



## **2022 ANNUAL REPORT**



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**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, 2022**

☐ 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**

**PLURI INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of  
incorporation or organization)

**98-0351734**

(I.R.S. Employer  
Identification No.)

**MATAM Advanced Technology Park,  
Building No. 5, Haifa, Israel**

(Address of principal executive offices)

**3508409**

(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>PLUR</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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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.

\$44,889,164

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

32,620,343 as of September 15, 2022

**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 “Pluri” mean Pluri 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 on Form 10-K, or Annual Report, that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Such forward-looking statements may be identified by, among other things, the use of forward-looking terminology such as “believes,” “intends,” “plans,” “expects,” “may,” “will,” “should,” or “anticipates” or the negative thereof or other variations thereon or comparable terminology, and similar expressions are intended to identify forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements appear in Item 1— “Business” and Item 7 — “Management’s discussion and Analysis of Financial Condition and Results of Operations,” (especially in the section titled “Outlook”) as well as elsewhere in this Annual Report and include, among other statements, statements regarding the following:

- the expected development and potential benefits from our products in regenerative medicine and food tech, as well as potentially in other industries and verticals that have a need for our mass scale and cost-effective cell expansion platform;
- our entering into certain contracts with third parties;
- the prospects of entering into additional license agreements, or other forms of cooperation with other companies, research organizations and medical institutions, including, without limitation Tnuva (as defined below);
- our pre-clinical and clinical study plans, including timing of initiation, expansion, enrollment, results, and conclusion of trials;
- achieving regulatory approvals;
- receipt of future funding from the Israel Innovation Authority, or IIA, the European Union’s Horizon programs, 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;
- developing capabilities for new clinical indications of placenta expanded, or PLX, cells and new products;
- the final results of our multinational Phase III trial program for the potential use of PLX cells in the treatment of muscle injury following arthroplasty for hip fracture;
- our expectation to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity;
- the possible impacts of cybersecurity incidents on our business and operations;
- 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.

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## PART I

### ITEM 1. BUSINESS.

#### Overview

We are a biotechnology company with an advanced cell-based technology platform. We have developed a unique three-dimensional, or 3D, technology platform for cell expansion with an industrial scale in-house Good Manufacturing Practice, or GMP, cell manufacturing facility. We are utilizing our technology in the field of regenerative medicine and food tech and plan to utilize it in other industries and verticals that have a need for our mass scale and cost-effective cell expansion platform.

We use our advanced cell-based technology platform in the field of regenerative medicine to develop placenta-based cell therapy product candidates for the treatment of inflammatory, muscle injuries and hematologic conditions. Our placental expanded, or PLX, cells are adherent stromal cells that are expanded using our 3D platform. Our PLX cells can be administered to patients off-the-shelf, without blood or tissue matching or additional manipulation prior to administration. PLX cells are believed to release a range of therapeutic proteins in response to the patient's condition.

Our operations are focused on the research, development and manufacturing of cells and cell-based products, conducting clinical studies and the business development of cell therapeutics and cell-based technologies, such as our recent collaboration with Tnuva Food Industries — Agricultural Cooperative in Israel Ltd., through its fully owned subsidiary, Tnuva Food-Tech Incubator (2019), Limited Partnership, or Tnuva, to use our technology to establish a cultivated food platform.

We expect to demonstrate a real-world impact and value from our cell-based technology platform, our current PLX pipeline and from other cell-based product candidates that may be developed based on our platform. Our business model for commercialization and revenue generation includes, but is not limited to, licensing deals, joint ventures, partnerships, joint development agreements and direct sale of our products.

We are now completing a multinational Phase III clinical study in muscle recovery following surgery for hip fracture, with sites in the United States, Europe and Israel. In the last year, we have completed a Phase II clinical study in Acute Respiratory Distress Syndrome, or ARDS, associated with COVID-19 and a Phase I clinical study for incomplete recovery following bone marrow transplantation. Additional areas of focus for clinical development include an investigator-led Phase I/II Chronic Graft versus Host Disease, or cGVHD, study in Israel, and an Acute Radiation Syndrome, or ARS, program under the U.S. Food and Drug Administration, or FDA, animal rule. We believe that each of these indications represents a severe unmet medical need.

We were incorporated in Nevada on May 11, 2001. Pluri Inc. has a wholly owned subsidiary, Pluri Biotech Ltd., or the Subsidiary, previously named Pluristem Ltd., which is incorporated under the laws of the State of Israel. In January 2020, the Subsidiary established a wholly owned subsidiary, Pluristem GmbH, which is incorporated under the laws of Germany. In January 2022, the Subsidiary established an additional subsidiary, Plurinuva Ltd., or Plurinuva, which is incorporated under the laws of Israel, which followed the execution of the collaboration agreement with Tnuva .

On July 26, 2022, we completed our legal entity name change from Pluristem Therapeutics Inc. to Pluri Inc., by merging a wholly-owned subsidiary with and into the Company, with us being the surviving corporation. The name change reflects a broader strategy of leveraging our 3D cell expansion technology to develop innovative cell-based products that can be harnessed for a range of fields beyond medicine, providing solutions for various areas of life. Effective July 26, 2022, our Nasdaq ticker symbol was changed to "PLUR."

#### Scientific Background

Cell therapy is an established 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 exhibit low immunogenicity, thus do not require tissue matching prior to administration, which allows the development of ready-to-use/“off-the-shelf” allogeneic products.

### **Our Technology**

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 during the years, has demonstrated batch-to-batch consistency, an important manufacturing challenge for biological products.

Our technology platform, a patented and validated state-of-the-art 3D cell expansion system, aims to advance novel cell-based solutions for a range of initiatives, including, but not limited to, pharmaceuticals, climate change, food security and animal welfare. Our method is uniquely accurate, scalable, cost-effective, and consistent from batch to batch. Our technology is currently implemented in the fields of regenerative medicine and food-tech.

### **Product Candidates**

We believe that our technology will continue to fuel medical research and develop pharmaceuticals, while also being used to potentially create novel cell-based solutions for other innovative initiatives — such as food-tech, agri-tech, and biologics. We aim to establish partnerships that leverage our 3D cell-based technology to additional industries that require effective, mass cell production.

#### ***Pluri Health***

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. 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 used in a Phase III multinational clinical study in recovery following surgery for hip fracture.

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

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

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

We have completed 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 process 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 cytokines, to transiently alter their secretion profile.

Modified PLX cells using CRISPR, or other gene editing technology: CRISPR is a unique technology which allows precise gene editing of cells. Using this technology, we 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 allogenic 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, or SPPB, a test for lower limb performance and functional status. We completed enrollment of 240 patients and the study was designed to assess the efficacy at six months and a year, as well as safety for up to two years.

On July 13, 2022, we announced topline results from our Phase III study of muscle regeneration following hip fracture surgery. PLX-PAD was demonstrated to be an effective accelerator of muscle strength and regeneration. A significant increase in Hip Abduction Strength (HAS) was observed at week 26 and week 52 for patients treated with PLX-PAD (n=120), in the injured leg (p=0.047, p=0.0022) and uninjured leg (p=0.073, p=0.0046) compared to placebo (n=120). The study did not meet the primary endpoint, which was the SPPB test at week 26. The study will continue to follow up with patients for up to 52 weeks for safety and other efficacy measures.

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, or VFD, from day 1 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. 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 were bringing our COVID-19 complicated by ARDS Phase II studies in the United States, Europe and Israel to clinical readout. The analysis was based on 89 patients enrolled.

On December 27, 2021, we announced topline results for our COVID-19 studies based on 89 patients enrolled. The studies did not meet the primary efficacy endpoint of statistically significant improvement of VFD at 28 days. Taking into consideration the baseline risk factors of the ARDS patients, no differences in the safety profile were observed between PLX-PAD and placebo. The U.S. study was recently completed, and the second study conducted in Europe and Israel is planned for completion during the third calendar quarter of 2022.

**Recovery Following HCT.** This Phase I study of PLX-R18 in HCT was completed in the United States and Israel. The study assessed the safety of PLX-R18 by assessing adverse events, safety labs and vital signs in patients receiving different doses of PLX-R18. One year follow up for all patients was completed in September 2021 and the results of the study were announced on March 23, 2022. PLX-R18 was well-tolerated with a favorable safety profile. Patients treated with PLX-R18 showed a mean increase in all three blood cell types compared to baseline with platelets ( $p<0.001$ ), hemoglobin ( $p=0.01$ ) and neutrophils ( $p=0.15$ ) levels increasing as early as 1 month following PLX-R18 administration and enduring up to 12 months following treatment. Additionally, the number of transfused units decreased from a mean monthly number of 5.09 for platelets and 2.91 for red blood cells at baseline to 0.55 for platelets ( $p=0.045$ ) and 0 for red blood cells ( $p=0.0005$ ) at 12 months.

**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 completed a Phase II study in IC which was conducted in the United States, Germany, South Korea and Israel. A total of 172 patients were treated in this study. IM administration of PLX-PAD cells was concluded to be safe and well tolerated. We completed 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 a 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 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 show an increase in recovery of blood lineages and a favorable safety profile. Furthermore, histopathological analysis and hematopoietic progenitor clonogenic assay of tissues collected show a significant increase in bone marrow cell numbers and improved regenerative capability into all blood lineages.

**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. 13 patients have been treated in this study to date.

### **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.

### **Our Activities in the Food Tech Sector**

On January 5, 2022, we signed definitive collaboration agreements with Tnuva through the Subsidiary. Under the definitive collaboration agreements, or the Joint Venture Agreement, we established a new company, Plurinuva, with the purpose of developing cultivated meat products of all types and kinds. Plurinuva is intended to be engaged in the development, manufacturing and commercialization of technology, know-how and products that will be based on licensed products, or the Licensed Products, relating to the field of cultivated meat, or the Field.

Pursuant to the Joint Venture Agreement, Tnuva entered into a share purchase agreement, or the SPA, with Plurinuva and the Subsidiary, pursuant to which Plurinuva issued on the closing date of the SPA, or the Closing Date, 187,500 ordinary shares, representing 15.79% of its share capital, to Tnuva, as well as a warrant to purchase additional shares of Plurinuva, in consideration of an aggregate of \$7.5 million in cash. In addition, pursuant to the SPA, in the event the Company decides to use its technology for the development of cultivated milk or fish products, Tnuva shall also have the right, for a period of seven years following the Closing Date, to participate in the formation of additional separate joint ventures for the development of those products.

The first warrant, or the First Warrant, issued to Tnuva permits Tnuva to purchase up to 125,000 ordinary shares of Plurinuva at an exercise price of \$40.00 per share and has a term commencing on the Closing Date and ending at the earlier of (i) six months from the Closing Date, (ii) immediately prior to and subject to the consummation of an initial public offering or acquisition of Plurinuva or (iii) the consummation of a financing round with a non-affiliated investor. In addition, on the six month anniversary of the Closing Date, and provided that the First Warrant has not expired, Plurinuva shall issue to Tnuva a second warrant, or the Second Warrant, which will permit Tnuva to purchase up to a number of ordinary shares of Plurinuva, or the then most senior securities issued by Plurinuva, in consideration for such amount equal to 200% of the remaining balance of the aggregate purchase price of the First Warrant, provided that Tnuva exercises at least 62,500 ordinary shares at a price per share of \$40.00, or \$2,500,000 in the aggregate, of the First Warrant. The Second Warrant's exercise price per share equals \$76.00. The Second Warrant has a term commencing on the six months anniversary of the Closing Date and ending at the earlier of (i) six months from its issuance, (ii) immediately prior to and subject to the consummation of an initial public offering or acquisition of Plurinuva or (iii) the consummation of a financing round with a non-affiliated investor. On August 23, 2022, the First Warrant was extended for an additional 90-day period, so that the exercise period will end on November 22, 2022.

On February 24, 2022, we announced the closing of the Joint Venture Agreement and the SPA, and on March 8, 2022, we announced the appointment of Eyal Rosenthal as Chief Executive Officer of Plurinuva.

Prior to the Closing Date, the Subsidiary and Plurinuva also executed a technology license agreement, or the License Agreement, and on the Closing Date, the Subsidiary and Plurinuva executed a transitional services agreement, or the Services Agreement. Pursuant to the License Agreement, the Subsidiary granted Plurinuva an exclusive, royalty

bearing, perpetual and irrevocable, worldwide, non-transferable (except under specific circumstances specified thereunder), sublicensable license to its technology for the use in the development of the Licensed Products in the Field. In addition, Plurinuva granted the Subsidiary, pursuant to the License Agreement, an exclusive, perpetual and irrevocable, worldwide, sublicensable, royalty-free, license to use, make, exploit and develop the improvements made by Plurinuva to the licensed technology outside of the Field. In consideration for the license, Plurinuva agreed to pay the Subsidiary royalties from its future net sales in the mid-single digits. Pursuant to the terms of the Services Agreement, the Subsidiary shall provide Plurinuva transitional services to support its development efforts, for an initial term of eighteen months, subject to mutual extension for an additional six months.

