

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

FORM 10-K

(Mark One)

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

For the fiscal year ended **June 30, 2021**

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
<b>Common Shares, par value \$0.00001</b>	<b>PSTI</b>	<b>The Nasdaq Global Market</b>

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.

\$174,929,346

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

32,004,785 as of September 3, 2021

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Our financial statements are stated in thousands United States Dollars 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 and the wholly owned subsidiary of our Israeli subsidiary in Germany, unless otherwise indicated or required by the context.

#### 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, as well as grants from other independent third parties;

- the receipt of funds pursuant to our agreement with the European Investment Bank, or the EIB Finance Agreement and EIB, respectively, and whether we will achieve the milestones necessary to receive funds thereunder;
- 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;
- our plan for the initiation of a multinational regulated clinical trial program for the potential use of PLX cells in the treatment of patients suffering from complications associated with the COVID-19 pandemic;
- 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;
- information with respect to any other plans and strategies for our business; and
- our expectations regarding the impact of the COVID-19 pandemic, including on our clinical trials and operations.

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

## PART I

### ITEM 1. BUSINESS.

#### Our Current Business

We are a biotechnology company focused in the field of regenerative medicine, and a leading developer of placenta-based cell therapy product candidates for the treatment of multiple inflammatory, muscle injuries and hematologic conditions. Our operations are focused on the research, development, manufacturing, conducting clinical trials and business development of cell therapeutics and related technologies.

Placental expanded, or 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. The cells are grown using our proprietary three-dimensional expansion technology and can be administered to patients off the-shelf, without blood or tissue matching prior to administration. PLX cells are believed to release a range of therapeutic proteins in response to the patient's condition, such as inflammation, muscle trauma, hematological disorders and radiation damage.

We are conducting several multinational clinical studies which consist of a Phase III clinical study in muscle recovery following surgery for hip fracture and two Phase II clinical studies in Acute Respiratory Distress Syndrome, or ARDS, associated with COVID-19 in the United States, Europe and Israel. In addition, we are focusing on other clinical programs in the hematological field such as a Phase I clinical study for incomplete recovery following bone marrow transplantation in the United States and Israel, an investigator-led Phase I/II Chronic Graft versus Host Disease, or cGVHD, study in Israel, and Acute Radiation Syndrome, or ARS, under the U.S. Food and Drug Administration, or FDA, animal rule. We believe that each of these indications is a severe unmet medical need.

Our manufacturing facility complies with the European, Japanese, Israeli, South Korean and the FDA's current Good Manufacturing Practice, or cGMP, requirements and has been inspected and approved by the European and Israeli regulators for production of PLX-PAD for late stage trials. We have also been granted manufacturer/importer authorization and cGMP Certification by the Israeli Ministry of Health, or MOH. If we obtain FDA and other regulatory approvals to market PLX cells, we expect to have in-house production capacity to grow PLX cells in commercial quantities.

Our goal is to make significant progress with our clinical pipeline and our clinical studies 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, licensing deals, joint ventures with pharmaceutical companies, direct sale of our products, and partnerships.

We were incorporated in Nevada in 2001, and we have a wholly owned subsidiary in Israel called Pluristem Ltd., or the Israeli Subsidiary, and a wholly owned subsidiary in Germany called Pluristem GmbH.

#### 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 deficiencies.

PLX cells do not require tissue matching prior to administration, which allows 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 after a full-term delivery of a healthy baby. Our PLX cells are adherent stromal cells that are expanded using a proprietary three-dimensional, or 3D, process. This system utilizes a synthetic scaffold to create an artificial 3D environment where placental-derived stromal cells can grow. Our automated proprietary 3D, cGMP approved, process enables the large-scale monitored and controlled production of reproducible, high quality cell products and can manufacture a large number of PLX doses. Additionally, our current manufacturing process, which has scaled up as compared to previous years, 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. Currently, our PLX products are administered intramuscular, or IM, using a standard needle and syringe.

### ***PLX-PAD***

Our first product candidate, PLX-PAD, is composed of maternal cells originating from the placenta. PLX-PAD is currently being used in a Phase III multinational clinical study in recovery following surgery for hip fracture, and in two Phase II clinical studies in ARDS associated with COVID-19 in the United States, Europe and Israel.

We have also conducted a pivotal Phase III multinational clinical study in the use of PLX-PAD for the treatment of Critical Limb Ischemia, or CLI, which we terminated in December 2020, and in a Phase II multinational clinical study in Intermittent Claudication, or IC.

PLX-PAD is also under clinical development in collaboration with Tel Aviv Sourasky Medical Center (Ichilov Hospital) through an investigator initiated study, and used in a Phase I/II for the treatment of Steroid-Refractory cGVHD.

### ***PLX-R18***

Our second product candidate, PLX-R18, is composed of fetal cells originated from the placenta.

We have completed enrollment in our first in human Phase I clinical study in incomplete hematopoietic recovery following hematopoietic cell transplantation, or HCT, in the United States and Israel.

Through our collaboration in the United States with the National Institutes of Health, or NIH, and the U.S. Department of Defense, or DoD, we are also developing a solution for ARS following or before exposure to massive radiation via the FDA Animal Rule regulatory pathway.

### ***Modified PLX cells***

In the last decade, we developed an allogeneic platform based on cells originated from the fetal and maternal cell from the placenta, and by using this platform we can produce large quantities of high-quality cells in automated and robust manufacturing suitable for cGMP environment. As a platform technology company, we are currently developing additional product candidates, which are modified or induced PLX cells:

Induced PLX cells: we are using cells from the placenta, induced with inflammatory cytokines, to transiently alter their secretion profile.

Modified PLX cells using CRISPR technology: CRISPR is a unique technology that opens the door for precise gene editing of cells. Using such technology can initiate the next evolution in cell therapy by allowing the reprogramming of cells for specific needs. Our aim is to incorporate the genetic engineering techniques into our cell manufacturing platform in order to develop large scale allogeneic engineered PLX products designed for specific indications.

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

**Orthopedic Indications.** Following FDA and European Medicine Agency, or EMA, clearance, a multinational Phase III study is currently being conducted in the United States, Europe and Israel. The primary endpoint of this study is the Short Physical Performance Battery (SPPB), a test for lower leg performance and functional status. The study is planned to include 240 patients and will assess efficacy at six months and a year, as well as safety for up to two years. Currently, over 95% of the study patients have been enrolled in this study.

Our Phase III study 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 IM injections of allogeneic PLX-PAD cells for the regeneration of injured gluteal musculature after total hip replacement had 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 patients.

**COVID-19 Complicated by ARDS.** In May 2020, the FDA cleared our Investigational New Drug Application, or IND, for a Phase II study of our PLX-PAD cells for treatment of severe COVID-19 cases complicated by ARDS and we initiated the study in June 2020. The U.S. study is a randomized, double-blind, placebo-controlled, multicenter, parallel-group intended to evaluate the efficacy and safety of IM injections of PLX-PAD for the treatment of severe COVID-19 cases complicated by ARDS. The primary endpoint is the number of ventilator free days during the 28-days following dosing. Secondary efficacy endpoints include all-cause mortality, duration of mechanical ventilation, ICU free-days, and hospitalization free-days. Safety and survival follow-up will be conducted until week 52. In addition, the FDA has cleared our Expanded Access Program, or EAP, for the use of our PLX-PAD cells to treat ARDS caused by COVID-19 outside of the Phase II COVID-19 complicated by ARDS study in the United States. The EAP approval was for up to 100 patients.

In August 2020, the PEI cleared our Phase II study in Germany titled, “A Randomized, Controlled, Multicenter, Parallel-Group Phase II Study to Evaluate the Efficacy and Safety of Intramuscular Injections of PLX PAD for the Treatment of severe COVID-19,” relating to the treatment of patients hospitalized with severe cases of COVID-19 complicated by ARDS. The primary efficacy endpoint of the study is the number of ventilator free days during the 28-days from day one through day 28 of the study. Secondary efficacy endpoints include all-cause mortality, duration of mechanical ventilation, ICU free-days, and hospitalization free-days. Safety and survival follow-up will be conducted until week 52. We enrolled patients in Europe and Israel under this protocol.

On July 8, 2021, we announced that we are bringing our COVID-19 complicated by ARDS Phase II studies in the United States, Europe and Israel to clinical readout. The analysis will be based on 89 patients enrolled. We expect to announce the topline results of the readout during the fourth quarter of 2021. We also announced that we will not pursue the previously announced plans in December 2020 to expand our COVID-19 program in Mexico in collaboration with Innovare R&D SA de CV.

**Recovery Following HCT.** This Phase I study of PLX-R18 in HCT, has completed enrollment of 21 patients in the United States and Israel. The study is designed to assess the safety of PLX-R18 by assessing adverse events, safety labs and vital signs in patients receiving different doses of PLX-R18. We expect to complete one year follow up for all patients in September 2021. In April 2021, we announced topline results of this study. The 21 patients enrolled in the United States and Israel were at least three months after the HCT procedure (median: 236 days) and had low blood counts in at least one blood cell lineage. They were assigned to one of three treatment arms: one million cells/kg, two million cells/kg or four million cells/kg. Each patient received two treatments of the assigned dose.

Data from the six-month follow-up were available for 14 of the 21 treated patients and demonstrated that (i) PLX-R18 was well-tolerated with a favorable safety profile; (ii) statistically significant improvement from baseline counts was observed in all cohorts for hemoglobin and platelet counts (p<0.05) and the patients in the high dose arm (4 million cells/kg) exhibited statistically significant improvements in all three blood cell lineages (p<0.01); (iii) approximately 60% of patients exhibited improvements in all three blood cell lineages: hemoglobin, neutrophil and platelet counts that are above the initial criteria for inclusion in the study and (iv) 13 patients were transfusion dependent at baseline; six of those became transfusion independent at 6 month follow-up and no patients who were transfusion independent at baseline became transfusion dependent.

**Peripheral and Cardiovascular Diseases.** We investigated the use of PLX-PAD cells for the treatment of peripheral arterial disease, or PAD, including IC and CLI.

We completed two Phase I safety/dose-escalating clinical studies for CLI, one in the United States and one in Germany. These CLI studies 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.

We conducted a pivotal Phase III study 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 study was conducted in the United States, Europe and Israel and enrolled 213 patients in total.

In December 2020, the independent Data Monitoring Committee, or DMC, issued its recommendation letter following an interim analysis relating to the CLI Phase III study. A clinical dataset was reviewed by the independent DMC for safety and analysis of the primary endpoint of amputation-free survival, defined as time to occurrence of major amputation of the index leg or death. Based on the review, the DMC concluded that the CLI study was unlikely to meet the primary endpoint by the time of the final analysis. Following the DMC's recommendation, we decided to terminate the CLI study.

**ARS.** We have conducted several animal studies for the evaluation of PLX-R18 for the treatment of ARS, in collaboration with the National Institute of Allergy and Infectious Diseases, or the NIAID. The NIH, funded and conducted a pilot study in non-human primates, or NHPs, to evaluate the therapeutic effect of PLX-R18 on hematological aspects of ARS. In 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 IM 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, or BLA, 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 NHPs 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, or MOU, 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 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 shows 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.

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



## 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 studies 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 MOH, Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, and also the Ministry of Food and Drug Safety, or MFDS, of South Korea.

## 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 133 issued patents and approximately 70 pending patent applications in the United States, Europe, China, Japan and Israel, as well as in additional countries worldwide, including 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 Israeli 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 is in addition to the grant of 13 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 and bedside thawing devices.

In February 2017, the Israeli Subsidiary signed an agreement with founders of a certain patent for a five-year option to purchase a certain patent for an amount of €1 million. The agreement includes yearly payments of €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 April 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 3D cell culturing technology for the potential manufacturing of cannabinoid-producing cells. In April 2020, we filed a Patent Cooperation Treaty, or PCT, application with respect to the technology. In June 2021, national or regional phase applications of the PCT were filed in the United States, Europe, Japan, Canada, and Israel.

In March 2020, we filed a U.S. provisional patent application titled "Methods and Compositions for Treating Viral Infections and Sequelae Thereof," which covers the use of placental adherent stromal cells for treating coronavirus infections and sequelae thereof. In May 2020, a related Israeli patent application was filed, which was allowed in March 2021. In March 2021, a PCT application as well as national applications were filed in the United States and Israel. In June 2021, national or regional phase applications of the PCT were filed in Europe and Mexico.

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 adherent stromal cell 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 sets forth 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.

The expiration dates of these patents, based on filing dates, range from 2027 to 2041. 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.

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.”

#### Our Patent Portfolio

<b>Patent Name/ Int. App. No.</b>	<b>Pending Jurisdictions</b>	<b>Granted Jurisdictions</b>	<b>Expiry Date</b>
<b>METHODS FOR CELL EXPANSION AND USES OF CELLS AND CONDITIONED MEDIA PRODUCED THEREBY FOR THERAPY PCT/IL2007/000380</b>	China, Hong Kong	Australia, Canada, China, Hong Kong, Europe, Israel, India, Japan, South Korea, Mexico, Russia, Singapore	March 23, 2027
<b>ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2008/001185</b>	United States, Israel	Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Mexico, Russia, United States, South Korea	September 2, 2028
<b>METHODS OF TREATING INFLAMMATORY COLON DISEASES PCT/IL2009/000527</b>		United States, Israel, Russia	May 26, 2029
<b>METHODS OF SELECTION OF CELLS FOR TRANSPLANTATION PCT/IL2009/000844</b>		Europe, Israel	September 1, 2029
<b>ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000846</b>		Australia, Canada, China, Europe, Hong Kong, Israel, India, Mexico, Russia, Singapore, United States	September 1, 2029
<b>ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY PCT/IL2009/000845</b>		United States, Europe, Israel	September 1, 2029
<b>ADHERENT STROMAL CELLS DERIVED FROM PLACENTAS OF MULTIPLE DONORS AND USES THEREOF PCT/IB2011/001413</b>	United States	Israel	Israel: April 21, 2031 U.S: March 22, 2027
<b>ADHERENT CELLS FROM PLACENTA AND USE OF SAME IN DISEASE TREATMENT PCT/IB2010/003219</b>	United States, Israel	Australia, Canada, China, Hong Kong, Europe, Israel, Mexico, New Zealand, United States	November 29, 2030

<b>METHODS AND SYSTEMS FOR HARVESTING ADHERENT STROMAL CELLS</b> PCT/IB2012/000933	China, Israel	Australia, Canada, Europe, Israel, India, South Korea, Mexico, Singapore, United States	April 15, 2032
<b>METHODS FOR TREATING RADIATION OR CHEMICAL INJURY</b> PCT/IB2012/000664	United States	Europe, Hong Kong, Israel, Japan, South Korea, United States	March 22, 2032
<b>SKELETAL MUSCLE REGENERATION USING MESENCHYMAL STEM CELLS</b> PCT/EP2011/058730		United States, Europe, Israel	May 27, 2031
<b>GENE AND PROTEIN EXPRESSION PROPERTIES OF ADHERENT STROMAL CELLS CULTURED IN 3D</b> PCT/IB2014/059114		Israel, United States	February 20, 2034
<b>DEVICES AND METHODS FOR CULTURE OF CELLS</b> PCT/IB2013/058184		United States, Israel	August 31, 2033
<b>METHODS FOR PREVENTION AND TREATMENT OF PREECLAMPSIA</b> PCT/IB2013/058186		China, Hong Kong, Europe, Israel, Japan, South Korea, United States	August 31, 2033
<b>METHOD AND DEVICE FOR THAWING BIOLOGICAL MATERIAL</b> PCT/IB2013/059808	China	Australia, Europe, Hong Kong, Israel, India, Japan, South Korea, Russia, Singapore, United States	October 31, 2033
<b>SYSTEMS AND METHODS FOR GROWING AND HARVESTING CELLS</b> PCT/IB2015/051559		Israel, United States	March 3, 2035
<b>METHODS AND COMPOSITIONS FOR TREATING AND PREVENTING MUSCLE WASTING DISORDERS</b> PCT/IB2015/059763		Israel, United States	December 18, 2035
<b>USE OF ADHERENT STROMAL CELLS FOR ENHANCING HEMATOPOIESIS IN A SUBJECT IN NEED THEREOF</b> PCT/IB2016/051585	United States, China, Israel		March 21, 2036
<b>ALTERED ADHERENT STROMAL CELLS AND METHODS OF PRODUCING AND USING SAME</b> PCT/IB2016/053310	Europe, China, Israel	United States	June 6, 2036
<b>METHODS AND COMPOSITIONS FOR TREATING CANCERS AND NEOPLASMS</b> PCT/IB2017/050868	United States, Japan, Canada, Australia, Israel	Europe	February 16, 2037
<b>METHODS AND COMPOSITIONS FOR TREATING NEUROLOGICAL DISORDERS</b> PCT/IB2018/052806	Israel, United States		April 23, 2038
<b>METHODS AND COMPOSITIONS FOR TUMOR ASSESSMENT</b> PCT/IB2018/050984	United States, Israel		February 18, 2038
<b>METHODS AND COMPOSITIONS FOR TREATING ADDICTIONS</b> PCT/IB2018/055473	Israel, United States		July 23, 2038

<b>METHODS AND COMPOSITIONS FOR DETACHING ADHERENT CELLS</b> Germany 10 2018 115 360.0	Germany		June 25-July 3, 2038
<b>DRUG CONTAINING HUMAN PLACENTA-ORIGIN MESENCHYMAL CELLS AND PROCESS FOR PRODUCING VEGF USING THE CELLS JP20030579842</b>		Japan	March 28, 2023
<b>METHODS AND COMPOSITIONS FOR PRODUCING CANNABINOIDS</b>	PCT, Canada, Europe, Israel, Japan, United States		April 28, 2040
<b>METHODS FOR EXPANDING ADHERENT STROMAL CELLS AND CELLS OBTAINED THEREBY</b> PCT/IB2019/052569	Israel, Singapore, United States		March 28, 2039
<b>METHODS AND COMPOSITIONS FOR TREATING SUBJECTS EXPOSED TO VESICANTS AND OTHER CHEMICAL AGENTS</b> PCT/IB2019/055074	Israel, United States		June 18, 2039
<b>METHODS AND COMPOSITIONS FOR FORMULATING AND DISPENSING PHARMACEUTICAL FORMULATIONS</b> PCT/IB2019/053115	United States	Israel	United States: April 16, 2039 Israel: April 26, 2038
<b>THERAPEUTIC DOSAGE REGIMENS COMPRISING ADHERENT STROMAL CELLS</b> PCT/IB2019/054828	Israel, United States		June 10, 2039
<b>MODULAR BIOREACTOR</b> PCT/IB2019/058429	Europe, Israel, South Korea, Singapore, United States		October 3, 2039
<b>THERAPEUTIC METHODS AND COMPOSITIONS</b> PCT/IB2019/059544	Israel, United States		November 6, 2039
<b>METHODS AND COMPOSITIONS FOR TREATING VIRAL INFECTIONS AND SEQUELAE THEREOF</b> PCT/IL2021/050268	PCT, United States, Europe, Israel, Mexico	Israel	First Israeli application: May 14, 2040 Other applications: March 11, 2041
<b>METHODS AND COMPOSITIONS FOR AESTHETIC AND COSMETIC TREATMENT AND STIMULATING HAIR GROWTH</b> PCT/IL2020/050363	PCT, United States, Europe, Canada, China, Japan, Israel, Australia		March 26, 2040
<b>METHODS FOR EXPANDING ADHERENT STROMAL CELLS AND CELLS OBTAINED THEREBY</b> IL277560	Israel		September 23, 2040

## ***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 was acquired by us and 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, which was extended from time to time 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 net sales of 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 for conducting clinical studies and commercialization of our PLX-PAD product candidate in South Korea in connection with two indications: the treatment of CLI and IC. We will continue to retain rights to our proprietary manufacturing technology and cell-related intellectual property.

The first clinical study that was performed as part of the CHA Agreement was a Phase II study 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 studies.

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 was conducted as 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 is 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 enables us to 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.

### NASA

In February 2019, we entered 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. Department of Defense

In August 2017, we announced that a pilot study of our PLX-R18 cell therapy was initiated by the DoD. The study examined 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 DoD.

### RESTORE

We are members of a large-scale research initiative, the RESTORE project which has received funding of €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. Currently, due to COVID-19, there is no open call for full proposal. The members of the RESTORE project continue to collaborate in attempt to collectively submit the grant application once such call is available.

### CRISPR-IL

In June 2020, we announced that we were selected as a member of the CRISPR-IL consortium, a group funded by the IIA. CRISPR-IL brings together the leading experts in life science and computer science from academia, medicine, and industry, to develop Artificial Intelligence, or AI, based end-to-end genome-editing solutions. These next-generation, multi-species genome editing products for human, plant, and animal DNA, have applications in the pharma, agriculture, and aquaculture industries. CRISPR-IL is funded by the IIA with a total budget of approximately \$10,000,000 of which, an amount of approximately \$480,000 is a direct grant allocated to us, for an initial period of 18 months, with a potential for extension of an additional 18 months, or the Second Period, with additional budget from the IIA.

In August 2021, we submitted an additional budget for the Second Period. The CRISPR-IL consortium program does not require us to pay royalties to the IIA.

### United Arab Emirates-based Abu Dhabi Stem Cells Center

In August 2020, we signed a non-binding MOU with the United Arab Emirates-based Abu Dhabi Stem Cells Center, a specialist healthcare center focused on cell therapy and regenerative medicine. The aim of the collaboration is to capitalize on each party's respective areas of expertise in cell therapies. The parties have agreed to exchange research results, share samples, join usage of equipment and testing, and other essential activities related to advancing the treatment and research of cell therapies for a broad range of medical conditions, including COVID-19.

We plan to continue to collaborate with universities, 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 Good Manufacturing Practice, or 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, MFDS, PMDA and the MOH. Our second product, PLX-R18, was cleared by the FDA and the MOH for clinical use. Furthermore, the site was inspected and approved by an European Union 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 the MOH and we received a cGMP Certification and manufacturer-importer authorization.

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 manufactured using the serum-free media.

#### **Government Regulation**

The development, manufacturing, and future marketing of our cell therapy product candidates are subject to the laws and regulations of governmental authorities in the United States, Europe and Israel, as well as other countries in which our products may be marketed in the future like Japan, and South Korea. In addition, the manufacturing conditions are specifically inspected by the MOH.

The FDA and the EMA must approve products prior to 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 undergoes 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 concerns, 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;
- The manufacture of the product according to GMP regulations and standards;
- Conducting adequate and well-controlled human clinical studies in compliance with Good Clinical Practice, or GCP, to establish the safety and efficacy of the product for its intended indication; and

- Potential post-marketing clinical testing and surveillance of the product after marketing approval, which can result in additional conditions on the approvals or suspension of clinical use.

Approval of a drug for clinical studies in humans and approval of marketing are sovereign decisions of states, made by national, or, in case of the European Union, international regulatory competent authorities.

