and development and clinical trials activities.

As of June 30, 2019, the Company's cash position (cash and cash equivalents, short-term bank deposits and restricted cash and long-term bank deposits) totaled approximately $24,795. The Company is addressing its liquidity issues by implementing initiatives to allow the continuation of its activities. The Company's current operating plan includes various assumptions concerning the level and timing of cash outflows for operating activities and capital expenditures. The Company's ability to successfully carry out its business plan, which includes a cost-reduction plan should it be unable to raise sufficient additional capital, is primarily dependent upon its ability to (1) obtain sufficient additional capital, (2) enter into license agreements to use or commercialize the Company's products and (3) receive other sources of funding, including non-diluting sources such as the Israeli Innovation Authority (the "IIA") grants, the European Union's Horizon 2020 program ("Horizon 2020") grants and other grants. There are no assurances, however, that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its products.

According to management estimates, liquidity resources as of June 30, 2019, together with the funds received under the Open Market Sales Agreement[SM] (the "Sales Agreement") with Jefferies LLC ("Jefferies"), as agent, during July and August 2019, will be sufficient to maintain the Company's operations into the first quarter of the Company's fiscal year 2021. The Company's inability to raise funds to carry out its business plan will have a severe negative impact on its ability to remain a viable company.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. The audited consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets or liabilities that might be necessary should the Company be unable to continue as a going concern.

*CHA Agreement*

On June 26, 2013, Pluristem entered into an exclusive license and commercialization agreement (the "CHA Agreement") with CHA Biotech Co. Ltd. ("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 ("CLI"), and Intermediate Claudication (collectively with CLI, 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.

**NOTE 1:-GENERAL (CONT.)**

The first clinical study as part of the CHA Agreement was a Phase II trial in Intermittent Claudication.

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 to commercialize PLX cell products in 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 the CHA Agreement, the license granted thereunder will terminate and all rights included therein will revert to the Company, and 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 250,000 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.

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

In January 2018, the Company sold its remaining investment in the CHA shares, for aggregate net proceeds of approximately $10,500, representing a net gain of $6,200, which is recorded in "Financial income, net" for the year ended June 30, 2018, and reclassified from other comprehensive income (loss).

*Chart Industries Agreement*

In November 2018, the Company entered into a license agreement with a subsidiary of Chart Industries, Inc. ("Chart"), regarding the Company's thawing device for cell-based therapies. Pursuant to the terms of the agreement, Chart obtained the exclusive rights to manufacture and market the thawing device in all territories worldwide, excluding Greater China, and the Company is entitled to receive royalties from sales of the product and supply of an agreed upon number of thawing devices. Royalties shall commence on the date of Chart's first commercial sale of the thawing device. As of June 30, 2019, commercial sale of the thawing device by Chart has not yet begun.

**c. Reverse stock split**

In July 2019, subsequent to the balance sheet date, the Board of Directors approved a 1-for-10 reverse stock split of the Company's (a) authorized shares of common stock; (b) issued and outstanding shares of common stock and (c) authorized shares of preferred stock. The reverse stock split became effective on July 25, 2019. All shares of common stock, options, warrants and securities convertible or exercisable into shares of common stock, as well as loss per share, have been adjusted to give retroactive effect to this reverse stock split for all periods presented.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**U.S. Dollars in thousands (except share and per share amounts)**

## 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**

Most of Pluristem Therapeutics' costs and assets are denominated in United States dollars ("dollar"). The Company's management believes that the dollar is the primary currency of the economic environment in which the Company operates. Thus, the dollar is the Company's functional and reporting currency. Accordingly, non-dollar denominated transactions and balances have been re-measured into the functional currency in accordance with Accounting Standards Codification ("ASC") 830, "Foreign Currency Matters". All transaction gains and losses from the re-measured monetary balance sheet items are reflected in the statements of income as financial income or expenses, as appropriate.

**c. Principles of consolidation**

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

**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 bank deposits**

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

**g. Long-term restricted bank deposits**

Long-term restricted bank 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. Investment in 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 stockholders' equity.

**NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

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 sold. The amortized cost of available for sale debt marketable securities is adjusted for amortization of premiums and accretion of discount to maturity. Such amortization, together with coupon 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 reason for the decline in value, the potential recovery period and the Company's intent to sell, including whether it is more likely than not that the Company will be required to sell the investment before recovery of cost basis. ASC 320-10-35, “Investments - Debt and Equity Securities”, requires other-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 the years ended June 30, 2018 and 2017, the Company recognized other-than-temporary impairment loss of $850 and $767, respectively (see Note 3). During the year ended June 30, 2019, the Company did not recognize any other-than-temporary impairment loss.

**i. Revenue Recognition**

On July 1, 2017, the Company adopted ASC 606, “Revenue from Contracts with Customers” using the modified retrospective method. Results for reporting periods beginning after July 1, 2017 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company’s historic accounting under ASC 605.

Revenue Recognition from sales of products:

Revenues are recognized when control of the promised goods is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods.

The Company determines revenue recognition through the following steps:

- identification of the contract with a customer;
- identification of the performance obligations in the contract;
- determination of the transaction price;
- allocation of the transaction price to the performance obligations in the contract; and
- recognition of revenue when, or as, the Company satisfies a performance obligation.

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

**NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

The Company's contracts with its customers are expected to include one type of product and thus have only one performance obligation, which is the transfer of control of the product. The Company's PLX cells have an alternative use and, as such, the performance obligation is considered to be satisfied at a point in time where the customer obtains control over the product.

The Company's contract with Chart includes variable consideration for which the Company estimates the most likely amount that should be included in the transaction price subject to constraints based on the specific facts and circumstances. Pursuant to the terms of the agreement, the Company is entitled to receive royalties from sales of the product and supply of an agreed upon number of thawing devices. Royalties shall commence on the date of Chart's first commercial sale of the thawing device.

As of June 30, 2019, commercial sales of the thawing device by Chart have not begun. Based on the Company's assessment, it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur, and therefore the Company is unable to recognize revenues with respect to the Chart agreement before the uncertainty associated with the variable consideration is subsequently resolved.

**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 | 10-40 |
| 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. |

**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 fiscal years 2019, 2018 and 2017, no impairment losses have been 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" ("ASC 505-50"). 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 ("RS") or restricted stock units ("RSUs")) 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.

**NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

The assumptions below are relevant to RS and RSUs granted in 2019, 2018 and 2017:

In accordance with ASC 718, RS and RSUs are measured at their fair value. All RS and RSUs to employees and directors granted in 2019, 2018 and 2017, 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 RS and RSUs 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 2019, 2018 and 2017, was $8.70, $14.00 and $14.10 per share, respectively.

During fiscal years 2019, 2018 and 2017, there were no options granted to employees or directors.

**m. Research and Development expenses and royalty bearing grants**

Research and development expenses, net of participations grants, are charged to the statement of operations as incurred. Pluristem receives grants from the IIA in the Ministry of Economy and Industry (formerly the Office of Chief Scientist's) for the purpose of partially funding approved research and development projects. The grants are not to be repaid, but instead Pluristem is obliged to pay royalties as a percentage of future sales if and when sales from the funded projects are generated. These grants are recognized as a deduction from research and development costs at the time the Company is entitled to such grants on the basis of the research and development costs incurred. Since the payment of royalties is not probable when the grants are received, the Company records a liability in the amount of the estimated royalties for each individual contract, when the related revenues are recognized, as part of Cost of revenues. For more information regarding such royalties commitments and regarding grants and participation received, see Note 8.

**n. Non-royalty bearing grant**

The Company participates in European Union research and development consortiums under Horizon 2020. In August 2016, the CLI program consortium was awarded a Euro 7,600 thousands (approximately $8,700) non-royalty bearing grant, of which, an amount of Euro 1,900 thousands (approximately $2,200) is a direct grant allocated to the Company. In July 2017, the consortium amended the consortium agreement, pursuant to which the original grant allocation was amended such that the Company received an additional direct grant of Euro 1,000 thousands (approximately $1,100). The additional direct grant was allocated to the Company from the total amount of the original grant. In September 2017, the Company’s Phase III study of PLX-PAD cell therapy in the treatment of muscle injury following surgery for hip fracture was awarded a Euro 7,400 thousands (approximately $8,400) grant, of which, an amount of Euro 2,550 thousands (approximately $2,900) is a direct grant allocated to the Company. In October 2017, the "nTRACK", a collaborative project carried out by an international consortium led by LEITAT, was awarded a Euro 6,800 thousands (approximately $7,700) non-royalty bearing grant, of which, an amount of Euro 500 thousands (approximately $570) is a direct grant allocated to the Company.

The non-royalty bearing grants for funding the projects are recognized at the time the Company is entitled to each such grant on the basis of the related costs incurred and recorded as a deduction from research and development expenses.

**o. Loss per share**

Basic and diluted 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 RSUs 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.

## NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

### p. 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.

### q. Concentration of credit risk

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

The majority of the Company's cash and cash equivalents, restricted cash and short-term and long-term deposits are mainly invested in dollar instruments of major banks in Israel and in the United States. Deposits in the United States may be in excess of insured limits and are not insured in other jurisdictions. Generally, these deposits may be redeemed upon demand and therefore bear minimal risk. The Company invests its surplus cash in cash deposits 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 utilizes options and forward 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.

### r. Severance pay

A 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.

Severance expenses for the years ended June 30, 2019, 2018 and 2017 were $632, $822 and $524, respectively.

**NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

**s. Fair value of financial instruments**

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, restricted cash, short-term and restricted bank deposits, accounts receivable and other current assets, 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 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 (see Note 4).

**t. Derivative financial instruments**

The Company accounts for derivatives and hedging based on ASC 815, “Derivatives and hedging”, as amended and related interpretations. ASC 815 requires the Company to recognize all derivatives on the balance sheet at fair value. If a derivative meets the definition of a hedge and is so designated, depending on the nature of the hedge, changes in the fair value of the derivative will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings (for fair value hedge transactions) or recognized in other comprehensive income (loss) until the hedged item is recognized in earnings (for cash flow hedge transactions).

The ineffective portion of a derivative's change in fair value is recognized in earnings. If a derivative does not meet the definition of a hedge, the changes in the fair value are included in earnings. Cash flows related to such hedges are classified as operating activities. The Company enters into option contracts in order to limit the exposure to exchange rate fluctuation associated with expenses mainly incurred in New Israeli Shekels (“NIS”). Since the derivative instruments that the Company holds do not meet the definition of hedging instruments under ASC 815, any gain or loss derived from such instruments is recognized immediately as "financial income, net".