Pursuant to the SPA, Tnuva and Plurinuva agreed to enter into a commercialization agreement within twelve months pursuant to which Tnuva shall be granted exclusive marketing, distribution and sale rights of the Licensed Products in Israel. Tnuva's exclusivity in the region will be subject to achieving and maintaining specific milestones. Plurinuva shall retain exclusive worldwide marketing, distribution, and sale rights for the Licensed Products worldwide, except in Israel.

### **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 137 issued patents and approximately 64 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).

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 and plant cells;
- composition of matter claims covering the cells;
- the therapeutic and cosmetic use of PLX cells for the treatment of a variety of conditions; and
- cell-culture, harvest, thawing and formulation 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, which 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

Patent Name/Int. App. No.	Pending Jurisdictions	Granted Jurisdictions	Expiry Date
<b>METHODS FOR CELL EXPANSION AND USES OF CELLS AND CONDITIONED MEDIA PRODUCED THEREBY FOR THERAPY</b> PCT/IL2007/000380	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</b> PCT/IL2008/001185	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</b> PCT/IL2009/000527		United States, Israel, Russia	May 26, 2029
<b>METHODS OF SELECTION OF CELLS FOR TRANSPLANTATION</b> PCT/IL2009/000844		Europe, Israel	September 1, 2029
<b>ADHERENT CELLS FROM PLACENTA TISSUE AND USE THEREOF IN THERAPY</b> PCT/IL2009/000846		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</b> PCT/IL2009/000845		United States, Europe, Israel	September 1, 2029
<b>ADHERENT STROMAL CELLS DERIVED FROM PLACENTAS OF MULTIPLE DONORS AND USES THEREOF</b> PCT/IB2011/001413	United States	Israel	Israel: April 21, 2031 U.S: March 22, 2027
<b>ADHERENT CELLS FROM PLACENTA AND USE OF SAME IN DISEASE TREATMENT</b> PCT/IB2010/003219	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>Patent Name/Int. App. No.</b>	<b>Pending Jurisdictions</b>	<b>Granted Jurisdictions</b>	<b>Expiry Date</b>
<b>DEVICES AND METHODS FOR CULTURE OF CELLS PCT/IB2013/058184</b>		United States, Israel	August 31, 2033
<b>METHODS FOR PREVENTION AND TREATMENT OF PREECLAMPSIA PCT/IB2013/058186</b>		China, Hong Kong, Europe, Israel, Japan, South Korea, United States	August 31, 2033
<b>METHOD AND DEVICE FOR THAWING BIOLOGICAL MATERIAL PCT/IB2013/059808</b>	China	Australia, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Russia, Singapore, United States	October 31, 2033
<b>SYSTEMS AND METHODS FOR GROWING AND HARVESTING CELLS PCT/IB2015/051559</b>		Israel, United States	March 3, 2035
<b>METHODS AND COMPOSITIONS FOR TREATING AND PREVENTING MUSCLE WASTING DISORDERS PCT/IB2015/059763</b>		Israel, United States	December 18, 2035
<b>USE OF ADHERENT STROMAL CELLS FOR ENHANCING HEMATOPOIESIS IN A SUBJECT IN NEED THEREOF PCT/IB2016/051585</b>	United States, Israel		March 21, 2036
<b>ALTERED ADHERENT STROMAL CELLS AND METHODS OF PRODUCING AND USING SAME PCT/IB2016/053310</b>	Europe, China, Israel	Europe, United States	June 6, 2036
<b>METHODS AND COMPOSITIONS FOR TREATING CANCERS AND NEOPLASMS PCT/IB2017/050868</b>	United States, Japan, Canada, Israel	Europe, Japan	February 16, 2037
<b>METHODS AND COMPOSITIONS FOR TREATING NEUROLOGICAL DISORDERS PCT/IB2018/052806</b>	Israel, United States		April 23, 2038
<b>METHODS AND COMPOSITIONS FOR TUMOR ASSESSMENT PCT/IB2018/050984</b>	United States	Israel	February 18, 2038
<b>METHODS AND COMPOSITIONS FOR TREATING ADDICTIONS PCT/IB2018/055473</b>	Israel, United States		July 23, 2038
<b>METHODS AND COMPOSITIONS FOR DETACHING ADHERENT CELLS Germany 10 2018 115 360.0</b>	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 PCT/IL2020/050477</b>	Canada, Europe, Hong Kong, Israel, Japan, United States		April 28, 2040



<b>Patent Name/Int. App. No.</b>	<b>Pending Jurisdictions</b>	<b>Granted Jurisdictions</b>	<b>Expiry Date</b>
<b>METHODS FOR EXPANDING ADHERENT STROMAL CELLS AND CELLS OBTAINED THEREBY PCT/IB2019/052569</b>	Israel, Singapore, United States		March 28, 2039
<b>METHODS AND COMPOSITIONS FOR TREATING SUBJECTS EXPOSED TO VESICANTS AND OTHER CHEMICAL AGENTS PCT/IB2019/055074</b>	Israel, United States		June 18, 2039
<b>METHODS AND COMPOSITIONS FOR FORMULATING AND DISPENSING PHARMACEUTICAL FORMULATIONS PCT/IB2019/053115</b>	United States	Israel	United States: April 16, 2039 Israel: April 26, 2038
<b>THERAPEUTIC DOSAGE REGIMENS COMPRISING ADHERENT STROMAL CELLS PCT/IB2019/054828</b>	Israel, United States		June 10, 2039
<b>MODULAR BIOREACTOR PCT/IB2019/058429</b>	Europe, Israel, Hong Kong, South Korea, Singapore, United States		October 3, 2039
<b>THERAPEUTIC METHODS AND COMPOSITIONS PCT/IB2019/059544</b>	Israel, United States		November 6, 2039
<b>METHODS AND COMPOSITIONS FOR TREATING VIRAL INFECTIONS AND SEQUELAE THEREOF PCT/IL2021/050268</b>	PCT, United States, Europe, Israel, Mexico	Israel	First Israeli application: May 14, 2040 Other applications: March 11, 2041 March 26, 2040
<b>METHODS AND COMPOSITIONS FOR AESTHETIC AND COSMETIC TREATMENT AND STIMULATING HAIR GROWTH PCT/IL2020/050363</b>	United States, Europe, Canada, China, Japan, Israel, Australia		
<b>METHODS FOR EXPANDING ADHERENT STROMAL CELLS AND CELLS OBTAINED THEREBY IL277560</b>	Israel		September 23, 2040

On January 8, 2022, we entered into a definitive license agreement with Takeda Pharmaceuticals International AG, or Takeda, a company based in Switzerland, which operates in the field of adipose-derived cells, pursuant to which we granted Takeda a global, non-exclusive license to use several of our patents (EP2591789, EP3103463, and 3091071), limited to adipose fat cells only, in the field of therapeutics, in exchange for Takeda ceasing its opposition with regards to said patents and paying us a lump sum of \$200,000. The license covers methods for expanding adherent stromal cells and specified second medical uses.

On January 10, 2022, we entered into a definitive license agreement with Novadip Biosciences, or Novadip, a company based in Belgium, which operates in the field of adipose-derived stem cells for cell therapy and cell-free therapy in respect of medical or cosmetic conditions, under which we granted Novadip a global, non-exclusive, royalty free license to use two of our patents (EP2591789, EP3103463), limited to non-placental cells and cell-derived therapies, sub-licensable only to Novadip's customers.

In April 2016, the Subsidiary entered into a licensing agreement with TES Holdings Co., Ltd., a venture company derived from the University of Tokyo, to obtain a key patent in Japan to cover the treatment of ischemic diseases with placental cell therapy. This license is subject to future single low-digit royalties from sales of our product for treatment in the field of ischemic diseases in Japan, until expiry of the patent in 2023. This license 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.

### ***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 2027. 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 our 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.

#### Horizon Europe

On September 6, 2022, we announced that a €7.5 million non-dilutive grant from the European Union's Horizon program has been awarded to PROTO (Advanced PeRsOnalized Therapies for Osteoarthritis), an international collaboration led by Charité Berlin Institute of Health Center for Regenerative Therapies. The goal of the PROTO project is to utilize our PLX-PAD cells in a Phase I/IIa study for the treatment of mild to moderate knee osteoarthritis. Final approval of the grant is subject to completion of the consortium and Horizon Europe grant agreements. The funds from the grant are expected to be allocated between Pluri and other members of the consortium in accordance with budget and work packages which will be determined by the consortium.

The Phase I/IIa study will be carried out by Charité. We, together with an international consortium under the leadership of Professor Tobias Winkler, Principal Investigator, at the Berlin Institute of Health Center of Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery

#### 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.

#### 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 was 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 October 2021, we received approval for an additional grant of approximately \$583,000 from the IIA pursuant to the CRISPR-IL consortium program, for an additional period of eighteen months.

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.

## ***In-House Clinical Manufacturing***

We have the in-house capability to perform clinical cell manufacturing. Our state-of-the-art Good 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 a 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.

We have 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. Additionally, as of January 31, 2022, conducting clinical studies within EMA countries is subject to clinical trials regulation. This European Union regulation requires:

- Filing a Central Clinical Trial Application utilizing the Clinical Trials Information System (CTIS) and obtaining an assessment and approval;
- Obtaining approval of local and central ethics committees as required to test the investigational product into humans in clinical studies;
- Conducting 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 in 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, 2022, we employed a total of 154 full-time employees and 5 part-time employees, of whom, 128 full-time employees and 5 part-time employees are engaged in research and development, manufacturing and clinical development.

As of August 30, 2022, we employed a total of 129 full-time employees and 6 part-time employees, of whom, 102 full-time employees and 6 part-time employees are engaged in research and development, manufacturing and clinical development.

The reduction in the number of our employees was part of an efficiency and cost reduction plan we initiated in June 2022.

### ***Competition***

Our legacy product candidates have focused on the regenerative medicine field. 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 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.

More recently, through our collaboration with Tnuva and the establishment of Plurinuva, we have begun to utilize our technology in the food tech field. Competitors in the cultivated meat domain include both producers of consumer-end-products, as well as those developing inputs for the production process. Plurinuva competes with companies that include Upside Foods, Future Meat, GOOD Meat, Mosa Meat, Aleph Farms, and Gourmey.

We believe that our ability to compete in the food tech field will derive from our experienced team, our unique 3D technology platform, and our industrial scale in-house GMP, cell manufacturing facility, together with our partner, Tnuva, which has vast experience in the food business.

### ***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 or recovered from COVID-19 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, if necessary. The COVID-19 global pandemic caused delays in enrollment of some of our clinical studies. 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 ongoing research work with various hospitals and academic institutions.

#### ***Available Information***

Additional information about us is contained on our Internet website at [www.pluri-biotech.com](http://www.pluri-biotech.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, Anti Bribery and Corruption and Anti Money Laundering and Terrorist Financing Compliance Policy, 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 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 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;
- 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;
- 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;
- 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;
- it may be difficult for investors in the United States to enforce any judgments obtained against us or some of our directors or officers;
- cybersecurity incidents may have an adverse impact on our business and operations;
- recent increasing global inflation could affect our ability to purchase materials needed for manufacturing and could increase the costs of our future product;
- we have a limited operating history in the field of food-tech to date and our prospects will be dependent on our ability to meet a number of challenges;
- our business and market potential in the field of food-tech are unproven, and we have limited insight into trends that may emerge and affect our business; and
- the research and development associated with technologies for cultivated meat manufacturing, is a lengthy and complex process.

#### **Risk Related to Our Business**

***We may need to raise additional financing to support the research, development and manufacturing of our cell based products in the future, but we cannot be sure we will be able to obtain additional financing on terms favorable to us when needed. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.***

It is highly likely that we will need to raise significant additional capital in the future. Although we were successful in raising capital in the past, our current financial resources are limited, and may not be sufficient to finance our operations until we become profitable, if that ever happens.

It is likely that we will need to raise additional funds in the 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, enter into collaborations and licensing deals or to otherwise raise capital. Any sale of our common shares in the future could result in dilution to existing shareholders and could adversely affect the market price of our common shares.

Also, we may not be able to raise additional capital in the future to support the development and commercialization of our 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 technology, which is currently in the development stage. If we are unable to complete the development and commercialization of our cell-based products successfully, or are unable to obtain the necessary regulatory approvals, our likelihood of profitability will be limited severely.***

We are engaged in the business of developing cell-based 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 cell-based products and/or licensing of our products, which will require additional research and development.

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 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.

***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 and we have not generate any material revenues to date. It is not clear when we will generate revenues or whether we will generate revenues in the future. 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.

***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.

***While we may seek partners for licensing deals, joint ventures, partnerships, and direct sale of our products in various industries, there is no guarantee we will be successful in doing so.***

To date, we have focused our efforts primarily in the regenerative medicine field, but we may seek partners for licensing deals, joint ventures, partnerships, and direct sale of our products or use of our technology in various industries. Licensing deals, joint ventures and partnerships in new fields involve numerous risks, including the potential integration of our technology and products in various new ways, which may or may not be successful. Such projects may require significant funds, time and attention of management and other key personnel. In addition, as we do not have experience in areas outside of the regenerative medicine field, we may lack the personnel to properly lead such initiatives. There can be no assurance that we will be successful in finding the relevant partners to fund and market the cell based products.