#### The Regulatory Process in the United States

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

- Submission of an IND 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 studies;
- FDA may grant approval for EAP prior to the completion of clinical studies, in order to allow access for the investigational drug, for patients that are excluded from the study;
- FDA may grant priority review status to expedite the BLA review process. Obtaining a Fast Track designation allows access for the request of priority review;
- Submission of a BLA for marketing authorization of the product, which must include adequate results of pre-clinical testing and clinical studies;
- Submission of BLA with a proof of efficacy that is based only on animal studies is feasible in instances where human efficacy studies cannot be conducted because the conduct of such studies is unethical and field studies 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 for each European country involved in the clinical study. The application may be filed via a centralized procedure, which makes it possible to obtain a coordinated assessment of an application for a clinical study that is to take place in several European countries;
- Obtaining approval of affiliated ethics committees to test the investigational product into humans in clinical studies;
- Adequate and well-controlled clinical studies 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 European Union. The EMA is expected to review and approve the MAA.

In May 2015, we were selected by the EMA for development of PLX-PAD cells via the EMA Adaptive Pathways Project.



## Other Regulations

In general, the approval procedure varies among countries, and may involve additional preclinical testing and clinical studies. 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 study 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 Studies

Typically, in the United States, as well as in the European Union, clinical development involves a three-phase process, although the phases may overlap. Phase I, clinical studies are conducted in 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.

Phase II clinical studies are conducted with a homogenous group of patients afflicted with the specific target disease, to explore preliminary efficacy, optimal dosages and confirm the safety profile. In some cases, an initial study is conducted in 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 study. Phase III clinical studies are generally large-scale, multi-center, controlled studies conducted with a heterogeneous group of patients afflicted with the target disease, aiming to provide statistically significant support of efficacy, as well as safety and potency. The Phase III studies are considered confirmatory for establishing the efficacy and safety profile of the drug and are critical for approval. In some circumstances, a regulatory agency may require Phase IV, or post-marketing studies in case additional information needs to be collected after the drug 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 study sites investigators to minimize risks and ensure high quality and integrity of the collected data. The sponsor of a clinical study is required to submit an annual safety report to the relevant regulatory agencies, in which serious adverse events are reported, and also to submit in an expedited manner any individual serious adverse events that are suspected to be related to the tested drug and are unexpected with its use. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the clinical study based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

## ***Employees***

As of June 30, 2021, we employed a total of 153 full-time employees and nine part-time employees, of whom, 129 full-time employees and nine part-time employees are engaged in research and development, manufacturing and clinical development.

## ***Competition***

The regenerative medicine field is characterized by intense competition, as global and local pharma players are becoming more engaged in the cell therapy field based on the advancements made in clinical studies 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., Celularity Inc., Tigenix NV (acquired by Takeda), SanBio Inc. 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.

## ***Impact of COVID-19***

In managing our ongoing global clinical studies, as well as our daily operations, in the ongoing COVID-19 global pandemic, we are taking all necessary precautions for the safety and well-being of patients, healthcare providers involved in our studies, and our employees. We are continuing our operational and manufacturing activities, subject to the directives of the MOH, with a dedicated team on site at our facilities. In addition, the majority of our employees have been vaccinated and we are using remote work technologies that enable the mitigation of office staff while allowing other activities to be conducted without the need for a physical presence in our facilities. The COVID-19 global pandemic caused delays in enrollment of some of our clinical studies. Despite these impacts, we currently hold supplies of PLX cells in inventory in Israel, and in secure storage facilities in Europe and the U.S. In addition, we are following the FDA and EMA guidelines regarding the management of clinical studies during COVID-19. However, the impact of the COVID-19 global pandemic is constantly evolving, and we may experience further impacts on our daily operations, including the need for employees to potentially self-isolate based on potential exposure to the virus, difficulties for our employees in travelling abroad, and delays in our clinical trials and our ongoing research work with various hospitals and academic institutions.

## ***Available Information***

Additional information about us is contained on our Internet website at [www.pluristem.com](http://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, or the 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](http://www.sec.gov). The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics, Trading Policy and the Charters for each of the Committees of our Board of Directors, or the Board.

## **ITEM 1A. RISK FACTORS.**

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this Annual Report on Form 10-K before making an investment decision. Our business, prospects, financial condition and results of operations may be materially and adversely affected as a result of any of the following risks. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in “Item 1A. Risk Factors” are forward-looking statements. 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, prospects, financial condition and results of operations.

### **Summary of Risk Factors**

Our business is subject to a number of risks, including risks that may adversely affect our business, financial condition and results of operations. These risks are discussed more fully below and include, but are not limited to, risks related to:

- the COVID-19 pandemic has caused interruptions and delays of our business plan and may have a significant adverse effect on our business;
- we have a history of losses and have not generated significant revenues to date. We expect to experience future losses and do not foresee generating significant or steady revenues in the immediate future;
- we may need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and could dilute our shareholders’ ownership interests, and such offers or availability for sale of a substantial number of our common shares may cause the price of our publicly traded shares to decline;
- we may become subject to claims by much larger and better funded competitors enforcing their intellectual property rights against us or seeking to invalidate our intellectual property or our rights thereto;
- clinical studies necessary to support the approval of our applications are often lengthy and expensive and require the enrollment of a large number of patients. Suitable patients may be difficult to identify and enroll. Any delay or failure of clinical trials could delay us from commercializing our product candidates, which would materially and adversely affect our results of operations and the value of our business;

- we may not be able to successfully license our product candidates;
- there are inherent risks in the manufacturing of our product candidates, including meeting relevant high regulatory standards, the failure of which could materially and adversely affect our results of operations and the value of our business;
- we may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, healthcare and security laws and regulations, which could expose us to criminal sanctions civil penalties, contractual damages, reputational harm and diminished profits and future earnings;
- we may be exposed to product liability and corporate claims and insurance may not be sufficient to cover these claims;
- in the United States and Europe, our business could be significantly and adversely affected by healthcare reform initiatives and/or other legislation or judicial interpretations of existing or future healthcare laws and/or regulations;
- if we are unable to obtain and maintain intellectual property protection covering our products and technology, others may be able to utilize our intellectual property, which would adversely affect our business;
- we are an international business, and we are exposed to various global and local risks that could have a material adverse effect on our financial condition and results of operations;
- the market prices of our common shares are subject to fluctuation and have been and may continue to be volatile, which could result in substantial losses for investors;
- we anticipate being subject to fluctuations in currency exchange rates because a significant portion of our business is conducted outside the United States and we are exposed to currency exchange fluctuations in other currencies such as the New Israeli Shekel, or NIS, and the Euro, because a significant portion of our expenses in Israel are paid in NIS, and we anticipate receipt of additional funds in Euros from the EIB Finance Agreement;
- restrictions and covenants contained in the EIB Finance Agreement may restrict our ability to conduct certain strategic initiatives;
- limitations we may face relating to the grants we have received from the IIA may impact our plans and future decisions;
- if there are significant shifts in the political, economic and military conditions in Israel and its neighboring countries, it could have a material adverse effect on our business relationships and profitability; and
- it may be difficult for investors in the United States to enforce any judgments obtained against us or some of our directors or officers.

## Risk Related to Our Business

***We may need to raise additional financing to support the research, development and manufacturing of our cell therapy 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 are dependent, to a certain extent, on our achieving certain milestones, 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 future in order to satisfy our working capital and capital expenditure requirements. Therefore, we are dependent on our ability to sell our common shares for funds, receive grants, potentially receive milestone payments pursuant to the EIB Finance Agreement, enter into collaborations and licensing deals or to otherwise raise capital. There can be no assurance that we will be able to obtain financing, including any funding under the EIB Finance Agreement. Any sale of our common shares in the future will result in dilution to existing shareholders and could adversely affect the market price of our common shares.

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 shares.

***Our likelihood of profitability depends on our ability to license and/or develop and commercialize our 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.

***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 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.

***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 product candidates 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, one Phase II clinical trial in IC and a multinational Phase III study in CLI. In addition, we currently have two ongoing Phase II FDA studies of PLX cells for the treatment of COVID-19 complicated by ARDS and one Phase III multinational clinical trial with our PLX-PAD product candidate in muscle recovery following surgery for hip fracture. In addition, our second product candidate, PLX-R18, is currently in a Phase I study for recovery following HCT. 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 product candidates.

***We have not generated significant or consistent revenues to date, 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 prior license agreement with United Therapeutics Corporation which was terminated in December 2015, we did not generate any material revenues and we have not generated any material revenues since that date. It is not clear when we will generate 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 shares, government grants and funds distributed pursuant to our EIB Finance Agreement. 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 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.

***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.

## Risks Related to Development, Clinical studies, and Regulatory Approval of Our Product Candidates

***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 share 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 candidate. 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 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, including as a result of COVID-19 pandemic;
- Government actions, such as those enacted during the ongoing COVID-19 pandemic, that limit the general populations movement;
- 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 and other related vendors 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;
- Third party clinical investigators and other related vendors may declare bankruptcy or terminate their business unexpectedly, which most likely will result in further delays in our clinical trials' anticipated schedule and cause additional expenditures;
- 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 facilities or our clinical manufacturing facilities are damaged or destroyed, our business and prospects would be adversely affected.***

If our processing and storage facilities, our clinical manufacturing facility 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 facility 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.

***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 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 regard 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 lengthier. 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 the treatment of COVID-19, 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.

***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 have conducted Phase I, Phase II and Phase III trials, and we are currently conducting one Phase III trial for our PLX-PAD product candidate, two Phase II studies of PLX cells for the treatment of severe COVID-19 complicated by ARDS, and a Phase I study 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.

***Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and as the data are subject to audit and verification procedures, that could result in material changes in the final data.***

From time to time, we may publish interim, "top-line," or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, "top-line," or interim data and final data could significantly harm our business prospects.



## Risk Related to Commercialization of Our Product Candidates

*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. 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.

*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.

## Risk Related to Intellectual Property

***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 adherent stromal cells in-house. Through our experience with adherent stromal cell-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.

***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 shares. 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 by the time our patents expire and 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 un-patentable 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 likely suffer.

***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.

## Risk Related to Our Common Shares

### *The price of our common shares may fluctuate significantly.*

The market for our common shares may fluctuate significantly. A number of events and factors may have an adverse impact on the market price of our common shares, 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 shares 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;
- future sales of our common shares, or the perception of such sales;
- disruptions in our manufacturing processes; and
- competition.

In addition, a global pandemic, such as the COVID-19 pandemic and 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 common shares may cause dilution.*

Future sales of our common shares, or the perception that such sales may occur, could cause immediate dilution and adversely affect the market price of our common shares. If we raise additional capital by issuing equity securities, the percentage ownership of our existing shareholders may be reduced, and accordingly these shareholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common shares. Given our need for cash and that equity raising is the most common type of fundraising for companies like ours, the risk of dilution is particularly significant for shareholders of our company.

## Risks Related to Foreign Exchange Rates

### *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 NIS and the Euro, because a significant portion of our expenses in Israel are paid in NIS, and we have also received €20 million pursuant to the EIB Finance Agreement, all of which subjects us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, and lease payments on our facilities. During the fiscal year ended June 30, 2021, or Fiscal Year 2021, 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.

### *The dollar cost of our loan from the EIB will be subject to currency valuations of the U.S. dollar and the Euro*

Following the receipt of the first tranche of the loan from the EIB, which was provided in Euros pursuant to the EIB Finance Agreement, we have established both a cash asset and a liability in our financial statements. If the Euro increases in value in relation to the U.S. dollar, both the asset and the liability of our loan from the EIB will increase, and if the Euro decreases in relation to the U.S. dollar, both the asset and liability will conversely decrease.

Since the tranche of the loan received from the EIB and the accumulated interest are payable together in a single installment within five years from disbursement of the tranche, and we are likely to use the cash received from the EIB to finance our operations, as time progress the cost basis of the liability is expected to increase and the cash asset is expected to decrease.

Therefore, the effect of currency fluctuations of the Euro in relation to the U.S. dollar on the liability resulting from the loan from the EIB is expected to be greater than the effect on the cash asset.

As part of our hedging strategy, we may use currency transactions of options and forward contracts to minimize the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the Euro, but there are no guaranties that we will be able to offset some or all the losses if the Euro inclines in value in relation to the U.S. dollar.

### *Our cash may be subject to a risk of loss and we may be exposed to fluctuations 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, 2021. Currently, we hold part of our cash 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.

## Other Risks

*The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business and operations.*

While COVID-19 is still spreading globally, and the final implications of the pandemic are difficult to estimate at this stage, it is clear that it has affected the lives of a large portion of the global population. At this time, the pandemic has caused states of emergency to be declared in various countries, travel restrictions imposed globally, quarantines established in certain jurisdictions and various institutions and companies being closed. We are actively monitoring any developments regarding the pandemic and we are taking any necessary measures to respond to the situation in cooperation with the various stakeholders.

COVID-19 infection of our workforce could result in a temporary disruption in our business activities, including manufacturing and other functions. Based on guidelines provided by the Israeli Government, we have increased as much as possible the capacity and arrangement for employees to work remotely, and although the vast majority of our employees have been vaccinated and we have adopted hybrid working models to minimize exposure, we cannot guaranty that there will be no infection and spread of the virus among our employees and staff.

The COVID-19 pandemic is also affecting the United States, Israel and global economies and has affected, and may continue to affect, the conduct of our clinical trials and may in the future affect our operations and those of third parties on which we rely, including by causing disruptions in our raw material supply. In that regard, to date we have experienced delays in enrolling patients in our various studies due to the COVID-19 pandemic.

In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our Phase III clinical trial related to muscle recovery following surgery for hip fracture. The evolving COVID-19 pandemic has already impacted, and may continue to, directly or indirectly impact the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff may not be able to physically arrive to the clinical sites. Additionally, such facilities and offices have been and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, thereby decreasing availability, in whole or in part, for clinical trial services. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. To date, during certain periods of the COVID-19 pandemic, our share price fluctuated significantly, and such fluctuation may continue to occur.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities, or on healthcare systems or the global economy as a whole if the pandemic continues for an extended period of time or significantly worsens. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

*Since 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."

*Since we have signed the EIB Finance Agreement, we have agreed to guaranty the loan and have also agreed to other limitations that require us to notify the EIB, and in some cases obtain their approval, before we engage with other banks for additional sources of funding or with potential partners for certain strategic activities.*

The EIB Finance Agreement contains certain limitations that we must adhere to such as the use of proceeds received from the EIB, the disposal of assets, substantive changes in the nature of our business, our potential execution of mergers and acquisitions, changes in our holding structure, distributions of future potential dividends and our engaging with other banks and financing entities for other loans.

*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 June 2021, 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. We cannot predict if or when armed conflict will take place and the duration of each conflict.

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 required to perform reserve duty until they are between 40 and 49 years old, depending upon the nature of their military service.

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.

## **Risk Related to Our Industry**

***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.

***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.

***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.



### **Risk Related to Our Dependence on Third Parties**

***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 continue to 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 declare bankruptcy or if they need to be replaced for whatever reason 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.

***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, cyber security incidents 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 GDPR 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.

***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 potential future revenue will be reduced.***

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

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

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition.

Even with orphan drug exclusivity, if a third party were to prepare or market a product which infringes upon our intellectual property, we may need to initiate litigation, which may be costly, to enforce our rights against such party. After an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation on its own neither shortens the development time or regulatory review time for a drug.

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

We develop our product candidates to treat rare and ultra-rare diseases, a space where medications are usually sold at high prices compared with other medications.

Accordingly, even if regulatory authorities approve our product candidates, the market may not be receptive to, and it may be difficult for us to achieve, a per-patient per-year price high enough to allow us to realize a return on our investment.

*We 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 gross monthly rent payment for these leased facilities as of July 2021 was 263,000 NIS (approximately \$80,000). For Fiscal Year 2021, we recognized a net expense (rent expenses after deducting deferred participation payments from MATAM) in the amount of \$702,000, according to the implementation of Accounting Standards Update No. 2016-02, "Leases."

We believe that the current space we have is adequate to meet our current and foreseeable 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 common shares trade on the Nasdaq Global Market and the Tel Aviv Stock Exchange under the symbol PSTI.

As of September 3, 2021, there were 89 holders of record, and 32,004,785 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. [RESERVED]

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

We are a biotechnology company focused in the field of regenerative medicine, and a leading developer of placenta-based cell therapy product candidates for the treatment of multiple inflammatory, muscle injuries and hematologic conditions. Our operations are focused on the research, development, manufacturing, conducting clinical trials and business development 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. The cells are grown using our proprietary three-dimensional expansion technology and can be administered to patients off the-shelf, without blood or tissue matching prior to administration. PLX cells are believed to release a range of therapeutic proteins in response to the patient's condition, such as inflammation, muscle trauma, hematological disorders and radiation damage.

We are conducting several multinational clinical studies which consist of a Phase III clinical study in muscle recovery following surgery for hip fracture and two Phase II clinical studies in ARDS associated with COVID-19 in the United States, Europe and Israel. In addition, we are focusing on other clinical programs in the hematological field such as a Phase I clinical study for incomplete recovery following bone marrow transplantation in the United States and Israel, an investigator-led Phase I/II cGVHD study in Israel, and ARS under the FDA animal rule. We believe that each of these indications is a severe unmet medical need.

Our manufacturing facility complies with the European, Japanese, Israeli, South Korean and the FDA's cGMP requirements and has been inspected and approved by the European and Israeli regulators for production of PLX-PAD for late stage trials. We have also been granted manufacturer/importer authorization and cGMP Certification by the MOH. If we obtain FDA and other regulatory approvals to market PLX cells, we expect to have in-house production capacity to grow PLX cells in commercial quantities.

Our goal is to make significant progress with our clinical pipeline and our clinical studies 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, licensing deals, joint ventures with pharmaceutical companies, direct sale of our products, and partnerships.

### Revenues

Revenues for the year ended June 30, 2020 were \$23,000 compared to no revenues for the year ended June 30, 2021. The revenues in the year ended June 30, 2020 were related to the sale of our PLX cells for research use.

### Research and Development, Net

Research and development net costs (costs less participation and grants by the IIA, Horizon 2020 and other parties) increased by 39% from \$21,577,000 for the year ended June 30, 2020 to \$30,066,000 for the year ended June 30, 2021. The increase is mainly attributed to (1) an increase in clinical study subcontractor expenses which mostly relates to ARDS associated with COVID-19 Phase II clinical studies, (2) an increase in payroll expenses related to payroll adjustments and exchange rate adjustment that relates to the strength of the NIS against the U.S. dollar, (3) increased share-based compensation expenses due to increased amount of restricted stock units, or RSUs, granted during the year ended June 30, 2021 compared to the amount of RSUs granted during the year ended June 30, 2020, and (4) a decrease in the participation of Horizon 2020 in our clinical programs. The increased research and development net costs were partially offset by a decrease in travel abroad expenses due to the COVID-19 pandemic.

### General and Administrative

General and administrative expenses increased by 159% from \$7,922,000 for the year ended June 30, 2020 to \$20,557,000 for the year ended June 30, 2021. The increase is mainly attributed to: (1) an increase in share-based compensation expenses related to the amount of RSUs granted, the fair value of such grants at the time of the grants and their expected vesting periods, including RSU awards to our CEO and Executive Chairman (see note 9(3) in our accompanying financial statements), (2) an increase in payroll expenses, mostly related to the entitlement of our Executive Chairman to certain adjustment fees pursuant to his amended consulting agreement, payroll adjustments, accruals for target bonuses for our CEO and Chief Financial Officer, or CFO, according to their amended employment agreements during the year ended June 30, 2021, and an exchange rate adjustment that relates to the strength of the NIS against the U.S. dollar, and (3) an increase in directors and officers insurance premium expense. The increase in general and administrative expenses was partially offset by a decrease in RSU expenses relating to RSUs granted to consultants, lower travel abroad expenses due to the COVID-19 pandemic and lower expenses related to the EIB Finance Agreement.

### Financial Income, Net

Financial income increased from \$324,000 for the year ended June 30, 2020 to \$758,000 for the year ended June 30, 2021. This increase is mainly attributable to (1) increased income from exchange rate differences related to the strength of the NIS against the U.S. dollar on deposits linked to NIS, and (2) increased interest income from bank deposits due to an increase in our deposits. The increase in financial income was partially offset by an increase in interest expenses relating to the EIB loan.

### Loss For The Year

Loss for the year ended June 30, 2021 amounted to \$49,865,000 as compared to a loss of \$29,152,000 for the year ended June 30, 2020. The changes were mainly due to increases in general and administrative expenses and research and development expenses, net, for the reasons mentioned above. Loss per share for the year ended June 30, 2021 was \$1.77, as compared to \$1.60 loss per share for the year ended June 30, 2020. The loss per share for the year increased mainly as a result of an increase in the loss for the year, offset by an increase in our weighted average number of shares due to the issuance of additional shares during Fiscal Year 2021.

The increase in weighted average common shares outstanding reflects the issuances of shares pursuant to a securities purchase agreement with certain institutional investors in February 2021, issuances of shares pursuant to our Open Market Sale Agreement<sup>SM</sup>, or the ATM Agreement, that we entered into with Jefferies LLC, or Jefferies, on July 16, 2020, and issuances of additional shares upon settlement of RSUs issued to directors, employees and consultants, and shares issued as a result of the exercise of outstanding warrants and options.

## Liquidity and Capital Resources

As of June 30, 2021, our total current assets were \$67,371,000 and our total current liabilities were \$11,517,000. On June 30, 2021, we had a working capital surplus of \$55,854,000 and an accumulated deficit of \$330,021,000.

As of June 30, 2020, our total current assets were \$48,461,000 and our total current liabilities were \$7,987,000. On June 30, 2020, we had a working capital surplus of \$40,474,000 and an accumulated deficit of \$280,156,000.

Our cash and cash equivalents and restricted cash as of June 30, 2021 amounted to \$31,838,000 which reflects an increase of \$22,609,000 from the \$9,229,000 reported as of June 30, 2020. Cash balances increased in the year ended June 30, 2021 for the reasons presented below.

Our cash used by operating activities was \$30,910,000 during the year ended June 30, 2021 and \$26,369,000 during the year ended June 30, 2020. Cash used by operating activities in the year ended June 30, 2021 primarily consisted of payments to subcontractors, suppliers, and professional services providers related to our ongoing clinical studies and payments of salaries to our employees, offset by participation of the IIA, Horizon 2020 and other grants. Cash used by operating activities in the year ended June 30, 2020 primarily consisted of payments to subcontractors, suppliers, and professional services providers primarily related to our ongoing clinical trials and payments of salaries to our employees, offset by participation of the IIA, Horizon 2020 and other grants.

Cash used for investing activities was \$7,265,000 during the year ended June 30, 2021 and \$30,458,000 during the year ended June 30, 2020. The investing activities in the year ended June 30, 2021 consisted primarily of cash used for investment in long-term deposits of \$10,953,000 and payments of \$373,000 related to investments in property and equipment, partially offset by the withdrawal of \$4,061,000 of short-term deposits. The investing activities in the year ended June 30, 2020 consisted primarily of cash used for investment in short-term deposits of \$17,949,000, investment in long-term deposits of \$12,239,000 and payments of \$270,000 related to investments in property and equipment.