The Company measured the fair value of the contracts in accordance with ASC 820. Foreign currency derivative contracts are classified within Level 2 as the valuation inputs are based on quoted prices and market observable data of similar instruments. As of June 30, 2019, the fair value of the options contracts was approximately $21 and is presented in “other current assets” (see Note 4). The net gains (losses) recognized in “Financial income, net” during the years ended June 30, 2019, 2018 and 2017, were $(105), ($264) and $481, respectively.

**u. Comprehensive income (loss):**

The Company accounts for comprehensive income (loss) in accordance with ASC 220, “Comprehensive Income”.

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

**NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

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 unrealized gains and losses on available for sale marketable securities.

**v. Reclassifications:**

Certain financial statement data for prior years have been reclassified to conform to current year financial statement presentation.

**w. Recently Adopted Accounting Pronouncement**

ASU No. 2016-18 – "Statement of Cash Flows" (Topic 230) ("ASU No. 2016-18"):

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-18. ASU 2016-18 requires that the consolidated statement of cash flows include the change in total cash and cash equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. ASU No. 2016-18 also requires a reconciliation between the total of cash and cash equivalents and restricted cash presented on the consolidated statement of cash flows and the cash and cash equivalents balance presented on the consolidated balance sheet. ASU No. 2016-18 was effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. The standard requires application using a retrospective transition method. The Company adopted this standard effective July 1, 2018 using the retrospective transition method, as required by ASU 2016-18.

The following table provides a reconciliation of cash and cash equivalents, and long term restricted cash reported within the consolidated balance sheets that sum to the total of such amounts in the consolidated statements of cash flows:

| | Year ended June 30, | | |
|---|---|---|---|
| | **2019** | 2018 | **2017** |
| Cash and cash equivalents | $ 4,106 | $ 8,821 | $ 4,707 |
| Restricted cash included in restricted cash and short-term bank deposits | 1,080 | 1,066 | 958 |
| Cash, cash equivalents and restricted cash shown in the consolidated statement of cash flows | $ 5,186 | $ 9,887 | $ 5,665 |

***Recently Issued Accounting Pronouncements***

ASU No. 2016-02 - "Leases" (Topic 842) ("ASU No. 2016-02"):

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current U.S. GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current U.S. GAAP, which requires only capital leases to be recognized on the balance sheet, the new guidance will require both types of leases to be recognized on the balance sheet. ASU No. 2016-02 is effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted.

**NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. If an entity chooses the second option, the entity must recast its comparative period financial statements and provide disclosures required by the new standard for the comparative periods. The Company adopted the new standard on July 1, 2019 using the effective date as its date of initial application. Consequently, financial information will not be updated and disclosures required under the new standard will not be provided for dates and periods before July 1, 2019. ASU No. 2016-02 provides a number of optional practical expedients in transition. The Company elected to adopt the 'package of practical expedients', which, under the new standard, permits it not to reassess its prior conclusions about lease identification, lease

classification and initial direct costs. The adoption of this new standard will materially affect the Company's consolidated balance sheets by recognizing new right-of-use ("ROU") assets and lease liabilities for operating leases. The impact on the Company's results of operations and cash flows is not expected to be material. Adoption of the standard will result in the recognition of additional lease liabilities for operating leases of approximately $2,250 - $2,450 and additional ROU which will be adjusted for the remaining balance of the deferred participation payments in the amounts of approximately $1,650 - $1,850. As of July 1, 2019, the ROU and lease liabilities estimate includes non-cancelable operating lease agreements (see Note 8a and 8b).

ASU No. 2018-07 - Compensation—Stock Compensation (Topic 718) ("ASU No. 2018-07"):

In June 2018, the FASB issued ASU 2018-07. The ASU expands the scope of ASU No. 2018-07 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of ASU No. 2018-07 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that ASU No. 2018-07 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU No. 2018-07 is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years with early adoption permitted. While the Company continues to assess the potential impact of ASU No. 2018-07, the Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

ASU No. 2018-18 - "Collaborative Arrangements (Topic 808) - Clarifying the Interaction between Topic 808 and Topic 606" ("ASU No. 2018-18"):

In November 2018, the FASB issued ASU No. 2018-18, which clarifies the interaction between Topic 808 and Topic 606 by (1) clarifying that certain transactions between collaborative arrangement participants should be accounted for under Topic 606, (2) adding unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 and (3) clarifying presentation guidance for transactions with a collaborative arrangement participant that are not accounted for under Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, or July 1, 2020 for the Company. The Company is currently evaluating the impact of adopting the ASU on its consolidated financial statements.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**U.S. Dollars in thousands (except share and per share amounts)**

## NOTE 3:- MARKETABLE SECURITIES

As of June 30, 2019 and 2018, all of the Company's marketable securities were classified as available-for-sale.

| | Year ended June 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | | 2018 | | |
| | Amortized cost | Other-than-temporary impairment | Fair value | Amortized cost | Other-than-temporary impairment | Fair value |
| **Available-for-sale - matures within one year:** | | | | | | |
| Stock and index linked notes | $ 850 | $ (850) | $ - | $ 850 | $ (850) | $ - |
| **Total** | $ 850 | $ (850) | $ - | $ 850 | $ (850) | $ - |

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.

The Company recognized other-than-temporary impairment loss on outstanding securities during the year ended June 30, 2018 and 2017, of $850 and $767, respectively. The Company did not recognize any other-than-temporary impairment loss on outstanding securities during the year ended June 30, 2019.

During the year ended June 30, 2018, the Company sold marketable securities for aggregate net proceeds (including redemptions) of approximately $21,890, representing a net gain of $8,440. The proceeds from the sale of such marketable securities are included in "Financial income, net", for the year ended June 30, 2018.

## NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

| | June 30, 2019 | June 30, 2018 |
|---|---|---|
| | Level 2 | Level 2 |
| Foreign currency derivative instruments not designated as hedge instruments | $21 | ($243) |
| Total financial assets (liabilities) | $21 | ($243) |

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**U.S. Dollars in thousands (except share and per share amounts)**

## NOTE 5:-OTHER CURRENT ASSETS

| | June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Accounts receivable from the Horizon 2020 grants | $ 991 | $ 626 |
| Prepaid expenses | 532 | 602 |
| Accounts receivable from the IIA | 179 | 58 |
| VAT receivables | 125 | 150 |
| Accounts receivable from the Ministry of Economy and Industry | 73 | 6 |
| Derivatives not designated as hedge instruments | 21 | - |
| Other receivables | 53 | 7 |
| Total | $ 1,974 | $ 1,449 |

## NOTE 6:-PROPERTY AND EQUIPMENT, NET

| | June 30, | |
|---|---|---|
| | 2019 | 2018 |
| **Cost:** | | |
| Laboratory equipment | $ 6,435 | $ 6,395 |
| Computers and peripheral equipment | 1,274 | 1,206 |
| Office furniture and equipment | 681 | 681 |
| Leasehold improvements | 8,614 | 8,611 |
| **Total Cost** | 17,004 | 16,893 |
| **Accumulated depreciation:** | | |
| Laboratory equipment | 5,634 | 4,903 |
| Computers and peripheral equipment | 1,147 | 1,060 |
| Office furniture and equipment | 600 | 511 |
| Leasehold improvements | 5,785 | 4,741 |
| **Total accumulated depreciation** | 13,166 | 11,215 |
| **Property and equipment, net** | $ 3,838 | $ 5,678 |

Depreciation expenses amounted to $1,962, $2,018 and $2,177, for the years ended June 30, 2019, 2018 and 2017, respectively.

## NOTE 7:-OTHER ACCOUNTS PAYABLE

| | June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Accrued vacation | $ 974 | $ 911 |
| Deferred income from the Horizon 2020 grant | - | 640 |
| Accrued payroll | 486 | 524 |
| Payroll institutions | 433 | 463 |
| Derivatives not designated as hedge instruments | - | 243 |
| Other payables | 240 | 240 |
| Total | $ 2,133 | $ 3,021 |

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**U.S. Dollars in thousands (except share and per share amounts)**

## NOTE 8:-COMMITMENTS AND CONTINGENCIES

**a.** In February 2015, the Company signed an addendum to its facility operating lease agreement (the "Addendum") with the lessor, which extended the lease 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 lease expense, net of lessor participation, under such arrangements, on a straight-line basis over the lease term.

As of June 30, 2019, aggregate minimum lease commitments under the active operating lease agreements are as follows:

| Fiscal year ending June 30, | |
|---|---|
| 2020 | $ 877 |
| 2021 | 886 |
| 2022 | 443 |
| Total | $ 2,206 |

Lease expenses, net of lessor participation, amounted to $615, $638 and $781, for the years ended June 30, 2019, 2018 and 2017, respectively.

The Subsidiary issued a bank guarantee in favor of the lessors in the amount of approximately $388.

**b.** The Subsidiary leases several motor vehicles under operating lease agreements, which expire in various dates during the years 2020 through 2022.

As of June 30, 2019, future aggregate minimum lease commitments under operating lease agreements are as follows:

| Fiscal year ending June 30, | |
|---|---|
| 2020 | $ 233 |
| 2021 | 157 |
| 2022 | 45 |
| Total | $ 435 |

Lease expenses amounted to $301, $294 and $233, for the years ended June 30, 2019, 2018 and 2017, respectively.

**c.** An amount of $692 of cash and deposits was pledged by the Subsidiary to secure certain derivatives and hedging transactions, a credit line and bank guarantees as of June 30, 2019.

**NOTE 8:-COMMITMENTS AND CONTINGENCIES (CONT.)**

**d.** 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 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% on sales of products and services derived 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, 2019, total grants obtained aggregated to approximately $27,353 and total royalties paid and accrued amounted to $169. As of June 30, 2019, the Company's liability in respect to royalties to the IIA amounted to $27,184, not including LIBOR interest as described above.

**e.** The Company has been awarded a marketing grant under the "Smart Money" program of the Israeli Ministry of Economy and Industry. The program's aim is to assist companies to extend their activities in international markets. The goal market that was chosen was Japan. The Israeli government granted the Company budget resources that are intended to be used to advance the Company's product candidate towards marketing in Japan and for regulatory activities there. As part of the program, the Company will repay royalties of 5% from the Company's income in Japan during five years, starting the year in which the Company will not be entitled to reimbursement of expenses under the program and will be spread for a period of up to 5 years or until the amount of the grant is fully paid.

As of June 30, 2019, total grants obtained under this Smart Money program amounted to approximately $112. As of June 30, 2019, the Company's contingent liability with respect to royalties for this "Smart Money" program was $112 and no royalties were paid or accrued.