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

***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 future 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 trials on clinical hold;
- Subjects do not enroll in our trials at the rate we expect.
- Government actions, such as those enacted during the ongoing COVID-19 pandemic, which 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 may not perform the clinical trials under the anticipated schedule or consistent with the clinical trial protocol, GCP and regulatory requirements.
- 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 may increase if we have material delays in a 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.

***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.

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.

***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.

***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.

***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, which 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.

#### **Risks Related to Our Food-Tech Business**

***Plurinuva has a limited operating history in the field of cultivated meat to date and its prospects will be dependent on its ability to meet a number of challenges.***

Plurinuva's business prospects are difficult to predict due to its lack of operational history in the new and emerging food tech field, and its success will be dependent on its ability to meet a number of challenges. Because it has a limited operating history in the field of cultivated meat and it is in the early stages of development, Plurinuva may not be able to evaluate its future prospects accurately. Plurinuva's prospects will be primarily dependent on its ability to successfully develop industrial scale cultivated meat technologies and processes, and market these to its potential customers. If Plurinuva is not able to successfully meet these challenges, its prospects, business, financial condition, and results of operations could be adversely impacted.

In addition, Plurinuva will be subject to changing laws, rules and regulations in the Israeli, United States, Asia Pacific, the European Union and other jurisdictions relating to the food tech industry. Such laws and regulations may negatively impact its ability to expand its business and pursue business opportunities. Plurinuva may also incur significant expenses to comply with the laws, regulations and other obligations that will apply to it.

***Plurinuva is primarily focused on utilizing its technology for the development of cultivated meat, and it has limited data on the performance of our and its technologies in the field of cultivated meat to date.***

Plurinuva does not currently have any products or technologies approved for sale and it is still in the early stages of development. To date, Plurinuva has limited data on the ability of our and its technologies to successfully manufacture cultivated meat, towards which they have devoted substantial resources to date. Plurinuva's current technologies are, in large part, based on our technologies and intellectual property. We may not be successful in developing its technologies in a manner sufficient to support its expected scale-ups and future growth, or at all. Plurinuva expects that a substantial portion of its efforts and expenditures over the next few years will be devoted to the development of technologies designed to enable Plurinuva to market industrial-scale cultivated meat manufacturing processes. Plurinuva cannot guarantee that it will be successful in developing these technologies, based on its current roadmap, or at all. If Plurinuva is able to successfully develop its cultivated meat technologies, it cannot ensure that it will obtain regulatory approval or that, following approval, upon commercialization its technologies will achieve market acceptance. Any such delay or failure could materially and adversely affect Plurinuva's financial condition, results of operations and prospects.

#### **Risk Related to Commercialization of Our Product Candidates**

***We may not successfully establish new collaborations, joint ventures or 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 development and in-house manufacturing of innovative new cell-based products and solutions powered by our 3D cell expansion technology platforms and establishing joint ventures and partnerships that leverage our cell expansion technology and cell-based product portfolio to expand product pipelines and meet cell-based manufacturing needs for a variety of industries. To date, we have a strategic partnership with Tnuva to use our technology to establish a cultivated food platform, with CHA for both the IC and CLI indications in Korea and with Chart for the thawing device. 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 cell therapy products will be heavily dependent on third party reimbursement policies.***

Our ability to successfully commercialize our cell therapy 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 of 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 this 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.

***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.

***We could fail to maintain the listing of our common shares on Nasdaq, which could seriously harm the liquidity of our shares and our ability to raise capital or complete a strategic transaction.***

The Nasdaq Stock Market has established continued listing requirements, including a requirement to maintain a minimum closing bid price of at least \$1.00 per share. If a company trades for 30 consecutive business days below such minimum closing bid price, it will receive a deficiency notice from Nasdaq. Assuming it is in compliance with the other continued listing requirements, Nasdaq would provide such company a period of 180 calendar days in which to regain compliance by maintaining a closing bid price at least \$1.00 per share for a minimum of ten consecutive business days. If we are not able to regain compliance, there is a risk that our common shares may be delisted from Nasdaq.

As of the date of this filing, our common shares are trading below \$1.00 per share. If the closing bid price of our common shares continues trading below \$1.00 per share for an aggregate of 30 consecutive business days, we will receive a deficiency notice from Nasdaq. If, in such circumstance, we are not able to regain compliance with the minimum bid price requirement within 180 days, our common shares will be subject to a delisting action by Nasdaq.

A delisting from Nasdaq would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on shareholders:

- the liquidity of our common shares;
- the market price of our common shares;
- the availability of information concerning the trading prices and volume of our common shares;
- our ability to obtain financing or complete a strategic transaction;
- the number of institutional and other investors that will consider investing in our common shares; and
- the number of market makers or broker-dealers for our common shares.



***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. 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, that bears 4% annual interest. All of these factors subject us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, and lease payments on our facilities. From time to time, we may apply a hedging strategy by using options and forward contracts to protect ourselves against some of the risks of currency exchange fluctuations and we are actively monitoring the exchange rate differences of the NIS, Euro and U.S. Dollar; however, we are still exposed to potential losses from currency exchange fluctuation.

***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, 2022. Currently, we hold most 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 ongoing COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business and operations.***

COVID-19 has had and continues to have a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. 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."

***Recent increasing global inflation may adversely affect our business results.***

The increasing inflation could affect our ability to purchase materials needed to support our research and operational activities, which in turn could result in higher burn rate and a higher end price of our future products. As a result, we may not be able to effectively develop our product candidates or cultivated meat products. If we are not able to successfully manage any increases in inflation, our prospects, business, financial condition, and results of operations could be adversely impacted.

***Since we have signed the EIB Finance Agreement, we agreed to guaranty the loan as well as agreed to 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.

***A cybersecurity incident, other technology disruptions or failure to comply with laws and regulations relating to privacy and the protection of data relating to individuals could negatively impact our business and our reputation.***

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.

During November 2021, we experienced a cybersecurity incident in which one or more third parties were able to impersonate one of our vendors by using a falsified email domain account and asked to make a payment to a false bank account. As a result of this incident, the third parties managed to extract a sum of approximately \$616,000 from us. Following the incident, we hired the services of a cybersecurity investigation firm to fully access the incident and notified the appropriate government authorities, including the banks involved in the transaction. During February 2022, with the assistance of local and global law enforcement agencies, we were able to recover an amount of approximately \$412,000 from the false bank account. Together with the reimbursement received from our insurance company, we were able to recover the full amount lost.

The cybersecurity incident has not had any material effect on our ability to meet our financial obligations, including our ability to carry out our operations and business activities, and our investigation has confirmed that, other than the funds referenced above, none of our information or data was stolen or damaged. Nonetheless, despite the implementation of security measures, including the steps we have taken following the November 2021 cybersecurity incident, our internal computer systems and those of our current and future CROs and other contractors and consultants may not prevent future incidents of a similar nature or other cyber-attacks. We are constantly exploring new and advanced security protection measures to prevent future cybersecurity incidents.

Future security breaches or any material system failure events 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.

In addition, we are subject to laws, rules and regulations in the Israeli, United States, the European Union and other jurisdictions relating to the collection, use and security of personal information and data. Such data privacy laws, regulations and other obligations may require us to change our business practices and may negatively impact our ability to expand our business and pursue business opportunities. We may incur significant expenses to comply with the laws, regulations and other obligations that apply to us. Additionally, the privacy- and data protection-related laws, rules and regulations applicable to us are subject to significant change. Several jurisdictions have passed new laws and regulations in this area, and other jurisdictions are considering imposing additional restrictions. Privacy- and data protection-related laws and regulations also may be interpreted and enforced inconsistently over time and from jurisdiction to jurisdiction. Any actual or perceived inability to comply with applicable privacy or data protection laws, regulations, or other obligations could result in significant cost and liability, litigation or governmental investigations, damage our reputation, and adversely affect our business.

***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.

***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 2022 was 291,000 NIS (approximately \$89,000). For Fiscal Year 2022, we recognized a net expense (rent expenses after deducting deferred participation payments from MATAM) in the amount of \$921,000, 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 are traded on the Nasdaq Global Market and the Tel Aviv Stock Exchange under the symbol "PLUR".

As of September 15, 2022, there were 50 holders of record, and 32,620,343 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 15<sup>th</sup> Avenue, 2<sup>nd</sup> 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 with an advanced cell-based technology platform. We have developed a unique three-dimensional, or 3D, technology platform for cell expansion with an industrial scale in-house GMP cell manufacturing facility. We are utilizing our technology in the field of regenerative medicine and food tech and plan to utilize it in other industries and verticals that have a need for our mass scale and cost-effective cell expansion platform.

We use our advanced cell-based technology platform in the field of regenerative medicine to develop placenta-based cell therapy product candidates for the treatment of inflammatory, muscle injuries and hematologic conditions. Our PLX cells are adherent stromal cells that are expanded using our 3D platform. Our PLX cells can be administered to patients off-the-shelf, without blood or tissue matching or additional manipulation prior to administration. PLX cells are believed to release a range of therapeutic proteins in response to the patient's condition.

Our operations are focused on the research, development and manufacturing of cells and cell-based products, conducting clinical studies and the business development of cell therapeutics and cell-based technologies, such as our recent collaboration with Tnuva Food Industries — Agricultural Cooperative in Israel Ltd., through its fully owned subsidiary, Tnuva, to use our technology to establish a cultivated food platform.

We expect to demonstrate a real-world impact and value from our cell-based technology platform, our current PLX pipeline and from other cell-based product candidates that may be developed based on our platform. Our business model for commercialization and revenue generation includes, but is not limited to, licensing deals, joint ventures, partnerships, joint development agreements and direct sale of our products.

We are now completing a multinational Phase III clinical study in muscle recovery following surgery for hip fracture, with sites in the United States, Europe and Israel. In the last year, we have completed a Phase II clinical study in Acute Respiratory Distress Syndrome, or ARDS, associated with COVID-19 and a Phase I clinical study for incomplete recovery following bone marrow transplantation. Additional areas of focus for clinical development include an investigator-led Phase I/II Chronic Graft versus Host Disease, or cGVHD, study in Israel, and an Acute Radiation Syndrome, or ARS, program under the U.S. Food and Drug Administration, or FDA, animal rule. We believe that each of these indications represents a severe unmet medical need.

We were incorporated in Nevada on May 11, 2001. Pluri Inc. has a wholly owned subsidiary, Pluri Biotech Ltd., or the Subsidiary, previously named Pluristem Ltd., which is incorporated under the laws of the State of Israel. In January 2020, the Subsidiary established a wholly owned subsidiary, Pluristem GmbH, which is incorporated under the laws of Germany. In January 2022, the Subsidiary established an additional subsidiary, Plurinuva Ltd., or Plurinuva, which is incorporated under the laws of Israel, which followed the execution of the collaboration agreement with Tnuva.



On July 26, 2022, we completed our legal entity name change from Pluristem Therapeutics Inc. to Pluri Inc., by merging a wholly-owned subsidiary with and into the Company, with us being the surviving corporation. The name change reflects a broader strategy of leveraging our 3D cell expansion technology to develop innovative cell-based products that can be harnessed for a range of fields beyond medicine, providing solutions for various areas of life. Effective July 26, 2022, our Nasdaq ticker symbol was changed to “PLUR.”

*RESULTS OF OPERATIONS — YEAR ENDED JUNE 30, 2022 COMPARED TO YEAR ENDED JUNE 30, 2021.*

**Revenues**

Revenues for the year ended June 30, 2022 were \$234,000, compared to no revenues for the year ended June 30, 2021. The revenues in the year ended June 30, 2022 were related to the revenue derived from our license agreement with Takeda and the sale of our PLX cells for research use.

**Research and Development, Net**

Research and development, net (costs less participation and grants by the IIA, Horizon 2020 and other parties) decreased by 19% from \$30,066,000 for the year ended June 30, 2021, to \$24,377,000 for the year ended June 30, 2022. The decrease is mainly attributed to a decrease in clinical study expenses following the termination of our CLI study, end of enrollment of our Phase II studies of ARDS associated with COVID-19, and end of enrollment in our Phase III hip study, as well as a decrease in share-based compensation expenses related to restricted share units, or RSUs, granted to employees and consultants. The decrease was partially offset by an increase in materials purchased to support our manufacturing plans, increased payroll expenses related to payroll adjustments and exchange rate fluctuations, and an increase in building lease costs following the extension of our lease contract.

**General and Administrative**

General and administrative expenses decreased by 15% from \$20,557,000 for the year ended June 30, 2021, to \$17,450,000 for the year ended June 30, 2022. The decrease is mainly attributed to a decrease in share-based compensation expenses related to market based vesting conditioned RSUs granted to our CEO and Chairman, partially offset by an increase in share-based compensation expenses related to the allocation of shares of Plurinuva to our CEO, CFO and Chairman pursuant to their employment or consulting agreement (see also notes 1e and 9b1 to the consolidated financial statements included elsewhere in this Annual Report) and increased payroll expenses related to new employees, payroll adjustments and exchange rate fluctuations.