Financing activities generated cash in the amount of \$61,402,000 during the year ended June 30, 2021 and \$60,870,000 during the year ended June 30, 2020. The cash generated in the year ended June 30, 2021 from financing activities is related to: (1) net proceeds of \$36,589,000 comprised of funds received from our registered direct offering which closed in February 2021 and common shares issuances made under the ATM Agreement, (2) proceeds of \$24,449,000 received from the EIB pursuant to the EIB Finance Agreement, and (3) net proceeds of \$364,000 from the exercise of outstanding warrants. The cash generated in the year ended June 30, 2020 from financing activities is related to net proceeds of \$43,262,000 from issuing our common shares under our prior Open Market Sales Agreement<sup>SM</sup> we executed with Jefferies LLC on February 6, 2019, net proceeds of \$14,901,000 from issuing our common shares in a registered direct offering in May 2020 and net proceeds of \$2,707,000 from issuing our common shares from the exercise of warrants.

On July 16, 2020, we entered into the ATM Agreement with Jefferies, pursuant to which we may issue and sell shares of our common shares having an aggregate offering price of up to \$75,000,000 from time to time through Jefferies. Upon entering into the ATM Agreement, we filed a new shelf registration statement on Form S-3, which was declared effective by the SEC on July 23, 2020. During the year ended June 30, 2021, we sold 1,045,097 of our common shares under the ATM Agreement at an average price of \$8.50 per share for aggregate net proceeds of approximately \$8,506,000.

In the year ended June 30, 2021, warrants to purchase up to 51,999 shares from our April 2019 firm commitment public offering were exercised by investors at an exercise price of \$7.00 per share, resulting in the issuance of 51,999 common shares for net proceeds of approximately \$364,000.

On February 2, 2021, we entered into a securities purchase agreement with several institutional investors, or the Investors, pursuant to which we sold, in a registered direct offering, directly to the Investors, 4,761,905 common shares, for gross proceeds of \$30,000,000. The aggregate net proceeds were approximately \$28,077,000, net of issuance expenses of approximately \$1,923,000.

In April 2020, we and our subsidiaries, Pluristem Ltd. and Pluristem GmbH, executed the EIB Finance Agreement for funding of up to €50 million in the aggregate, payable in three tranches. The proceeds from the EIB Finance Agreement are intended to support our research and development in the European Union to further advance our regenerative cell therapy platform, and to bring the products in our pipeline to market. The proceeds from the EIB Finance Agreement are expected to be deployed in three tranches, subject to the achievement of certain clinical, regulatory and scaling up milestones.

During June 2021, we received the first tranche in the amount of \$24,449,000 (€20 million) pursuant to the EIB Finance Agreement. The amount received is due to be repaid on June 1, 2026 and bears annual interest of 4% to be paid together with the principal of the loan. As of June 30, 2021, the interest accrued was in the amount of \$78,000 (€65,000).

### *Non-dilutive grants*

During the years ended June 30, 2021 and 2020, we received total cash grants of approximately \$239,000 and \$1,227,000, respectively, from the European Union research and development consortiums relating to the Horizon 2020 program.

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

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, 2021, no royalties were paid 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.

In May 2020, we were selected as a member of the CRISPR-IL consortium, a group funded by the IIA. CRISPR-IL brings together the leading experts in life science and computer science from academia, medicine, and industry, to develop AI based end-to-end genome-editing solutions. CRISPR-IL is funded by the IIA with a total budget of approximately \$10,000,000 of which, an amount of approximately \$480,000 is a direct grant allocated to us, for a period of 18 months, with a potential for extension of an additional 18 months and additional budget from the IIA. CRISPR-IL participants include leading companies, and medical and academic institutions. As of June 30, 2021, we received total grants of approximately \$401,000 in cash from the IIA pursuant to the CRISPR-IL consortium program. The CRISPR-IL consortium program does not require any obligation to pay royalties.

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 €7,600,000 (approximately \$8,500,000) non-royalty bearing 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 covered a significant portion of the CLI program costs. An amount of €1,900,000 (approximately \$2,100,000) is a direct grant allocated to us, and the Company also had 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 €1,177,000 (approximately \$1,295,000). The additional direct grant was allocated to us from the total amount of the original grant. As of June 30, 2021, we received €2,615,000 (approximately \$2,946,000) and we expect to receive an additional €461,000 (approximately \$548,000).

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 €7,400,000 (approximately \$8,300,000) 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 € 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. As of June 30, 2021, we received €2,166,000 (approximately \$2,540,000) and we expect to receive an additional €382,000 (approximately \$454,000).

In October 2017, the nTRACK, a collaborative project carried out by an international consortium led by Leitit was awarded a €6,800,000 (approximately \$7,600,000) non-royalty bearing grant. An amount of €500,000 (approximately \$560,000) 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. As of June 30, 2021, we received €414,000 (approximately \$473,000) and we expect to receive an additional €73,000 (approximately \$87,000).



## Outlook

We have accumulated a deficit of \$330,021,000 since our inception in May 2001. We do not expect to generate any significant revenues from sales of products in the next twelve months. Our cash needs may increase in the foreseeable future. We expect to generate revenues, from the sale of licenses to use our technology or products, but in the short and medium terms will unlikely exceed our costs of operations.

We may 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.

We are continually looking for sources of funding, including non-diluting sources such as collaboration with other companies via licensing agreements, the EIB Finance Agreement, the IIA grants, the European Union grant and other research grants, and sales of our common shares.

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

## Application of Critical Accounting Policies and Estimates

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. GAAP. 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.

## Share-Based Compensation

Share-based compensation is considered a critical accounting policy due to the significant expenses of RSUs which were granted to our employees, directors and consultants. In Fiscal Year 2021, we recorded share-based compensation expenses related to options, restricted shares and RSUs in the amount of \$13,968,000.

In accordance with ASC 718, "Compensation-Stock Compensation", or ASC 718, RSUs granted to employees and directors are measured at their fair value on the grant date. All RSUs granted in fiscal years 2021 and 2020 were granted for no consideration; therefore their fair value was equal to the share price at the date of grant unless the RSUs include a market-based condition in which case the fair value RSUs at the date of grant was calculated using the Monte Carlo model. The RSUs granted in Fiscal Year 2021 to non-employee consultants were measured at their fair value on the grant date in accordance with ASU No. 2018-07 - "Compensation—Share Compensation".

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 13% for the shares granted to employees and 0% for the shares granted to our directors and officers and non-employee 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, share-based compensation expenses, rent and maintenance expenses. The following table provides a breakdown of the related costs for fiscal years 2020 and 2021 (in thousands of dollars):

	Year ended June 30,	
	2021	2020
Payroll and related expenses	\$ 10,563	\$ 8,478
Materials expenses	2,843	2,821
Clinical trials expenses	10,024	6,021
Depreciation expenses	1,252	1,453
Consultants and subcontractor expenses	2,411	1,351
Rent and maintenance expenses	1,369	1,227
Share-based compensation expenses	1,538	556
Other Research and development expenses	533	1,189
Total expenses	30,533	23,096
Less: Research and development participation grants	(467)	(1,519)
Research and development expenses, net	\$ 30,066	\$ 21,577

We invest heavily in research and development. Research and development expenses, net, were our major operating expenses, representing 59% and 73% of the total operating expenses for each of our fiscal years 2021 and 2020, respectively. We expect that in the upcoming years our research and development expenses, net, will continue to be our major operating expense.

#### **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, 2021, we had \$31.25 million in cash and cash equivalents, \$34.31 million in short-term bank deposits and restricted deposits and \$23.27 million in long-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 and Euro. As of June 30, 2021, 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

### Foreign Currency Exchange Risk - NIS

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, 2021, we own net financial balances in NIS of approximately (\$1,614,000).

Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate loss of approximately \$179,000, while assuming a 10% devaluation of the NIS against the U.S. dollars, we would experience an exchange rate gain of approximately \$147,000, 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,	
	2020	2021
Average rate for period	3.507	3.322
Rate at period-end	3.466	3.260

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.

### Foreign Currency Exchange Risk - Euro (€)

Following the receipt of the first tranche in amount of €20 million (approximately \$24 million) of the loan from the EIB pursuant to the EIB Finance Agreement, we have established both a cash asset and a liability in our financial statements. If the Euro increases in value in relation to the U.S. dollar, both the asset and liability of our loan from the EIB will increase, and if the Euro decreases in relation to the U.S. dollar, both the asset and liability will conversely decrease.

Since the tranche and the accumulated interest are payable together in a single installment within five years from disbursement of the tranche, and we are likely to use the cash received to finance our operations, as time progress the cost basis of the liability of our loan is expected to increase and the cash asset is expected to decrease.

As part of our hedging strategy, we may use currency transactions of options and forward contracts to minimize the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the Euro

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

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

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

<a href="#">Reports of Independent Registered Public Accounting Firm, dated September 13, 2021</a>	F-2 - F-3
<a href="#">Consolidated Balance Sheets</a>	F-4 - F-5
<a href="#">Consolidated Statements of Operations</a>	F-6
Consolidated Statements of Comprehensive Loss	
<a href="#">Statements of Changes in Equity</a>	F-7 - F-8
<a href="#">Consolidated Statements of Cash Flows</a>	F-9
<a href="#">Notes to the Consolidated Financial Statements</a>	F-10 - F-31

**PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES**  
**CONSOLIDATED FINANCIAL STATEMENTS**  
**As of June 30, 2021**

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PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES  
CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2021

U.S. DOLLARS IN THOUSANDS

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## Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of Pluristem Therapeutics Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Pluristem Therapeutics Inc. and its subsidiaries (the "Company") as of June 30, 2021, and the related consolidated statements of operations, of changes in shareholders' equity and of cash flows for the year then ended, including 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, 2021, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

### Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

/s/ Kesselman & Kesselman  
Certified Public Accountants (Isr.)  
A member firm of PricewaterhouseCoopers International Limited

Haifa, Israel  
September 13, 2021  
We have served as the Company's auditor since 2021.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To the Stockholders and Board of Directors Of**

**PLURISTEM THERAPEUTICS INC.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Pluristem Therapeutics Inc. and its subsidiaries (the "Company") as of June 30, 2020, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for the year ended June 30, 2020 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, 2020, and the results of its operations and its cash flows for the year ended June 30, 2020, in conformity with U.S. generally accepted accounting principles.

**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 Public Company Accounting Oversight Board (United States) (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 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 from 2003 to 2020.

Tel Aviv, Israel  
September 10, 2020



**CONSOLIDATED BALANCE SHEETS**

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

	Note	June 30,	
		2021	2020
<b>ASSETS</b>			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 31,241	\$ 8,270
Short-term bank deposits	2f	33,709	37,514
Restricted cash	2f	597	555
Prepaid expenses and other current assets	3	1,824	2,122
<u>Total current assets</u>		<u>67,371</u>	<u>48,461</u>
LONG-TERM ASSETS:			
Long-term deposits		23,269	12,249
Restricted bank deposits	2g	-	404
Severance pay fund		664	631
Property and equipment, net	4	1,499	2,516
Operating lease right-of-use asset	6	728	1,259
Other long-term assets		7	12
<u>Total long-term assets</u>		<u>26,167</u>	<u>17,071</u>
<u>Total assets</u>		<u>\$ 93,538</u>	<u>\$ 65,532</u>

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,	
		2021	2020
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES</b>			
Trade payables		\$ 2,526	\$ 1,968
Accrued expenses		5,941	3,018
Operating lease liability	6	634	1,020
Other accounts payable	5	2,416	1,981
<u>Total current liabilities</u>		<u>11,517</u>	<u>7,987</u>
<b>LONG-TERM LIABILITIES</b>			
Accrued severance pay		920	879
Operating lease liability	6	100	565
Loan from the European Investment Bank (EIB)	7	23,850	-
<u>Total long-term liabilities</u>		<u>24,870</u>	<u>1,444</u>
COMMITMENTS AND CONTINGENCIES	8		
<b>SHAREHOLDERS' EQUITY</b>			
Share capital:	9		
Common shares, \$0.00001 par value per share: Authorized: 60,000,000 shares Issued and outstanding: 31,957,782 shares as of June 30, 2021; 25,492,713 shares as of June 30, 2020		*	*
Additional paid-in capital		387,172	336,257
Accumulated deficit		(330,021)	(280,156)
<u>Total shareholders' equity</u>		<u>57,151</u>	<u>56,101</u>
<u>Total liabilities and shareholders' equity</u>		<u>\$ 93,538</u>	<u>\$ 65,532</u>

(\*) Less than \$1

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

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	Note	Year ended June 30,	
		2021	2020
Revenues	2h	-	23
Cost of revenues		-	-
Gross profit		-	23
Operating Expenses:			
Research and development expenses		(30,533)	(23,096)
Less: participation grants by the Israel Innovation Authority, Horizon 2020 and other parties		467	1,519
Research and development expenses, net	21	(30,066)	(21,577)
General and administrative expenses		(20,557)	(7,922)
Total operating loss		(50,623)	(29,476)
Financial income, net	10	758	324
Loss for the year		<u>\$ (49,865)</u>	<u>\$ (29,152)</u>
Loss per share:			
Basic and diluted loss per share		<u>\$ (1.77)</u>	<u>\$ (1.60)</u>
Weighted average number of shares used in computing basic and diluted loss per share		<u>28,113,636</u>	<u>18,197,303</u>

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

**STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**

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

	Common Share		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
<b>Balance as of July 1, 2019</b>	15,082,852	\$ (*)	\$ 272,825	\$ (251,004)	\$ 21,821
Share-based compensation to employees, directors and non-employee consultants	357,755	(*)	2,562	-	2,562
Issuance of common shares under Open Market Sales Agreement, net of aggregate issuance costs of \$3,573 (Note 9b)	8,060,950	(*)	43,262	-	43,262
Issuance of common shares related to May 2020 registered direct offering, net of issuance costs of \$99 (Note 9d)	1,587,302	(*)	14,901	-	14,901
Exercise of options by employees and non-employee consultants	15,884	(*)	-	-	-
Exercise of warrants by investors (Note 9c)	386,678	(*)	2,707	-	2,707
Round up of shares due to reverse share split effectuated on July 25, 2019 (Note 9a)	1,292	(*)	-	-	-
Loss for the year	-	-	-	(29,152)	(29,152)
<b>Balance as of June 30, 2020</b>	<u>25,492,713</u>	<u>\$ (*)</u>	<u>\$ 336,257</u>	<u>\$ (280,156)</u>	<u>\$ 56,101</u>

(\*) Less than \$1

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

## STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Common Share		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
<b>Balance as of July 1, 2020</b>	25,492,713	\$ (*)	\$ 336,257	\$ (280,156)	\$ 56,101
Share-based compensation to employees, directors and non-employee consultants	591,033	(*)	13,968	-	13,968
Issuance of common shares under ATM Agreement, net of issuance costs of \$380 (Note 9e)	1,045,097	(*)	8,506	-	8,506
Issuance of common shares related to February 2021 registered direct offering net of issuance costs of \$1,923 (Note 9g)	4,761,905	(*)	28,077	-	28,077
Exercise of options by employees and non-employee consultants	15,035	(*)	-	-	-
Exercise of warrants by investors (Note 9f)	51,999	(*)	364	-	364
Loss for the year	-	-	-	(49,865)	(49,865)
<b>Balance as of June 30, 2021</b>	<u>31,957,782</u>	<u>\$ (*)</u>	<u>\$ 387,172</u>	<u>\$ (330,021)</u>	<u>\$ 57,151</u>

(\*) Less than \$1

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,	
	2021	2020
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Loss for the year	\$ (49,865)	\$ (29,152)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation	1,370	1,570
Share-based compensation to employees, directors and non-employee consultants	13,968	2,562
Decrease (increase) in prepaid expenses and other current assets and other long-term assets	303	(150)
Increase (decrease) in trade payables	578	(291)
Decrease in operating lease right-of-use asset and liability, net	(321)	(295)
Increase (decrease) in other accounts payable, accrued expenses, other long-term liabilities and other current liabilities	3,353	(638)
Decrease (increase) in interest receivable on short-term deposits	(256)	45
Long term interest payable pursuant to EIB loan	78	-
Linkage differences and interest on long-term deposits and restricted bank deposits	(126)	(11)
Accrued severance pay, net	8	(9)
Net cash used for operating activities	<u>\$ (30,910)</u>	<u>\$ (26,369)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	\$ (373)	\$ (270)
Proceeds from withdrawal of (investment in) short-term deposits	4,061	(17,949)
Investment in long-term deposits and restricted bank deposits	(10,953)	(12,239)
Net cash used for investing activities	<u>\$ (7,265)</u>	<u>\$ (30,458)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds related to issuance of common shares, net of issuance costs	\$ 36,589	\$ 58,163
Proceeds related to exercise of warrants	364	2,707
Proceeds from EIB loan	24,449	-
Net cash provided by financing activities	<u>\$ 61,402</u>	<u>\$ 60,870</u>
<b>EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS</b>	(618)	-
Increase in cash, cash equivalents and restricted cash	22,609	4,043
Cash, cash equivalents and restricted cash at the beginning of the period	9,229	5,186
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 31,838</u>	<u>\$ 9,229</u>

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)**

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**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. In January 2020, the Subsidiary established a wholly owned subsidiary, Pluristem GmbH (the “German Subsidiary”) which is incorporated under the laws of Germany. Pluristem Therapeutics, the Subsidiary and the German Subsidiary are referred to as the “Company” or “Pluristem”. The Subsidiary and the German Subsidiary are referred to as the “Subsidiaries”.

The Company’s common shares are traded on the Nasdaq Global Market and on the Tel-Aviv Stock Exchange under the symbol “PSTT”.

- b. The Company is a bio-technology company focused in the field of regenerative medicine and operates in one business segment. The Company is developing placenta-based cell therapy product candidates for the treatment of muscle trauma, hematological disorders, radiation damage and inflammation.

The Company has incurred an accumulated deficit of approximately \$330,021 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of June 30, 2021, the Company’s total shareholders’ equity amounted to \$57,151. During the year ended June 30, 2021, the Company incurred losses of \$49,865 and its negative cash flow from operating activities was \$30,910.

As of June 30, 2021, the Company’s cash position (cash and cash equivalents, short-term bank deposits and long-term bank deposits) totaled approximately \$88,219. The Company plans to continue to finance its operations from its current resources, by entering into licensing or other commercial agreements, from grants to support its research and development activities from sales of its equity securities and from the proceeds from the loan previously provided by the European Investment Bank (the “EIB”, see also note 7), as well as the potential additional draw down of funds from the Finance Contract (as defined herein) executed with the EIB, assuming applicable milestones will be achieved. Management believes that its current resources, together with its existing operating plan, are sufficient for the Company to meet its obligations as they come due at least for a period of twelve months from the date of the issuance of these consolidated financial statements. There are no assurances, however, that the Company will be able to obtain an adequate level of financial resources that are required for the long-term development and commercialization of its products.

**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**

The Company’s management believes that the dollar is the primary currency of the economic environment in which the Company and the Subsidiaries operate. 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.

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

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**NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)****c. Principles of consolidation**

The consolidated financial statements include the accounts of Pluristem Therapeutics and the Subsidiaries. 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. Revenue Recognition**

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.



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)****i. 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
Leasehold improvements	The shorter of the expected useful life or the term of the lease.

**j. 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 2021 and 2020, no triggering events were identified, and no impairment losses were recorded.

**k. Accounting for share-based compensation**

The Company accounts for share-based compensation in accordance with ASC 718, "Compensation-Share Compensation" ("ASC 718"). 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 share options granted using the Black-Scholes option-pricing model. The Company accounts for employees' share-based payment awards classified as equity awards (restricted shares ("RS") or restricted share 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 recognized compensation cost for an award with service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award.

The fair value of service-based share option grants is estimated on the grant date using a Black-Scholes option-pricing model and compensation expense related to share option grants is recognized on a graded vesting schedule over the vesting period. For share options containing a market condition, the market conditions are required to be considered when calculating the grant date fair value. ASC 718 requires selection of a valuation technique that best fits the circumstances of an award. In order to reflect the substantive characteristics of the market condition option award, a Monte Carlo simulation valuation model was used to calculate the grant date fair value of such share options. Expense for the market condition share options is recognized over the derived service period as determined through the Monte Carlo simulation model.

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

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

In accordance with ASC 718, RS and RSUs are measured at their fair value. All RS and RSUs to employees and directors granted during fiscal 2021 and 2020, were granted for no consideration. Therefore, their fair value was equal to the share price at the date of grant, unless the RSUs include a market-based condition in which case the fair value RSUs at the date of grant was calculated using the Monte Carlo model.

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 fiscal 2021 and 2020, was \$9.76 and \$3.65 per share, respectively.

During fiscal years 2021 and 2020, there were no options granted to employees or directors.

**l. Research and Development expenses, royalty bearing grants and non-royalty bearing grants**

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for research and development activities, including clinical trials, manufacturing costs and professional services. All costs associated with research and developments are expensed as incurred.

Grants received from the Israel Innovation Authority (the "IIA") were recognized when the grant becomes receivable, provided there was reasonable assurance that the Company will comply with the conditions attached to the grant and there was reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred.

Research and development expenses, net for the year ended June 30, 2021 and 2020 include participation in research and development expenses in the amount of approximately \$467 and \$1,519, respectively.

Clinical trial expenses are charged to research and development expense as incurred. The Company accrues for expenses resulting from obligations under contracts with clinical research organizations ("CROs"). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments are recorded as other assets, which will be recognized as expenses as services are rendered.

During fiscal years 2021 and 2020, the Company also received non-royalty bearing grants from the European Union research and development consortiums, under Horizon 2020, and from the IIA, under the CRISPR-IL consortium, in the amount of approximately \$566 and \$1,227, for the year ended June 30, 2021 and 2020, respectively. 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.

**m. Loss per share**

Basic and diluted loss per share is computed based on the weighted average number of common shares outstanding during each year. All outstanding share 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. The total weighted average number of shares related to the outstanding options, warrants and RSU's excluded from the calculations of diluted net earnings per share due to their anti-dilutive effect was 5,700,994 and 3,708,807 for the years ended June 30, 2021 and 2020, respectively.

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

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

## 1. Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

## 2. Uncertainty in income taxes

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

**o. 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.

**p. Severance pay**

The 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.

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

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

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, 2021 and 2020 were \$748 and \$604, respectively.

**q. 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 derivative instruments at fair value under ASC 820, "Fair Value Measurement" ("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.

The Company measures its liability pursuant to the Finance Contract with the EIB based on the aggregate outstanding amount of the combined principal and accrued interest. The Company does not reflect its liability for future royalty payments pursuant to the Finance Contract with the EIB since the royalty payments are to be paid as a percentage of the Company's future consolidated revenues, pro-rated to the amount disbursed, beginning in the fiscal year 2024 and continuing up to and including its fiscal year 2030, which cannot be measured at this time.

**r. Derivative financial instruments**

The Company accounts for derivatives and hedging based on ASC 815, "Derivatives and hedging", as amended and related interpretations ("ASC 815"). 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).

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 Company's current hedging 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".

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

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

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, 2021 and 2020, the fair value of the options contracts was immaterial and is presented in "other current assets" (see Note 3). The net gains (losses) recognized in "Financial income, net" during the years ended June 30, 2021 and 2020, were \$35 and \$13, respectively.

**s. Leases**

Operating leases are included in operating lease right-of-use ("ROU") asset, accrued expenses, and operating lease liability. ROU assets represent Company's right to use an underlying asset for the lease term and lease liabilities represent obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date as the rate implicit in the lease is not readily determinable. The determination of the incremental borrowing rate requires management judgment based on information available at lease commencement. The operating lease ROU assets also include adjustments for prepayments, accrued lease payments and exclude lease incentives. Lease terms may include options to terminate the lease when it is reasonably certain that such options will be exercised. Operating lease cost is recognized on a straight-line basis over the expected lease term. Lease agreements entered into after the adoption of ASC 842, "Leases" that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on the balance sheets.