**f.** The Company was awarded an additional Smart Money grant of approximately $229 from Israel's Ministry of Economy and Industry to facilitate certain marketing and business development activities with respect to its advanced cell therapy products in the Chinese market, including Hong Kong. The Israeli government granted the Company budget resources that are intended to be used to advance the Company's product candidate towards marketing in the China-Hong Kong markets. The Company will also receive close support from Israel's trade representatives stationed in China, including Hong Kong, along with experts appointed by the Smart Money program. As part of the program, the Company will repay royalties of 5% from the Company's revenues in the region for a five year period, beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and will be spread for a period of up to 5 years or until the amount of the grant is fully paid.

As of June 30, 2019, the aggregate amount of grant obtained from this Smart Money program was approximately $26. As of June 30, 2019, the Company's contingent liability with respect to royalties for this "Smart Money" program is $26 and no royalties were paid or accrued.

**g.** In December, 2016, the Company announced that it will collaborate with the New York Blood Center ("NYBC") on pre-clinical studies of its placental expanded R-18 cells ("PLX-R18") to enhance the efficacy of umbilical cord blood transplantation. The project has been selected to receive a conditional award of $900 from Israel-United States Binational Industrial Research and Development Foundation ("BIRD Foundation"), of which an amount of $585 is a direct grant allocated to the Company.

**NOTE 8:-COMMITMENTS AND CONTINGENCIES (CONT.)**

Per the terms of the project, the Company provided the PLX-R18 cells and the NYBC were responsible for conducting and supporting the studies. Amounts received in connection with this award were presented in "Other long-term liabilities".

As of June 30, 2019, the aggregate amount of grant obtained from the BIRD Foundation was approximately $264. During the year ended June 30, 2019, the Company and NYBC mutually agreed to terminate the project and therefore, pursuant to the terms of the agreement with the BIRD Foundation and NYBC, the Company derecognized the BIRD Foundation liability. The total amounts received in connection with this award were recognized as a deduction from research and development costs, and an amount to be received of $14 is presented in "other current assets" as of June 30, 2019.

**h.** In September 2017, the Company signed an agreement with the Tel-Aviv Sourasky Medical Center (Ichilov Hospital) to conduct a Phase I/II trial of PLX-PAD cell therapy for the treatment of Steroid-Refractory Chronic Graft-Versus-Host-Disease ("GvHD").

As part of the agreement with the Tel-Aviv Sourasky Medical Center (Ichilov Hospital), the Company will pay royalties of 1% from its net sales of the PLX-PAD product relating to GvHD, with a maximum aggregate royalty amount of approximately $250.

**i.** In July, 2018, the Company was awarded a marketing grant of approximately $52 under the "Shalav" program of the Israeli Ministry of Economy and Industry. The grant is intended to facilitate certain marketing and business development activities with respect to the Company's advanced cell therapy products in the U.S. market. As part of the program, the Company will repay royalties of 3%, but only with respect to the Company's revenues in the U.S. market in excess of $250 of its revenues in fiscal year 2018, upon the earlier of the five year period beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and/or until the amount of the grant, which is linked to the Consumer Price Index, is fully paid.

As of June 30, 2019, total grants obtained under the "Shalav" program amounted to approximately $40. As of June 30, 2019, the Company's contingent liability with respect to royalties for the "Shalav" program was $40 and no royalties were paid or accrued.

**NOTE 9: - STOCKHOLDERS' EQUITY**

The Company's authorized common stock consists of 30,000,000 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 1,000,000 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.

**a. Reverse stock split:**

In July, 2019, subsequent to the balance sheet date, the Board of Directors approved a 1-for-10 reverse stock split of the Company's (a) authorized shares of common stock; (b) issued and outstanding shares of common stock and (c) authorized shares of preferred stock. The reverse split became effective on July 25, 2019.

**NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)**

The reverse stock split will not have any effect on the stated par value of the common stock. All shares of common stock, options, warrants and securities convertible or exercisable into shares of common stock, as well as loss per share, have been adjusted to give retroactive effect to this reverse stock split for all periods presented.

**b.** On January 25, 2017, the Company issued, pursuant to an underwriting agreement relating to a firm commitment public offering, an aggregate of 1,408,163 shares of common stock and warrants to purchase up to an aggregate of 844,898 shares of common stock, inclusive of the underwriter's over-allotment option, which was exercised in full, for aggregate gross proceeds of $17,250. The net proceeds, after deducting underwriting commissions, discounts and other expenses related to the offering were approximately $15,718.

**c.** In the year ended June 30, 2018, a total of 828,703 warrants from the January 2017 offering were exercised by investors at an exercise price of $14.00 per share, resulting in the issuance of 82,871 shares of common stock for net proceeds of approximately $1,160.

**d.** In July 2017, pursuant to a shelf registration statement on Form S-3, declared effective by the Securities and Exchange Commission (the "SEC") on June 23, 2017, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc. (collectively, the "Agents"), which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell shares of common stock having an aggregate offering price of up to $80,000 through the Agents acting as sales agent. During the year ended June 30, 2018, the Company sold 359,941 shares of common stock under the ATM Agreement at an average price of $14.30 per share for aggregate proceeds of approximately $4,985, net of issuance expenses of $174. During the year ended June 30, 2019, the Company sold 170,600 shares of common stock under the ATM Agreement at an average price of $12.30 per share for aggregate proceeds of approximately $1,952, net of issuance expenses of $148.

On February 4, 2019, the Company notified the Agents of the termination of the ATM Agreement.

**e.** On October 31, 2017, the Company completed a public offering in Israel, pursuant to the Company's existing shelf registration statement on Form S-3 in the United States and a shelf registration statement filed in Israel, pursuant to which the Company raised aggregate gross proceeds of $15,051 through the sale of 900,000 shares of the Company's common stock at a purchase price of NIS 59 (approximately $16.70) per share. The net proceeds, after deducting fees and expenses related to the offering, were approximately $13,646.

**f.** Pursuant to a shelf registration on Form S-3 declared effective by the SEC on June 23, 2017, on February 6, 2019, the Company entered into the Sales Agreement with Jefferies which provides that, upon the terms and subject to the conditions and limitations in the sales agreement, the Company may elect, from time to time, to offer and sell shares of common stock having an aggregate offering price of up to $50,000 through Jefferies acting as sales agent. During the year ended June 30, 2019, the Company sold 236,800 shares of common stock under the Sales Agreement at an average price of $9.70 per share for aggregate net proceeds of approximately $2,051, net of issuance expenses of $255.

**g.** On April 8, 2019, the Company sold, pursuant to an underwriting agreement relating to a firm commitment public offering (the "Public Offering"), an aggregate of 2,857,143 shares of common stock and warrants to purchase 2,857,143 shares of common stock, inclusive of the underwriter's over-allotment option which was exercised in full, for aggregate gross proceeds of $20,000.

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

**NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)**

The warrants issued in the Public Offering are exercisable for a period of five years from issuance and have an exercise price of $7.00 per share. In addition, on April 8, 2019, the Company sold, pursuant to a subscription agreement with a certain investor in a registered direct offering (the "Registered Direct Offering"), 142,857 shares of common stock, for aggregate gross proceeds of $1,000. The net proceeds from the Public Offering and the Registered Direct Offering, after deducting underwriting commissions and discounts and other expenses related to the offerings, were $19,464.
As of June 30, 2019, 2,857,143 warrants to purchase share of our common stock are outstanding.

**h. Stock options, RS and RSUs to employees, directors and consultants:**

The Company adopted, after receiving stockholder approval, the 2005 Stock Option Plan in 2005 (the "2005 Plan"). Under the 2005 Plan, stock options, RS and RSUs were granted to the Company's officers, directors, employees and consultants. The 2005 Plan expired on December 31, 2018. The Company adopted, after receiving stockholder approval, the 2016 Equity Incentive Plan in 2016 (the "2016 Plan"). Under the 2016 Plan, stock options, RS and RSUs may be granted to the Company's officers, directors, employees and consultants or the officers, directors, employees and consultants of our Subsidiary. In addition, at the Company's annual meeting of its stockholders, held on June 13, 2019, the Company's stockholders approved the 2019 Equity Compensation Plan (the "2019 Plan"). Under the 2019 Plan, stock options, RS and RSUs may be granted to the Company's officers, directors, employees and consultants or the officers, directors, employees and consultants of the Subsidiary.

As of June 30, 2019, the number of shares of common stock authorized for issuance under the 2016 Plan amounted to 383,400 for calendar year 2016, of which 363,400 are available for future grant under the 2016 Plan. As of June 30, 2019, the number of shares of common stock authorized for issuance under the 2019 Plan amounted to 3,204,055, all of which are available for future grant under the 2019 Plan.

**(1) Options to employees and directors:**

The Company accounts for its stock options to employees and directors under the fair value method in accordance with ASC 718, "Compensation—Stock Compensation". A summary of the Company's activity for stock options granted to employees and directors under the 2005 Plan is as follows:

| | Year ended June 30, 2019 | |
|---|---|---|
| | Number | Weighted Average Exercise Price |
| Options outstanding at beginning of period | 31,500 | $ 6.20 |
| Options forfeited | (30,750) | $ 6.20 |
| Options exercised | (750) | $ 6.20 |
| Options outstanding at end of the period | - | - |

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

**NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)**

**(2) Options to non-employees:**

A summary of the stock options to non-employee consultants under the 2005 Plan and 2016 Plan is as follows:

| | Year ended June 30, 2019 | | | |
|---|---|---|---|---|
| | Number | Weighted Average Exercise Price | Weighted Average Remaining Contractual Terms (in years) | Aggregate Intrinsic Value Price |
| Stock options outstanding at beginning of period | 50,060 | $ 0.06 | | |
| Stock options granted | 40,805 | $ - | | |
| Stock options exercised | (1,100) | $ 2.82 | | |
| Stock options forfeited | (185) | $ - | | |
| Stock options outstanding at end of the period | 89,580 | $ - | 7.63 | $555 |
| Stock options exercisable at the end of the period | 42,601 | $ - | 7.26 | $264 |
| Stock options vested and expected to vest at the end of the period | 89,580 | $ - | 7.63 | $555 |

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

| | Year ended June 30, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Research and development expenses | $ 117 | $ 107 | $ 7 |
| General and administrative expenses | 167 | 61 | 39 |
| | $ 284 | $ 168 | $ 46 |

**(3) RS and RSUs to employees and directors:**

The following table summarizes the activity related to unvested RS and RSUs granted to employees and directors under the 2005 Plan and 2016 Plan for the year ended June 30, 2019:

| | Number |
|---|---|
| Unvested at the beginning of period | 629,361 |
| Granted | 498,100 |
| Forfeited | (45,830) |
| Vested | (285,998) |
| Unvested at the end of the period | 795,633 |
| Expected to vest after June 30, 2019 | 769,922 |

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

**NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)**

Compensation expenses related to RS and RSUs granted to employees and directors were recorded as follows:

| | Year ended June 30, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Research and development expenses | $ 1,401 | $ 1,273 | $ 1,558 |
| General and administrative expenses | 3,003 | 4,577 | 1,645 |
| | $ 4,404 | $ 5,850 | $ 3,203 |

Unamortized compensation expenses related to RS and RSUs granted to employees and directors to be recognized over an average time of approximately 3.75 years are approximately $4,180.