**Total Financial Income, Net**

Financial income, net decreased from \$758,000 for the year ended June 30, 2021 to \$219,000 for the year ended June 30, 2022. This decrease is mainly attributable to an increase in interest expenses related to the EIB loan provided to us in June 2021 pursuant to the EIB Finance Agreement and losses from hedging transactions due to strength of the U.S Dollar against the Euro, partially offset by exchange rate income on lease liability due to the strength of the U.S Dollar against the NIS and exchange rates adjustments relating to the EIB loan.

**Net Loss for the Year**

Net loss decreased from \$49,865,000 for the year ended June 30, 2021 to \$41,374,000 for the year ended June 30, 2022. The decrease was mainly due to a decrease in research and development expenses, net, and a decrease in general and administrative expenses for the reasons mentioned above. We had a net loss attributed to our non-controlling interest in Plurinuva for the year ended June 30, 2022 of \$132,000.

Loss per share for the year ended June 30, 2022 was \$1.28, as compared to \$1.77 loss per share for the year ended June 30, 2021. The change in the loss per share was mainly as a result of a decrease in the loss for the year, partially offset by an increase in our weighted average number of shares due to the issuance of additional shares during Fiscal Year 2022.

The increase in weighted average common shares outstanding reflects the issuance of additional shares upon settlement of RSUs issued to directors, employees and consultants.



## Liquidity and Capital Resources

As of June 30, 2022, our total current assets were \$57,747,000 and our total current liabilities were \$6,829,000. On June 30, 2022, we had a working capital surplus of \$50,918,000 and an accumulated deficit of \$371,263,000.

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.

Our cash and cash equivalents and restricted cash as of June 30, 2022, amounted to \$10,779,000, which reflects a decrease of \$21,059,000 from the \$31,838,000 reported as of June 30, 2021. Our bank deposits as of June 30, 2022, amounted to \$45,244,000 compared to \$56,978,000 as of June 30, 2021. Our cash equivalents and restricted cash decreased in the year ended June 30, 2022 for the reasons presented below.

Our cash used in operating activities was \$36,501,000 during the year ended June 30, 2022, and \$30,910,000 during the year ended June 30, 2021. Cash used in operating activities in the year ended June 30, 2022, and in the year ended on 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 or other third parties.

Cash provided by investing activities was \$11,783,000 during the year ended June 30, 2022, as opposed to cash used for investing activities of \$7,265,000 during the year ended June 30, 2021. Cash provided by investing activities in the year ended June 30, 2022 consisted primarily of the withdrawal of \$23,269,000 of long-term deposits, partially offset by cash investment in short-term deposits of \$11,206,000 and payments of \$280,000 related to investments in property and equipment. Cash used for 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.

Financing activities provided cash in the amount of \$7,500,000 during the year ended June 30, 2022, and \$61,402,000 during the year ended June 30, 2021. The cash provided in the year ended June 30, 2022, from financing activities is related to net proceeds of \$7,500,000 received from an investment by Tnuva in Plurinuva. The cash provided in the year ended June 30, 2021 from financing activities is related to: (1) net proceeds of \$36,589,000 from our registered direct offering which closed in February 2021 and common share issuances made under the Open Market Sale Agreement<sup>SM</sup>, or the ATM Agreement, that we entered into with Jefferies LLC, or Jefferies, on July 16, 2020, (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.

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, net of issuance expenses of \$380,000. During the year ended June 30, 2022, we did not sell of our any common shares under the ATM Agreement.

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. During the year ended June 30, 2022, no warrants to purchase shares were exercised.

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. We do not expect to receive additional funds pursuant to the EIB Finance Agreement.

During June 2021, we received the first tranche in the amount of €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, 2022, the interest accrued was in the amount of €865,000. In addition to the interest payable to the EIB, the EIB is also entitled to royalty payments, pro-rated to the amount disbursed from the EIB loan, on our consolidated revenues beginning in the fiscal year 2024 up to and including its fiscal year 2030, in an amount equal to up to 2.3% of our consolidated revenues below \$350 million, 1.2% of our consolidated revenues between \$350 million and \$500 million and 0.2% of our consolidated revenues exceeding \$500 million.

#### *Non-dilutive grants*

During the year ended June 30, 2022, we did not receive any cash grants from the European Union research and development consortiums relating to the Horizon 2020 program, as opposed to approximately \$239,000 received in cash during the year ended June 30, 2021.

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, 2022, no royalties were paid to the IIA. Through June 30, 2022, total grants obtained from the IIA aggregated to approximately \$27,743,000 and total royalties paid and accrued amounted to \$169,000.

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 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 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 was a direct grant allocated to us, for an initial period of 18 months. During October 2021, we received an approval for an additional grant of approximately \$583,000 from the IIA pursuant to the CRISPR-IL consortium program, for an additional period of eighteen months. The CRISPR-IL consortium program does not include any obligation to pay royalties.

As of June 30, 2022 and 2021, we received total grants of approximately \$694,000 and \$401,000 in cash from the IIA pursuant to the CRISPR-IL consortium program, respectively.

In July 2017, we were awarded the Smart Money grant of approximately \$229,000 from Israel's Ministry of Economy. The Israeli government granted us budget resources to advance our product candidate towards marketing in China-Hong Kong markets. The Smart Money program ended on April 2022. As of June 30, 2022, we received total grants of approximately \$179,000 in cash from Israel's Ministry of Economy for the Smart Money program.

In August 2016, our CLI program in the European Union was awarded a €7,600,000 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 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. The additional direct grant was allocated to us from the total amount of the original grant. As of June 30, 2022, we received a total of €2,615,000 (approximately \$2,946,000) and we expect to receive an additional €461,000 (approximately \$479,000).

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 grant, as part of the European Union's Horizon 2020 program. This Phase III study was a collaborative project carried out by an international consortium led by Charité, together with us, and with participation of additional third parties. The grant covered a significant portion of the project costs. An amount of € 2,550,000 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, 2022, we received a total of €2,166,000 (approximately \$2,540,000) and we expect to receive an additional €382,000 (approximately \$397,000).

In October 2017, the nTRACK, a collaborative project carried out by an international consortium led by Leitat was awarded a €6,800,000 non-royalty bearing grant. An amount of €500,000 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, 2022, we received a total of €414,000 (approximately \$473,000) and we expect to receive an additional €73,000 (approximately \$76,000).

### **Outlook**

We have accumulated a deficit of \$371,263,000 since our inception in May 2001. We do not expect to generate any significant revenues from sales of products in the next twelve months. 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 technology and maintain our research and development and clinical study activities.

We are continually looking for sources of funding, including non-diluting sources such as collaboration with other companies via licensing agreements, 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 twelve 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 2022, we recorded share-based compensation expenses related to options, restricted shares and RSUs in the amount of \$8,909,000.

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 2022 and 2021 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 2022 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 fair value of shares of Plurinuva granted to CEO, CFO and Chairman (see details in Item 11 below) was calculated using the Monte Carlo model, and fair value of the options of Plurinuva granted to employees and officers were calculated using the Black Scholes model.

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 16% 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 study 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 2021 and 2022 (in thousands of dollars):

	Year ended June 30,	
	2022	2021
Payroll and related expenses . . . . .	\$ 11,128	\$ 10,563
Materials expenses . . . . .	3,468	2,843
Clinical trials expenses . . . . .	5,036	10,024
Depreciation expenses. . . . .	964	1,252
Consultants and subcontractor expenses. . . . .	1,013	2,411
Rent and maintenance expenses . . . . .	1,781	1,369
Share-based compensation expenses . . . . .	592	1,538
Other Research and development expenses . . . . .	623	533
Total expenses. . . . .	24,605	30,533
Less: Research and development participation grants . . . . .	(228)	(467)
Research and development expenses, net . . . . .	<u>\$ 24,377</u>	<u>\$ 30,066</u>

We invest heavily in research and development. Research and development expenses, net, were our major operating expenses, representing 59% of the total operating expenses for each of our fiscal years 2022 and 2021, 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.

Not applicable.

**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:

Report of Independent Registered Public Accounting Firm, dated September 21, 2022 . . . . .	F-2 – F-3
Consolidated Balance Sheets . . . . .	F-4 – F-5
Consolidated Statements of Operations . . . . .	F-6
Statements of Changes in Equity . . . . .	F-7 – F-8
Consolidated Statements of Cash Flows . . . . .	F-9
Notes to the Consolidated Financial Statements . . . . .	F-10 – F-31

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**PLURI INC. AND ITS SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS**

**As of June 30, 2022**

**U.S. DOLLARS IN THOUSANDS**

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Statements of Changes in Shareholders' Equity .....	F-7 – F-8
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## **Report of Independent Registered Public Accounting Firm**

To the board of directors and shareholders of Pluri Inc.

### ***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Pluri Inc. and its subsidiaries (the “Company”) as of June 30, 2022 and 2021, and the related consolidated statements of operations, of changes in shareholders’ equity and of cash flows for the years 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 as of June 30, 2022 and 2021, and the results of its operations and its cash flows for the years 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 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 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 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 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 audits 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 audits provide a reasonable basis for our opinion.

### ***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

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#### *Establishment of Plurinuva*

As described in Note 1d to the consolidated financial statements, on February 24, 2022, the Company established Plurinuva together with Tnuva for the purpose of developing cultured meat products. Tnuva invested in Plurinuva \$7.5 million for ordinary shares and warrants to purchase ordinary shares. The principal considerations for our determination that performing procedures relating to the establishment of Plurinuva is a critical audit matter are (i) the audit efforts to determine such a transaction was properly accounted for by the Company; and (ii) involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, reading the agreements, public filings and the Company's minutes from meetings of the Board of Directors. We inquired executive officers, key members and legal counsel of the Company, and the Audit Committee regarding the transaction. We researched accounting alternatives to evaluate the Company's accounting approach. We involved a valuation professional, with specialized skills and knowledge, who assisted in evaluating the valuation methodology which was included in the accounting analysis for the transaction. We analyzed the impacts of the transaction on the Company's financial statements. In addition, we evaluated the overall sufficiency of audit evidence obtained over the establishment of Plurinuva.

/s/ Kesselman & Kesselman

Certified Public Accountants (Isr.)

A member firm of PricewaterhouseCoopers International Limited

Haifa, Israel

September 21, 2022

We have served as the Company's auditor since 2021.

PLURI INC. AND ITS SUBSIDIARIES

**CONSOLIDATED BALANCE SHEETS**

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

		June 30,	
	Note	2022	2021
<b>ASSETS</b>			
CURRENT ASSETS:			
Cash and cash equivalents . . . . .		\$ 9,772	\$ 31,241
Short-term bank deposits . . . . .		45,244	33,709
Restricted cash . . . . .	2f	1,007	597
Prepaid expenses and other current assets . . . . .	3	1,724	1,824
<u>Total</u> current assets . . . . .		<u>57,747</u>	<u>67,371</u>
LONG-TERM ASSETS:			
Long-term bank deposits . . . . .	2f	—	23,269
Restricted bank deposits . . . . .	2g	634	—
Severance pay fund . . . . .		661	664
Property and equipment, net . . . . .	4	739	1,499
Operating lease right-of-use asset . . . . .	6	8,270	728
Other long-term assets . . . . .		14	7
<u>Total</u> long-term assets . . . . .		<u>10,318</u>	<u>26,167</u>
<u>Total</u> assets . . . . .		<u>\$ 68,065</u>	<u>\$ 93,538</u>

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

PLURI INC. AND ITS SUBSIDIARIES

**CONSOLIDATED BALANCE SHEETS**

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

		June 30,	
	Note	2022	2021
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables . . . . .		\$ 1,785	\$ 2,526
Accrued expenses . . . . .		1,630	5,941
Operating lease liability . . . . .	6	619	634
Accrued vacation and recuperation . . . . .		1,053	1,203
Other accounts payable . . . . .	5	1,742	1,213
Total current liabilities . . . . .		6,829	11,517
LONG-TERM LIABILITIES			
Accrued severance pay . . . . .		867	920
Operating lease liability . . . . .	6	6,505	100
Loan from the European Investment Bank ("EIB") . . . . .	7	21,678	23,850
Total long-term liabilities . . . . .		29,050	24,870
COMMITMENTS AND CONTINGENCIES . . . . .	8		
SHAREHOLDERS' EQUITY			
Share capital:. . . . .	9		
Common shares, \$0.00001 par value per share: Authorized: 60,000,000 shares issued and outstanding: 32,507,491 shares as of June 30, 2022; 31,957,782 shares as of June 30, 2021 . . . . .		*	*
Additional paid-in capital . . . . .		401,302	387,172
Accumulated deficit . . . . .		(371,263)	(330,021)
Total shareholders' equity . . . . .		30,039	57,151
Non-controlling interests . . . . .		2,147	—
Total equity . . . . .		32,186	57,151
Total liabilities and equity . . . . .		\$ 68,065	\$ 93,538

(\*) Less than \$1

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

PLURI INC. AND ITS SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	Note	Year ended June 30,	
		2022	2021
Revenues . . . . .	2h	\$ 234	\$ —
Operating expenses:			
Research and development expenses . . . . .		\$ (24,605)	\$ (30,533)
Less: participation by the Israel Innovation Authority, Horizon 2020 and other parties . . . . .		228	467
Research and development expenses, net . . . . .	2l	(24,377)	(30,066)
General and administrative expenses . . . . .		(17,450)	(20,557)
Operating loss . . . . .		(41,593)	(50,623)
Financial income, net . . . . .		1,106	836
Interest expense . . . . .		(887)	(78)
Total financial income, net . . . . .	10	219	758
Net loss . . . . .		\$ (41,374)	\$ (49,865)
Net loss attributed to non-controlling interests . . . . .		(132)	—
Net loss attributed to shareholders . . . . .		(41,242)	(49,865)
Loss per share:			
Basic and diluted loss per share . . . . .		\$ (1.28)	\$ (1.77)
Weighted average number of shares used in computing basic and diluted loss per share . . . . .		32,192,074	28,113,636

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

PLURI INC. AND ITS SUBSIDIARIES

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Common Share		Additional	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	Shareholders'
			Capital		Equity
<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 Open Market Sales Agreement, net of issuance costs of \$380 (Note 9(1)a) . . . . .	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 9(1)c) . . . . .	4,761,905	(*)	28,077	—	28,077
Exercise of options by employees and non-employee consultants . . . . .	15,035	(*)	—	—	—
Exercise of warrants by investors (Note 9(1)b) . . . . .	51,999	(*)	364	—	364
Net loss . . . . .	—	—	—	(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.