**t. Loss contingencies**

The Company may become involved, from time to time, in various lawsuits and legal proceedings which arise in the ordinary course of business. The Company records accruals for loss contingencies to the extent that it concludes their occurrence is probable and that the related liabilities are estimable.

**u. Recently Issued Accounting Pronouncements**

ASU No. 2016-13 - "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"):

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans, and other instruments, entities will be required to use a new forward-looking "expected loss" model that generally will result in the earlier recognition of allowances for losses. The guidance also requires increased disclosures. The amendments contained in ASU 2016-13 were originally effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years for the Company. In November 2019, the FASB issued ASU No. 2019-10, which delayed the effective date of ASU 2016-13 for smaller reporting companies (as defined by the U.S. Securities and Exchange Commission, "SRC") to fiscal years beginning after December 15, 2022, including interim periods. Early adoption is permitted. The Company meets the definition of an SRC and is adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements but does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

**v. Comprehensive loss**

For all periods presented, loss is the same as comprehensive loss as there are no comprehensive income items.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 3: - PREPAID EXPENSES AND OTHER CURRENT ASSETS**

	<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>
Accounts receivable from the Horizon 2020 grants	\$ 1,089	\$ 1,071
Prepaid expenses	333	445
Accounts receivable from the IIA	-	142
Value Added Tax (VAT) receivables	382	336
Accounts receivable from the Ministry of Economy and Industry	19	35
Derivatives not designated as hedge instruments	1	67
Other receivables	-	26
<b>Total</b>	<b>\$ 1,824</b>	<b>\$ 2,122</b>

**NOTE 4: - PROPERTY AND EQUIPMENT, NET**

	<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cost:</b>		
Laboratory equipment	\$ 6,715	\$ 6,514
Computers and peripheral equipment	1,473	1,322
Office furniture and equipment	681	681
Leasehold improvements	8,662	8,661
<b>Total Cost</b>	<b>17,531</b>	<b>17,178</b>
<b>Accumulated depreciation:</b>		
Laboratory equipment	6,152	5,955
Computers and peripheral equipment	1,310	1,221
Office furniture and equipment	663	646
Leasehold improvements	7,907	6,840
<b>Total accumulated depreciation</b>	<b>16,032</b>	<b>14,662</b>
<b>Property and equipment, net</b>	<b>\$ 1,499</b>	<b>\$ 2,516</b>

Depreciation expenses amounted to \$1,370 and \$1,570 for the years ended June 30, 2021 and 2020, respectively.

During the fiscal years ended June 30, 2021 and 2020, the Company recorded a reduction of \$ 0 and \$74, respectively, to the cost accumulated depreciation of fully depreciated equipment no longer in use.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 5: - OTHER ACCOUNTS PAYABLE**

	<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>
Accrued vacation and recuperation	\$ 1,203	\$ 928
Deferred income from the Horizon 2020 grant and CRISPR-IL	40	126
Accrued payroll	612	489
Payroll institutions	561	438
<b>Total</b>	<b>\$ 2,416</b>	<b>\$ 1,981</b>

**NOTE 6: - LEASES**

The Company has various operating leases for office space that expire through fiscal 2022 and vehicles that expire through fiscal 2025. Below is a summary of the Company's operating right-of-use assets and operating lease liabilities as of June 30, 2021:

	<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>
Operating right-of-use assets	\$ 728	\$ 1,259
Operating lease liabilities, current	634	1,020
Operating lease liabilities long-term	100	565
<b>Total operating lease liabilities</b>	<b>\$ 734</b>	<b>\$ 1,585</b>

Minimum lease payments for the Company's ROU assets over the remaining lease periods as of June 30, 2021 are as follows:

	<b>June 30, 2021</b>
2022	664
2023	99
2024	5
<b>Total undiscounted lease payments</b>	<b>\$ 768</b>
<b>Less: Interest</b>	<b>34</b>
<b>Present value of lease liabilities</b>	<b>\$ 734</b>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 6: - LEASES (CONT.)**

The components of lease expense and supplemental cash flow information related to leases for the year ended June 30, 2021 were as follows:

	<b>Year ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Components of lease expense</b>		
Operating lease cost, net *	\$ 984	\$ 919
Sublease income	\$ 55	\$ 51
<b>Supplemental cash flow information</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ 1,214	\$ 1,152
Supplemental non-cash information related to lease liabilities arising from obtaining ROU assets	\$ 154	\$ 83

\* The operating lease costs are presented net after elimination of deferred participation payments in amount of \$248.

As of June 30, 2021, the weighted average remaining lease term is 1.2 years, and the weighted average discount rate is 10 percent. The discount rate was determined based on the estimated collateralized borrowing rate of the Company, adjusted to the specific lease term and location of each lease.

**NOTE 7: - LOAN FROM THE EIB**

On April 30, 2020, Pluristem entered into a finance contract (the "Finance Contract") with the EIB, pursuant to which Pluristem, through the German Subsidiary can obtain a loan in the amount of up to €50 million, subject to certain milestones being reached (the "Loan"), payable in three tranches, with the first tranche consisting of €20 million, second of €18 million and third of €12 million for a period of 36 months from the signing of the Finance Contract.

The tranches will be treated independently, each with its own interest rate and maturity period. The interest rate is 4% in the aggregate (consisting of a 0% fixed interest rate and a 4% deferred interest rate payable upon maturity, respectively) per year for the first tranche, 4% in the aggregate (consisting of a 1% fixed interest rate and a 3% deferred interest rate payable upon maturity, respectively) per year for the second tranche and 3% (consisting of a 1% fixed interest rate and a 2% deferred interest rate payable upon maturity, respectively) per year for the third tranche.

In addition to any interest payable on the Loan, the EIB is entitled to receive royalties from future revenues, if any, of Pluristem for a period of seven years starting in 2024, in an amount equal to between 0.2% to 2.3% of the Company's consolidated revenues, pro-rated to the amount disbursed from the Loan to Pluristem beginning in the fiscal year 2024 and continuing up to and including its fiscal year 2030.

During June 2021, Pluristem received the first tranche in an amount of \$24,449 (€20 million) of the Finance Contract. The amount received is due on June 1, 2026 and bears annual interest of 4% to be paid with the principal of the Loan. As of June 30, 2021, the linked principal balance in the amount of \$23,772 and the interest accrued in the amount of \$78 are presented as part of the Loan at long term liabilities (See also note 8h).



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

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**NOTE 8: - COMMITMENTS AND CONTINGENCIES**

- a. As of June 30, 2021, an amount of \$597 of cash and deposits was pledged by the Subsidiary to secure its credit line and bank guarantees.
- b. 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, 2021, total grants obtained aggregated to approximately \$27,743 and total royalties paid and accrued amounted to \$169. As of June 30, 2021, the Company’s contingent liability in respect to royalties to the IIA amounted to \$27,574, not including LIBOR interest as described above.

- c. 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, 2021, total grants obtained under this Smart Money program amounted to approximately \$112. As of June 30, 2021, the Company’s contingent liability with respect to royalties for this “Smart Money” program was \$112 and no royalties were paid or accrued.

- d. 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.
- e. As of June 30, 2021, the aggregate amount of grant obtained from this Smart Money program was approximately \$160. As of June 30, 2021, the Company’s contingent liability with respect to royalties for this “Smart Money” program is \$160 and no royalties were paid or accrued.

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

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

- f. 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 (“cGVHD”).

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 cGVHD, with a maximum aggregate royalty amount of approximately \$250.

- g. 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, 2021, total grants obtained under the “Shalav” program amounted to approximately \$52. As of June 30, 2021, the Company’s contingent liability with respect to royalties for the “Shalav” program was \$52 and no royalties were paid or accrued.

- h. On April 30, 2020, Pluristem entered into the Finance Contract with the EIB, pursuant to which the German Subsidiary can obtain the Loan in the amount of up to €50 million, subject to certain milestones being reached, payable in three tranches. The first tranche in amount of \$23,772 (€20 million) was received during June 2021.

The EIB is entitled to receive royalties from future revenues, if any, of Pluristem for a period of seven years starting in 2024, in an amount equal to between 0.2% to 2.3% of the Company’s consolidated revenues, pro-rated to the amount disbursed from the Loan to Pluristem beginning in the fiscal year 2024 and continuing up to and including its fiscal year 2030.

**NOTE 9: - SHAREHOLDERS’ EQUITY**

- (1) The Company’s authorized common shares consist of 60,000,000 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 shareholders. 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 shares are entitled to equal ratable rights to dividends and distributions with respect to the common share, as may be declared by the Board of Directors out of funds legally available. The Company’s authorized preferred shares consist of 1,000,000 shares of preferred share, 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 preferred shares have been issued.

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

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**NOTE 9: - SHAREHOLDERS' EQUITY (CONT.)****a. Reverse share split:**

In July 2019, the Board of Directors approved a 1-for-10 reverse share split of the Company's (a) authorized common shares; (b) issued and outstanding common shares and (c) authorized preferred shares. The reverse split became effective on July 25, 2019. The reverse share split did not have any effect on the stated par value of the common shares. All common shares, options, warrants and securities convertible or exercisable into common shares, as well as loss per share, were adjusted to give retroactive effect to this reverse share split for all periods presented.

- b.** Pursuant to a shelf registration on Form S-3 declared effective by the Securities and Exchange Commission on June 23, 2017, on February 6, 2019, the Company entered into the Open Market Sale Agreement<sup>SM</sup> (the "Sales Agreement") with Jefferies LLC ("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 common shares 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 common shares 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.

During the year ended June 30, 2020, the Company sold 8,060,950 common shares under the Sales Agreement at an average price of \$5.81 per share for aggregate net proceeds of approximately \$43,262, net of issuance expenses of \$3,573.

On June 30, 2020, this shelf registration statement on Form S-3 expired, and as a result thereof, the Sales Agreement was terminated.

- c.** During the year ended June 30, 2020, a total of 386,678 warrants to purchase shares from the April 2019 offering were exercised by investors at an exercise price of \$7.00 per share, resulting in the issuance of 386,678 common shares for net proceeds of approximately \$2,707.
- d.** On May 5, 2020, the Company entered into a securities purchase agreement with two institutional investors (the "Investors") pursuant to which the Company sold, in a registered public offering directly to the Investors, 1,587,302 common shares for net proceeds of approximately \$14,901.
- e.** Pursuant to a shelf registration on Form S-3 declared effective by the SEC on July 23, 2020, in July 2020 the Company entered into a new Open Market Sale Agreement ("ATM Agreement") with Jefferies, 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 common shares having an aggregate offering price of up to \$75,000 through Jefferies acting as sales agent. During the year ended June 30, 2021, the Company sold 1,045,097 common shares under the ATM Agreement at an average price of \$8.50 per share for aggregate net proceeds of approximately \$8,506, net of issuance expenses of \$380.
- f.** During the year ended June 30, 2021, a total of 519,990 warrants to purchase common shares from the April 2019 offering were exercised by investors at an exercise price of \$7.00 per share, resulting in the issuance of 51,999 common shares for net proceeds of approximately \$364.
- g.** On February 2, 2021, the Company, entered into a securities purchase agreement, with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, by the Company directly to the investors, 4,761,905 common shares for gross proceeds of \$30,000. The aggregate net proceeds were approximately \$28,077, net of issuance expenses of \$1,923.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 9: - SHAREHOLDERS' EQUITY (CONT.)****h. Share options, RS and RSUs to employees, directors and consultants:**

The Company adopted, after receiving shareholder approval, the 2005 Share Option Plan in 2005 (the "2005 Plan"). Under the 2005 Plan, share 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 shareholder approval, the 2016 Equity Incentive Plan in 2016 (the "2016 Plan"). Under the 2016 Plan, share 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 Subsidiaries. In addition, at the Company's annual meeting of its shareholders, held on June 13, 2019, the Company's shareholders approved the 2019 Equity Compensation Plan (the "2019 Plan").

Under the 2019 Plan, share 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, 2021, the number of common shares authorized for issuance under the 2016 Plan amounted to 879,945 for calendar year 2021, of which 859,945 are available for future grant during calendar year 2021 under the 2016 Plan. As of June 30, 2021, the number of common shares authorized for issuance under the 2019 Plan amounted to 3,783,807, all of which are available for future grant under the 2019 Plan.

**(2) Options to consultants:**

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

	Year ended June 30, 2020			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Share options outstanding at beginning of period	89,580	\$ -		
Share options granted	1,050	\$ -		
Share options exercised	(15,884)	\$ -		
Share options forfeited	(19,875)	\$ -		
Share options outstanding at end of the period	54,871	\$ -	7.89	\$ 485
Share options exercisable at the end of the period	48,621	\$ -	7.81	\$ 430
Share options vested and expected to vest at the end of the period	54,871	\$ -	7.89	\$ 485

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: - SHAREHOLDERS' EQUITY (CONT.)

	Year ended June 30, 2021			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Share options outstanding at beginning of period	54,871	\$ -	-	
Share options granted	-	\$ -	-	
Share options exercised	(15,035)	\$ -	-	
Share options forfeited	-	\$ -	-	
Share options outstanding at end of the period	39,836	\$ -	6.99	\$ 158
Share options exercisable at the end of the period	36,086	\$ -	6.94	\$ 143
Share options unvested	3,750			
Share options vested and expected to vest at the end of the period	39,836	\$ -	6.99	\$ 158

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

	Year ended June 30,	
	2021	2020
Research and development expenses	\$ -	\$ (35)
General and administrative expenses	11	64
	\$ 11	\$ 29

**(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, 2016 Plan and 2019 Plan for the years ended June 30, 2021 and 2020:

	Year ended June 30,	
	2021	2020
	Number	
Unvested at the beginning of period	415,194	795,633
Granted	2,646,120	19,500
Forfeited	(76,804)	(101,256)
Vested	(580,095)	(298,683)
Unvested at the end of the period	2,404,415	415,194
Expected to vest after the end of period	2,404,415	402,491

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

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

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

	Year ended June 30,	
	2021	2020
Research and development expenses	\$ 1,363	\$ 578
General and administrative expenses	12,253	1,786
	<u>\$ 13,616</u>	<u>\$ 2,364</u>

Unamortized compensation expenses related to RSUs granted to employees and directors is approximately \$10,174 to be recognized by the end of March 2025.

**Market-based awards**

In September 2020, the Company granted two of its executive officers an aggregate of 1,000,000 RSUs (500,000 each) under the 2019 Plan.

The RSUs will vest in full upon the achievement of a milestone of the Company increasing the market capitalization of its common shares on the Nasdaq Global Market to \$550,000 within no more than three years from the date of grant.

For market-based awards, the Company determines the grant-date fair value utilizing a Monte Carlo simulation model, which incorporates various assumptions including expected share price volatility, risk-free interest rates, and the expected date of a qualifying event. The Company estimates the volatility of the common shares based on its historical share price volatility for a period of 4 years from the grant date based on the daily changes in the share price. The risk-free interest rate is based on the zero-coupon yield of U.S. Treasury bonds for the expiration date of the RSUs.

The fair value of the market-based award uses the assumptions noted in the following table:

Risk-free interest rates	0.16%
Dividend yield	0%
Expected volatility	69.44%

The Company recognizes compensation expenses for the value of its market-based awards based on the results of the Monte Carlo valuation model. The fair value of the market-based awards granted on the grant date was \$7.28 per share and the expected time for the market condition to achieve, based on the Monte Carlo valuation model, is thirteen and a half months from the date of the grant. As of June 30, 2021, the Company recognized \$5,156 of expenses included in general and administrative expenses.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 9: - SHAREHOLDERS' EQUITY (CONT.)

**(4) RSUs to consultants:**

The following table summarizes the activity related to unvested RS and RSUs granted to consultants for the years ended June 30, 2021 and 2020:

	Year ended June 30,	
	2021	2020
	Number	
Unvested at the beginning of period	6,250	30,107
Granted	110,000	42,000
Forfeited	(29,063)	(6,785)
Vested	(10,938)	(59,072)
Unvested at the end of the period	<u>76,249</u>	<u>6,250</u>

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

	Year ended June 30,	
	2021	2020
Research and development expenses	\$ 176	\$ 14
General and administrative expenses	165	155
	<u>\$ 341</u>	<u>\$ 169</u>

## i. Summary of warrants and options:

Warrants / Options	Exercise Price per Share	Options and Warrants for Common Share	Options and Warrants Exercisable for Common Share	Weighted Average Remaining Contractual Terms (in years)
<b>Warrants:</b>	\$ 7.00	2,418,466	2,418,466	2.77
	\$ 14.00	762,028	762,028	1.06
<b>Total warrants</b>		<u>3,180,494</u>	<u>3,180,494</u>	
<b>Options:</b>	\$ 0.00001	39,835	36,085	6.98
<b>Total options</b>		<u>39,835</u>	<u>36,085</u>	
<b>Total warrants and options</b>		<u>3,220,329</u>	<u>3,216,579</u>	

This summary does not include 2,480,664 RSUs that are not vested as of June 30, 2021.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 10: - FINANCIAL INCOME, NET**

	<b>Year ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
Foreign currency translation differences, net	\$ 332	\$ (41)
Bank and broker commissions	(23)	(32)
Interest income on deposits	492	384
Gain from derivatives and fair value hedge derivatives	35	13
EIB loan interest expenses	(78)	-
	<u>\$ 758</u>	<u>\$ 324</u>

**NOTE 11: - TAXES ON INCOME**

## A. 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.

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, 2021. 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.



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

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**NOTE 11: - TAXES ON INCOME (CONT.)**

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.

**2. The Subsidiary:**

Consolidated taxable income of Pluristem Therapeutics and the Subsidiary (the "Consolidated tax unit") is subject to tax at the rate of 23% in 2021 and 2020.

The Consolidated tax unit is filing its consolidated 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 tax liability is calculated 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 Subsidiary has not received final tax assessments since its incorporation, however the assessments of the Subsidiary are deemed final through 2015.

**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 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 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).

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

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**NOTE 11: - TAXES ON INCOME (CONT.)***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.

*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, which prescribes, among others, amendments in the Law (“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 (“Amendment No. 71”). According to Amendment No. 71, the tax rate on preferred income from 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 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 \$2.9 billion). Other qualifying companies with global consolidated revenue below NIS 10 billion, would be subject to a 12% tax rate.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 11: - TAXES ON INCOME (CONT.)**

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).

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 IIA. Companies wishing to exit from the regime in the future will not be subject to claw back 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 research and development 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 (23% in 2020).

As of June 30, 2021, the Company's management believes that the Company meets the conditions mentioned above to be considered as a Technological Preferred Enterprise.

3. Pluristem GmbH:

The tax rate applicable to the German Subsidiary is the corporate tax rate of 15%, which is derived from the German Corporation Tax Act and Solidarity surcharge of 5.5% from the 15% corporate tax rate. This corporate tax rate excludes trade tax, which rate depends on the municipality in which the German Subsidiary conducts its business. Trade tax is calculated on the basis of the trade income, to which the tax rate of 3.5% is applied. The measured amount is then multiplied by the applicable rate of assessment, the registered office of the German Subsidiary is in Potsdam, and in Potsdam, the applicable rate of assessment is 455%.

B. Carryforward losses for tax purposes

As of June 30, 2021, Pluristem Therapeutics had a U.S. federal net operating loss carryforward for income tax purposes in the amount of approximately \$34,836. Net operating loss carryforwards arising in taxable years, can be carried forward and offset against taxable income for 20 years and expire between 2023 and 2038.

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.

In January 2018, Pluristem Therapeutics registered as an Israeli resident with the ITA and the Israeli Value Added Tax Authorities. As of June 30, 2021, Pluristem Therapeutics and the Subsidiary consolidated accumulated losses, for tax purposes, are approximately \$86,949, which may be carried forward and offset against taxable business income and business capital gain in the future for an indefinite period.

The Subsidiary has accumulated losses, for tax purposes, as of June 30, 2021, in the amount of approximately \$129,286, which may be carried forward and offset against taxable business income and business capital gain in the future for an indefinite period.

The German Subsidiary has accumulated losses, for tax purposes, as of June 30, 2021, in the amount of approximately \$584, which may be carried forward and offset against taxable business income and business capital gain in the future for an indefinite period.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 11: - TAXES ON INCOME (CONT.)**

## C. Loss before income taxes

The components of loss before income taxes are as follows:

	Year ended June 30,	
	2021	2020
Consolidated loss of Pluristem Therapeutics and the Israeli subsidiary	\$ 49,432	\$ 29,001
Pluristem GmbH	433	151
	<u>\$ 49,865</u>	<u>\$ 29,152</u>

## D. 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:

	June 30,	
	2021	2020
Deferred tax assets:		
Operating loss carryforwards	\$ 57,304	\$ 49,034
Research and development credit carryforwards	5,907	5,432
Issuance costs	352	-
Allowances and reserves	336	271
Total deferred tax assets before valuation allowance	63,899	54,737
Valuation allowance	<u>(63,899)</u>	<u>(54,737)</u>
Net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

As of June 30, 2021 and 2020, the Company has provided full valuation allowances in respect of deferred tax assets resulting from tax loss carryforwards and other temporary differences, since it has a history of operating losses and due to 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, 2021 and 2020, there were no unrecognized tax benefits that if recognized would affect the annual effective tax rate.

**Reconciliation of taxes at the federal statutory rate to Company's provision for income taxes:**

In 2021 and 2020, the main reconciling item of the statutory tax rate of the Company (21% to 23%) to the effective tax rate (0%) is tax loss carryforwards, share-based compensation and other deferred tax assets for which a full valuation allowance was provided.

**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, 2021. Based on the aforementioned evaluation, management has concluded that our disclosure controls and procedures were effective as of June 30, 2021.

***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 U.S. GAAP.

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 U.S. GAAP, 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, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework in *Internal Control—Integrated Framework*. Based on that assessment under those criteria, management has determined that, as of June 30, 2021, our internal control over financial reporting was effective.

***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 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.**

Not applicable.

## 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:

<b>Name</b>	<b>Position Held With Company</b>	<b>Age</b>	<b>Date First Elected or Appointed</b>
Zami Aberman	Executive Chairman	67	June 23, 2019
Yaky Yanay	President	50	February 4, 2014
	Director		February 5, 2015
	Chief Executive Officer		June 23, 2019
Chen Franco-Yehuda	Chief Financial Officer, Treasurer and Secretary	38	March 14, 2019
Doron Birger	Director	70	July 15, 2021
Mark Germain	Director	70	May 17, 2007
Moria Kwiat	Director	41	May 15, 2012
Rami Levi	Director	59	June 1, 2021
Varda Shalev	Director	62	July 15, 2021
Maital Shemesh-Rasmussen	Director	51	June 1, 2021
Doron Shorrer	Director	68	October 2, 2003

#### *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. 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, 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 CFO 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 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, Israel, 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.

#### **Chen Franco-Yehuda**

Ms. Franco-Yehuda was appointed as our Chief Financial Officer, or CFO, effective as of March 17, 2019. Prior to being appointed as our CFO, Ms. 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, Ms. 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.