**(4) RS and RSUs to consultants:**

The following table summarizes the activity related to unvested RS and RSUs granted to consultants for the year ended June 30, 2019:

| | Number |
|---|---|
| Unvested at the beginning of period | 19,956 |
| Granted | 41,176 |
| Vested | (31,025) |
| Unvested at the end of the period | 30,107 |

Compensation expenses related to RS and RSUs granted to consultants were recorded as follows:

| | Year ended June 30, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Research and development expenses | $ 48 | $ 43 | $ 19 |
| General and administrative expenses | 410 | 487 | 394 |
| | $ 458 | $ 530 | $ 413 |

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

**NOTE 9: - STOCKHOLDERS' EQUITY (CONT.)**

**i. Summary of warrants and options:**

| Warrants / Options | Exercise Price per Share | Options and Warrants for Common Stock | Options and Warrants Exercisable for Common Stock | Weighted Average Remaining Contractual Terms (in years) |
|---|---|---|---|---|
| **Warrants:** | $ 7.00 | 2,857,143 | 2,857,143 | 4.77 |
| | $ 14.00 | 762,028 | 762,028 | 3.06 |
| | $ 28.50 | 408,000 | 408,000 | 1.00 |
| **Total warrants** | | **4,027,171** | **4,027,171** | |
| **Options:** | $ 0.00 | 89,580 | 42,601 | 7.62 |
| **Total options** | | **89,580** | **42,601** | |
| **Total warrants and options** | | **4,116,751** | **4,069,772** | |

This summary does not include 825,740 RS and RSUs that are not vested as of June 30, 2019.

**NOTE 10:-OTHER INCOME**

In December 2017, the Subsidiary was awarded approximately $43 (NIS 150 thousand) by the Israeli Ministry of Labor, Social Affairs and Social Services related to its "Equal Employment" program which aims to reward and honor Israeli employers who demonstrate and promote gender equality in employment.

**NOTE 11:-FINANCIAL INCOME, NET**

| | Year ended June 30, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Foreign currency translation differences, net | ($ 26) | $ 52 | $ 182 |
| Bank and broker commissions | (27) | (62) | (67) |
| Interest income on deposits | 385 | 276 | 122 |
| Gain (loss) related to marketable securities, net | - | 8,478 | 254 |
| Other than temporary impairment loss | - | (850) | (767) |
| Gain (loss) from derivatives and fair value hedge derivatives | (105) | (264) | 481 |
| Other financial expense | (2) | (25) | - |
| | $ 225 | $ 7,605 | $ 205 |

## NOTE 12:-TAXES ON INCOME

A. Tax assessments:

The Subsidiary has not received final tax assessments since its incorporation; however, the assessments of the Subsidiary are deemed final through 2013.

B. Tax rates applicable to the Company:

1. Pluristem Therapeutics:

The U.S. federal tax rate applicable to Pluristem Therapeutics is the corporate federal tax rate of 21%, which is the result of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). Such corporate tax rate excludes state tax and local tax, if any, which rates depend on the state and city in which Pluristem Therapeutics conducts its business.

On December 22, 2017, the Tax Act was signed into law in the United States, lowering the corporate federal income tax rate from 35% to 21%, effective January 1, 2018.

The Tax Act provided for a one-time transition tax on certain foreign earnings for the tax year 2017, and taxation of Global Intangible Low-Taxed Income ("GILTI") earned by foreign subsidiaries beginning after December 31, 2017. The GILTI tax imposes a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The Tax Act also makes certain changes to the depreciation rules and implements new limits on the deductibility of certain executive compensation paid by Pluristem Therapeutics. Finally, while the Tax Act removes the 20 year limitation on net operating losses generated after December 31, 2017, all losses generated after December 31, 2017 can only be used to offset 80% of net income in the year they will be utilized.

The Company recognized the income tax effects of the Tax Act in its 2018 annual consolidated financial statements in accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), which provides SEC staff guidance for the application of ASC 740, "Income Taxes", in the reporting period in which the 2017 Tax Act was enacted. In accordance with SAB 118, deferred tax assets and liabilities were re-measured to reflect the revised corporate income tax rate of 21%. This re-measurement was fully offset by a valuation allowance, resulting in no impact to the Company's income tax expense for the fiscal year ended June 30, 2019. As a result, the Company's financial results reflect in the income tax effects of the Tax Act, for which the accounting under ASC 740 is complete.

There was no one-time transition tax for the Company under the Tax Act, nor will there be GILTI tax due for the current year, since the Subsidiary had losses for every year to date.

In January 2018, Pluristem Therapeutics registered as an Israeli resident with the Israel Tax Authority (the "ITA") and the Israeli Value Added Tax Authorities. As a result, as of such date, Pluristem Therapeutics is classified as a dual resident for tax purposes, as a resident in both Israel and the United States.

In June 2018, Pluristem Therapeutics and the Subsidiary submitted an election notice to the ITA to file a consolidated tax return in Israel commencing with the 2018 tax year.

**NOTE 12:-TAXES ON INCOME (CONT.)**

2. The Subsidiary:

Taxable income of Israeli companies is subject to tax at the rate of 23% in 2019, 23% in 2018 and 24%in 2017.

The Subsidiary is filing its tax reports in dollars based on specific regulations of the ITA which allow, in specific circumstances, filing tax reports in dollars ("Dollar Regulations"). Under the Dollar Regulations, the Subsidiary calculates its tax liability in dollars according to certain orders. The tax liability, as calculated in dollars, is translated into NIS according to the exchange rate as of June 30 of each year.

**The Law for the Encouragement of Capital Investments, 1959 (the "Law"):**

The Subsidiary has programs which meet the criteria of a “Beneficiary Enterprise”, in accordance with the Law, under the Alternative Benefit Track starting with 2007 as the election year (the "2007 Program") and 2012 as an election year to the expansion of its "Beneficiary Enterprise" program (the "2012 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).

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).

In respect of expansion programs pursuant to Amendment No. 60 to the Encouragement Law, the duration of the benefit period has been amended, such that it 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 have not passed since the beginning of the election year.

The benefit period for the Subsidiary's 2007 Program expired in 2018 (12 years since the beginning of the election year– 2007) and the benefit period for the Subsidiary's 2012 Program is expected to 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 taxes 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).

*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 but not more than 20% depreciation per year) from the first year of the assets operation.

**NOTE 12:-TAXES ON INCOME (CONT.)**

*Conditions for the entitlement to the benefits:*

The above mentioned benefits are conditional upon the fulfillment of the conditions stipulated by the 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.

*Amendments to the Law:*

In December 2010, the "Knesset" (Israeli Parliament) passed the Law for Economic Policy for 2011 and 2012 (Amended Legislation), 2011 (the "Amendment"), which prescribes, among others, amendments in the Law for the Encouragement of Capital Investments, 1959 (the "Amendment No. 68"). Amendment No. 68 became effective as of January 1, 2011. According to Amendment No. 68, the benefit tracks in the Law were modified and a flat tax rate became applicable to a company for all preferred income under its status as a preferred company with a preferred enterprise.

On August 5, 2013, the Knesset issued the Law for Changing National Priorities (Legislative Amendments for Achieving Budget Targets for 2013 and 2014), 2013 which consists of Amendment No. 71 to the Law for the Encouragement of Capital Investments, 1959 (the "Amendment No. 71"). According to Amendment No. 71, the tax rate on preferred income form a preferred enterprise in 2014 and thereafter will be 16% (in development area A it will be 9%).

Amendment No. 71 also prescribes that any dividends distributed to individuals or foreign residents from the preferred enterprise's earnings as above will be subject to tax at a rate of 20%.

The Subsidiary did not apply Amendment No. 71 with respect to the preferred enterprise status, but may choose to apply Amendment No. 71 in the future.

Innovation Box Regime "Technological Preferred Enterprise":

In December 2016, the Knesset approved amendments to the Law that introduce an innovation box regime (the "Innovation Box Regime") for intellectual property (IP)-based companies, enhance tax incentives for certain industrial companies and reduce the standard corporate tax rate and certain withholding rates starting in 2017.

The Innovation Box Regime was tailored by the Israeli government to a post-base erosion and profit shifting ("BEPS") world, encouraging multinationals to consolidate IP ownership and profits in Israel along with existing Israeli research and development ("R&D") functions. Tax benefits created to achieve this goal include a reduced corporate income tax rate of 6% on IP-based income and on capital gains from future sale of IP.

The 6% rate would apply to qualifying Israeli companies that are part of a group with global consolidated revenue of over NIS 10 billion (approximately US $2.9 billion). Other qualifying companies with global consolidated revenue below NIS 10 billion, would be subject to a 12% tax rate. However, if the Israeli company is located in Jerusalem or in certain northern or southern parts of Israel, the tax rate is further reduced to 7.5%. Additionally, withholding tax on dividends for foreign investors would be subject to a reduced rate of 4% for all qualifying companies (unless further reduced by a treaty).

**NOTE 12:-TAXES ON INCOME (CONT.)**

Entering the regime is not conditioned on making additional investments in Israel, and a company could qualify if it invested at least 7% of the last three years' revenue in R&D (or incurred at least NIS 75 million in R&D expenses per year) and met one of the following three conditions:

1. At least 20% of its employees are R&D employees engaged in R&D (or employs, in total, more than 200 R&D employees);
2. Venture capital investments in the aggregate of NIS 8 million were previously made in the company; or
3. Average annual growth over three years of 25% in sales or employees.

Companies not meeting the above conditions may still be considered as a qualified company at the discretion of the Israeli Innovation Authority of the Ministry of Economy and Industry (formerly, the "Office of the Chief Scientist"). Companies wishing to exit from the regime in the future will not be subject to clawback of tax benefits. The Knesset also approved a stability clause in order to encourage multinationals to invest in Israel. Accordingly, companies will be able to confirm the applicability of tax incentives for a 10-year period under a pre-ruling process. Further, in line with the new Organization for Economic Co-operation and Development Nexus Approach, the Israeli Finance Minister will promulgate regulations to ensure companies are benefiting from the regime to the extent qualifying R&D expenditures are incurred. The regulations were set to be finalized by March 31, 2017, with new amendments to the Law coming into effect after the regulations have been finalized.