PLURI INC. AND ITS SUBSIDIARIES

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Shareholders' Equity						Non-controlling Interests	Total Equity
	Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity			
	Shares	Amount						
Balance as of July 1, 2021.....	31,957,782	\$ (*)	\$ 387,172	\$ (330,021)	\$ 57,151	\$ —	\$ 57,151	
Share-based compensation to employees, directors, and non-employee consultants (Note 9(2)). . . . .	549,709	(*)	8,473	—	8,473	436	8,909	
Establishment of Plurinuva and non-controlling interest in Plurinuva (Notes 1d).....	—	—	5,657	—	5,657	1,843	7,500	
Net loss . . . . .	—	—	—	(41,242)	(41,242)	(132)	(41,374)	
Balance as of June 30, 2022 .....	32,507,491	\$ (*)	\$ 401,302	\$ (371,263)	\$ 30,039	\$ 2,147	\$ 32,186	

(\*) Less than \$1

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

**PLURI INC. AND ITS SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**U.S. Dollars in thousands**

	<b>Year ended June 30</b>	
	<b>2022</b>	<b>2021</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss .....	\$ (41,374)	\$ (49,865)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation .....	1,053	1,370
Share-based compensation to employees, directors and non-employee consultants .....	8,909	13,968
Decrease in prepaid expenses and other current assets and other long-term assets .....	93	303
Increase (decrease) in trade payables .....	(758)	578
Increase (decrease) in other accounts payable and accrued expenses .....	(3,932)	3,353
Decrease in operating lease right-of-use asset and liability .....	(1,148)	(321)
Increase in interest receivable on short-term deposits .....	(329)	(256)
Effect of exchange rate changes on cash, cash equivalents, deposits and restricted cash .....	3,207	(126)
Long term interest payable pursuant to EIB loan .....	(2,172)	78
Accrued severance pay, net .....	(50)	8
Net cash used for operating activities .....	<u>\$ (36,501)</u>	<u>\$ (30,910)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment .....	\$ (280)	\$ (373)
Proceeds from withdrawal of short-term deposits .....	12,063	4,061
Investment in long-term deposits .....	—	(10,953)
Net cash provided by (used for) investing activities .....	<u>\$ 11,783</u>	<u>\$ (7,265)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds related to issuance of common shares, net of issuance costs .....	\$ —	\$ 36,589
Proceeds related to exercise of warrants .....	—	364
Proceeds related to investment in subsidiary by non-controlling interest .....	7,500	—
Proceeds from EIB loan .....	—	24,449
Net cash provided by financing activities .....	<u>\$ 7,500</u>	<u>\$ 61,402</u>
<b>EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH</b>		
Increase (decrease) in cash, cash equivalents and restricted cash .....	(3,207)	(618)
Increase (decrease) in cash, cash equivalents and restricted cash .....	(20,425)	22,609
Cash, cash equivalents and restricted cash at the beginning of the period .....	31,838	9,229
Cash, cash equivalents, restricted cash and restricted bank deposits at the end of the period .....	<u>\$ 11,413</u>	<u>\$ 31,838</u>
<b>Reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets:</b>		
Cash and cash equivalents .....	9,772	31,241
Restricted cash .....	1,007	597
Long- term restricted bank deposits .....	634	—
<b>Total cash, cash equivalents, restricted cash and restricted bank deposits ..</b>	<u><b>\$ 11,413</b></u>	<u><b>\$ 31,838</b></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)

## NOTE 1: — GENERAL

- a. Effective July 26, 2022, Pluri Inc., a Nevada corporation (“Pluri”), changed its name from Pluristem Therapeutics Inc. The Company also changed its symbol on the Nasdaq Global Market and Tel-Aviv Stock Exchange From “PSTI” to “PLUR”.

Pluri was incorporated on May 11, 2001. Pluri has a wholly owned subsidiary, Pluri-Biotech Ltd. (formerly known as 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. In January 2022, the Subsidiary established a subsidiary, Plurinuva Ltd. (“Plurinuva”), which is incorporated under the laws of Israel, which followed the execution of the collaboration agreement with Tnuva Food Industries — Agricultural Cooperative in Israel Ltd. (through its fully owned subsidiary, Tnuva Food-Tech Incubator (2019), Limited Partnership (“Tnuva”). Pluri, the Subsidiary, the German Subsidiary and Plurinuva are referred to as the “Company” or “Pluri.” The Subsidiary, the German Subsidiary and Plurinuva are referred to as the “Subsidiaries.”

- b. The Company is a bio-technology company with an advanced cell-based technology platform, which operates in one business segment. The Company has developed a unique three-dimensional (“3D”) technology platform for cell expansion with an industrial scale in-house Good Manufacturing Practice cell manufacturing facility. Pluri currently uses its technology in the field of regenerative medicine and food tech and plans to utilize it in other industries and verticals that have a need for mass scale and cost-effective cell expansion platform such as agri-tech and biologics. Pluri is focused on the research, development and manufacturing of cell-based products, conducting clinical studies and the business development of cell therapeutics and cell-based technologies providing potential solutions for various fields.
- c. The Company has incurred an accumulated deficit of approximately \$371,263 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of June 30, 2022, the Company’s total shareholders’ equity amounted to \$30,039. During the year ended June 30, 2022, the Company incurred losses of \$41,242 and its negative cash flow from operating activities was \$36,501.

As of June 30, 2022, the Company’s cash position (cash and cash equivalents, short-term bank deposits, long-term bank deposits, restricted cash and restricted bank deposits) totaled \$56,657. 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, and from sales of its equity securities and from the proceeds received from the loan previously provided by the European Investment Bank (the “EIB”, see also note 7). The Company’s 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 is no assurance, 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.

- d. On January 5, 2022, the Subsidiary entered into definitive agreements (the “Agreements”) with Tnuva pursuant to which the Subsidiary and Tnuva established Plurinuva, with the purpose of developing cultured meat products. Plurinuva received exclusive, global, royalty bearing licensing rights to use Pluri’s proprietary technology, intellectual property and knowhow in the field of cultured meat. Tnuva invested \$7,500 in Plurinuva and received 187,500 of Plurinuva’s ordinary shares, representing 15.79% of the Plurinuva share capital as of February 24, 2022 (the “Closing Date”). In addition, Tnuva received Warrants to invest up to an additional \$7,500 over a period of twelve months following the Closing Date.

The First Warrant issued to Tnuva permits Tnuva to purchase up to 125,000 ordinary shares of Plurinuva at an exercise price of \$40.00 per share, and has a term commencing on the Closing Date and ending at the earlier of (i) six months from the Closing Date, (ii) immediately prior to and subject to the consummation of an initial



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 1: — GENERAL (cont.)**

public offering or acquisition of Plurinuva or (iii) the consummation of a financing round with a non-affiliated investor. In addition, on the six month anniversary of the Closing Date, and provided that the First Warrant has not expired, Plurinuva agreed to issue a Second Warrant to Tnuva which will permit Tnuva to purchase up to a number of ordinary shares of Plurinuva, or the then most senior securities issued by Plurinuva, in consideration for such amount equal to 200% of the remaining balance of the aggregate purchase price of the First Warrant, provided that Tnuva exercises at least 62,500 ordinary shares at a price per share of \$40.00, or \$2,500 in the aggregate, of the First Warrant. The Second Warrant's exercise price per share equals \$76.00. The Second Warrant has a term commencing on the six month anniversary of the Closing Date and ending at the earlier of (i) six months from its issuance, (ii) immediately prior to and subject to the consummation of an initial public offering or acquisition of Plurinuva or (iii) the consummation of a financing round with a non-affiliated investor.

The Company allocated the total consideration of \$7,500 received in an amount equal to \$6,718 for the ordinary shares and \$782 for the Warrants.

The Company determined the fair value of the ordinary shares and the warrants utilizing a Monte Carlo simulation model (Level 3 classification), which incorporates various assumptions including expected stock price volatility, risk-free interest rate, and the expected date of a qualifying event. The Company estimated the volatility of the ordinary shares of Plurinuva based on data from similar companies operating in the food tech field.

The main assumptions used in the Monte Carlo simulation model are as follows:

Risk-free interest rate . . . . .	1.08%
Expected stock price volatility . . . . .	85%

The consideration allocated to the shares issued was divided between the non-controlling interests ("NCI") and the Company's shareholders as this transaction is a transaction with the NCI.

The consideration allocated to the warrants was recognized against the NCI.

On August 23, 2022, Plurinuva and Tnuva executed an amendment to the warrant agreement, extending the exercise period of the First Warrant from six months to nine months from the Closing Date. All other terms remained unchanged.

- e. On February 26, 2022, the Subsidiary allocated a total of 45,936 of its shares in Plurinuva, which constitute approximately 3.87% of Plurinuva's ordinary shares, to its Chairman, Chief Executive Officer and Chief Financial Officer, pursuant to the terms of their respective employment and/or consulting agreements with the Company. Following such allocations, the Company holds 80.34% of the outstanding equity in Plurinuva. As a result, the Company recognized compensation expenses in the amount of \$1,646 representing the fair value of the respective allocated shares.
- f. Based on the Company's current assessment, the Company does not expect material impact on its operations due to the worldwide spread of COVID-19. However, The Company may experience delays if the pandemic worsens and continues for an extended period of time and it is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented by governments to combat the virus throughout the world.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES****Basis of presentation**

The consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”).

**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. Estimates are primarily used for, but not limited to, valuation of share-based compensation, valuation of warrants, determining the valuation and terms of leases. These estimates, judgments and assumptions can affect the amounts reported in the financial statements and accompanying notes, and actual results could differ from those estimates.

**b. Functional currency**

The U.S. dollar is the primary currency of the economic environment in which the Company and the Subsidiaries operate. Thus, the U.S. 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 consolidated statements of operations as financial income or expenses, as appropriate.

**c. Principles of consolidation**

The consolidated financial statements include the accounts of the Company and its Subsidiaries.

Non-controlling interests in subsidiaries represent the equity in subsidiaries not attributable, directly or indirectly, to the Company. Non-controlling interests are presented in equity separately from the equity attributable to the shareholders of the Company. Profit or loss and components of other comprehensive income or loss are attributed to the Company and to non-controlling interests. Losses are attributed to non-controlling interests even if they result in a negative balance of non-controlling interests in the consolidated statements of operations.

The Company treats transactions with non-controlling interests as transactions with its equity owners. Accordingly, for sales or purchases of shares to or from non-controlling interests, the difference between any consideration received or paid and the portion sold or acquired of the carrying value of the net assets of the subsidiary is recorded in equity.

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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)****f. Restricted cash and short-term bank deposits**

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**

A contract with a customer exists only when: (i) the parties to the contract have approved it and are committed to perform their respective obligations, (ii) the Company can identify each party's rights regarding the distinct goods or services to be transferred ("performance obligations"), (iii) the Company can determine the transaction price for the goods or services to be transferred, (iv) the contract has commercial substance and (v) it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Revenues are recognized when the control of the promised goods or the performance of the obligations are transferred to the customer, in an amount that reflects the consideration to which the Company expects to be entitled to, excluding sales taxes.

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.

**i. Property and equipment**

Property and equipment are stated at cost, net of accumulated depreciation and impairments. 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.

**Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)****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 2022 and 2021, no triggering events were identified, and no impairment losses were recorded.