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

### **Doron Birger**

Mr. Birger became a director of the Company in July 2021. Mr. Doron Birger has been serving as the chairman of the board of directors of Sight Diagnostic Ltd. since June 2014, Nurami Medical Ltd. since April 2016, Ultrasight Medical Imaging Ltd. from June 2019, Intelicanna Ltd. (TASE: INTL) from April 2021 and Matricelf Ltd. (TASE:MTLF ) from December 2020, and as a director of IceCure Medical Ltd. (TASE: ICCM) since August 2012, Vibrant Ltd. since December 2014, Hera Med Ltd. (ASX: HMD) since November 2019, Citrine Global (OTC: CTGL) since March 2020, Kadimastem Ltd. (TASE: KDST) since December 2020 and Netiv Ha'or, a subsidiary of the Israel Electric Corporation Ltd., since March 2020 and as chairman and director in a variety of non-profit organizations. Prior to that, Mr. Birger has served as member of the board of directors of MCS Medical Compression Systems (DBN) Ltd. (TASE:MDCL) from March 2015 to May 2018, Mekorot National Water Company Ltd. from November 2015 to November 2018, and chairman of the board of directors of Insulin Medical Ltd. (TASE: INSL) from March 2016 to August 2017, IOptima Ltd. from June 2012 to June 2019, MST Medical Surgical Technologies Ltd. from August 2009 to June 2019, Highcon Ltd. from November 2014 to January 2018, Magisto Ltd. from September 2009 to July 2019, Real Imaging Ltd. from November 2018 to April 2019 and Medigus Ltd. (Nasdaq and TASE: MDGS) from May 2015 to September 2018. Mr. Birger holds a BA and MA in economics from the Hebrew University, Israel.

We believe that Mr. Birger's qualifications to sit on our Board include his extensive experience in the high-tech sector and life-science industry, his experience serving as a director of public companies, his vast skill and expertise in accounting and economics as well as his knowledge and familiarity with corporate finance.

### **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 through September 30, 2019, 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 has served as the chairman 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 Scientific and Clinical Researcher at AquaPass Medical, a medical device company that develops a treatment for heart failure. Between 2018 to 2021, she served as an analyst at aMoon, a leading Israeli life sciences venture fund. Between 2016 to 2017, 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 at the interface between biology and materials field. She is the co-author of multiple scientific papers. Dr. Kwiat holds a Ph.D. in Chemistry specializing in nanotechnology and material sciences, M.Sc. and B.Sc. in Biotechnology, from Tel Aviv University, Israel.

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.



**Rami Levi**

Mr. Levi became a director of the Company in June 2021. Mr. Levi is the Founder and President of Catalyst Group International, LLC where, since 2009, he has provided consulting services relating to strategic planning to notable clients in the private and public sectors. From 2004 to 2006, he served as Senior Deputy General and Head of Marketing Administration at Israel's Ministry of Tourism. He holds an MA with Honors in Political Science from The Hebrew University of Jerusalem, Israel.

We believe that Mr. Levi's qualifications to sit on our Board include his experience in strategic planning, business development and activities in the government sector.

**Varda Shalev**

Prof. Shalev became a director of the Company in July 2021. Prof. Shalev, MD has been serving as a professor at the department of epidemiology at the medical school of Tel Aviv University, Israel since 2019. She has also been serving as a member of the board of directors of BATM Advanced Communications Ltd. since November 2018. She is the Chief Medical Officer of Alike Ltd. since May 2020. Prof. Shalev established the Department of Medical Informatics at Maccabi Health Care and was responsible for planning and developing its computerized medical systems. She has pioneered the development of multiple disease registries to support chronic disease management. She has also served as the director of primary care division at Maccabi Health Care from October 2013 to June 2015 and as the Chief Executive Officer of the research and innovation center (KSM Institute and Maccabitech the epidemiological and clinical research arm of Israel's Maccabi Healthcare Services) at Maccabi Health Care from July 2015 to May 2020. Prof. Shalev holds an MD from Ben Gurion University, Israel, and an MPH in Public Health Administration from Clark University, Massachusetts and her Doctoral Fellowship in Medical Informatics from Johns Hopkins University.

We believe that Prof. Shalev's qualifications to sit on our Board include her experience working in clinical environments and research settings at the intersection of health and technology.

**Maital Shemesh-Rasmussen**

Ms. Shemesh-Rasmussen became a director of the Company in June 2021. Ms. Shemesh-Rasmussen has served as the Chief Commercial Officer of Octave Bioscience, Inc. since February 2021. Prior to this role, Ms. Shemesh-Rasmussen served as the Global Head of Marketing at Roche Diagnostics Information Solutions between 2018 and 2020. Between 2016 and 2018, she worked at Fitango Health, Inc. where she focused on marketing and business development. Between 2013 and 2016, she led Product Marketing at the Oracle Health Sciences Global Business Unit, as well as Marketing and Business Development in the Oracle Digital Health Innovation Unit. Prior to these positions, Ms. Shemesh-Rasmussen served as Vice President at JPMorgan Chase Bank from 2002 until 2007. Ms. Shemesh-Rasmussen holds a BA in Behavioral Sciences from Ben Gurion University, Israel.

We believe that Ms. Shemesh-Rasmussen's qualifications to sit on our Board include her experience in marketing for pharmaceutical companies, science, business development and investment banking.

**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 BA in Economics and Accounting and an M.B.A. in Business Administration (specialization in finance and banking) from the Hebrew University of Jerusalem, Israel, 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.

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

#### *Audit Committee and Audit Committee Financial Expert*

Until May 31, 2021, the members of our Audit Committee were Doron Shorrer, Isaac Braun and Moria Kwiat. Mr. Braun was not re-nominated as a director for the 2021 annual meeting of shareholders, held on June 1, 2021, or the 2021 Annual Meeting, and his membership on the Board and Audit Committee terminated on June 1, 2021. Effective June 3, 2021, the Board appointed Ms. Shemesh -Rasmussen to serve on the Audit Committee. Mr. Shorrer is the Chairman of the Audit Committee, and our Board has determined that all members of the Audit Committee are “independent” as defined by the rules of the SEC and the Nasdaq rules and regulations. The Board also determined that Mr. Shorrer is an Audit Committee financial expert. The Audit Committee operates under a written charter that is posted on our website at [www.pluristem.com](http://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 report provided by us to the SEC, our shareholders 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 seven meetings from during Fiscal Year 2021.

#### *Compensation Committee*

Until May 31, 2021, the members of our Compensation Committee were Doron Shorrer and Isaac Braun. Mr. Braun was not re-nominated as a director for the 2021 Annual Meeting, and his membership on the Board and Compensation Committee terminated that day. Effective June 3, 2021, the Board appointed Ms. Kwiat to serve on the Compensation Committee. 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](http://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 eight meetings during Fiscal Year 2021. During Fiscal Year 2021 the Compensation Committee engaged Deloitte Israel to review the Company’s existing compensation structure for its executive officers and non-executive directors. Such review included a benchmark analysis that evaluated the compensation that we pay our CEO, CFO, Executive Chairman and non-executive directors in comparison to our peer group. On September 10, 2020, our Board, upon recommendation from our Compensation Committee, approved new compensation arrangements for our CEO, CFO and Executive Chairman as well as an updated compensation policy for our non-executive directors.

#### *Nominating Committee*

The members of our Nominating Committee are Mark Germain and Doron Shorrer. Mr. Germain is the Chairman of the Nominating Committee. The Board has determined that all of the members of the Nominating Committee are “independent” as defined by the rules of the SEC and Nasdaq rules and regulations. The Nominating Committee operates under a written charter that is posted on our website, [www.pluristem.com](http://www.pluristem.com). The information on our website is not incorporated by reference into this Annual Report. The primary responsibilities of our Nominating Committee include:

- Overseeing the composition and size of the Board, developing qualification criteria for Board members and actively seeking, interviewing and screening individuals qualified to become Board members for recommendation to the Board;
- Recommending the composition of the Board for each annual meeting of shareholders; and
- Reviewing periodically with the Chairman of the Board and the Chief Executive Officer the succession plans relating to positions held by directors, and making recommendations to the Board with respect to the selection and development of individuals to occupy those positions.

### *Director Nominations*

The Nominating Committee is responsible for developing and approving criteria, with Board approval, for candidates for Board membership. The Nominating Committee is responsible for overseeing the composition and size of the Board, developing qualification criteria for Board members and actively seeking, interviewing and screening individuals qualified to become Board members for recommendation to the Board and for recommending the composition of the Board for each of the Company's annual meetings. The Board as a whole is responsible for nominating individuals for election to the Board by the shareholders and for filling vacancies on the Board that may occur between annual meetings of the shareholders.

Nominees for director will be selected on the basis of their integrity, business acumen, knowledge of our business and industry, age, experience, diligence, conflicts of interest and the ability to act in the interests of all shareholders. No particular criteria will be a prerequisite or will be assigned a specific weight, nor does the Company have a diversity policy. The Company believes that the backgrounds and qualifications of its directors, considered as a group, should provide a composite mix of experience, knowledge and abilities that will allow the Board to fulfill its responsibilities.

We have never received communications from shareholders recommending individuals to any of our independent directors. Therefore, we do not yet have a policy with regard to the consideration of any director candidates recommended by shareholders. In Fiscal Year 2021, we did not pay a fee to any third party to identify or evaluate, or assist in identifying or evaluating, potential nominees for our Board. We have not received any recommendations from shareholders for Board nominees. All of the nominees for election at the 2021 Meeting were current members of our Board, at that time.

### *Code of Ethics*

Our Board has adopted a Code of Business Conduct and Ethics that applies to, among other persons, members of our Board, 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](http://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.

### *Delinquent Section 16(a) Reports*

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common shares, to file reports regarding ownership of, and transactions in, our securities with the SEC and to provide us with copies of those filings.

We have reviewed all forms provided to us or filed with the SEC. Based on that review and on written information given to us by our executive officers and directors, we believe that all Section 16(a) filings during the past fiscal year were filed on a timely basis and that all directors, executive officers and 10% beneficial owners have fully complied with such requirements during the past fiscal year, other than three reports on Form 4, filed on July 7, 2020, May 27, 2021 and June 1, 2021, which were filed late by Clover Wolf Capital – Limited Partnership, resulting in 4 transactions, 3 transactions and 6 transactions, respectively, not being reported on a timely basis.

## ITEM 11. EXECUTIVE COMPENSATION.

### Compensation Discussion and Analysis

The Compensation Committee of our Board 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 regarding the compensation of our CEO, Executive Chairman and CFO, and any other executive officers we may hire from time to time. Our named executive officers for Fiscal Year 2021 are those three individuals listed in the “Summary Compensation Table” below. Other information concerning the structure, roles and responsibilities of our Compensation Committee is set forth in Item 10 – “Directors, Executive Officers and Corporate Governance —Compensation Committee” above.

At our 2021 annual meeting of shareholders, we provided our shareholders with the opportunity to cast an advisory vote on our then named executive officers’ compensation. Over 88% of the votes cast on this “2021 say-on-pay vote” were voted in favor of the proposal. We have considered the 2021 say-on-pay vote and we believe that the support from our shareholders for the 2021 say-on-pay vote proposal indicates that our shareholders are supportive of our approach to executive compensation. At our 2019 annual meeting of shareholders, 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. As such, from time to time, the Compensation Committee, and/or the Board, may engage external consultants to provide the Company with data that the Compensation Committee and/or Board may deem to be appropriate in determining the compensation of our executive officers, and the compensation, if any, paid to the members of the Board.

With respect to equity compensation, the Compensation Committee makes awards to executives under our equity compensation plans as approved by the Board. 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 shares 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 bonuses; (iii) long-term equity incentive compensation in the form of RSU awards; and (iv) benefits and perquisites.

In establishing overall executive compensation levels and making specific compensation decisions for our executive officers in Fiscal Year 2021, 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 addition, the Compensation Committee conducted a compensation benchmark analysis for the executive officers. In that regard, our Compensation Committee decided to provide our Executive Chairman, Mr. Aberman, our CEO, Mr. Yanay, and our CFO, Ms. Franco-Yehuda with base salaries, RSU awards, acceleration of such awards under certain circumstances, and performance based bonuses in their respective employment and/or consulting agreement.

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.

On September 10, 2020, our Board, upon recommendation from our Compensation Committee, approved new compensation arrangements for our CEO, CFO and Executive Chairman as well as our non-executive directors. In that regard, the Compensation Committee engaged Deloitte Israel to review the Company's compensation structure for its executive officers and non-executive directors. Such review included a benchmark analysis that evaluated the compensation that we pay our CEO, CFO, Executive Chairman and non-executive directors in comparison to our peer group. When evaluating the appropriateness of our compensation peer group, the Compensation Committee seeks to construct and approve a peer group of companies in similar industries of similar size, similar region or similar market cap to that of our Company. As a result, the Company has revised its compensation structure for its CEO, CFO, Executive Chairman and non-executive directors as further described herein, which impacted such compensation for the fiscal year ending June 30, 2021.

## **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), independent third party market data such as compensation benchmark 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, financial 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, for example, as it conducted during Fiscal Year 2021, 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 and/or 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 September 10, 2020, at the recommendation of our Compensation Committee, following the benchmarking review conducted, our Board approved, effective as of January 1, 2021, on the one hand, an increase to the base monthly salary of our CEO and CFO such that the respective salaries will increase to 99,000 NIS and 65,000 NIS, and on the other hand, a decrease to the monthly consulting fee of our Executive Chairman to 142,250 NIS per month starting January 1, 2021 and effective through the earlier of December 31, 2021 or the filing of a BLA. Upon the expiration of the consulting agreement, we currently intend to enter into a new consulting agreement with Mr. Aberman or an entity which he controls.

## **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, to reward our executive officers, each of Mr. Yanay and Mr. Aberman will be entitled to a bonus equal to 1.5%, and Ms. Franco-Yehuda will be entitled to a bonus equal to 0.5%, of amounts received by us from non-dilutive funding received, among other things, from corporate partnering and strategic deals.

Our Board approved a target bonus to our CEO, equal to up to seven times his monthly salary and to our CFO, of up to five and a half times her monthly salary, subject to milestones and performance targets that was set by our Compensation Committee. In addition, according to their employment agreements, Ms. Franco-Yehuda and Mr. Yanay are also entitled to a special bonus of up to three times of their monthly salary at the discretion of the Board.

During Fiscal Year 2021, we have not paid bonuses in cash to our CEO and CFO, but accrued \$126,000 and \$64,000, respectively, for certain target bonuses as a result of the achievement of certain operational, commercial and financial goals that were defined by the Compensation Committee. Following the Board approval, we expect to pay such bonuses during October 2021.

## Long-Term Equity Incentive Compensation

Long-term incentive compensation allows the executive officers to share in any appreciation in the value of our common shares. The Compensation Committee believes that share 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. We do not have a formula relating to the level of awards that is competitive within the biotechnology industry. 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. For our executive management team, 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 shares at a par value of \$0.00001, subject to continued employment with our Company or the achievement of certain business or market milestones. 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, CEO and CFO are entitled to acceleration of the vesting of their awards in the following circumstances: (1) if we terminate their employment or consulting arrangement with us or any of our subsidiaries for a reason other than "Justifiable Cause" (as defined in their employment or consulting arrangement contract), they will be entitled to acceleration of 100% of any unvested award and (2) if they resign, they will be entitled to acceleration of up to 50% of any unvested award subject to the approval of the Board and (3) in the event of a change in control as defined in their consulting or employment agreement, as long as they continue to provide services to the Company or its subsidiaries, they will be entitled to an acceleration of 100% of any unvested RSUs. All grants are approved, upon receipt of recommendation by our Compensation Committee, by our Board.

In September 2020, following a benchmark analysis conducted by our compensation committee, we decided to grant our CEO and Executive Chairman 1,000,000 RSUs each. Of this award, 500,000 RSUs that were granted to each of them were linked to achievement of a market condition – our reaching \$550 million of market capitalization during the three year period from the date of the grant. We believe that such compensation aligns executive officers' interests with those of our shareholders.

For clarification purposes, the acceleration mechanism detailed above does not apply to the 500,000 RSUs granted to each of our CEO and Executive Chairman in September 2020, that were linked to the achievement of our market capitalization reaching of \$550 million during the three year period from the date of the grant.

## Benefits and Perquisites

Generally, benefits available to Mr. Yanay and Ms. 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.

While the agreement will be terminated on the earlier of December 31, 2021 or upon the filing of a BLA, we have agreed to pay Mr. Aberman an adjustment fee as provided above, but only during the period between January 1, 2021 and December 31, 2021, or in the event of a change of control equal to nine months of consulting fees; provided, however that such adjustment fees shall be paid in two installments as follows: (i) 38,250 NIS paid on January 1, 2021, and 1,307,250 NIS on December 31, 2021. In July 2021, the Board revised Mr. Aberman's eligibility to adjustment fees to 1,515,600 NIS in total to include nine months of car and related expenses, 1,477,350 NIS of which will be paid on December 31, 2021.



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.

In conjunction with the adjustments made to the base salaries during Fiscal Year 2021, the employment agreement of our CFO was amended to also provide for an adjustment fee that equals her monthly salary amount multiplied by three, plus the number of years the employment agreement remained in force from June 30, 2020, but in any event no more than six months of adjustment fees in the aggregate.

Ms. Chen Franco-Yehuda is also 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.

### Report of the Compensation Committee

The Compensation Committee has reviewed and discussed the foregoing Compensation Discussion and Analysis prepared under Item 402(b) of Regulation S-K with our management and, based on such review and discussions, the Compensation Committee recommended to our Board 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

Moria Kwiat

### Summary Compensation Table

The following table shows the particulars of compensation owed to our named executive officers for the fiscal years ended June 30, 2021 and 2020. We do not currently have any other executive officers.

Name and Principal Position	Fiscal Year <sup>(1)</sup>	Salary (\$) <sup>(2)</sup>	Non-Equity Plan Compensation (\$) <sup>(3)</sup>	Bonus (\$) <sup>(4)</sup>	Share-based Awards (\$) <sup>(5)</sup>	All Other Compensation (\$) <sup>(6)</sup>	Total (\$)
Zami Aberman	2021	556,475 <sup>(7)</sup>	-	-	8,741,402	508,074	9,805,951
<i>Executive Chairman</i>	2020	439,704 <sup>(7)</sup>	-	-	-	61,540	501,244
Yaky Yanay	2021	459,016 <sup>(8)</sup>	126,000	-	8,741,402	27,588	9,354,006
<i>CEO</i>	2020	320,911 <sup>(8)</sup>	-	-	-	29,466	350,377
Chen Franco-Yehuda	2021	251,642	64,000	-	1,020,000	14,653	1,350,295
<i>CFO</i>	2020	179,229	-	14,426	-	14,035	207,690

- (1) The information is provided for each fiscal year, which begins on July 1 and ends on June 30.
- (2) Amounts paid for Salary which were originally denominated in NIS, were translated into U.S. dollars at the then current exchange rate for each payment. The salaries of Mr. Yanay and Ms. Franco-Yehuda 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.  
  
For Mr. Yanay and Mr. Aberman, their salaries also include additional amounts equal to one monthly salary of NIS 80,000, or approximately \$25,000 and NIS 149,500, or approximately \$44,000, respectively.
- (3) For Mr. Yanay and Ms. Franco-Yehuda, we have accrued, but have not yet paid, bonuses during Fiscal Year 2021 of \$126,000 and \$64,000 respectively, for certain target bonuses as a result of the achievement of certain milestones that were defined by the Compensation Committee. We expect to pay such bonuses during October 2021.
- (4) In fiscal year 2020, we paid to Ms. Franco-Yehuda a onetime bonus of NIS 50,000, or approximately \$14,000.

- (5) The fair value recognized for the share-based awards was determined as of the grant date in accordance with Accounting Standard Codification, or ASC, Topic 718. The assumptions used in the calculations for these amounts are included in Note 9 to our audited consolidated financial statements for Fiscal Year 2021 included elsewhere in this Annual Report (see also “Grants of Plan-Based Awards” table presented below).
- (6) Mr. Aberman is entitled to adjustment fees of NIS 1,515,600, or approximately \$443,000, out of which we paid NIS 38,250, or approximately \$11,000, during Fiscal Year 2021, and we expect to pay the rest of the adjustment fees during January 2022. Additionally, this column includes costs in connection with car or car expenses reimbursement and mobile phone expenses for Mr. Aberman. We have also paid Mr. Yanay the tax associated with the company car benefit included in this column, which is grossed-up. For Mr. Yanay the gross-up is part of the amount in the “Salary” column.
- (7) Includes \$6,201 and \$18,486 paid in cash to Mr. Aberman as compensation for services as a director in fiscal year 2021 and 2020 respectively. Starting October 2020, Mr. Aberman was not entitled to compensation for services as a director.
- (8) Includes \$6,194 and \$18,400 paid in cash to Mr. Yanay as compensation for services as a director in Fiscal Year 2021 and 2020, respectively. Starting October 2020, Mr. Yanay was not entitled to compensation for services as a director.

### **Employment and Consulting Agreements**

During Fiscal Year 2021, we had 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 currently receives a monthly consulting fee of NIS 142,500 (approximately \$43,000 per month). On September 10, 2020, at the recommendation of our Compensation Committee, our Board approved, effective as of January 1, 2021 a decrease to the monthly consulting fee of our Executive Chairman from 149,500 to NIS 142,250 per month. In addition, Mr. Aberman was entitled once a year to receive an additional amount that equals the monthly consulting fee. All amounts that were paid, were paid plus value added tax. Mr. Aberman is also entitled to a performance-based bonus of 1.5% from amounts received by us from non-diluting funding and strategic deals during the term of his consulting agreement and nine months afterwards. Mr. Aberman is also entitled to car expenses reimbursement.
- (b) Starting January 1, 2021, Mr. Yanay’s monthly salary is NIS 99,000, approximately \$30,000 per month. On September 10, 2020, at the recommendation of our Compensation Committee, our Board approved, effective as of January 1, 2021, an increase to the base salary of our CEO such that the salary will increase to NIS 99,000 from NIS 80,000. Mr. Yanay is provided with a cellular phone and a Company car pursuant to the terms of his agreement. Furthermore, Mr. Yanay is entitled to a performance based bonus of 1.5% from amounts received by us from non-diluting funding and strategic deals and a target bonus equal to up to seven times his monthly salary subject to milestones and performance targets that was set by our Compensation Committee. The Board may also grant Mr. Yanay a discretionary bonus of up to 3 months of his monthly salary.
- (c) Starting January 1, 2021 Ms. Franco-Yehuda’s monthly salary is NIS 65,000. On September 10, 2020, at the recommendation of our Compensation Committee, our Board approved, effective as of January 1, 2021, an increase to the base salary of our CFO such that the salary will increase to NIS 65,000 from NIS 42,000. Ms. Franco-Yehuda receives car and cellular phone expense reimbursements pursuant to the terms of her agreement. Furthermore, Ms. Franco-Yehuda is entitled to a performance based bonus of 0.5% from amounts received by us from non-diluting funding and strategic deals and a target bonus equal to up to five and a half times her monthly salary, subject to milestones and performance targets that was set by our Compensation Committee. The Board may also grant Ms. Franco-Yehuda a discretionary bonus of up to 3 months of her monthly salary.