Taxable income which is not produced as part of "Preferred Enterprise" income will be taxed at the regular tax rate (24% in 2017).

As of December 31, 2018, the Company's management believes that the Company meets the conditions mentioned above to be considered as a Technological Preferred Enterprise.

C. Carryforward losses for tax purposes

As of June 30, 2019, Pluristem Therapeutics had U.S. federal net operating loss carryforward for income tax purposes in the amount of approximately $34,836. 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 2039.

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 has accumulated losses, for tax purposes, as of June 30, 2019, in the amount of approximately $155,515, 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:

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

## NOTE 12:-TAXES ON INCOME (CONT.)

| | June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Deferred tax assets: | | |
| U.S. net operating loss carryforward | $ 7,316 | $ 7,485 |
| Israeli net operating loss and research and development expenses carryforward | 40,866 | 33,538 |
| Allowances and reserves | 283 | 274 |
| Total deferred tax assets before valuation allowance | 48,465 | 41,297 |
| Valuation allowance | (48,465) | (41,297) |
| Net deferred tax asset | $ - | $ - |

As of June 30, 2019 and 2018, 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, 2019 and 2018, 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 2019, 2018 and 2017, the main reconciling item of the statutory tax rate of the Company (21% to 35% in 2019, 2018 and 2017) 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 13:-SUBSEQUENT EVENTS

a. As of September 12, 2019, the Company had sold 439,900 shares of common stock at an average price of $4.95 per share under the Sales Agreement (see Note 9f).

**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, 2019. Based on the aforementioned evaluation, management has concluded that our disclosure controls and procedures were effective as of June 30, 2019.

***Management's Annual 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, 2019. 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, 2019, 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 year 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

Our directors and executive officers, their ages, positions currently held, and duration of such, are as follows:

| Name | Position Held With Company | Age | Date First Elected or Appointed |
|---|---|---|---|
| Zami Aberman | Executive Chairman | 65 | June 23, 2019 |
| Yaky Yanay | President<br>Director<br>Chief Executive Officer | 48 | February 4, 2014<br>February 5, 2015<br>June 23, 2019 |
| Chen Franco-Yehuda | Chief Financial Officer, Treasurer and Secretary | 36 | March 14, 2019 |
| Nachum Rosman | Director | 73 | October 9, 2007 |
| Doron Shorrer | Director | 66 | October 2, 2003 |
| Hava Meretzki | Director | 50 | October 2, 2003 |
| Isaac Braun | Director | 66 | July 6, 2005 |
| Israel Ben-Yoram | Director | 59 | January 26, 2005 |
| Mark Germain | Director | 69 | May 17, 2007 |
| Moria Kwiat | Director | 40 | 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 as our Executive Chairman since June 2019, as our Co-Chief Executive Officer from March 2017 until June 2019, as our CEO from November 2005 until March 2017, and as President of the Company from September 2005 until February 2014. 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. Since October 2015, he has served as a Director of The Alliance for Regenerative Medicine. He has 25 years of experience in marketing and management in the high technology industry. Mr. Aberman has held the CEO and Chairman positions of various companies located in Israel, the United States, Europe, Japan and Korea.

Mr. Aberman has 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 previously served 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 holding those positions, Mr. Aberman served as the President and CEO of Elbit Vision System Ltd. (EVSNF.OB), a company engaged in automatic optical inspection. Before joining the Company, Mr. Aberman served as President and CEO of Netect Ltd., a company 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.

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. Yanay became a director of the Company in February 2015. He has served as our President from February 2014 and as our CEO from June 2019, previously serving as Co-CEO from March 2017. Mr. Yanay has served in variety of executive positions in Pluristem since 2006 including as our Chief Financial Officer from November 2006 until February 2014 and from February 2015 until March 2017. He also served as our Chief Operating Officer from February 2014 until March 2017. From November 2006 to February 2014, he served as our Secretary and served as our Executive Vice President from March 2013 until February 2014. From 2015 to 2018, Mr. Yanay served as the Co-Chairman of Israel Advanced Technology Industries (IATI), the largest umbrella organization representing Israel's high tech and life science industries and since August 2012 has continually served as a Director of IATI, representing Israel's life sciences industry. Prior to joining the Company, Mr. Yanay founded and served as Chairman of "The Israeli Life Science Forum" and also served as the Chief Financial Officer, or CFO, of Elbit Vision Systems Ltd., a public company. In addition, from July 2010 to April 2018, he served on the Board of Directors of Elbit Vision Systems Ltd. Prior to these positions, Mr. Yanay served as manager of audit groups of the technology sector at Ernst & Young Israel.

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 has held CEO and Chief Financial Officer, or CFO, positions in Israel, the United States and England. In these positions he was responsible for, among other things, 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 in 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 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 at each of Sigma Mutual Funds Ltd., Food Save Ltd. and G.D.M. Investments Ltd.

Mr. Shorrer has served as a director of Provident Fund for employees of the Israel Electric Company Ltd. and between 1999 and 2004 he was Chairman of the board of directors 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. In addition, Mr. Shorrer served as a director of Hebrew University employees and Massad Bank from the International Bank group from 2009 to 2018.

Among his 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 diverse audience ranging from private concerns to government ministries.

Mr. Shorrer holds a B.A. in Economics and Accounting and an M.B.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 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 a partner at the Meretzki law firm in Haifa, Israel. Ms. Meretzki specializes in civil, trade and labor law, and she is 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 has co-founded and served as a board member of several high-tech start-ups in the areas of e-commerce, security, messaging, search engines and biotechnology. Mr. Braun is involved with advising private companies in the areas of capital raising 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 Israeli accounting firm of Mor, Ben-Yoram and Partners 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 operating in parallel to Mor, Ben-Yoram and Partners. Mor, Ben-Yoram Ltd. 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), each of which were traded on the Nasdaq Stock Market LLC, or Nasdaq. Mr. Ben-Yoram is a member of the Society of Trust and Estate Practitioners.

Mr. Ben-Yoram received a B.A. in accounting from Tel Aviv University, 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-listed 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. Mr. Germain has been a merchant banker serving primarily the biotech and life sciences industries for over five years. 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 that was sold in 1991. In addition to being a director of the Company, Mr. Germain is a Managing Director at The ÆNTIB Group, a boutique merchant bank. From June 2018, Mr. Germain also served as Vice Chairman of the board of BiondVax Pharmaceuticals Ltd., a company based in Israel engaging in a Phase III clinical trials for a universal flu vaccine, and, effective September 30, 2019 he will serve as the chairmen of the board of BiondVax Pharmaceuticals Ltd.

Mr. Germain also serves or served as a director of the following companies that were reporting companies in the past: ChromaDex Inc., 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 biotech 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 an analyst at aMoon, a leading Israeli life sciences venture fund. Previously she was a consultant and analyst at Frost & Sullivan, producing equity research for public companies in the healthcare domain. Dr. Kwiat has a broad academic background and scientific experience in inter-disciplinary fields, with specific expertise in the interface between the biology and materials fields. She is the co-author of multiple scientific papers.

Dr. Kwiat holds a Post-Doctoral degree in nanotechnology and material sciences, a Ph.D. in Chemistry and a M.Sc. and B.Sc. in Biotechnology, from Tel Aviv University.

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

**Chen Franco-Yehuda**

Mrs. Franco-Yehuda was appointed as our CFO, effective as of March 17, 2019. Prior to being appointed as our Chief Financial Officer, Mrs. Franco-Yehuda served as the Company's Head of Accounting and Financial Reporting since July 2016 and, prior to that, the Company's Controller since May 2013. Before joining the Company, from October 2008 to April 2013, Mrs. Franco-Yehuda served as a manager of audit groups relating to public and private companies in various industries at PricewaterhouseCoopers (PwC) and also as a lecturer of accounting classes at the Open University of Israel from 2009 to 2014.

Mrs. Franco-Yehuda holds a bachelor's degree in economics and accounting from Haifa University, and is a certified public accountant in Israel.

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 eight meetings from July 1, 2018 through June 30, 2019 (fiscal year 2019).

*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 five meetings during fiscal year 2019. The Compensation Committee did not receive advice from or retain any consultants during fiscal year 2019.

*Compensation Committee Interlocks and Insider Participation*

During the fiscal year ended June 30, 2019, 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 existing independent directors consider and recommend board nominees and address corporate governance matters that may arise from time to time. 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. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Conduct by posting such information on the website address specified above.

**Item 11. Executive Compensation.**

**Compensation Discussion and Analysis**

The Compensation Committee of our Board of Directors is comprised solely of independent directors as defined by Nasdaq 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, Executive Chairman and CFO. Our named executive officers for fiscal year 2019 are those four individuals listed in the *2019* "*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 2019 shareholders meeting, we provided our shareholders with the opportunity to cast an advisory vote on our then named executive officers' compensation. Over 70% of the votes cast on this "2019 say-on-pay vote" were voted in favor of the proposal. We have considered the 2019 say-on-pay vote and we believe that the support from our shareholders for the 2019 say-on-pay vote proposal indicates that our shareholders are supportive of our approach to executive compensation. At our 2019 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;
- 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 equity compensation 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 RSU grants; and (iv) benefits and perquisites.

In establishing overall executive compensation levels and making specific compensation decisions for our executive officers in 2019, 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. In that regard, our Compensation Committee has decided to provide our Executive Chairman, Mr. Aberman, and our CEO, Mr. Yanay, with base salaries, RSU awards, acceleration of such awards under certain circumstances, and performance based bonuses in their respective employment and/or consulting agreement, as opposed to certain terms contained in our CFO's employment agreement and compensation package, based on their respective positions, seniority and scope of responsibilities.

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 our CEO recommendations for the compensation of our CFO. Our 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.

On March 14, 2019, the Board of Directors approved the appointment of Mrs. Franco-Yehuda as our CFO. On May 6, 2019, the Board of Directors, upon the recommendation of our Compensation Committee, approved the new officer agreement with Mrs. Franco-Yehuda, our CFO, which provided for an increase to her annual salary, in light of her new responsibilities and also, under certain circumstances, for acceleration of awards issued to Mrs. Franco-Yehuda.

On June 30, 2019, the Board of Directors, upon the recommendation of our Compensation Committee, approved, as part of a comprehensive plan to reduce expenses, the reduction of the annual salary of our CEO and the annual compensation paid to our Executive Chairman, each by 25% from their current levels until the earlier of closing market capitalization on the Nasdaq Capital Market reaching $170 million; or (2) June 30, 2020.