**k. 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 and RSUs grants are recognized on a graded vesting schedule over the vesting period. For RSUs 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 RSU award, a Monte Carlo simulation valuation model was used to calculate the grant date fair value of such RSUs. Expense for a market condition RSU is recognized over the derived service period as determined through the Monte Carlo simulation model.

All RS and RSUs to employees and directors granted during fiscal 2022 and 2021, 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 of 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 RS and RSUs granted during fiscal years 2022 and 2021, was \$2.87 and \$9.76 per share, respectively.

**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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)**

Grants received from the Israel Innovation Authority (the “IIA”) are 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 (see also note 8b).

Research and development expenses, net for the year ended June 30, 2022 and 2021 include participation in research and development expenses in the amount of approximately \$228 and \$467, respectively.

Clinical study 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 study expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended.

During fiscal years 2022 and 2021, 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 \$293 and \$566, for the year ended June 30, 2022 and 2021, 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.

The CRISPR-IL consortium is a group funded by the IIA, comprised of leading experts in life science and computer science from academia, medicine, and industry, in order to develop AI based end-to-end genome-editing solutions.

**m. Loss per share**

Basic and diluted loss per share is computed by dividing losses by the weighted average number of common shares outstanding during the year, including unexercised vested options with a par value price. All outstanding share options, unvested RSUs and warrants 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 RSUs excluded from the calculations of diluted net loss per share due to their anti-dilutive effect was 5,247,803 and 5,700,994 for the years ended June 30, 2022, and 2021, respectively.

**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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)**

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 bank deposits.

The majority of the Company's cash and cash equivalents, restricted cash, short-term and long-term deposits are mainly invested in dollar, EURO and NIS deposits 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.

**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 obligation exists 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, for whom their agreement is not subject to Section 14 of the Severance Pay Law, the Subsidiary's liability for severance pay is calculated pursuant to Israeli Severance Pay Law, based on the most recent salary of the employees multiplied by the number of years of employment, as of the balance sheet date. Employees are entitled to one month's salary for each year of employment or a portion thereof. The Company's liability for all of its employees is fully provided by monthly deposits with insurance policies and by an accrual. The value of these policies is recorded as an asset in the Company's balance sheet.

The deposited funds 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 accumulated up to the balance sheet date. Severance expenses for the years ended June 30, 2022 and 2021 were \$835 and \$748, 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 expenses, 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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)**

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.

On April 30, 2020, the Company, through the German Subsidiary, entered into a finance contract (the “Finance Contract”) with the EIB, pursuant to which 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 Company measures its liability pursuant to the Finance Contract (see also note 7) 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 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”) and its loan from the EIB that is linked to the Euro. Since the derivative instruments that the Company holds do not meet the definition of hedging instruments under ASC 815, any gain or loss derived from such instruments is recognized immediately as “financial income, net”.

The Company measured the fair value of the contracts in accordance with ASC 820. Foreign currency derivative contracts are classified within Level 2 as the valuation inputs are based on quoted prices and market observable data of similar instruments. As of June 30, 2022, the fair value of the options contracts is presented in “Other accounts payable” (see note 5) and as of June 30, 2021, the fair value of the options contracts is presented in “Other current assets” (see note 3). The net gains (losses) recognized in “Financial income, net” during the year ended June 30, 2022 and 2021 were (\$373) and \$35 respectively (see note 10).

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)****s. Leases**

Operating leases are included in operating lease right-of-use (“ROU”) asset, 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. Operating lease cost is recognized on a straight-line basis over the expected lease term. Lease agreements with a noncancelable term of less than 12 months are not recorded on the balance sheets.

The Company accounts for an extension of a lease term that was not part of the original lease as a modification. As a result, the Company reallocate contract consideration between the lease and non-lease components, reassess lease classification, and remeasure the lease liability and right-of-use asset prospectively. Assumptions such as the discount rate, fair value of the underlying asset, and variable rents based on a rate or index will be updated as of the modification date.

Lease terms will include options to extend or terminate the lease when it is reasonably certain that the Company will either exercise or not exercise the option to renew or terminate the lease.

**t. Recently Issued Accounting Pronouncements not yet adopted**

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 rules (“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.

In November 2021, the FASB issued ASU 2021-10 “Government Assistance (Topic 832)”, which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity’s financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021.



PLURI INC. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2: — SIGNIFICANT ACCOUNTING POLICIES (cont.)

The Company does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

u. Comprehensive loss

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

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.

NOTE 3: — PREPAID EXPENSES AND OTHER CURRENT ASSETS

	June 30,	
	2022	2021
Accounts receivable from the Horizon 2020 grants . . . . .	\$ 952	\$ 1,089
Prepaid expenses . . . . .	403	333
Value Added Tax (VAT) receivables . . . . .	344	382
Accounts receivable from the Ministry of Economy and Industry . . . . .	3	19
Derivatives instruments . . . . .	—	1
Other receivables . . . . .	22	—
Total . . . . .	<u>\$ 1,724</u>	<u>\$ 1,824</u>

NOTE 4: — PROPERTY AND EQUIPMENT, NET

	June 30,	
	2022	2021
<b>Cost:</b>		
Laboratory equipment . . . . .	\$ 6,784	\$ 6,715
Computers and peripheral equipment . . . . .	1,619	1,473
Office furniture and equipment . . . . .	681	681
Leasehold improvements . . . . .	8,740	8,662
<b>Total cost . . . . .</b>	<u>17,824</u>	<u>17,531</u>
<b>Accumulated depreciation:</b>		
Laboratory equipment . . . . .	6,321	6,152
Computers and peripheral equipment . . . . .	1,409	1,310
Office furniture and equipment . . . . .	678	663
Leasehold improvements . . . . .	8,677	7,907
<b>Total accumulated depreciation . . . . .</b>	<u>17,085</u>	<u>16,032</u>
<b>Property and equipment, net . . . . .</b>	<u>\$ 739</u>	<u>\$ 1,499</u>

Depreciation expenses amounted to \$1,053 and \$1,370 for the years ended June 30, 2022 and 2021, respectively.

Most of the Company's property and equipment is located in Israel.

PLURI INC. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 5: — OTHER ACCOUNTS PAYABLE

	June 30,	
	2022	2021
Deferred income from the Horizon 2020 grant and CRISPR-IL .....	\$ 112	\$ 40
Accrued payroll .....	624	612
Derivatives instruments .....	457	—
Payroll institutions .....	549	561
Total .....	\$ 1,742	\$ 1,213

NOTE 6: — LEASES

Towards the termination of the previous facility operating lease agreement, the Company signed, in December 2021, an addendum to its facility operating lease agreement (the “Addendum”) with the lessor, which extended the lease period to December 2026. In addition the Company has the option to extend the term of the lease (the “Extension Option”) for an additional period of five years until December 2031. The Company reflected the Extension Option during the evaluation of the lease liability and right-of-use asset. The monthly lease payments are approximately NIS 291,000 or \$94 which are linked to the consumer price index and will increase by 10% in the event the Company exercises its Extension Option. In addition, the Company has operating leases for vehicles that expire through fiscal year 2025. Below is a summary of the Company’s operating right-of-use assets and operating lease liabilities:

	June 30,	
	2022	2021
Operating right-of-use assets .....	\$ 8,270	\$ 728
Operating lease liabilities, current .....	619	634
Operating lease liabilities long-term .....	6,505	100
Total operating lease liabilities .....	\$ 7,124	\$ 734

Maturities of operating lease liabilities as of June 30, 2022 are as follows:

	June 30, 2022
2023 .....	1,279
2024 .....	1,203
2025 .....	1,115
2026 .....	999
2027 .....	1,049
2028 and thereafter .....	4,947
Total undiscounted lease payments .....	\$ 10,592
Less: interest .....	(3,468)
Present value of lease liabilities .....	\$ 7,124

PLURI INC. AND ITS SUBSIDIARIES

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, 2022 are as follows:

	Year ended June 30,	
	2022	2021
<b>Components of lease expense</b>		
Operating lease payments linked to index, net* . . . . .	\$ 1,196	\$ 984
Sublease income . . . . .	\$ 9	\$ 55
<b>Supplemental cash flow information</b>		
Cash paid for amounts included in the measurement of lease liabilities . . . . .	\$ 1,305	\$ 1,214
Supplemental non-cash information related to lease liabilities arising from obtaining ROU assets . . . . .	\$ 8,250	\$ 154

\* The operating lease payments are linked to the consumer price index and are presented net after elimination of deferred participation payments in amount of \$124 and \$248 for the year ended June 30, 2022 and 2021 respectively.

As of June 30, 2022, the weighted average remaining lease term is 9.1 years, and the weighted average discount rate is 9 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.

For vehicles, the lease period is usually 3 years.

NOTE 7: — LOAN FROM THE EIB

On April 30, 2020, the German Subsidiary 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, 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 annual interest rate is 4% (consisting of a 0% fixed interest rate and a 4% deferred interest rate payable upon maturity,) for the first tranche, 4% (consisting of a 1% fixed interest rate and a 3% deferred interest rate payable upon maturity) for the second tranche and 3% (consisting of a 1% fixed interest rate and a 2% deferred interest rate payable upon maturity) for the third tranche.

In addition to any interest payable on the Loan, the EIB is entitled to receive royalties from future revenues for a period of seven years starting at the beginning of fiscal year 2024 and continuing up to and including its fiscal year 2030 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.

During June 2021, Pluri received the first tranche in an amount of €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, 2022, the linked principal balance in the amount of \$20,779 and the interest accrued in the amount of \$899 are presented among long term liabilities.

The Finance Contract also contains certain limitations such as the use of proceeds received from the EIB, limitations relates to disposal of assets, substantive changes in the nature of the Company's business, changes in holding structure, distributions of future potential dividends and engaging with other banks and financing entities for other loans.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 8: — COMMITMENTS AND CONTINGENCIES**

- a. As of June 30, 2022, an amount of \$1,641 of cash and deposits was pledged by the Subsidiary to secure its hedging transaction, credit line, lease agreement 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.

As of June 30, 2022, 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 was awarded a 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 support from Israel’s trade representatives stationed in China, including Hong Kong, along with experts appointed by the Smart Money program. As part of the program, the Company will repay royalties of 5% from the Company’s revenues in the region for a five year period, beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and will be spread for a period of up to 5 years or until the amount of the grant is fully paid. As of June 30, 2022, the grant received from this Smart Money program was approximately \$179, program has ended and no royalties were paid or accrued.
- d. 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 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.
- e. 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, 2022, the aggregate amount of the grant received is approximately \$52 and no royalties were paid or accrued.

- f. As to potential royalties to the EIB, see note 7.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****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 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, 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 preferred shares, 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.
- a. 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. During the year ended June 30, 2022 the Company did not sell any common shares under the ATM Agreement.
  - b. During the year ended June 30, 2021, a total of 519,990 warrants 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. During the year ended June 30, 2022 no warrants were exercised.
  - c. 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, 4,761,905 common shares for gross proceeds of \$30,000. The aggregate net proceeds were approximately \$28,077, net of issuance costs of \$1,923.
- (2) **Share options, RS and RSUs to employees, directors and consultants:**

The Company adopted a Share Option Plan in 2005, an Equity Incentive Plan in 2016 and an Equity Compensation Plan in 2019 (together, the "Plans").

Under the Plans, 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, 2022, 4,765,698 common shares are available for future grants under the Plans.

PLURI INC. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: — SHAREHOLDERS' EQUITY (cont.)

a. Options to consultants:

A summary of the share options to non-employee consultants is as follows:

	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

  

	Year ended June 30, 2022			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Share options outstanding at beginning of period. . . . .	39,836	\$ —	6.99	158
Share options granted . . . . .	55,000	\$ 2.18	7.62	—
Share options exercised. . . . .	—	\$ —	—	—
Share options forfeited . . . . .	(3,791)	\$ —		
Share options outstanding at end of the period. . . . .	91,045	\$ 1.32	7.05	\$ 44
Share options exercisable at the end of the period . . . . .	43,545	\$ 0.38	6.74	\$ 44
Share options unvested . . . . .	47,500	\$ 2.18		
Share options vested and expected to vest at the end of the period . . . . .	91,045	\$ 1.32	7.05	\$ 44

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

	Year ended June 30,	
	2022	2021
General and administrative expenses . . . . .	30	11
	\$ 30	\$ 11

PLURI INC. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: — SHAREHOLDERS' EQUITY (cont.)

**b. RSUs to employees and directors:**

The following table summarizes the activity related to unvested RSUs granted to employees and directors under the Plans, for the years ended June 30, 2022 and 2021:

	Year ended June 30,	
	2022	2021
	Number	
Unvested at the beginning of period . . . . .	2,404,415	415,194
Granted . . . . .	85,000	2,646,120
Forfeited . . . . .	(49,691)	(76,804)
Vested . . . . .	(504,709)	(580,095)
Unvested at the end of the period . . . . .	1,935,015	2,404,415
Expected to vest after the end of period . . . . .	1,899,416	2,356,134

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

	Year ended June 30,	
	2022	2021
Research and development expenses . . . . .	\$ 524	\$ 1,363
General and administrative expenses . . . . .	7,913	12,253
	<u>\$ 8,437</u>	<u>\$ 13,616</u>

Unamortized compensation expenses related to RSUs granted to employees and directors is approximately \$3,094 to be recognized by the end of June 2026.