### *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 and car expenses multiplied by nine. We paid NIS 38,250, or approximately \$11,000, of the adjustment fee in January 2021 and we expect to pay an additional NIS 1,477,350, or approximately \$432,000, in January 2022; (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 six, 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 Ms. Franco-Yehuda’s employment, she is entitled to a severance payment, under Section 14 of the Israeli Severance Pay Law, and an adjustment fee that equals her monthly salary amount multiplied by three, plus the number of years the employment agreement remains in force from June 30, 2020, but in any event no more than six years in the aggregate.

In addition, Mr. Aberman, Mr. Yanay and Ms. Franco-Yehuda are entitled to acceleration of the vesting of their share options and restricted share in the following circumstances: (1) if we terminate their employment for a reason other than cause (as may be defined in each respective agreement), 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, subject to the approval of the Board. In addition, Mr. Aberman, Mr. Yanay and Ms. 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.

For clarification purposes, the acceleration mechanism detailed above does not apply to the 500,000 RSUs granted to each of our CEO and Executive Chairman in September 2020, that were linked to the achievement of our market capitalization reaching of \$550 million during the three year period from the date of the grant.

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, 2021.

<b>Officer</b>	<b>Salary</b>	<b>Accelerated Vesting of RSUs<sup>(1)</sup></b>	<b>Total</b>
<b>Zami Aberman</b>			
Terminated due to officer resignation	\$ 453,792	\$ 841,500 <sup>(2)</sup>	\$ 1,295,292
Terminated due to discharge of officer	\$ 453,792	\$ 1,683,000 <sup>(3)</sup>	\$ 2,136,792
Change in control	-	\$ 1,683,000 <sup>(4)</sup>	\$ 1,683,000
<b>Yaky Yanay</b>			
Terminated due to officer resignation	\$ 565,689 <sup>(5)</sup>	\$ 841,500 <sup>(2)</sup>	\$ 1,407,189
Terminated due to discharge of officer	\$ 565,689 <sup>(5)</sup>	\$ 1,683,000 <sup>(3)</sup>	\$ 2,248,689
Change in control	-	\$ 1,683,000 <sup>(4)</sup>	\$ 1,683,000
<b>Chen Franco Yehuda</b>			
Terminated due to officer resignation	\$ 79,755	\$ 169,290 <sup>(2)</sup>	\$ 249,045
Terminated due to discharge of officer	\$ 79,755	\$ 338,580 <sup>(3)</sup>	\$ 418,335
Change in control	-	\$ 338,580 <sup>(4)</sup>	\$ 338,580

- (1) Value shown represents the difference between the closing market price of our common shares on June 30, 2021 of \$3.96 per share and the applicable exercise price of each grant.
- (2) Up to 50% of all unvested RSUs issued under the applicable equity incentive plans vest upon resignation under the terms of those plans, subject to the approval of the Board at its sole discretion.
- (3) All unvested RSUs issued under the applicable equity incentive plans vest upon an involuntary termination due to discharge, except for cause, excluding 500,000 RSUs that will vest upon achievement of increasing market capitalization of our common shares on the Nasdaq Global Market to \$550 million within no more than 3 years from the date of grant.
- (4) All unvested RSUs issued under the applicable equity incentive plans vest upon a change in control under the terms of those plans excluding 500,000 RSUs that will vest upon achievement of increasing market capitalization of our common shares on the Nasdaq Global Market to \$550 million within no more than 3 years from the date of grant.
- (5) As of June 30, 2021, the value of the severance fund net of Mr. Yanay is \$220,000. For severance payments, we will need to pay the difference between Mr. Yanay's eligibility to receive severance payment and the value of the fund, which as of June 30, 2021, amounted to \$345,000.

*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 share options, RSUs or restricted shares at the discretion of our Board in the future.

## Outstanding Equity Awards at the End of Fiscal Year 2021

The following table presents the outstanding equity awards held as of June 30, 2021 by our named executive officers, all of which have been issued pursuant to our 2019 Equity Compensation Plan, or the 2019 Plan, and 2016 Equity Compensation Plan, or the 2016 Plan:

Name	Number of shares that have not vested (#)	Market value of shares that have not vested (\$)	Equity incentive plan awards: Number of shares that have not vested (#)	Equity incentive plan awards: Market value of shares that have not vested (\$)
Zami Aberman	-	-	500,000 <sup>(1)</sup>	1,980,000
	406,250 <sup>(2)</sup>	1,608,750	-	-
	18,750 <sup>(3)</sup>	74,250	-	-
Yaky Yanay	-	--	500,000 <sup>(1)</sup>	1,980,000
	406,250 <sup>(2)</sup>	1,608,750	-	-
	18,750 <sup>(3)</sup>	74,250	-	-
Chen Franco-Yehuda	750 <sup>(4)</sup>	2,970	-	-
	3,500 <sup>(5)</sup>	13,860	-	-
	81,250 <sup>(6)</sup>	321,750	-	-

(1) 500,000 RSUs vest in full upon milestone achievement of increasing our market capitalization on the Nasdaq Global Markets to \$550 million within no more than three years from the date of grant.

(2) 406,250 RSUs vest in 13 equal installments of 31,250 on September 10, 2021 and every three months thereafter.

(3) 18,750 RSUs vest in six equal installments of 3,125 on September 19, 2021 and every three months thereafter.

(4) 750 RSUs vest in six equal installments of 125 on September 19, 2021 and every three months thereafter.

(5) 3,500 RSUs vest in seven equal installments of 500 on September 28, 2021 and every three months thereafter.

(6) 81,250 RSUs vest in 13 equal installments of 6,250 on September 11, 2021 and every three months thereafter.

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

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

### Director Compensation

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 2021:

Name	Fees Earned or Paid in		Total (\$)
	Cash (\$)	Stock Awards (\$) <sup>(1)</sup>	
Isaac Braun <sup>(2)</sup>	34,207	204,000	238,207
Mark Germain	110,175 <sup>(4)</sup>	204,000	314,175
Moria Kwiat	35,412	204,000	239,412
Rami Levi <sup>(3)</sup>	17,500	144,400	161,900
Maital Shemesh-Rasmussen <sup>(3)</sup>	17,750	144,400	162,150
Doron Shorrer	46,026	204,000	250,026

- (1) The fair value recognized for the Stock 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 9 to our consolidated financial statements for Fiscal Year 2021 included elsewhere in this Annual Report.
- (2) Effective as of June 1, 2021, Mr. Braun ceased to serve on the Board.
- (3) Effective as of January 5, 2021, this director was appointed to serve on the Board.
- (4) Includes a bonus to Mr. Germain in the amount of \$75,000 for his contribution in connection with the EIB Finance Agreement.

On September 10, 2020, our Board, upon the recommendation of our Compensation Committee, approved the change of their compensation components to an annual fee of \$35,000. In addition, members of our Board of Director committees are compensated as follows (i) the Chairman of our Audit Committee receives an additional annual fee of \$10,000 and, in the event of an annual equity grant issued to directors, or an Annual Director Grant, an additional 10% of equity securities in addition to such grant, and each other member of the Audit Committee shall receive an additional annual fee of \$3,000 and, in the event of an Annual Director Grant, an additional 3% of equity securities in addition to such grant; (ii) the Chairman of our Compensation Committee receives an additional annual fee of \$4,000 and, in the event of an Annual Director Grant, an additional 4% of equity securities in addition to such grant, and each other member of the Compensation Committee receives an additional annual fee of \$2,000 and, in the event of an Annual Director Grant, an additional 2% of equity securities in addition to such grant; and (iii) the Chairman of our Nominating Committee receives an additional annual fee of \$4,000 and, in the event of an Annual Director Grant, an additional 4% of equity securities in addition to such grant, and each other member of the Nominating Committee receives an additional annual fee of \$2,000 and, in the event of an Annual Director Grant, an additional 2% of equity securities in addition to such grant.

In exceptional circumstances members of the Board may receive bonuses of up to \$75,000 per year for extraordinary performance, as well as discretionary bonuses in special circumstances as the Board or the Compensation Committee may decide. During 2021, we paid Mr. Mark Germain \$75,000 for his contribution in connection with the EIB Finance Agreement.

During Fiscal Year 2021, we paid a total of \$187,081 excluding the bonus paid to Mr. Germain in cash to directors as compensation.

As of June 30, 2021, we have outstanding grants to our non-executive directors aggregating 382,612 restricted shares and RSUs of which 260,156 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
Isaac Braun <sup>(1)</sup>	78,621	78,621
Mark Germain	100,645	60,998
Moria Kwiat	55,750	34,594
Rami Levi	20,000	0
Maital Rasmussen	20,000	0
Doron Shorrer	107,596	85,943
<b>Total</b>	<b>382,612</b>	<b>260,156</b>

(1) Mr. Braun was not re-nominated as a director nominee, and therefore, effective as of June 1, 2021, Mr. Braun ceased to serve on the Board.

For all directors, the vesting of directors' share options, RSUs and restricted share accelerates in the following circumstances: (1) if the director is not re-nominated to serve on the Board or the director is not re-elected by stockholders at a special or annual meeting, this will result in the acceleration of 100% of any unvested award, and (2) the voluntary resignation of a director will result in the acceleration of up to 50% of any unvested award subject to Board approval. In addition, a change in control will result in the acceleration of 100% of any unvested award of our directors.

Mr. Braun was not re-nominated as a director nominee at the 2021 Annual Meeting and on June 1, 2021, all unvested awards held by Mr. Braun were accelerated, resulting in the vesting of 22,139 RSUs for Mr. Braun.

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 2021.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The following table sets forth certain information, to the best knowledge and belief of the Company, as of September 3, 2021 (unless provided herein otherwise), with respect to holdings of our common shares by (1) each person known by us to be the beneficial owner of more than 5% of the total number of our common shares 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.

Unless otherwise indicated, the address of each person listed below is c/o Pluristem Therapeutics Inc., MATAM Advanced Technology Park, Building No. 5, Haifa, Israel, 3508409.

<u>Name of Beneficial Owner</u>	<u>Beneficial Number of Shares<sup>(1)</sup></u>	<u>Percentage of Shares Beneficially Owned</u>
<u>Directors and Named Executive Officers</u>		
Zami Aberman Executive Chairman of the Board of Directors	621,630 <sup>(2)</sup>	1.9%
Yaky Yanay CEO, President and Director	548,474 <sup>(2)</sup>	1.7%
Chen Franco-Yehuda CFO	39,091	*
Doron Birger Director	-	*
Doron Shorrer Director	91,506 <sup>(5)</sup>	*
Isaac Braun Director	88,621 <sup>(3)</sup>	*
Maital Rasmussen Director	3,750	*
Mark Germain Director	63,681	*
Moria Kwiat Director	42,543 <sup>(4)</sup>	*
Rami Levi Director	3,750	*
Varda Shalev Director	-	*
<u>Directors and Executive Officers as a group (11 persons)</u>	<u>1,503,046<sup>(6)</sup></u>	<u>4.7%</u>
<u>5% Shareholders</u>		
<u>Clover Wolf Capital – Limited Partnership</u>	<u>2,340,085<sup>(7)</sup></u>	<u>7%</u>

\* less than 1%

- (1) Based on 32,004,785 common shares issued and outstanding as of September 3, 2021. Except as otherwise indicated, we believe that the beneficial owners of the common shares 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 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 a warrant to acquire up to 7,143 shares.
- (3) Includes a warrant to acquire up to 5,000 shares.
- (4) Includes a warrant to acquire up to 2,857 shares.
- (5) Includes a warrant to acquire up to 1,429 shares.
- (6) Includes warrants to acquire up to 23,572 shares.
- (7) Based solely on information provided by the holder. Clover Wolf Ltd. is the General Partner of Clover Wolf Capital – Limited Partnership. Adi Wolf is the Managing Member and Chief Executive Officer of Clover Wolf Capital – Limited Partnership and also the Chief Executive Officer of Clover Wolf Ltd. All investment decisions are made by Adi Wolf, and thus the power to vote or direct the votes of these common share, as well as the power to dispose or direct the disposition of such common shares is held by Adi Wolf through Clover Wolf Capital – Limited Partnership and Clover Wolf Ltd. The address of Clover Wolf Capital – Limited Partnership is 24 Bodenhimer Street, Tel Aviv, Israel 6200838.

### **Equity Compensation Plan Information**

At our annual meeting of our shareholders held on May 31, 2016, our shareholders approved the 2016 Plan. Under the 2016 Plan, options, restricted share 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 common shares, restricted shares and RSUs, in each calendar year, in a number not exceeding 2.75% of the number of our common shares issued and outstanding on a fully diluted basis on the immediately preceding December 31.

In addition, at our annual meeting of our shareholders held on June 13, 2019, our shareholders approved the 2019 Plan. Under the 2019 Plan, options, restricted shares 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 common shares, restricted shares and RSUs in a number not exceeding 16% of the number common shares 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, 2021:

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	39,835	\$ 0.00001	4,677,366

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.

Except for the arrangements described in Item 11, during fiscal years 2021 and 2020, we did not participate in any transaction, and we are not currently participating in any proposed transaction, or series of transactions, in which the amount involved exceeded the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which, to our knowledge, any of our directors, officers, five percent beneficial security holders, or any member of the immediate family of the foregoing persons had, or will have, a direct or indirect material interest.

The Board has determined that Doron Birger, Doron Shorrer, Mital Shemesh-Rasmussen, Mark Germain, Moria Kwiat, and Varda Shalev 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 our independent registered public accounting firm to the Company and paid in the last two fiscal years were as follows:

	Twelve months ended on June 30, 2021	Twelve months ended on June 30, 2020
Audit Fees	\$ 105,000	\$ 110,041
Audit-Related Fees	None	None
Tax Fees	\$ 28,507	\$ 27,072
All Other Fees	<u>None</u>	<u>None</u>
Total Fees	<u>\$ 133,507</u>	<u>\$ 137,113</u>

*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, (ii) the review of our quarterly consolidated financial statements for our quarterly reports on Form 10-Q, (iii) audit services provided in connection with other regulatory or statutory filings.

*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 the independent registered public accounting firm are 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.

On March 25, 2021, our Audit Committee dismissed Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, as our independent registered public accounting firm, effective after their completion of the review of the Company's consolidated financial statements for the three months ending March 31, 2021. In addition, on March 25, 2021, our Audit Committee appointed Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, or PWC, as our independent registered public accounting firm for the fiscal year ending June 30, 2021, whose appointment took place upon the dismissal of our former auditors.

The Audit Committee has considered the nature and amount of fees billed by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, and Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, and believes that the provision of services for activities unrelated to the audit was compatible with maintaining Kost Forer Gabbay & Kasierer's independence and it is compatible with maintaining Kesselman & Kesselman's, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, independence.

As of June 30, 2021, we have accrued approximately \$70,000 for the annual audit fees for the Fiscal Year ended June 30, 2021, which we expect to pay PWC during fiscal year 2022.

## PART IV

### ITEM 15. EXHIBITS.

- 3.1 [Composite Copy of the Company's Articles of Incorporation as amended on July 2, 2020 \(incorporated by reference to Exhibit 4.1 of our registration statement on Form S-3 filed on July 16, 2020\).](#)
- 3.2 [Composite Copy \(marked\) of the Company's Articles of Incorporation as amended on July 2, 2020 \(incorporated by reference to Exhibit 4.2 of our registration statement on Form S-3 filed on July 16, 2020\).](#)
- 3.3 [Amended and Restated By-laws as amended on September 10, 2020 \(incorporated by reference to Exhibit 3.3 of our annual report on Form 10-K filed on September 10, 2020\).](#)
- 4.1 [Form of Common Share 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 Share Purchase Warrant dated April 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 \(incorporated by reference to Exhibit 4.3 of our annual report on Form 10-K filed on September 10, 2020\).](#)
- 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+	<a href="#"><u>Summary of Directors' Ongoing Compensation (incorporated by reference to Exhibit 10.8 of our annual report on Form 10-K filed on September 10, 2020).</u></a>
10.9+	<a href="#"><u>Form of Indemnification Agreement between Pluristem Therapeutics Inc. and each of our directors and officers (incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q filed on February 8, 2021).</u></a>
10.10+	<a href="#"><u>2016 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 4, 2016).</u></a>
10.11+	<a href="#"><u>Form of Share 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).</u></a>
10.12+	<a href="#"><u>Form of Restricted Share 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).</u></a>
10.13+	<a href="#"><u>Form of Restricted Share 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).</u></a>
10.14+	<a href="#"><u>2019 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 25, 2019).</u></a>
10.15+	<a href="#"><u>Form of Share Option Agreement under the 2019 Equity Compensation Plan (incorporated by reference to Exhibit 10.19 of our annual report on Form 10-K filed on September 12, 2019).</u></a>
10.16+	<a href="#"><u>Form of Restricted Share Agreement under the 2019 Equity Compensation Plan (incorporated by reference to Exhibit 10.20 of our annual report on Form 10-K filed on September 12, 2019).</u></a>
10.17+	<a href="#"><u>Form of Restricted Share Agreement (Israeli directors and officers) under the 2019 Equity Compensation Plan (incorporated by reference to Exhibit 10.21 of our annual report on Form 10-K filed on September 12, 2019).</u></a>
10.18*+	<a href="#"><u>Form of Restricted Stock Unit Agreement (executive officers) under the 2019 Equity Compensation Plan.</u></a>
10.19*+	<a href="#"><u>Form of Restricted Stock Unit Agreement (directors) under the 2019 Equity Compensation Plan.</u></a>
10.20*+	<a href="#"><u>Form of Restricted Stock Unit Agreement (employees) under the 2019 Equity Compensation Plan.</u></a>
10.21+	<a href="#"><u>Amended and Restated Consulting Agreement between Pluristem Ltd. and Rose High Tech Ltd. dated September 10, 2020 (incorporated by reference to Exhibit 10.17 of our annual report on Form 10-K filed on September 10, 2020).</u></a>
10.22+	<a href="#"><u>Amended and Restated Employment Agreement between Pluristem Ltd. and Yaky Yanay dated September 10, 2020 (incorporated by reference to Exhibit 10.18 of our annual report on Form 10-K filed on September 10, 2020).</u></a>
10.23+	<a href="#"><u>Amended and Restated Employment Agreement between Pluristem Ltd. and Chen Franco-Yehuda dated September 10, 2020 (incorporated by reference to Exhibit 10.19 of our annual report on Form 10-K filed on September 10, 2020).</u></a>
10.24^	<a href="#"><u>Finance Contract between the European Investment Bank, as Lender, and Pluristem GmBH, as borrower, and Pluristem Therapeutics Inc. and Pluristem Ltd., as Original Guarantors, dated April 29, 2020 (incorporated by reference to Exhibit 10.21 of our annual report on Form 10-K filed on September 10, 2020).</u></a>

10.25	<a href="#">Guarantee Agreement by and among the European Investment Bank, Pluristem Therapeutics, Inc. and Pluristem GmbH, dated September 30, 2020 (incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q filed on November 5, 2020).</a>
10.26	<a href="#">Guarantee Agreement by and among the European Investment Bank, Pluristem Ltd. and Pluristem GmbH dated, September 30, 2020 (incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q filed on November 5, 2020).</a>
10.27	<a href="#">Open Market Sales Agreement, dated July 16, 2020, between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.2 of our registration statement on Form S-3 filed on July 16, 2020).</a>
10.28*+	<a href="#">Letter agreement by and between Pluristem Ltd. and Rose High Tech Ltd., dated September 13, 2021.</a>
10.29*+	<a href="#">Letter agreement by and between Pluristem Ltd. and Yaky Yanay, dated September 13, 2021.</a>
10.30*+	<a href="#">Letter agreement by and between Pluristem Ltd. and Chen Franco-Yehuda, dated September 13, 2021.</a>
21.1	<a href="#">List of Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 of our annual report on Form 10-K filed on September 10, 2020).</a>
23.1*	<a href="#">Consent of Kost Forer Gabbay &amp; Kasierer, A member of Ernst &amp; Young Global.</a>
23.2*	<a href="#">Consent of Kesselman &amp; Kesselman, Independent Registered Public Accounting Firm.</a>
31.1*	<a href="#">Certification pursuant to Rule 13a-14(a)/15d-14(a) of Yaky Yanay.</a>
31.2*	<a href="#">Certification pursuant to Rule 13a-14(a)/15d-14(a) of Chen Franco-Yehuda.</a>
32.1**	<a href="#">Certification pursuant to 18 U.S.C. Section 1350 of Yaky Yanay.</a>
32.2**	<a href="#">Certification pursuant to 18 U.S.C. Section 1350 of Chen Franco-Yehuda.</a>
101*	The following materials from our Annual Report on Form 10-K for the fiscal year ended June 30, 2021 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.

^ Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to Pluristem if publicly disclosed.

**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

Dated: September 13, 2021

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 13, 2021

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

Dated: September 13, 2021

By: /s/ Zami Aberman  
Zami Aberman, Executive Chairman of the Board of  
Directors

Dated: September 13, 2021

By: /s/ Doron Birger  
Doron Birger, Director

Dated: September 13, 2021

By: /s/ Mark Germain  
Mark Germain, Director

Dated: September 13, 2021

By: /s/ Moria Kwiat  
Moria Kwiat, Director

Dated: September 13, 2021

By: /s/ Rami Levi  
Rami Levi, Director

Dated: September 13, 2021

By: /s/ Prof. Varda Shalev  
Prof. Varda Shalev, Director

Dated: September 13, 2021

By: /s/ Maital Shemesh-Rasmussen  
Maital Shemesh-Rasmussen, Director

Dated: September 13, 2021

By: /s/ Doron Shorrer  
Doron Shorrer, Director

Dated: September 13, 2021

Pluristem Therapeutics Inc.

## RESTRICTED STOCK UNITS AGREEMENT

Made as of \_\_\_\_\_

BETWEEN: Pluristem Therapeutics Inc.  
 A company incorporated in Nevada, USA  
 (hereinafter the "Company")

AND: Name :  
 I.D. No.:  
 Address:  
 (hereinafter the "Participant")

WHEREAS, on March 28, 2019, the Company duly adopted and the Compensation Committee approved the 2019 Equity Compensation Plan and on June 13, 2019, the Company's stockholders approved the adoption of the 2019 Equity Compensation Plan, a copy of which has been made available to the Optionee, forming an integral part hereof (the "Plan"); and –

WHEREAS, pursuant to the Plan, the Company has decided to grant Restricted stock Units of the Company to the Optionee, as detailed within Exhibit A, and the Optionee has agreed to such grant, subject to all the terms and conditions as set forth in the Plan and as provided herein;

NOW, THEREFORE, it is agreed as follows:

1. Preamble and Definitions

- 1.1 The preamble to this Agreement constitutes an integral part of this Agreement, as do the terms of the Plan.
- 1.2 Unless otherwise defined herein, capitalized terms used herein shall have the meaning ascribed to them in the Plan.

2. Grant of Restricted Stock Units

- 2.1 The Company hereby grants to the Participant the number of Restricted Stock Units as set forth in Exhibit A hereto, subject to the terms and the conditions as set forth in the Plan and as provided herein.
- 2.2 The Participant is aware that the Company intends in the future to issue additional shares and to grant additional options to various entities and individuals, as the Company in its sole discretion shall determine.