**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 Executive Chairman and CEO, each of them is entitled to a bonus equal to 1.5% of amounts received by us from non-dilutive funding received, among other things, from corporate partnering and strategic deals. This is designed to support our business strategy to enter into multiple license agreements with pharmaceutical companies.

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 year 2019.

**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. Our Executive Chairman and CEO are entitled to acceleration of the vesting of their awards in the following circumstances: (1) if we terminate their employment, they will be entitled to acceleration of 100% of any unvested award and (2) if they resign, they will be entitled to acceleration of 50% of any unvested award. In addition, our Executive Chairman, CEO and CFO are entitled to an acceleration of 100% of any unvested RSUs in the event of a change in control as defined in their consulting or employment agreement. All grants are approved, upon receipt of recommendation by our Compensation Committee, by our Board of Directors.

**Benefits and Perquisites**

Generally, benefits available to Mr. Yanay and Mrs. Franco-Yehuda 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, or reimbursement for car or phone expenses, which are customary benefits in Israel to managers and officers. Our Executive Chairman and CEO are also entitled to receive, once a year, a fixed sum equal to the amount of the monthly compensation to such Executive Chairman and CEO.

In addition, 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 9. Mr. Yanay is 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, and an additional adjustment fee that equals the monthly salary amount multiplied by 6, plus the number of years the employment agreement remains in force from September 12, 2018, but in any event no more than 9 years in the aggregate.

Mrs. Chen Franco-Yehuda is entitled to severance pay upon termination of employment for any reason, including retirement, based on 8.333% of her monthly base salary, according to section 14 of the Severance Pay Law, 1963.

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

**Summary Compensation Table**

The following table shows the particulars of compensation paid to our named executive officers for the fiscal years ended June 30, 2019 and 2018. We do not currently have any other executive officers.

| Name and Principal Position | Fiscal Year | Salary ($) (1) | Stock-based Awards ($)(2) | All Other Compensation ($)(3) | Total ($) |
|---|---|---|---|---|---|
| Zami Aberman Executive Chairman (previously Co-CEO) | 2019(4) | 551,137(5) | 478,500 | 66,857 | 1,096,494 |
| | 2018 | 524,450(5) | - | 68,384 | 592,834 |
| Yaky Yanay | 2019(6) | 396,632(7) | 461,100 | 29,253 | 886,985 |

| | | | | | |
|---|---|---|---|---|---|
| Chief Executive Officer (previously Co-CEO) | 2018 | 416,740(7) | - | 26,619 | 443,359 |
| Chen Franco-Yehuda CFO | 2019 (8) | 78,889 | 112,329 | 13,599 | 204,817 |
| Erez Egozi Former CFO | 2019 (9) | 116,701 | 139,200 | 68,807 | 324,708 |
| | 2018 | 163,212 | 142,197 | 20,304 | 325,713 |

(1) Salary payments which were in NIS, were translated into US$ at the then current exchange rate for each payment. The salaries of Mr. Yanay, Mrs. Franco-Yehuda and Mr. Egozi are comprised of base salaries and additional payments and provisions such as welfare benefits, paid time-off, life and disability insurance and other customary or mandatory social benefits to employees in Israel.

(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(l) to our consolidated financial statements for fiscal year 2019 included elsewhere in this Annual Report.

(3) Represents cost to us in connection with car or car expenses reimbursement and mobile phone expenses. The Company also pays our CEO and Executive Chairman the tax associated with this benefit, which is grossed up and included in the “all other compensation” column for Mr. Aberman. Mr. Yanay’s gross up is part of the amount in the Salary column in the table above.

(4) Mr. Aberman ceased to serve as our Co-CEO and commenced to serve solely in his capacity as Executive Chairman on June 24, 2019. The compensation reflects amounts received during the entire fiscal year.

(5) Includes $23,068 and $21,151 paid to Mr. Aberman as compensation for services as a director in fiscal year 2019 and 2018 respectively.

(6) Mr. Yanay ceased to serve as our Co-CEO and commenced to serve as the sole CEO on June 24, 2019. The compensation reflects amounts received during the entire fiscal year.

(7) Includes $23,582 and $24,003 paid to Mr. Yanay as compensation for services as a director in fiscal year 2019 and 2018, respectively.

(8) Mrs. Franco-Yehuda was appointed as our Chief Financial Officer on March 14, 2019. The compensation reflects amounts received during the entire fiscal year.

(9) Mr. Egozi ceased to be our Chief Financial Officer on March 14, 2019. The compensation reflects amounts received during the entire fiscal year. Amounts received following March 14, 2019 are included in all other compensation.

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

(a) Mr. Aberman is engaged with us as a consultant and received a monthly consulting fee of $31,250. On September 12, 2018, our Board approved an increase of the monthly consulting fees payable to Mr. Aberman, from $31,250 per month (at a U.S. dollar rate not less than 4.35 NIS) to 149,500 NIS (approximately $41,500 per month), effective as of September 1, 2018.

In addition, Mr. Aberman is entitled once a year to receive an additional amount that equals the monthly consulting fee. All amounts above are paid plus value added tax. Mr. Aberman is also entitled to a performance based bonus of one and a half percent (1.5%) from amounts received by us from non-diluting funding and strategic deals. Mr. Aberman is entitled to car expenses reimbursement. In addition, on September 12, 2018, Mr. Aberman's annual director fees were increased to $20,000 from $17,610 (set at a rate of 4.25 NIS per U.S. dollar). The reason for the increases in Mr. Aberman's consulting fees and director fees were due to the fact that Mr. Aberman had not received an increase since May 2011, and the Board determined such an increase was appropriate in light of his years of service to the Company. On June 30, 2019, our Board of Directors, upon the recommendation of our Compensation Committee, approved the reduction of the annual compensation paid to Mr. Aberman, and his annual fees paid to him as a director, by 25% from his current levels until the earlier of closing market capitalization on the Nasdaq Capital Market reaching $170 million; or (2) June 30, 2020.

(b) During fiscal years 2019 and 2018, Mr. Yanay's monthly salary was 80,000 NIS, while in fiscal year 2017 it was 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 was entitled to a performance based bonus of one percent (1.0%) from amounts received by us from non-diluting funding and strategic deals which, effective as of September 12, 2018, was increased to one and a half percent (1.5%) due to his increased responsibilities. In addition, Mr. Yanay's annual compensation as a director was $20,000 (set at a rate of 4.25 NIS per U.S. dollar). On June 30, 2019, our Board of Directors, upon the recommendation of our Compensation Committee, approved the reduction of the annual salary of Mr. Yanay, and the annual fees paid to him as a director, by 25% from his current levels until the earlier of closing market capitalization on the Nasdaq Capital Market reaching $170 million; or (2) June 30, 2020.

(c) Mrs. Franco-Yehuda's monthly salary is 36,000 NIS. Mrs. Franco-Yehuda receives car and cellular phone expense reimbursements pursuant to the terms of her agreement.

(d) Starting December 1, 2017, Mr. Egozi's monthly salary was 38,000 NIS. Mr. Egozi was provided with a cellular phone and a Company car pursuant to the terms of his employment agreement with the Company. Mr. Egozi ceased to be our Chief Financial Officer on March 14, 2019.

*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 9; (ii) in the event of termination of Mr. Yanay employment, he is entitled to a severance payment, under Israeli law, that equals a month's compensation for each twelve-month period of employment or otherwise providing services to the Company, and an additional adjustment fee that equals the monthly base salary multiplied by 6, plus the number of years the employment agreement is in force from September 12, 2018, but in any event no more than nine months in the aggregate; and (iii) in the event of termination of Mrs. Franco-Yehuda's employment, she is entitled to a severance payment, under Israeli law, that equals a month's compensation for each twelve-month period of employment or otherwise providing services to 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 awards and (2) if they resign, they will be entitled to acceleration of 50% of any unvested award. In addition, Mr. Aberman, Mr. Yanay and Mrs. Franco-Yehuda are also entitled to acceleration of 100% of any unvested award in case of our change in control as defined in their respective consulting and employment agreements.

The following table displays the value of what our CEO, Executive Chairman and CFO would have received from us had their employment been terminated, or a change in control of us happened on June 30, 2019.

| Officer | Salary | Accelerated Vesting of RSUs (1) | Total |
|---|---|---|---|
| Zami Aberman | | | |
| Terminated due to officer resignation | $ 377,314 | $ 457,250 (2) | $ 834,564 |
| Terminated due to discharge of officer | $ 377,314 | $ 914,500 (3) | $ 1,291,814 |
| Change in control | - | $ 914,500 (4) | $ 914,500 |
| Yaky Yanay | | | |
| Terminated due to officer resignation | $ 364,891 (5) | $ 452,600 (2) | $ 817,491 |
| Terminated due to discharge of officer | $ 364,891 (5) | $ 905,200 (3) | $ 1,270,091 |
| Change in control | - | $ 905,200 (4) | $ 905,200 |
| Chen Franco Yehuda | | | |
| Terminated due to officer resignation | $ 35,358 | - | $ 35,358 |
| Terminated due to discharge of officer | $ 35,358 | - | $ 35,358 |
| Change in control | - | $ 86,180 (4) | $ 86,180 (4) |

(1) Value shown represents the difference between the closing market price of our shares of common stock on June 30, 2019 of $6.20 per share and the applicable exercise price of each grant.

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

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

(4) All unvested 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, except for those we are obligated to maintain pursuant to the Israeli law, 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, 2019:

| Name | Grant Date | All Other Stock Awards: Number of Shares of Stock or Units # | Grant Date Fair Value of Stock Awards ($) |
|---|---|---|---|
| Zami Aberman | December 19, 2018 | 55,000 (1) | 478,500 |
| Yaky Yanay | December 19, 2018 | 53,000 (2) | 461,100 |
| Chen Franco-Yehuda | December 19, 2018 | 2,600 (3) | 21,189 |
| | March 28, 2019 | 10,000 (4) | 91,140 |
| Erez Egozi (Former CFO) | December 19, 2018 | 16,000 (5) | 139,200 |

(1) Grant of RSUs was made pursuant to our 2016 Equity Compensation Plan, or the 2016 Plan. The grant vests as follows:

a. 30,000 RSUs vest over a two-year period from the date of grant, as follows: 25% after 6 months from date of grant and the remaining shares vest in 6 equal installments every 3 months thereafter, and

b. 25,000 RSUs vest as follows: 12.5% vest on March 19, 2021 and the remaining shares vest in 7 equal installments every 3 months thereafter.