General and administrative expenses include:

1 — Compensation expenses for the year ended June 30, 2022, in the amount of \$1,646 were related to 45,936 ordinary shares of Plurinuva that were allocated during February 2022 to the Company's Chairman, Chief Executive Officer and Chief Financial Officer, each pursuant to the terms of their respective employment and/or consulting agreements (see note 1d).

2 — Market-based awards:

In September 2020, the Company granted its Chairman and Chief Executive Officer an aggregate of 1,000,000 RSUs (500,000 each) under the Plans.

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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 9: — SHAREHOLDERS' EQUITY (cont.)**

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. For the year ended June 30, 2022 and 2021 the Company recognized \$2,127 and \$5,156 of expenses included in general and administrative expenses, respectively.

**c. Options to employees and directors:**

Compensation expenses related to options of Plurinuva granted to Plurinuva's employees were recorded as follows:

	<b>Year ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
Research and development expenses .....	\$ 21	\$ —
General and administrative expenses .....	155	—
	<u>\$ 176</u>	<u>\$ —</u>

**d. RSUs to consultants:**

The following table summarizes the activity related to unvested RS and RSUs granted to non-employee consultants for the years ended June 30, 2022 and 2021:

	<b>Year ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>Number</b>	
Unvested at the beginning of period .....	76,249	6,250
Granted .....	10,000	110,000
Forfeited .....	—	(29,063)
Vested .....	(45,000)	(10,938)
Unvested at the end of the period .....	<u>41,249</u>	<u>76,249</u>

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

	<b>Year ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
Research and development expenses .....	\$ 47	\$ 176
General and administrative expenses .....	219	165
	<u>\$ 266</u>	<u>\$ 341</u>



PLURI INC. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 9: — SHAREHOLDERS' EQUITY (cont.)

e. 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)
Warrants: .....	\$ 7.00	2,418,466	2,418,466	1.77
	\$ 14.00	762,028	762,028	0.06
Total warrants .....		3,180,494	3,180,494	
Options: .....	\$ 0.00001	91,045	43,545	7.05
Total options .....		91,045	43,545	
Total warrants and options .....		3,271,539	3,224,039	

This summary does not include 1,976,264 RSUs that are not vested as of June 30, 2022.

NOTE 10: — FINANCIAL INCOME (EXPENSES), NET

	Year ended June 30,	
	2022	2021
Foreign currency translation differences, net .....	\$ 922	\$ 332
Bank and broker commissions .....	(25)	(23)
Interest income on deposits .....	581	492
Gain (loss) from derivatives .....	(372)	35
Financial income, net .....	1,106	836
EIB loan interest expenses .....	(887)	(78)
	\$ 219	\$ 758

NOTE 11: — TAXES ON INCOME

a. Tax rates applicable to the Company:

1. Pluri:

The U.S. corporate federal tax rate applicable to Pluri is 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 Pluri conducts its business.

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 Pluri. All losses generated after December 31, 2017 can only be used to offset 80% of net income in the year they will be utilized.

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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 11: — TAXES ON INCOME (cont.)**

In January 2018, Pluri 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, Pluri is classified as a dual resident for tax purposes both in Israel and the United States.

In June 2018, Pluri Inc. 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 Pluri and the Subsidiary (the “Consolidated tax unit”) is subject to tax at the rate of 23% in 2022 and 2021.

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 2017.

**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).

*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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. Dollars in thousands (except share and per share amounts)****NOTE 11: — TAXES ON INCOME (cont.)***Conditions for the entitlement to the benefits:*

The above mentioned benefits are conditional upon the fulfillment of the conditions stipulated by the Law, regulations promulgated thereunder, and the Ruling with respect to the beneficiary enterprise. Non-compliance with the conditions may cancel all or part of the benefits and refund of the amount of the benefits, including interest. Company's 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.

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).

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

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

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

Companies not meeting the above conditions may still be considered as a qualified company at the discretion of the 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 2022).

As of June 30, 2022, 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 corporate tax rate applicable to the German Subsidiary is 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 by determining the Trade Tax Base with 3.5% of the trade income and applying the tax factor which differs according to the specific municipality in Germany and equals 455% for the municipality of Potsdam.

4. Plurinuva:

Plurinuva is an Israeli tax resident and is subject to corporate income tax at the rate of 23%.

b. Carryforward losses for tax purposes

As of June 30, 2022, Pluri had a U.S. federal net operating loss carryforward for income tax purposes in the amount of \$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.

The Subsidiary has accumulated losses, for tax purposes, as of June 30, 2022, 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.

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

In January 2018, Pluri registered as an Israeli resident with the ITA and the Israeli Value Added Tax Authorities. As of June 30, 2022, Pluri and the subsidiaries consolidated accumulated losses, for tax purposes, are approximately \$122,375, 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, 2022, in the amount of approximately \$588, which may be carried forward and offset against taxable business income and business capital gain in the future for an indefinite period.

## c. Loss before income taxes

The components of loss before income taxes are as follows:

	<b>Year ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
Consolidated loss of Pluri and the Israeli subsidiaries . . . . .	\$ 41,370	\$ 49,432
Pluristem GmbH . . . . .	4	433
	<u>\$ 41,374</u>	<u>\$ 49,865</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:

	<b>June 30,</b>	
	<b>2022</b>	<b>2021</b>
Deferred tax assets:		
Operating loss carryforwards . . . . .	\$ 65,384	\$ 57,304
Research and development credit carryforwards . . . . .	5,583	5,907
Issuance costs . . . . .	—	352
Allowances and reserves . . . . .	286	336
Total deferred tax assets before valuation allowance . . . . .	71,253	63,899
Valuation allowance . . . . .	(71,253)	(63,899)
Net deferred tax asset . . . . .	<u>\$ —</u>	<u>\$ —</u>

As of June 30, 2022 and 2021, 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, 2022 and 2021, 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 2022 and 2021, the main reconciling item of the statutory tax rate of the Company (21% to 23%) to the effective tax rate (0%) is tax loss carryforward and research and development credit carryforward 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, 2022. Based on the aforementioned evaluation, management has concluded that our disclosure controls and procedures were effective as of June 30, 2022.

***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, 2022. 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, 2022, 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 2022 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:

Name	Position Held with Company	Age	Date First Elected or Appointed
Zami Aberman	Chairman	69	June 23, 2019
Yaky Yanay	President	51	February 4, 2014
	Director		February 5, 2015
	Chief Executive Officer		June 23, 2019
Chen Franco-Yehuda	Chief Financial Officer, Treasurer and Secretary	39	March 14, 2019
Doron Birger	Director	71	July 15, 2021
Rami Levi	Director	60	June 1, 2021
Varda Shalev	Director	63	July 15, 2021
Maital Shemesh-Rasmussen	Director	53	June 1, 2021

#### *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 Chairman since January 2022, as Executive Chairman from June 2019 until December 2021, 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 40 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), now part of the USTER Group, a company engaged in automatic optical inspection. Before joining the Company, Mr. Aberman served as President and CEO of Netect Ltd., a company specializing in the field of internet security software and was the co-founder, President and CEO of Associative Computing Ltd., which developed an associative parallel processor for real-time video processing. He also served as Chairman of Display Inspection Systems Inc., specializing in laser-based inspection machines and as President and CEO of Robomatix Technologies Ltd.

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

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

### **Yaky Yanay**

Mr. Yanay became a director of the Company in February 2015. He has served as our President from February 2014 and as our CEO from June 2019, previously serving as Co-CEO from March 2017. Mr. Yanay has served in variety of executive positions in Pluri 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 CFO, Treasurer, and Secretary of Pluri, effective as of March 17, 2019. She is responsible for managing financial and corporate strategy, and is also in charge of the finance, IT, investor relations, PR and legal departments. 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. Mrs. Franco-Yehuda also serves as a member of the board of directors of Brenmiller Energy Ltd. (Nasdaq: BNRG, TASE: BNRG,) since August 2022 and a director at Plurinuva Ltd. since February 2022.

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. Birger has been serving as the chairman of the board of directors of Sight Diagnostic Ltd. since June 2014, as chairman of the board of directors of Nurami Medical Ltd., or Nurami, from April 2016 to March 2022, and is currently a director of Nurami, Ultrasight Medical Imaging Ltd. from June 2019, Intelicanna Ltd. (TASE: INTL) from April 2021 until April 2022, Matricelf Ltd. (TASE:MTLF) from December 2020, Galooli from September 21 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.

#### **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.

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**

Professor Shalev became a director of the Company in July 2021. Professor Shalev 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. from May 2020. Professor 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 also served as the director of primary care division at Maccabi Health Care from October 2013 to June 2015 and as the Founder and 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. Professor 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.

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.

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

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

Until June 2021, the members of our Audit Committee were Mr. Doron Shorrer, Mr. Doron Birger and Ms. Maital Shemesh-Rasmussen. Mr. Shorrer was not re-nominated as a director for the 2022 annual meeting of shareholders, held on June 21, 2022, or the 2022 Annual Meeting, and his membership on the Board and Audit Committee terminated on June 21, 2022. As a result of the vacancy, the Board appointed Mrs. Varda Shalev to serve on the Audit Committee in place of Mr. Shorrer. Mr. Birger 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. Birger is an Audit Committee financial expert. The Audit Committee operates under a written charter that is posted on our website at [www.pluri-biotech.com](http://www.pluri-biotech.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 2022.

#### *Compensation Committee*

Until June 23, 2022, the members of our Compensation Committee were Doron Shorrer and Moria Kwiat. Mr. Shorrer and Mrs. Kwiat were not re-nominated as a director for the 2022 Annual Meeting, and their membership on the Board and Compensation Committee terminated as of June 23, 2022. As a result of the vacancies, the Board appointed Ms. Maital Shemesh-Rasmussen and Ms. Varda Shalev to serve on the Compensation Committee. Ms. Shemesh-Rasmussen is the Chairman of 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.pluri-biotech.com](http://www.pluri-biotech.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 2022.

#### *Nominating Committee*

The members of our Nominating Committee are Rami Levi and Maital Shemesh-Rasmussen. Mr. Levi 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.pluri-biotech.com](http://www.pluri-biotech.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 2022, 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 2022 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.pluri-biotech.com](http://www.pluri-biotech.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 the Form 4s filed on July 26, 2021 by Doron Birger and Varda Shalev, which were each filed one week late.

## ITEM 11. EXECUTIVE COMPENSATION.

### Summary Compensation Table

The following table shows the particulars of compensation owed to our CEO and two other most highly compensated executive officers, or our named executive officers, for the fiscal years ended June 30, 2022 and 2021. 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>	Share-based Awards (\$) <sup>(4)</sup>	All Other Compensation (\$)	Total (\$)
Zami Aberman	2022	432,043 <sup>(6)</sup>	—	—	751,472 <sup>(8)</sup>	1,183,515
Chairman*	2021	556,475 <sup>(6)</sup>	—	8,741,402	508,074 <sup>(5)</sup>	9,805,951
Yaky Yanay	2022	488,569	64,000	—	745,610 <sup>(9)</sup>	1,297,726
CEO	2021	459,016 <sup>(7)</sup>	126,000	8,741,402	27,588	9,354,006
Chen Franco-Yehuda	2022	310,253	44,000	—	253,953 <sup>(10)</sup>	607,915
CFO	2021	251,642	64,000	1,020,000	14,653	1,350,295

\* Mr. Aberman served as our Executive Chairman until January 2022.

(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.

(3) During October 2021, we paid Mr. Yanay and Ms. Franco-Yehuda in cash the accrued bonuses for Fiscal Year 2021 in the amounts of \$126,000 and \$64,000 respectively.

For Mr. Yanay and Ms. Franco-Yehuda, we have accrued, but have not yet paid, bonuses during Fiscal Year 2022 of \$64,000 and \$44,000 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 2022.

(4) 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 for Fiscal Year 2021 are included in Note 9 to our audited consolidated financial statements for Fiscal Year 2022 and 2021 respectively, included elsewhere in this Annual Report (see also “Grants of Plan-Based Awards” table presented below).

(5) Mr. Aberman was entitled to adjustment fees of NIS 1,515,600, out of which we paid NIS 1,477,350, during Fiscal Year 2022 and NIS 38,250 during Fiscal Year 2021, which amount to a total of approximately \$500,000.

(6) Includes \$60,338 and \$6,201 paid in cash to Mr. Aberman as compensation for services as a director in fiscal year 2022 and 2021, respectively. In fiscal year 2022, also includes \$103,330 paid in cash in lieu of accrued vacation days.

(7) Includes \$6,194 paid in cash to Mr. Yanay as compensation for services as a director in Fiscal Year 2021. Starting October 2020, Mr. Yanay was not entitled to compensation for services as a director.