3. Restricted Period Per Section 102

The following provisions shall apply for the purpose of the tax benefits under Section 102 of the Israeli Income Tax Ordinance 1961 (the "Ordinance"):

- (a) Restricted Period Per Section 102 of the Ordinance ("Section 102"). In accordance with the requirements of Section 102(b)(2) as now in place and as may be amended in the future, the Restricted Stock Units shall be granted to the Participant and held in trust by the Trustee for the benefit of Participant for a period of no less than twenty four (24) months from the date of grant in which the Restricted Stock Units were granted and placed with a Trustee (during the Restricted Period Per Section 102 the Participant will not be allowed to order the Trustee to sell the Restricted Stock Units held by him/her on behalf of the Participant or transfer the Restricted Stock Units from Trustee's hands).

In order to apply the tax benefits of Section 102, the Restricted Stock Units may not be sold or transferred (other than through a transfer by will or by operation of law), and no power of attorney or transfer deed shall be given in respect thereof (other than a power of attorney for the purpose of participation in general meetings of shareholders, when applicable).

- (b) End of Restricted Period Per Section 102. Upon the completion of the Restricted Period Per Section 102 as now in place and as may be amended in the future, Participant shall be entitled to receive from the Trustee the Restricted Stock Units, which have vested, subject to the provisions of the Plan concerning the continued employment of Participant at the Company or any Affiliate of the Company, and subject to any other provisions set forth herein or in the Plan, and Participant shall be entitled to sell the vested Restricted Stock Units subject to the other terms and conditions of this Restricted Stock Units Agreement and the Plan, including the provisions relating to the payment of tax set forth below.
-

#### 4. Adjustments

Notwithstanding anything to the contrary in Section 8.1 (g) of the Plan and in addition thereto, the vesting of the Restricted Stock Units shall accelerate in the following circumstances: (i) in case of the termination by the Company of the Recipient's employment or consulting arrangement with the Company or any subsidiary, for reasons other than Justifiable Cause, 100% of any unvested Restricted Stock Units; (ii) in case of the termination by the Recipient of the Recipient's employment or consulting arrangement by with Company or any subsidiary, 50% of any unvested Restricted Stock Units at the discretion of the Board of the Parent Company; and (iii) in the event of a Change of Control (as hereinafter defined) of the Company, and provided the Employee is still employed or providing services to the Company or a subsidiary, 100% of any unvested Restricted Stock Units, provided that such acceleration shall take place as of the date which is ten (10) days prior to the effective date of the Change of Control and the Committee shall notify the Participant that the unvested Restricted Stock Units are fully vested for a period of ten (10) days from the date of such notice.

For purposes of this Agreement, "Change of Control" shall mean the occurrence of any of the following: (i) any one person, or more than one person acting as a group or in concert, acquires beneficial ownership of stock of the Company that, together with stock held by such person or group, constitutes more than thirty percent (30%) of the total voting power of the stock of the Company; (ii) any consolidation or merger of the Company into another corporation or entity where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own, directly or indirectly, securities representing in the aggregate more than fifty percent (50%) of the combined voting power of all the outstanding securities of the surviving corporation (or of its ultimate parent corporation, if any); (iii) the sale, lease or other transfer of all or substantially all of the Company's assets to an independent, unaffiliated third party in a single transaction or a series of related transactions; or (iv) the date that fifty percent (50%) or more of the members of the Company's Board of Directors is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by fifty percent (50%) or more of the members of the Company's Board of Directors prior to the date of the appointment or election.

#### 5. Vesting: Period

Subject to the provisions of the Plan, Restricted Stock Units shall vest according to the Vesting Dates set forth in Exhibit A hereto, provided that the Participant is an Employee of or providing services to the Company and/or its Affiliates on the applicable Vesting Date. Where there is a discrepancy between the terms of Exhibit A and the terms of the Plan, Exhibit A shall govern.

#### 6. Restrictions on Transfer of Restricted Stock Units

- 6.1 The transfer of Restricted Stock Units shall be subject to the limitations set forth in the Plan and in the Company's Articles of Association and any shareholders' agreement to which the holders of ordinary shares of the Company are bound.
- 6.2 With respect to any Approved 102 Awards, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, a Participant shall not sell or release from trust any Restricted Stock Units, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Participant.
- 6.3 With respect to Unapproved 102 Awards, if the Participant ceases to be employed by the Company or any Affiliate, the Participant shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.
- 6.4 The Participant shall not dispose of any Shares in transactions which violate, in the opinion of the Company, any applicable laws, rules and regulations.
- 6.5 The Participant agrees that the Company shall have the authority to endorse upon the certificate or certificates representing the Shares such legends referring to the foregoing restrictions, and any other applicable restrictions as it may deem appropriate (which do not violate the Participant's rights according to this Restricted Stock Units Agreement).



7. Taxes: Indemnification

- 7.1 Any tax consequences arising from this grant, from the payment for Restricted Stock Units or from any other event or act (of the Company and/or its Affiliates, the Trustee or the Participant), hereunder, shall be borne solely by the Participant. The Company and/or its Affiliates and/or the Trustee shall withhold taxes according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. Furthermore, the Participant hereby agrees to indemnify the Company and/or its Affiliates and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Participant.
- 7.2 The Participant will not be entitled to receive from the Company and/or the Trustee any Restricted Stock Units prior to the full payments of the Participant's tax liabilities arising from Restricted Stock Units which were granted to him/her. For the avoidance of doubt, neither the Company nor the Trustee shall be required to release any share certificate to the Participant until all payments required to be made by the Participant have been fully satisfied.
- 7.3 The receipt of the Restricted Stock Units may result in tax consequences. THE PARTICIPANT IS ADVISED TO CONSULT A TAX ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING THIS AWARD OR DISPOSING OF THE SHARES.
- 7.4 With respect to Approved 102 Restricted Stock Units, the Participant hereby acknowledges that he/she is familiar with the provisions of Section 102 and the regulations and rules promulgated thereunder, including without limitations the type of the Award granted hereunder and the tax implications applicable to such grant. The Participant accepts the provisions of the trust agreement signed between the Company and the Trustee, attached as Exhibit C hereto, and agrees to be bound by its terms.

8. Participant's Representations

- 8.1 The Participant hereby agrees that the terms of section 102 of the Ordinance shall apply regarding to the Restricted Stock Units granted.
- 8.2 The Participant is obliged not to sell or remove from the Trustee the Restricted Stock Units granted to him/her prior to the end of restricted period as defined by Section 102.
- 8.3 The Participant is aware of the directives set forth in Section 102, and of the tax route that was chosen under Section 102 and its implications.
- 8.4 The Participant hereby accepts the terms of the Trust Agreement signed between the Company and the Trustee.
- 8.5 Notwithstanding anything to the contrary, in case that a Participant is entitled to receive dividend in cash, the proceeds of such dividend may be wired to the Participant, after deduction of all applicable taxes.
- 8.6 Prior to the issuance of the Restricted Stock Units by the Company to the Participant, the Participant hereby agrees to sign any and all documents required by any applicable law and/or by the Company's Articles of Association or bylaws.

9. Miscellaneous

- 9.1 Confidentiality. The Participant shall regard the information in this Restricted Stock Units Agreement and its exhibits attached hereto as confidential information and the Participant shall not reveal its contents to anyone except when required by law or for the purpose of obtaining legal or tax advice.
- 9.2 Continuation of Employment or Service. Neither the Plan nor this Restricted Stock Units Agreement shall impose any obligation on the Company or an Affiliate to continue the Participant's employment or service and nothing in the Plan or in this Restricted Stock Units Agreement shall confer upon the Participant any right to continue in the employ or service of the Company and/or an Affiliate or restrict the right of the Company or an Affiliate to terminate such employment or service at any time.
- 9.4 Entire Agreement. Subject to the provisions of the Plan, to which this Restricted Stock Units Agreement is subject, this Restricted Stock Units Agreement, together with the exhibits hereto, constitute the entire agreement between the Participant and the Company with respect to Restricted Stock Units granted hereunder, and supersedes all prior agreements, understandings and arrangements, oral or written, between the Participant and the Company with respect to the subject matter hereof.

9.5 Failure to Enforce – Not a Waiver. The failure of any party to enforce at any time any provisions of this Restricted Stock Units Agreement or the Plan shall in no way be construed to be a waiver of such provision or of any other provision hereof.

9.6 Provisions of the Plan. The Restricted Stock Units provided for herein are granted pursuant to the Plan and said Restricted Stock Units and this Restricted Stock Units Agreement are in all respects governed by the Plan and subject to all of the terms and provisions of the Plan.

Any interpretation of this Restricted Stock Units Agreement will be made in accordance with the Plan but in the event there is any contradiction between the provisions of this Restricted Stock Units Agreement and the Plan, the provisions of the Restricted Stock Units Agreement will prevail.

9.7 Binding Effect. The Plan and this Restricted Stock Units Agreement shall be binding upon the heirs, executors, administrators and successors of the parties hereof.

9.8 Notices. All notices or other communications given or made hereunder shall be in writing and shall be delivered or mailed by registered mail or delivered by email or facsimile with written confirmation of receipt to the Participant and/or to the Company at the addresses shown on the letterhead above, or at such other place as the Company may designate by written notice to the Participant. The Participant is responsible for notifying the Company in writing of any change in the Participant's address, and the Company shall be deemed to have complied with any obligation to provide the Participant with notice by sending such notice to the address indicated herein.

Pluristem Therapeutics Inc.:

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Signature: \_\_\_\_\_

I, the undersigned, hereby acknowledge receipt of a copy of the Plan and accept the Restricted Stock Units subject to all of the terms and provisions thereof. I have reviewed the Plan and this Restricted Stock Units Agreement in its entirety, have had an opportunity to obtain the advice of counsel prior to executing this Restricted Stock Units Agreement, and fully understand all provisions of this Restricted Stock Units Agreement. I agree to notify the Company upon any change in the residence address indicated herein.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature

Attachments:

Exhibit A and Exhibit B: Terms of the Restricted Stock Units

Exhibit C: 2019 Equity Compensation Plan

Exhibit D: Trust Agreement

EXHIBIT A

TERMS OF THE RESTRICTED STOCK UNITS AWARD

Name of the Participant:	
Date of Grant:	
Designation:	
1. Number of Restricted Stock Units granted:	
2. Purchase Price:	
3. Vesting Dates:	
4. Restriction Period:	

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## Pluristem Therapeutics Inc.

## RESTRICTED STOCK UNITS AGREEMENT

Made as of \_\_\_\_\_

**BETWEEN:** **Pluristem Therapeutics Inc.**  
A company incorporated in Nevada, USA  
(hereinafter the “**Company**”)

**AND:** Name:  
I.D. No.:  
Address:  
(hereinafter the “**Participant**”)

**WHEREAS** on March 28, 2019, the Company duly adopted and the Compensation Committee approved the 2019 Equity Compensation Plan and on June 13, 2019, the Company’s stockholders approved the adoption of the 2019 Equity Compensation Plan, a copy of which has been made available to the Participant, forming an integral part hereof (the “**Plan**”); and –

**WHEREAS** Pursuant to the Plan, the Company has decided to grant Restricted Stock Units of the Company to the Participant, as detailed within Exhibit A, and the Participant has agreed to such grant, subject to all the terms and conditions as set forth in the Plan and as provided herein;

NOW, THEREFORE, it is agreed as follows:

**1. Preamble and Definitions**

- 1.1 The preamble to this Agreement constitutes an integral part of this Agreement, as do the terms of the Plan.
- 1.2 Unless otherwise defined herein, capitalized terms used herein shall have the meaning ascribed to them in the Plan.

**2. Grant of Restricted Stock Units**

- 2.1 The Company hereby grants to the Participant the number of Restricted Stock Units as set forth in **Exhibit A** hereto, subject to the terms and the conditions as set forth in the Plan and as provided herein.
- 2.2 The Participant is aware that the Company intends in the future to issue additional shares and to grant additional options to various entities and individuals, as the Company in its sole discretion shall determine.

**3. Restricted Period Per Section 102**

The following provisions shall apply for the purpose of the tax benefits under Section 102 of the Ordinance:

- (a) **Restricted Period Per Section 102.** In accordance with the requirements of Section 102(b)(2) as now in place and as may be amended in the future, the Restricted Stock Units shall be granted to the Participant and held in trust by the Trustee for the benefit of Participant for a period of no less than twenty four (24) months from the date of grant in which the Restricted Stock Units were granted and placed with a Trustee (during the Restricted Period Per Section 102 the Participant will not be allowed to order the Trustee to sell the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit held by him/her on behalf of the Participant or transfer the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit from Trustee’s hands).
-

In order to apply the tax benefits of Section 102, the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit may not be sold or transferred (other than through a transfer by will or by operation of law), and no power of attorney or transfer deed shall be given in respect thereof (other than a power of attorney for the purpose of participation in general meetings of shareholders, when applicable).

- (b) **End of Restricted Period Per Section 102.** Upon the completion of the Restricted Period Per Section 102 as now in place and as may be amended in the future, Participant shall be entitled to receive from the Trustee the Restricted Stock Units or one share of Common Stock for each Restricted Stock Unit, subject to the vesting schedule, and to the provisions of the Plan concerning the continued employment of Participant at the Company or any Affiliate of the Company, and subject to any other provisions set forth herein or in the Plan, and Participant shall be entitled to sell the vested Restricted Stock Units subject to the other terms and conditions of this Restricted Stock Units Agreement and the Plan, including the provisions relating to the payment of tax set forth below.

#### **4. Adjustments**

Notwithstanding anything to the contrary in Section 8.1 (g) of the Plan and in addition thereto, Any unvested equity compensation award issued to the Director shall accelerate in the following circumstances: (1) if the Director is not re-nominated to serve on the Board or the Director is not re-elected by stockholders at a special or annual meeting, this will result in the acceleration of 100% of any unvested award and (2) the voluntary resignation of the Director will result in the acceleration of up to 50% of any unvested award subject to approval of the Board of Directors. In addition, a Change in Control will result in the acceleration of 100% of any unvested award of our directors.

For purposes of this Agreement, "Change in Control" shall mean the occurrence of any of the following: (i) any one person, or more than one person acting as a group or in concert, acquires beneficial ownership of stock of the Company that, together with stock held by such person or group, constitutes more than thirty percent (30%) of the total voting power of the stock of the Parent Company; (ii) any consolidation or merger of the Company into another corporation or entity where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own, directly or indirectly, securities representing in the aggregate more than fifty percent (50%) of the combined voting power of all the outstanding securities of the surviving corporation (or of its ultimate parent corporation, if any); (iii) the sale, lease or other transfer of all or substantially all of the Company's assets to an independent, unaffiliated third party in a single transaction or a series of related transactions; or (iv) the date that fifty percent (50%) or more of the members of the Board is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by fifty percent (50%) or more of the Company's Board prior to the date of the appointment or election.

**5. Vesting: Period**

Subject to the provisions of the Plan, Restricted Stock Units shall vest according to the Vesting Dates set forth in **Exhibit A** hereto, provided that the Participant is an Employee of or providing services to the Company and/or its Affiliates on the applicable Vesting Date. Where there is a discrepancy between the terms of **Exhibit A** and the terms of the Plan, **Exhibit A** shall govern.

**6. Restrictions on Transfer of Restricted Stock Units**

- 6.1 The transfer of Restricted Stock Units shall be subject to the limitations set forth in the Plan and in the Company's Articles of Association and any shareholders' agreement to which the holders of ordinary shares of the Company are bound.
- 6.2 With respect to any Approved 102 Awards, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, a Participant shall not sell or release from trust any Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Participant.
- 6.3 With respect to Unapproved 102 Awards, if the Participant ceases to be employed by the Company or any Affiliate, the Participant shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.
- 6.4 The Participant shall not dispose of any Shares in transactions which violate, in the opinion of the Company, any applicable laws, rules and regulations.
- 6.5 The Participant agrees that the Company shall have the authority to endorse upon the certificate or certificates representing the Shares such legends referring to the foregoing restrictions, and any other applicable restrictions as it may deem appropriate (which do not violate the Participant's rights according to this Restricted Stock Units Agreement).

**7. Taxes: Indemnification**

- 7.1 Any tax consequences arising from this grant, from the payment for Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit, or from any other event or act (of the Company and/or its Affiliates, the Trustee or the Participant), hereunder, shall be borne solely by the Participant. The Company and/or its Affiliates and/or the Trustee shall withhold taxes according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. Furthermore, the Participant hereby agrees to indemnify the Company and/or its Affiliates and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Participant.

- 7.2 The Participant will not be entitled to receive from the Company and/or the Trustee any Restricted Stock Units prior to the full payments of the Participant's tax liabilities arising from Restricted Stock Units which were granted to him/her. For the avoidance of doubt, neither the Company nor the Trustee shall be required to release any share certificate to the Participant until all payments required to be made by the Participant have been fully satisfied.
- 7.3 The receipt of the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit may result in tax consequences. THE PARTICIPANT IS ADVISED TO CONSULT A TAX ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING THIS AWARD OR DISPOSING OF THE SHARES.
- 7.4 With respect to Approved 102 Restricted Stock Units, the Participant hereby acknowledges that he/she is familiar with the provisions of Section 102 and the regulations and rules promulgated thereunder, including without limitations the type of the Award granted hereunder and the tax implications applicable to such grant. The Participant accepts the provisions of the trust agreement signed between the Company and the Trustee, attached as **Exhibit C** hereto, and agrees to be bound by its terms.

**8. Participant's Representations**

- 8.1 The Participant hereby agrees that the terms of section 102 of the Tax Ordinance ("Section 102") shall apply regarding to the Restricted Stock Units granted.
- 8.2 The Participant is obliged not to sell or remove from the Trustee the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit granted to him/her prior to the end of restricted period as defined by Section 102.
- 8.3 The Participant is aware of the directives set forth in Section 102, and of the tax track that was chosen under Section 102 and its implications.
- 8.4 The Participant hereby accepts the terms of the Trust Agreement signed between the Company and the Trustee.
- 8.5 Notwithstanding anything to the contrary and only after the elapse of the Restriction Period (*sec 12ii of the plan*), in case that a Participant is entitled to receive dividend in cash, the proceeds of such dividend may be wired to the Participant, after deduction of all applicable taxes.
- 8.6 Prior to the issuance of the Restricted Stock Units by the Company to the Participant, the Participant hereby agrees to sign any and all documents required by any applicable law and/or by the Company's Articles of Association or bylaws.

**9. Miscellaneous**

- 9.1 Confidentiality. The Participant shall regard the information in this Restricted Stock Units Agreement and its exhibits attached hereto as confidential information and the Participant shall not reveal its contents to anyone except when required by law or for the purpose of gaining legal or tax advice.

- 9.2 Continuation of Employment or Service. Neither the Plan nor this Restricted Stock Units Agreement shall impose any obligation on the Company or an Affiliate to continue the Participant's employment or service and nothing in the Plan or in this Restricted Stock Units Agreement shall confer upon the Participant any right to continue in the employ or service of the Company and/or an Affiliate or restrict the right of the Company or an Affiliate to terminate such employment or service at any time.
- 9.3 Method of Payment. Payment of the aggregate Purchase Price shall be made, at the sole discretion of the Board, by any of the following (a) cash, (b) check (c) a combination thereof, at the election of the Participant. The Payment shall be made in U.S. Dollars if permissible by law, the payment may also be made in New Israeli Shekel ("NIS") at the representative rate of exchange for the U.S. Dollar published by the Bank of Israel on the day of date of grant.
- 9.4 Entire Agreement. Subject to the provisions of the Plan, to which this Restricted Stock Units Agreement is subject, this Restricted Stock Units Agreement, together with the exhibits hereto, constitute the entire agreement between the Participant and the Company with respect to Restricted Stock Units granted hereunder, and supersedes all prior agreements, understandings and arrangements, oral or written, between the Participant and the Company with respect to the subject matter hereof.
- 9.5 Failure to Enforce - Not a Waiver. The failure of any party to enforce at any time any provisions of this Restricted Stock Units Agreement or the Plan shall in no way be construed to be a waiver of such provision or of any other provision hereof.
- 9.6 Provisions of the Plan. The Restricted Stock Units provided for herein are granted pursuant to the Plan and said Restricted Stock Units and this Restricted Stock Units Agreement are in all respects governed by the Plan and subject to all of the terms and provisions of the Plan.
- Any interpretation of this Restricted Stock Units Agreement will be made in accordance with the Plan but in the event there is any contradiction between the provisions of this Restricted Stock Units Agreement and the Plan, the provisions of the Restricted Stock Units Agreement will prevail.
- 9.7 Binding Effect. The Plan and this Restricted Stock Units Agreement shall be binding upon the heirs, executors, administrators and successors of the parties hereof.
- 9.8 Notices. All notices or other communications given or made hereunder shall be in writing and shall be delivered or mailed by registered mail or delivered by email or facsimile with written confirmation of receipt to the Participant and/or to the Company at the addresses shown on the letterhead above, or at such other place as the Company may designate by written notice to the Participant. The Participant is responsible for notifying the Company in writing of any change in the Participant's address, and the Company shall be deemed to have complied with any obligation to provide the Participant with notice by sending such notice to the address indicated herein.



**Pluristem Therapeutics Inc.:**

per: Name: \_\_\_\_\_

Position: \_\_\_\_\_

Signature: \_\_\_\_\_

I, the undersigned, hereby acknowledge receipt of a copy of the Plan and accept the Restricted Stock Units subject to all of the terms and provisions thereof. I have reviewed the Plan and this Restricted Stock Units Agreement in its entirety, and fully understand all provisions of this Restricted Stock Units Agreement. I agree to notify the Company upon any change in the residence address indicated herein.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature

**Attachments:**

**Exhibit A: Terms of the Restricted Stock Units**

**Exhibit B: 2019 Equity Incentive Plan**

**Exhibit C: Trust Agreement**

**EXHIBIT A**

**TERMS OF THE RESTRICTED STOCK UNITS AWARD**

<b>Name of the Participant:</b>	
<b>Date of Grant:</b>	
<b>Designation:</b>	
<b>1. Number of Restricted Stock Units granted:</b>	
<b>2. Purchase Price:</b>	
<b>3. Vesting Dates:</b>	
<b>4. Restriction Period:</b>	

\_\_\_\_\_  
Participant

\_\_\_\_\_  
Company

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## Pluristem Therapeutics Inc.

## RESTRICTED STOCK UNITS AGREEMENT

Made as of \_\_\_\_\_

**BETWEEN:** Pluristem Therapeutics Inc.

A company incorporated in Nevada, USA

(hereinafter the "Company")

**AND:** Name :

I.D. No.:

Address:

(hereinafter the "Participant")

**WHEREAS** on March 28, 2019, the Company, and the Compensation Committee, duly adopted and approved the 2019 Equity Compensation Plan and on June 13, 2019, the Company's stockholders approved the adoption of the 2019 Equity Compensation Plan, a copy of which has been made available to the Optionee, forming an integral part hereof (the "Plan"); and –

**WHEREAS** Pursuant to the Plan, the Company has decided to grant Restricted Stock Units of the Company to the Participant, as detailed within **Exhibit A**, and the Participant has agreed to such grant, subject to all the terms and conditions as set forth in the Plan and as provided herein;

NOW, THEREFORE, it is agreed as follows:

**1. Preamble and Definitions**

- 1.1 The preamble to this Agreement constitutes an integral part of this Agreement, as do the terms of the Plan.
- 1.2 Unless otherwise defined herein, capitalized terms used herein shall have the meaning ascribed to them in the Plan.