(2) Grant of RSUs was made pursuant to our 2016 Plan. The grant vests as follows:

a. 28,000 RSUs vest over a two-year period from the date of grant, as follows: 25% after 6 months from date of grant and the remaining shares vest in 6 equal installments every 3 months thereafter, and

b. 25,000 RSUs vest as follows: 12.5% vest on March 19, 2021 and the remaining shares vest in 7 equal installments every 3 months thereafter.

(3) Grant of RSUs was made pursuant to our amended and restated 2005 Stock Option Plan, or the 2005 Plan. The grant vests as follows:

a. 1,000 RSUs vest over a two-year period from the date of grant, as follows: 25% after 6 months from date of grant and the remaining shares vest in 6 equal installments every 3 months thereafter,

b. 1,000 RSUs vest as follows: 12.5% vest on March 19, 2021 and the remaining shares vest in 7 equal installments every 3 months thereafter, and

c. 600 RSUs vest on December 19, 2020.

(4) Grant of RSUs was made pursuant to our 2016 Plan. The grant vests as follows:

a. 6,000 RSUs vest over a two-year period from the date of grant, as follows: 25% after 6 months from date of grant and the remaining shares vest in 6 equal installments every 3 months thereafter, and

b. 4,000 RSUs vest as follows: 12.5% vest on June 28, 2021 and the remaining shares vest in 7 equal installments every 3 months thereafter.

(5) Grant of RSUs was made pursuant to our 2016 Plan. The grant vests as follows:

a. 8,000 RSUs vest over a two-year period from the date of grant, as follows: 25% after 6 months from date of grant and the remaining shares vest in 6 equal installments every 3 months thereafter,

b. 5,000 RSUs vest as follows: 12.5% vest on March 19, 2021 and the remaining shares vest in 7 equal installments every 3 months thereafter, and.

c. 3,000 RSUs vest upon achievement of certain operational and financial goals.

In conjunction with Mr. Egozi's departure as CFO, 172,500 out of 272,500 RSUs outstanding as of June 30, 2019, vested in July 2019, while the remaining outstanding RSUs were forfeited.

**Outstanding Equity Awards at the End of Fiscal Year 2019**

The following table presents the outstanding equity awards held as of June 30, 2019 by our named executive officers:

| **Number of Securities Underlying Unexercised** | | |
|---|---|---|
| | **Stock Awards** | |
| Name | **Number of shares that have not vested (#)** | **Market value of shares that have not vested ($)** |
| Zami Aberman | 100,000 (1) | $620,000 |
| | 47,500 (2) | $294,500 |
| Yaky Yanay | 100,000 (1) | $620,000 |
| | 46,000 (3) | $285,200 |
| Erez Egozi (10) | 7,500 (4) | $46,500 |
| | 5,750 (5) | $35,650 |
| | 14,000 (6) | $86,800 |
| Chen Franco-Yehuda | 1,550 (7) | $9,610 |
| | 2,350 (8) | $14,570 |
| | 10,000 (9) | $62,000 |

(1) 100,000 RSUs vest in 8 equal installments of 12,500 on September 22, 2019 and every 3 months thereafter.

(2) 47,500 RSUs vest as follows:

a. 22,500 RSUs vest in 6 equal installments of 3,750 on September 19, 2019 and every 3 months thereafter, and

b. 25,000 RSUs vest in 8 equal installments of 3,125 on March 19, 2021 and every 3 months thereafter.

(3) 46,000 RSUs vest as follows:

a. 21,000 RSUs vest in 6 equal installments of 3,500 on September 19, 2019 and every 3 months thereafter, and

b. 25,000 RSUs vest in 8 equal installments of 3,125 on March 19, 2021 and every 3 months thereafter.

(4) 7,500 RSUs vest in 8 equal installments of 937.5 on September 22, 2019 and every 3 months thereafter.

(5) 5,750 RSUs vest as follows:

a. 750 RSUs vest in 2 equal installments of 375 on September 14, 2019 and December 14, 2019,

b. 5,000 RSUs vest as follows: 50% vest on June 14, 2020 and 50% vest on June 14, 2021, and

(6) 14,000 RSUs vest as follows:

a. 6,000 RSUs vest in 6 equal installments of 375 on September 19, 2019 and every 3 months thereafter,

b. 5,000 RSUs vest in 8 equal installments of 3,125 on March 19, 2021 and every 3 months thereafter, and

c. 3,000 RSUs vest upon achievement of certain operational and financial goals.

(7) 1,550 RSUs vest as follows:

a. 300 RSUs vest in 2 equal installments of 150 on September 14, 2019 and December 14, 2019, and

b. 1,250 RSUs vest as follows: 50% vest on June 14, 2020 and 50% vest on June 14, 2021.

(8) 2,350 RSUs vest as follows:

a. 750 RSUs vest in 6 equal installments of 125 on September 19, 2019 and every 3 months thereafter,

b. 1,000 RSUs vest in 8 equal installments of 125 on March 19, 2021 and every 3 months thereafter, and

c. 600 RSUs vest on December 19, 2022.

(9) 10,000 RSUs vest as follows:

a. 6,000 RSUs vest as follows: 25% after 6 months from date of grant and the remaining shares vest in 6 equal installments every 3 months thereafter, and

b. 4,000 RSUs vest as follows: 12.5% vest on June 28, 2021 and the remaining shares vest in 7 equal installments every 3 months thereafter.

(10) In conjunction with Mr. Egozi's departure as CFO, 17,250 out of 27,250 RSUs outstanding as of June 30, 2019, vested in July 2019, while the remaining outstanding 10,000 RSUs were forfeited on July 16, 2019.

**Option Exercises and Stock Vested Table**

The following table presents the named executive officers' RSUs that vested during fiscal year 2019 by our named executive officers. No options were exercised by our named executive officers, and 11,000 and 5,500 options granted to our Executive Chairman and our CEO, respectively, expired in fiscal year 2019.

| | Stock Awards | |
|---|---|---|
| **Name** | **Number of Shares Acquired on Vesting (#)** | **Value Realized on Vesting ($)** |
| Zami Aberman | 62,500 | 547,750 |
| Yaky Yanay | 62,000 | 544,900 |
| Chen Yehuda-Franco | 1,088 | 10,103 |
| Erez Egozi | 10,075 | 86,050 |

**Long-Term Incentive Plans-Awards in Last Fiscal Year**

We have no long-term incentive plans, other than the 2016 Plan and the 2019 Equity Compensation Plan, or the 2019 Plan, described in Item 12 below.

**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 year 2019:

| **Name** | **Fees Earned or Paid in Cash ($)** | **Stock-based Awards ($) (1)** | **Total ($)** |
|---|---|---|---|
| Mark Germain | 20,933 | 97,223 | 118,156 |
| Nachum Rosman | 29,722 | 98,528 | 128,250 |
| Doron Shorrer | 29,650 | 98,528 | 128,178 |
| Hava Meretzki | 26,401 | 70,470 | 96,871 |
| Isaac Braun | 23,911 | 70,470 | 94,381 |
| Israel Ben-Yoram | 29,690 | 86,783 | 116,473 |
| Moria Kwiat | 25,858 | 58,725 | 84,583 |

(1) 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(l) to our consolidated financial statements for fiscal year 2019 included elsewhere in this Annual Report.

We reimburse our directors for expenses incurred in connection with attending board meetings according to a written and Board approved policy. We provide the following compensation for directors: effective as of September 12, 2018, we increased the annual director compensation from $12,500 to $15,000; 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. On June 30, 2019, our Board of Directors, upon the recommendation of our Compensation Committee, approved the reduction of the annual fees paid to each of our directors, by 25% from their current levels until the earlier of closing market capitalization on the Nasdaq Capital Market reaching $170 million; or (2) June 30, 2020. The non-executive directors, as a group, 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, as determined by the Board of Directors and/or the Compensation Committee.

During fiscal year 2019, we paid a total of $186,165 in cash to directors as compensation. This amount does not include compensation to Mr. Aberman and Mr. Yanay in their capacity as directors, which is reflected in the Summary Compensation Table for fiscal year 2019 above. As of June 30, 2019, we granted our non-executive directors 492,576 options, restricted shares and RSUs (not including 74,392 options that expired by June 30, 2019) of which 327,485 were exercisable or vested, as the case may be, as follows:

| **Name** | **Total of Options, restricted shares and RSUs Granted** | **Total of restricted shares and RSUs exercisable and vested** |
|---|---|---|
| Mark Germain | 80,646(1) | 44,773 |
| Nachum Rosman | 83,596(2) | 45,319 |
| Doron Shorrer | 87,596(3) | 69,543 |
| Hava Meretzki | 58,621(4) | 46,078 |
| Isaac Braun | 58,621(5) | 46,078 |
| Israel Ben-Yoram | 87,746(6) | 52,725 |
| Moria Kwiat | 35,750 | 22,969 |
| **Total** | **492,576** | **327,485** |

(1) Excludes 30,750 options that expired at or prior to June 30, 2019.

(2) Excludes 6,375 options that expired at or prior to June 30, 2019.

(3) Excludes 11,676 options that expired at or prior to June 30, 2019.

(4) Excludes 9,520 options that expired at or prior to June 30, 2019.

(5) Excludes 9,393 options that expired at or prior to June 30, 2019.

(6) Excludes 6,678 options that expired at or prior to June 30, 2019.

For all directors, 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 award and (2) termination of a director’s position by resignation will result in the acceleration of 50% of any unvested award.

Other than as described above, 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 as per policy approved by our Compensation Committee. 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 year 2019.

**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 September 4, 2019 (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 |
|---|---|---|
| Directors and Named Executive Officers | | |
| Zami Aberman<br>Executive Chairman of the Board of Directors<br>(and previously Co-CEO) | 381,006 (2) | 2.5% |
| Yaky Yanay<br>CEO, President and Director | 309,098 (2) | 2.0% |
| Chen Franco-Yehuda<br>CFO | 5,591 | * |
| Erez Egozi<br>Former CFO | 30,713 | * |
| Israel Ben-Yoram<br>Director | 69,966 (2) | * |
| Isaac Braun<br>Director | 57,231 (3) | * |
| Mark Germain<br>Director | 46,375 | * |
| Moria Kwiat<br>Director | 29,668 (4) | * |
| Hava Meretzki<br>Director | 58,431 (5) | * |
| Nachum Rosman<br>Director | 46,942 | * |
| Doron Shorrer<br>Director | 74,024 (6) | * |
| Directors and Executive Officers as a group (10 persons) | 1,078,332 (7) | 7.1% |

_____

* = less than 1%

(1) Based on 15,547,621 shares of common stock issued and outstanding as of September 4, 2019. 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 warrants to acquire up to 7,143 shares.

(3) Includes warrants to acquire up to 5,000 shares.

(4) Includes warrants to acquire up to 2,858 shares.

(5) Includes 11,200 shares owned by Mrs. Meretzki's husband, Shai Meretzki.

(6) Includes warrants to acquire up to 1,429 shares.

(7) Includes warrants to acquire up to 30,716 shares.

**Equity Compensation Plan Information**

At our annual meeting of our stockholders held on May 31, 2016, our stockholders approved 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 RSUs, 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.

In addition, at our annual meeting of our stockholders held on June 13, 2019, our stockholders approved the 2019 Plan. Under the 2019 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 2019 Plan, the plan administrator is authorized to grant options to acquire shares of common stock, shares of Restricted Stock and RSUs in a number not exceeding 16% of the number of shares of common stock issued and outstanding immediately prior to the grant of such awards on a fully diluted basis.

The following table summarizes certain information regarding our equity compensation plans as of June 30, 2019:

| Plan Category | Number of securities to be issued upon exercise of outstanding options | Weighted-average exercise price of outstanding options | Number of securities remaining available for future issuance under equity compensation plans (2016 Plan and 2019 Plan) |
|---|---|---|---|
| Equity compensation plan approved by security holders | 89,580 | $0 | 3,567,455 |

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

Except for the arrangements described in Item 11 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 year 2019, in which the amount involved in the transaction exceeded or exceeds $120,000.

The Board of Directors has determined that Doron Shorrer, Nachum Rosman, Israel Ben-Yoram, Isaac Braun and Mark Germain are "independent" directors, 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 June 30, 2019 | Twelve months ended on June 30, 2018 |
|---|---|---|
| Audit Fees | $172,014 | $126,747 |
| Audit-Related Fees | None | None |
| Tax Fees | $19,831 | $40,829 |
| All Other Fees | $26,231 | $21,134 |
| Total Fees | $218,076 | $188,710 |

*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 fillings and (iv) fees related to the offering we closed in April 2019 and with respect to the Sales Agreement.

*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 as well as other grant 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.**

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|---|---|
| 3.1* | Composite Copy of the Company's Articles of Incorporation as amended on July 25, 2019. |
| 3.2* | Composite Copy (marked) of the Company's Articles of Incorporation as amended on July 25, 2019. |
| 3.2 | Amended and Restated By-laws (incorporated by reference to Exhibit 3.1 of our current report on Form 8-K filed on March 29, 2017). |
| 4.1 | Form of Common Stock Purchase Warrant dated January 25, 2017 (incorporated by reference to Exhibit 4.1 of our current report on Form 8-K filed on January 20, 2017). |
| 4.2 | Form of Common Stock Purchase Warrant dated March 2019 (incorporated by reference to Exhibit 4.1 of our current report on Form 8-K filed on April 5, 2019). |
| 4.3* | Description of Securities. |
| 10.1 | 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). |
| 10.2 | 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). |
| 10.3 | 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). |
| 10.4 | 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). |
| 10.5 | 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). |
| 10.6 | Assignment Agreement dated May 15, 2007 between Pluristem Therapeutics Inc. and Yeda Research and Development Ltd. (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on May 24, 2007). |
| 10.7 | 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). |
| 10.8* | Summary of Directors' Ongoing Compensation. + |
| 10.10 | 2016 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 4, 2016). + |

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|---|---|
| 10.14 | Form of Stock Option Agreement under the 2016 Equity Compensation Plan (incorporated by reference to Exhibit 10.17 of our annual report on Form 10-K filed on September 7, 2016). + |
| 10.15 | Form of Restricted Stock Agreement under the 2016 Equity Compensation Plan (incorporated by reference to Exhibit 10.18 of our annual report on Form 10-K filed on September 7, 2016). + |
| 10.16 | Form of Restricted Stock Agreement (Israeli directors and officers) under the 2016 Equity Compensation Plan (incorporated by reference to Exhibit 10.19 of our annual report on Form 10-K filed on September 7, 2016). + |
| 10.17 | 2019 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 25, 2019). + |
| 10.18* | Form of Stock Option Agreement under the 2019 Equity Compensation Plan. + |
| 10.19* | Form of Restricted Stock Agreement under the 2019 Equity Compensation Plan. + |
| 10.20* | Form of Restricted Stock Agreement (Israeli directors and officers) under the 2019 Equity Compensation Plan. + |
| 10.21 | Consulting Agreement between Pluristem Ltd. and Rose High Tech Ltd. dated September 12, 2018 (incorporated by reference to Exhibit 10.20 of our annual report on Form 10-K filed on September 12, 2018). + |
| 10.22 | Employment Agreement between Pluristem Ltd. and Yaky Yanay dated September 12, 2018 (incorporated by reference to Exhibit 10.20 of our annual report on Form 10-K filed on September 12, 2018). + |
| 10.23 | Employment Agreement between Pluristem Ltd. and Erez Egozi dated September 12, 2018 (incorporated by reference to Exhibit 10.20 of our annual report on Form 10-K filed on September 12, 2018). + |
| 10.24 | Employment Agreement between Pluristem Ltd. and Chen Franco-Yehuda dated September 12, 2018 (incorporated by reference to Exhibit 10.20 of our quarterly report on Form 10-Q filed on May 6, 2019). + |
| 10.25 | Open Market Sales Agreement, dated February 6, 2019, between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.1 of our quarterly report on Form 10-Q filed on February 6, 2019). |
| 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 Yaky Yanay. |
| 31.2* | Certification pursuant to Rule 13a-14(a)/15d-14(a) of Chen Franco-Yehuda. |
| 32.1** | Certification pursuant to 18 U.S.C. Section 1350 of Yaky Yanay. |
| 32.2** | Certification pursuant to 18 U.S.C. Section 1350 of Chen Franco-Yehuda. |

101 * The following materials from our Annual Report on Form 10-K for the fiscal year ended June 30, 2019 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.

**Item 16. Form 10-K Summary.**

None.

**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/ Yaky Yanay
Yaky Yanay, Chief Executive Officer and President

Dated: September 12, 2019

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/ Yaky Yanay
Yaky Yanay, Chief Executive Officer, President and Director
(Principal Executive Officer)
Dated: September 12, 2019

By: /s/ Chen Franco-Yehuda
Chen Franco-Yehuda, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
Dated: September 12, 2019

By: /s/ Zami Aberman
Zami Aberman, Executive Chairman of the Board of Directors
Dated: September 12, 2019

By: /s/ Israel Ben-Yoram
Israel Ben-Yoram, Director
Dated: September 12, 2019

By: /s/ Isaac Braun
Isaac Braun, Director
Dated: September 12, 2019

By: /s/ Mark Germain
Mark Germain, Director
Dated: September 12, 2019

By: /s/ Moria Kwiat
Moria Kwiat, Director
Dated: September 12, 2019

By: /s/ Hava Meretzki
Hava Meretzki, Director
Dated: September 12, 2019

By: /s/ Nachum Rosman
Nachum Rosman, Director
Dated: September 12, 2019

By: /s/ Doron Shorrer
Doron Shorrer, Director
Dated: September 12, 2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-3 (Registration No. 333-218916) and in the Registration Statements on Form S-8 (Registration No. 333-229535, 333-222888, 333-217770, 333-212299, 333-206848, 333-196537, 333-173777 and 333-162577) pertaining to the Amended and Restated 2005 Stock Option Plan and the 2016 Equity Compensation Plan of Pluristem Therapeutics Inc. of our reports dated September 12, 2019, with respect to the consolidated financial statements of Pluristem Therapeutics Inc., and the effectiveness of internal control over financial reporting of Pluristem Therapeutics Inc., included in this Annual Report (Form 10-K) for the year ended June 30, 2019.

/s/ Kost Forer Gabbay & Kasierer

Haifa, Israel
September 12, 2019

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

Exhibit 31.1

CERTIFICATION

I, Yaky Yanay, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended June 30, 2019, of Pluristem Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 12, 2019

/s/ Yaky Yanay
Yaky Yanay
Chief Executive Officer, President
(Principal Financial Officer)

Exhibit 31.2

CERTIFICATION

I, Chen Franco-Yehuda, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended June 30, 2019, of Pluristem Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 12, 2019

By: /s/ Chen Franco-Yehuda

Chen Franco-Yehuda
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report on Form 10-K of Pluristem Therapeutics Inc. (the "Company") for the period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, as the Chief Executive Officer and President of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350 that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: September 12, 2019

/s/ Yaky Yanay
Yaky Yanay
Chief Executive Officer, President

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report on Form 10-K of Pluristem Therapeutics Inc. (the "Company") for the period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, as the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350 that, to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 12, 2019

By: /s/ Chen Franco-Yehuda
_____

Chen Franco-Yehuda
Chief Financial Officer

Pluristem Therapeutics Inc.

Inspired by Life

# CORPORATE INFORMATION

***Executive Officers***

Zami Aberman
Executive Chairman of the Board

Yaky Yanay
Chief Executive Officer and President

Chen Franco-Yehuda
Chief Financial Officer, Treasurer and Secretary

***Directors***

Zami Aberman
Executive chairman of the Board

Yaky Yanay
Chief Executive Officer and President

Israel Ben-Yoram
Partner at Mor, Ben-Yoram and Partners accounting firm

Isaac Braun
Active in several hi-tech start-up companies as investor, co-founder and director

Mark Germain
Active in several biotech companies as investor, founder, director and/or chairman of the board

Moria Kwiat
Analyst at a venture capital fund, holds Ph.D. in Chemistry and Biotechnology from Tel Aviv University

Hava Meretzki
Partner at Meretzki Law Firm

Nachum Rosman
Active in several hi-tech start-up companies as director

Doron Shorrer
Active in several financial companies as a consultant and director

***Corporate Address***

Matam Advanced Technology Park
Building No. 5, Haifa 3508409
Israel

***Independent Auditors***

Kost Forer Gabbay & Kasierer,
A Member of Ernst & Young Global
Tel Aviv, Israel

***Counsel***

Zysman, Aharoni, Gayer & Sullivan & Worcester LLP
1633 Broadway, 32nd Floor
New York, New York 10019
U.S.A.

***Transfer Agent***

American Stock Transfer & Trust Company
6201 15th Avenue
2nd Floor
Brooklyn, NY 11219
U.S.A.

***Stock Market Information***

Pluristem'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'.

***Annual Meeting***

The Annual Meeting of Stockholders will be held at 4:00 p.m., local time, on June 29, 2020, at Pluristem's offices in Haifa, Israel.

***Annual Report on Form 10-K***

Pluristem's Annual Report on Form 10-K (without exhibits) is available free of charge by writing to Pluristem at the address set forth above. You can also obtain a copy of the filing by going to the following website: http://www.sec.gov.

***Website***

http://www.pluristem.com