**2. Grant of Restricted Stock Units**

- 2.1 The Company hereby grants to the Participant the number of Restricted Stock Units as set forth in **Exhibit A** hereto, subject to the terms and the conditions as set forth in the Plan and as provided herein.
- 2.2 The Participant is aware that the Company intends in the future to issue additional shares and to grant additional options to various entities and individuals, as the Company in its sole discretion shall determine.

**3. Restricted Period Per Section 102**

The following provisions shall apply for the purpose of the tax benefits under Section 102 of the Ordinance:

- 3.1 **Restricted Period Per Section 102.** In accordance with the requirements of Section 102(b)(2) as now in place and as may be amended in the future, the Restricted Stock Units shall be granted to the Participant and held in trust by the Trustee for the benefit of Participant for a period of no less than twenty four (24) months from the date of grant in which the Restricted Stock Units were granted and placed with a Trustee (during the Restricted Period Per Section 102 the Participant will not be allowed to order the Trustee to sell the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit held by him/her on behalf of the Participant or transfer the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit from Trustee's hands).

In order to apply the tax benefits of Section 102, the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit may not be sold or transferred (other than through a transfer by will or by operation of law), and no power of attorney or transfer deed shall be given in respect thereof (other than a power of attorney for the purpose of participation in general meetings of shareholders, when applicable).

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- 3.2 **End of Restricted Period Per Section 102.** Upon the completion of the Restricted Period Per Section 102 as now in place and as may be amended in the future, Participant shall be entitled to receive from the Trustee the Restricted Stock Units or one share of Common Stock for each Restricted Stock Unit, subject to the vesting schedule, and to the provisions of the Plan concerning the continued employment of Participant at the Company or any Affiliate of the Company, and subject to any other provisions set forth herein or in the Plan, and Participant shall be entitled to sell the vested Restricted Stock Units subject to the other terms and conditions of this Restricted Stock Units Agreement and the Plan, including the provisions relating to the payment of tax set forth below.

**4. Adjustments**

Notwithstanding anything to the contrary in Section 8.1 (o) of the Plan and in addition thereto, if in any such Transaction as described in Section 8.1 (o) of the Plan, the Successor Company (or parent or subsidiary of the Successor Company) does not agree to assume or substitute for the Restricted Stock Units, the Vesting Dates, unless reasonably determined otherwise by the Board, shall be accelerated so that any unvested Restricted Stock Units shall be immediately vested in full as of the date which is ten (10) days prior to the effective date of the Transaction, and the Committee shall notify the Participant that the unvested Restricted Stock Units are fully vested for a period of ten (10) days from the date of such notice. If the successor Company (or parent or subsidiary of the Successor Company) agrees to assume or substitute for the Restricted Stock Units and Participant's employment with the Successor Company is terminated by the Successor Company without "Cause" within one year of the closing of such Transaction, the Vesting Dates shall be accelerated so that any unvested portion of the substituted Restricted Stock Units shall be immediately vested in full as of the date of such termination without Cause.

**5. Vesting: Period**

Subject to the provisions of the Plan, Restricted Stock Units shall vest according to the Vesting Dates set forth in **Exhibit A** hereto, provided that the Participant is an Employee of or providing services to the Company and/or its Affiliates on the applicable Vesting Date. Where there is a discrepancy between the terms of **Exhibit A** and the terms of the Plan, **Exhibit A** shall govern.

**6. Restrictions on Transfer of Restricted Stock Units**

- 6.1 The transfer of Restricted Stock Units shall be subject to the limitations set forth in the Plan and in the Company's Articles of Association and any shareholders' agreement to which the holders of common shares of the Company are bound.

- 6.2 With respect to any Approved 102 Awards, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, a Participant shall not sell or release from trust any Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Participant.
- 6.3 With respect to Unapproved 102 Awards, if the Participant ceases to be employed by the Company or any Affiliate, the Participant shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.
- 6.4 The Participant shall not dispose of any Shares in transactions which violate, in the opinion of the Company, any applicable laws, rules and regulations.
- 6.5 The Participant agrees that the Company shall have the authority to endorse upon the certificate or certificates representing the Shares such legends referring to the foregoing restrictions, and any other applicable restrictions as it may deem appropriate (which do not violate the Participant's rights according to this Restricted Stock Units Agreement).

**7. Taxes; Indemnification**

- 7.1 Any tax consequences arising from this grant, from the payment for Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit, or from any other event or act (of the Company and/or its Affiliates, the Trustee or the Participant), hereunder, shall be borne solely by the Participant. The Company and/or its Affiliates and/or the Trustee shall withhold taxes according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. Furthermore, the Participant hereby agrees to indemnify the Company and/or its Affiliates and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Participant.
- 7.2 The Participant will not be entitled to receive from the Company and/or the Trustee any Restricted Stock Units prior to the full payments of the Participant's tax liabilities arising from Restricted Stock Units which were granted to him/her. For the avoidance of doubt, neither the Company nor the Trustee shall be required to release any share certificate to the Participant until all payments required to be made by the Participant have been fully satisfied.
- 7.3 The receipt of the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit may result in tax consequences. THE PARTICIPANT IS ADVISED TO CONSULT A TAX ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING THIS AWARD OR DISPOSING OF THE SHARES.

- 7.4 With respect to Approved 102 Restricted Stock Units, the Participant hereby acknowledges that he/she is familiar with the provisions of Section 102 and the regulations and rules promulgated thereunder, including without limitations the type of the Award granted hereunder and the tax implications applicable to such grant. The Participant accepts the provisions of the trust agreement signed between the Company and the Trustee, attached as **Exhibit B** hereto, and agrees to be bound by its terms.

**8. Participant's Representations**

- 8.1 The Participant hereby agrees that the terms of section 102 of the Ordinance shall apply regarding to the Restricted Stock Units granted.
- 8.2 The Participant is obliged not to sell or remove from the Trustee the Restricted Stock Units and any shares of common stock underlying each Restricted Stock Unit granted to him/her prior to the end of restricted period as defined by Section 102.
- 8.3 The Participant is aware of the directives set forth in Section 102, and of the tax track that was chosen under Section 102 and its implications.
- 8.4 The Participant hereby accepts the terms of the Trust Agreement signed between the Company and the Trustee.
- 8.5 Notwithstanding anything to the contrary and only after the elapse of the Restriction Period (as defined in the Plan), in case that a Participant is entitled to receive dividend in cash, the proceeds of such dividend may be wired to the Participant, after deduction of all applicable taxes.
- 8.6 Prior to the issuance of the Restricted Stock Units by the Company to the Participant, the Participant hereby agrees to sign any and all documents required by any applicable law and/or by the Company's Articles of Association or bylaws.

**9. Miscellaneous**

- 9.1 Confidentiality. The Participant shall regard the information in this Restricted Stock Units Agreement and its exhibits attached hereto as confidential information and the Participant shall not reveal its contents to anyone except when required by law or for the purpose of gaining legal or tax advice.
- 9.2 Continuation of Employment or Service. Neither the Plan nor this Restricted Stock Units Agreement shall impose any obligation on the Company or an Affiliate to continue the Participant's employment or service and nothing in the Plan or in this Restricted Stock Units Agreement shall confer upon the Participant any right to continue in the employ or service of the Company and/or an Affiliate or restrict the right of the Company or an Affiliate to terminate such employment or service at any time.
- 9.3 Method of Payment. Payment of the aggregate Purchase Price shall be made, at the sole discretion of the Board, by any of the following (a) cash, (b) check (c) a combination thereof, at the election of the Participant. The Payment shall be made in U.S. Dollars if permissible by law, the payment may also be made in New Israeli Shekel ("NIS") at the representative rate of exchange for the U.S. Dollar published by the Bank of Israel on the day of date of grant.

- 9.4 Entire Agreement. Subject to the provisions of the Plan, to which this Restricted Stock Units Agreement is subject, this Restricted Stock Units Agreement, together with the exhibits hereto, constitute the entire agreement between the Participant and the Company with respect to Restricted Stock Units granted hereunder, and supersedes all prior agreements, understandings and arrangements, oral or written, between the Participant and the Company with respect to the subject matter hereof.
- 9.5 Failure to Enforce - Not a Waiver. The failure of any party to enforce at any time any provisions of this Restricted Stock Units Agreement or the Plan shall in no way be construed to be a waiver of such provision or of any other provision hereof.
- 9.6 Provisions of the Plan. The Restricted Stock Units provided for herein are granted pursuant to the Plan and said Restricted Stock Units and this Restricted Stock Units Agreement are in all respects governed by the Plan and subject to all of the terms and provisions of the Plan.
- Any interpretation of this Restricted Stock Units Agreement will be made in accordance with the Plan but in the event there is any contradiction between the provisions of this Restricted Stock Units Agreement and the Plan, the provisions of the Restricted Stock Units Agreement will prevail.
- 9.7 Binding Effect. The Plan and this Restricted Stock Units Agreement shall be binding upon the heirs, executors, administrators and successors of the parties hereof.
- 9.8 Notices. All notices or other communications given or made hereunder shall be in writing and shall be delivered or mailed by registered mail or delivered by email or facsimile with written confirmation of receipt to the Participant and/or to the Company at the addresses shown on the letterhead above, or at such other place as the Company may designate by written notice to the Participant. The Participant is responsible for notifying the Company in writing of any change in the Participant's address, and the Company shall be deemed to have complied with any obligation to provide the Participant with notice by sending such notice to the address indicated herein.

**Pluristem Therapeutics Inc.:**

per: Name: \_\_\_\_\_

Position: \_\_\_\_\_

Signature: \_\_\_\_\_

I, the undersigned, hereby acknowledge receipt of a copy of the Plan and accept the Restricted Stock Units subject to all of the terms and provisions thereof. I have reviewed the Plan and this Restricted Stock Units Agreement in its entirety, and fully understand all provisions of this Restricted Stock Units Agreement. I agree to notify the Company upon any change in the residence address indicated herein.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature

**Attachments:**

**Exhibit A: Terms of the Restricted Stock Units**

**Exhibit B: Trust Agreement**

**Exhibit C: 2019 Equity Incentive Plan**



**EXHIBIT A**

**TERMS OF THE RESTRICTED STOCK UNITS AWARD**

<b>Name of the Participant:</b>	
<b>Date of Grant:</b>	
<b>Designation:</b>	
<b>1. Number of Restricted Stock Units granted:</b>	
<b>2. Purchase Price:</b>	
<b>3. Vesting Dates:</b>	
<b>4. Restriction Period:</b>	

\_\_\_\_\_  
Participant

\_\_\_\_\_  
Company

## AGREEMENT

This **CLARIFICATION TO AMENDED AND RESTATED CONSULTING AGREEMENT** (this "Agreement") dated as of September 13, 2021, by and between Pluristem Ltd. (the "Company") and Rose High Tech Ltd. of Tel Mond, Israel (the "Consultant"). Each of the Company and the Consultant shall be referred to collectively as the "Parties" and individually as a "Party."

## WITNESSETH

**WHEREAS**, the Company and the Consultant entered into an Amended and Restated Consulting Agreement dated as of September 10, 2020 (the "Consulting Agreement") pursuant to which the Consultant was retained by the Company upon the terms and conditions therein; and

**WHEREAS**, the Company and the Consultant seek to clarify provisions relating to the acceleration of certain awards as set forth in the Consulting Agreement; and

**NOW, THEREFORE**, in consideration of the mutual promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each of the parties agree with the others as follows:

1. Unless otherwise defined herein, all terms and conditions used in this Agreement shall have the meanings assigned to such terms in the Consulting Agreement.

2. Paragraph 3 of Section 5 ("Stock based awards") of the Consulting Agreement is hereby deleted in its entirety and replaced with the following:

"For certain Awards, Zami Aberman shall be entitled to immediate acceleration of the of unvested Awards in the following circumstances: (i) in case of the termination by the Company of the Consulting Agreement for reasons other than as set forth in Section 4.5 of this Agreement, 100% of any unvested Awards; (ii) in case of the termination by the Consultant of the Consulting Agreement, 50% of any unvested Awards at the discretion of the Board of the Parent Company; and (iii) in the event of a Change of Control (as hereinafter defined) of the Parent Company, and provided the Consultant is still providing services to the Parent Company or a subsidiary, 100% of any unvested Awards."

The Parties further agree that the above referenced acceleration provision is not intended to apply to the Consultant's awards that provide for market based condition.

3. Further Assurances. Each Party hereto, without additional consideration, shall cooperate, shall take such further action and shall execute and deliver such further documents as may be reasonably requested by the other Party hereto in order to carry out the provisions and purposes of this Agreement.

4. Counterparts. This Agreement may be signed in counterparts with the same effect as if the signature on each counterpart were upon the same instrument. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5. Headings. The headings of Articles and Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation.

6. Waiver. Neither any failure nor any delay by any party in exercising any right, power or privilege under this Agreement or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege.

7. Severability. The invalidity or unenforceability of any provisions of this Agreement pursuant to any applicable law shall not affect the validity of the remaining provisions hereof, but this Agreement shall be construed as if not containing the provision held invalid or unenforceable in the jurisdiction in which so held, and the remaining provisions of this Agreement shall remain in full force and effect. If the Agreement may not be effectively construed as if not containing the provision held invalid or unenforceable, then the provision contained herein that is held invalid or unenforceable shall be reformed so that it meets such requirements as to make it valid or enforceable.

8. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Israel, without giving effect to the rules respecting conflict-of-law. Any disputes arising from this Agreement shall be resolved pursuant to Section 8 of the Consulting Agreement.

[REMAINDER OF PAGE LEFT BLANK INTENTIONALLY]

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IN WITNESS WHEREOF, the parties hereto have caused this Clarification to Amended and Restated Consulting Agreement to be duly executed as of the day and year first above written.

Company:

**PLURISTEM LTD.**

By: /s/ Yaacov (Yaky) Yanay

Name: Yaacov (Yaky) Yanay

By: /s/ Chen Franco-Yehuda

Name: Chen Franco-Yehuda

Consultant:

/s/ Zami Aberman

Rose High Tech Ltd.

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## AGREEMENT

This **CLARIFICATION TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (this "Agreement") dated as of September 13, 2021, by and between Pluristem Ltd. (the "Company") and Mr. Yaacov (Yaky) Yanay (the "Executive"). Each of the Company and the Executive shall be referred to collectively as the "Parties" and individually as a "Party."

WITNESSETH:

**WHEREAS**, the Company and the Executive entered into an Amended and Restated Employment Agreement dated as of September 10, 2020 (the "Employment Agreement") pursuant to which the Executive was employed by the Company upon the terms and conditions therein; and

**WHEREAS**, the Company and the Executive seek to clarify provisions relating to the acceleration of certain awards as set forth in the Employment Agreement; and

**NOW, THEREFORE**, in consideration of the mutual promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each of the parties agree with the others as follows:

1. Unless otherwise defined herein, all terms and conditions used in this Agreement shall have the meanings assigned to such terms in the Employment Agreement.

2. Paragraph 3 of Section 3.11 ("Stock based awards") of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

"For certain Awards, Employee shall be entitled to immediate acceleration of the of unvested Awards in the following circumstances: (i) in case of the termination by the Company of the Employment Agreement for reasons other than Justifiable Cause, 100% of any unvested Awards; (ii) in case of the termination by Employee of the Employment Agreement, 50% of any unvested Awards at the discretion of the Board of the Parent Company; and (iii) in the event of a Change of Control (as hereinafter defined) of the Parent Company, and provided the Employee is still employed or providing services to the Parent Company or a subsidiary, 100% of any unvested Awards."

The Parties further agree that the above referenced acceleration provision is not intended to apply to the Executive's awards that provide for market based condition.

3. Effect on Existing Awards. The Parties mutually agree that the clarification set forth in Section 2 of this Agreement shall have immediate effect on all of Executive's existing award agreements, including, but not limited to, those Restricted Stock Unit award agreements dated September 10, 2020.

4. Further Assurances. Each Party hereto, without additional consideration, shall cooperate, shall take such further action and shall execute and deliver such further documents as may be reasonably requested by the other Party hereto in order to carry out the provisions and purposes of this Agreement.

5. Counterparts. This Agreement may be signed in counterparts with the same effect as if the signature on each counterpart were upon the same instrument. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

6. Headings. The headings of Articles and Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation.

7. Waiver. Neither any failure nor any delay by any party in exercising any right, power or privilege under this Agreement or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege.

8. Severability. The invalidity or unenforceability of any provisions of this Agreement pursuant to any applicable law shall not affect the validity of the remaining provisions hereof, but this Agreement shall be construed as if not containing the provision held invalid or unenforceable in the jurisdiction in which so held, and the remaining provisions of this Agreement shall remain in full force and effect. If the Agreement may not be effectively construed as if not containing the provision held invalid or unenforceable, then the provision contained herein that is held invalid or unenforceable shall be reformed so that it meets such requirements as to make it valid or enforceable.

9. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Israel, without giving effect to the rules respecting conflict-of-law. Any disputes arising from this Agreement shall be resolved pursuant to Section 8.7 of the Employment Agreement.

[REMAINDER OF PAGE LEFT BLANK INTENTIONALLY]

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IN WITNESS WHEREOF, the parties hereto have caused this Clarification to Amended and Restated Employment Agreement to be duly executed as of the day and year first above written.

Company:

**PLURISTEM LTD.**

By: /s/ Zami Aberman

Name: Zami Aberman

By: /s/ Chen Franco-Yehuda

Name: Chen Franco-Yehuda

Executive:

/s/ Yaacov (Yaky) Yanay

Yaacov (Yaky) Yanay

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## AGREEMENT

This **CLARIFICATION TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (this "Agreement") dated as of September 13, 2021, by and between Pluristem Ltd. (the "Company") and Ms. Chen Franco-Yehuda (the "Executive"). Each of the Company and the Executive shall be referred to collectively as the "Parties" and individually as a "Party."

WITNESSETH:

**WHEREAS**, the Company and the Executive entered into an Amended and Restated Employment Agreement dated as of September 10, 2020 (the "Employment Agreement") pursuant to which the Executive was employed by the Company upon the terms and conditions therein; and

**WHEREAS**, the Company and the Executive seek to clarify provisions relating to the acceleration of certain awards as set forth in the Employment Agreement; and

**NOW, THEREFORE**, in consideration of the mutual promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each of the parties agree with the others as follows:

1. Unless otherwise defined herein, all terms and conditions used in this Agreement shall have the meanings assigned to such terms in the Employment Agreement.

2. Paragraph 3 of Section 3.11 ("Stock based awards") of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

"For certain Awards, Employee shall be entitled to immediate acceleration of the of unvested Awards in the following circumstances: (i) in case of the termination by the Company of the Employment Agreement for reasons other than Justifiable Cause, 100% of any unvested Awards; (ii) in case of the termination by Employee of the Employment Agreement, 50% of any unvested Awards at the discretion of the Board of the Parent Company; and (iii) in the event of a Change of Control (as hereinafter defined) of the Parent Company, and provided the Employee is still employed or providing services to the Parent Company or a subsidiary, 100% of any unvested Awards."

3. Effect on Existing Awards. The Parties mutually agree that the clarification set forth in Section 2 of this Agreement shall have immediate effect on all of Executive's existing award agreements, including, but not limited to, those Restricted Stock Unit award agreements dated September 10, 2020.

4. Further Assurances. Each Party hereto, without additional consideration, shall cooperate, shall take such further action and shall execute and deliver such further documents as may be reasonably requested by the other Party hereto in order to carry out the provisions and purposes of this Agreement.

5. Counterparts. This Agreement may be signed in counterparts with the same effect as if the signature on each counterpart were upon the same instrument. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

6. Headings. The headings of Articles and Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation.

7. Waiver. Neither any failure nor any delay by any party in exercising any right, power or privilege under this Agreement or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege.

8. Severability. The invalidity or unenforceability of any provisions of this Agreement pursuant to any applicable law shall not affect the validity of the remaining provisions hereof, but this Agreement shall be construed as if not containing the provision held invalid or unenforceable in the jurisdiction in which so held, and the remaining provisions of this Agreement shall remain in full force and effect. If the Agreement may not be effectively construed as if not containing the provision held invalid or unenforceable, then the provision contained herein that is held invalid or unenforceable shall be reformed so that it meets such requirements as to make it valid or enforceable.

9. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Israel, without giving effect to the rules respecting conflict-of-law. Any disputes arising from this Agreement shall be resolved pursuant to Section 8.7 of the Employment Agreement.

[REMAINDER OF PAGE LEFT BLANK INTENTIONALLY]

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IN WITNESS WHEREOF, the parties hereto have caused this Clarification to Amended and Restated Employment Agreement to be duly executed as of the day and year first above written.

Company:

**PLURISTEM LTD.**

By: /s/ Zami Aberman

Name: Zami Aberman

By: /s/ Yaacov (Yaky) Yanay

Name: Yaacov (Yaky) Yanay

Executive:

/s/ Chen Franco-Yehuda

Ms. Chen Franco-Yehuda

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טל. +972-3-6232525  
פקס +972-3-5622555  
ey.com

קוסט פורר גבאי את קסירר  
דרך מנחם בגין 144 א'  
תל-אביב 6492102

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-3 (Registration No. 333-239890) and in the Registration Statement on Form S-8 (Registration No. 333- 248685, 333-248686, , 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, the 2016 Equity Compensation Plan and the 2019 Equity Compensation Plan of Pluristem Therapeutics Inc. of our report dated September 10, 2020, with respect to the consolidated financial statements of Pluristem Therapeutics Inc., included in this Annual Report (Form 10-K) of Pluristem Therapeutics Inc., dated September 13, 2021.

Tel Aviv, Israel  
September 13, 2021

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

A member firm of Ernst & Young Global Limited





CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (Registration No. 333-239890) and in the Registration Statements on Form S-8 (Nos. 333- 248685, 333-248686, 333-229535, 333-222888, 333-217770, 333-212299, 333-206848, 333-196537, 333-173777 and 333-162577) of Pluristem Therapeutics Inc. of our report dated September 13, 2021 relating to the financial statements, which appears in this Annual Report on Form 10-K of Pluristem Therapeutics Inc.

/s/ Kesselman & Kesselman  
Certified Public Accountants (Isr.)  
A member firm of PricewaterhouseCoopers International Limited

Haifa, Israel  
September 13, 2021

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Kesselman & Kesselman, Building 25, MATAM, P.O BOX 15084 Haifa, 3190500, Israel,  
Telephone: +972 -4- 8605000, Fax: +972 -4- 8605001, [www.pwc.com/il](http://www.pwc.com/il)

## CERTIFICATION

I, Yaky Yanay, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended June 30, 2021, 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 13, 2021

/s/ Yaky Yanay

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

## CERTIFICATION

I, Chen Franco-Yehuda, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended June 30, 2021, 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 13, 2021

By: /s/ Chen Franco-Yehuda  
Chen Franco-Yehuda  
Chief Financial Officer  
(Principal Financial Officer)

**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, 2021, 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 13, 2021

/s/ Yaky Yanay

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Yaky Yanay

Chief Executive Officer, President

**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, 2021, 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 13, 2021

By: /s/ Chen Franco-Yehuda

Chen Franco-Yehuda  
Chief Financial Officer