(8) On February 26, 2022, the Subsidiary allocated 19,987 of its shares in Plurinuva to Mr. Aberman pursuant to the terms of his consulting agreement. The fair value recognized for these shares was \$705,000.

This column also includes costs in connection with car and mobile phone expenses for Mr. Aberman in the amount of \$46,000 for Fiscal Year 2022.

(9) On February 26, 2022, the Subsidiary allocated 19,987 of its shares in Plurinuva to Mr. Yanay pursuant to the terms of his employment agreements. The fair value recognized for these shares was \$705,000.

This column also includes costs in connection with car and mobile phone expenses for Mr. Yanay in the amount of \$41,000 for Fiscal Year 2022.

We have also paid Mr. Yanay the tax associated with the company car benefit, which is grossed-up and is part of the amount in the “Salary” column.

(10) On February 26, 2022, the Subsidiary allocated 6,562 of its shares in Plurinuva to Ms. Franco-Yehuda pursuant to the terms of her employment agreements. The fair value recognized for these shares was \$235,000.

This column also includes costs in connection with a company car or car expenses reimbursement and mobile phone expenses for Ms. Franco-Yehuda in the amount of \$19,000 for Fiscal Year 2022.

## **Employment and Consulting Agreements**

During Fiscal Year 2022, we had the following written agreements and other arrangements concerning compensation with our named executive officers:

- (a) Mr. Aberman served as our Executive Chairman until December 31, 2021, and on January 1, 2022, we entered into a new consulting agreement, or the New Agreement, with Mr. Aberman pursuant to which Mr. Aberman serves as our Chairman of the Board of Directors and currently receives a monthly consulting fee of NIS 30,500 (approximately \$9,400 per month).

On December 1, 2021, at the recommendation of our Compensation Committee, our Board approved, effective as of January 1, 2022, a decrease to the monthly consulting fee of Mr. Aberman from 142,500 to NIS 30,500 per month. 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, to the extent entered into prior to December 31, 2022. Mr. Aberman is also entitled to a monthly car expenses reimbursement of NIS 4,000.

- (b) Starting January 1, 2021, Mr. Yanay's monthly salary is NIS 99,000, approximately \$30,000 per month. 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. Ms. Franco-Yehuda also receives cellular phone expense reimbursements and is entitled to car expense reimbursements or Company car 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 an immediate and unilateral termination of Mr. Aberman's New Consulting Agreement by the Company, he will be entitled to receive one month of consulting fee in the amount of NIS 30,500. (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 RSUs 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 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, Chairman and CFO would have received from us had their employment been terminated, or a change in control of us happened on June 30, 2022.

Officer	Salary	Accelerated Vesting of RSUs <sup>(1)</sup>	Total
<b>Zami Aberman</b>			
Terminated due to officer resignation . . . . .	\$ —	\$ 179,688 <sup>(2)</sup>	\$ 188,402
Immediately terminated due to discharge of officer . . . . .	\$ 9,857	\$ 359,375 <sup>(3)</sup>	\$ 368,089
Change in control . . . . .	—	\$ 359,375 <sup>(4)</sup>	\$ 359,375
<b>Yaky Yanay</b>			
Terminated due to officer resignation . . . . .	\$ 560,842 <sup>(5)</sup>	\$ 179,688 <sup>(2)</sup>	\$ 740,529
Terminated due to discharge of officer . . . . .	\$ 560,842 <sup>(5)</sup>	\$ 359,375 <sup>(3)</sup>	\$ 920,217
Change in control . . . . .	—	\$ 359,375 <sup>(4)</sup>	\$ 359,375
<b>Chen Franco Yehuda</b>			
Terminated due to officer resignation . . . . .	\$ 92,857	\$ 36,250 <sup>(2)</sup>	\$ 129,107
Terminated due to discharge of officer . . . . .	\$ 92,857	\$ 72,500 <sup>(6)</sup>	\$ 165,357
Change in control . . . . .	—	\$ 72,500 <sup>(6)</sup>	\$ 72,500

- (1) Value shown represents the difference between the closing market price of our common shares on June 30, 2022, of \$1.25 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 granted on September 10, 2020, 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 granted on September 10, 2020, 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) Pursuant to his employment agreement, in case of termination, Mr. Yanay is entitled to adjustment fees of \$255,000. In addition, as of June 30, 2022 Mr. Yanay is eligible to receive severance payments of \$306,000, out of which \$266,000 have been accrued in his severance fund. Therefore, 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, 2022, amounted to \$40,000.
- (6) All unvested RSUs issued under the applicable equity incentive plans vest upon an involuntary termination due to discharge, except for cause, or upon a change in control.

#### *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 2022

The following table presents the outstanding equity awards held as of June 30, 2022, 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:	Equity incentive plan awards:
			Number of shares that have not vested (#)	Market value of shares that have not vested (\$)
Zami Aberman	—	—	500,000 <sup>(1)</sup>	625,000
	281,250 <sup>(2)</sup>	351,563	—	—
	6,250 <sup>(3)</sup>	7,813	—	—
Yaky Yanay	—	—	500,000 <sup>(1)</sup>	625,000
	281,250 <sup>(2)</sup>	351,563	—	—
	6,250 <sup>(3)</sup>	7,813	—	—
Chen Franco-Yehuda	250 <sup>(4)</sup>	313	—	—
	1,500 <sup>(5)</sup>	1,875	—	—
	56,250 <sup>(6)</sup>	70,313	—	—

- (1) 500,000 RSUs granted on September 10, 2020 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) 281,250 RSUs vest in 9 equal installments of 31,250 on September 10, 2022, and every three months thereafter.
- (3) 6,250 RSUs vest in 2 equal installments of 3,125 on September 19, 2022, and every three months thereafter.
- (4) 250 RSUs vest in 2 equal installments of 125 on September 19, 2022, and every three months thereafter.
- (5) 1,500 RSUs vest in 3 equal installments of 500 on September 28, 2022, and every three months thereafter.
- (6) 56,250 RSUs vest in 9 equal installments of 6,250 on September 10, 2022, 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 2022, excluding Mr. Aberman who served as Executive Chairman until December 31, 2021, and whose compensation is included in the Summary Compensation Table above:

Name	Fees Earned or Paid in Cash (\$) <sup>(4)</sup>	Stock Awards (\$) <sup>(1)</sup>	Total (\$)
Doron Birger <sup>(3)</sup>	36,057	73,400	109,457
Varda Shalev <sup>(3)</sup>	33,637	73,400	107,037
Mark Germain <sup>(2)</sup>	38,025	—	38,025
Moria Kwiat <sup>(2)</sup>	36,700	—	36,700
Rami Levi	35,000	—	35,000
Maital Shemesh-Rasmussen	38,000	—	38,000
Doron Shorrer <sup>(2)</sup>	50,012	—	50,012

- (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 2022 included elsewhere in this Annual Report.

- (2) Effective as of June 21, 2022, as a result of the voting outcome from the 2022 Annual Meeting, these directors were not re-elected to the Company's Board of Directors, and vacated their seats on the Board, and their respective committees, effective immediately.
- (3) Effective as of July 15, 2021, this director was appointed to serve on the Board.
- (4) Excluding VAT.

During 2022, we paid no bonuses to the directors listed above.

As of June 30, 2022, we have outstanding grants to our non-executive directors aggregating 343,991 RSUs of which 264,665 were exercisable or vested, as the case may be, as follows:

Name	Total of restricted shares and RSUs granted and outstanding	Total unvested restricted shares and RSUs.
Doron Birger . . . . .	20,000	16,250
Varda Shalev . . . . .	20,000	16,250
Mark Germain <sup>(1)</sup> . . . . .	100,645	—
Moria Kwiat <sup>(1)</sup> . . . . .	55,750	—
Rami Levi . . . . .	20,000	13,750
Maital Shemesh-Rasmussen . . . . .	20,000	13,750
Doron Shorrer <sup>(1)</sup> . . . . .	107,596	—
<b>Total</b> . . . . .	<b>343,991</b>	<b>60,000</b>

- (1) These directors were not re-elected to the Company's Board at the 2022 Annual Meeting.

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.

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 2022.



**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 15, 2022 (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 Pluri Inc., MATAM Advanced Technology Park, Building No. 5, Haifa, Israel, 3508409.

<b>Name of Beneficial Owner</b>	<b>Beneficial Number of Shares<sup>(1)</sup></b>	<b>Percentage of Shares Beneficially Owned</b>
<b><u>Directors and Named Executive Officers</u></b>		
Yaky Yanay CEO, President and Director . . . . .	685,973 <sup>(2)</sup>	2.1%
Chen Franco-Yehuda CFO . . . . .	66,591	*
Doron Birger Director . . . . .	6,250	*
Maital Shemesh-Rasmussen Director . . . . .	8,750	*
Rami Levi Director . . . . .	8,750	*
Varda Shalev Director . . . . .	6,250	*
Zami Aberman Chairman of the Board of Directors . . . . .	839,747 <sup>(2)</sup>	2.6%
Directors and Executive Officers as a group (7 persons) . . . . .	1,875,547 <sup>(5)</sup>	5.0%
<b><u>5% Shareholders</u></b>		
David M. Slager . . . . .	1,685,038 <sup>(6)</sup>	5.2%

\* less than 1%

(1) Based on 32,620,343 Common Shares issued and outstanding as of September 15, 2022. 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 2,857 shares.

(4) Includes a warrant to acquire up to 1,429 shares.

(5) Includes a warrant to acquire up to 18,572 shares.

(6) Based solely upon a Schedule 13G filed by Mr. Slager, Regals Capital Management LP, or Regals Management, and Regals Fund LP, or Regals Fund, with the SEC on January 26, 2022. Regals Fund directly owned 1,071,938 shares. Regals Management, as the investment manager of Regals Fund, may be deemed to beneficially own the shares owned directly by Regals Fund. Mr. Slager, as the managing member of the general partner of Regals Management, may be deemed to beneficially own the shares beneficially owned by Regals Management, in addition to the 613,100 shares he owns directly.

## 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, 2022:

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 . . . . .	91,045	\$ 0.00001	4,765,113

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

Except for the arrangements described in Item 11, during fiscal years 2022 and 2021, 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, Rami Levi, Varda Shalev and Mital Shemesh-Rasmussen 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 in the last two fiscal years were as follows:

	Twelve months ended June 30, 2022	Twelve months ended June 30, 2021
Audit Fees . . . . .	\$ 114,532	\$ 105,000
Audit-Related Fees . . . . .	6,214	None
Tax Fees . . . . .	14,624	28,507
All Other Fees . . . . .	36,975	None
Total Fees . . . . .	<u>\$ 172,345</u>	<u>\$ 133,507</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.

*Audit-Related Fees.* These fees were comprised of fees related to the annual comfort letter relating to our ATM Agreement.

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

*All Other Fees.* These fees were comprised of (i) assistance in preparation of our periodical report to IIA, (ii) hours devoted to review the agreements of Plurinuva its establishment , (iii) working hours devoted to the cyber-incident described in the risk factors contained elsewhere in this Annual Report on Form 10-K.

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.

As of June 30, 2022, we have accrued approximately \$86,000 for the annual Audit Fees for Fiscal Year 2022 and approximately \$22,000 for Other Fees, which we expect to pay PricewaterhouseCoopers during fiscal year 2023.

## 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 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).
- 3.3 Articles of Merger between Pluristem Therapeutics Inc. and Pluri Inc. (incorporated by reference to Exhibit 3.1 of our current report on Form 8-K filed on July 25, 2022).
- 4.1 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).
- 4.2 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 December 31, 2021 (incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q filed on February 7, 2022).
- 10.3 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).
- 10.4+ 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).
- 10.5+ 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).
- 10.6+ 2016 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 4, 2016).
- 10.7+ 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).
- 10.8+ 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).
- 10.9+ 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).
- 10.10+ 2019 Equity Compensation Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 25, 2019).
- 10.11+ 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).
- 10.12+ 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).
- 10.13+ 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).
- 10.14+ Form of Restricted Stock Unit Agreement (executive officers) under the 2019 Equity Compensation Plan (incorporated by reference to Exhibit 10.18 of our annual report on Form 10-K filed on September 13, 2021).
- 10.15+ Form of Restricted Stock Unit Agreement (directors) under the 2019 Equity Compensation Plan (incorporated by reference to Exhibit 10.19 of our annual report on Form 10-K filed on September 13, 2021).
- 10.16+ Form of Restricted Stock Unit Agreement (employees) under the 2019 Equity Compensation Plan (incorporated by reference to Exhibit 10.20 of our annual report on Form 10-K filed on September 13, 2021).
- 10.17+ Consulting Agreement between Pluristem Ltd. and Mr. Zalman (Zami) Aberman dated January 1, 2022 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on January 3, 2022).

- 10.18+ 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).
- 10.19+ 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).
- 10.20+ Letter agreement by and between Pluristem Ltd. and Chen Franco-Yehuda, dated September 13, 2021 (incorporated by reference to Exhibit 10.30 of our annual report on Form 10-K filed on September 13, 2021).
- 10.21^ 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).
- 10.22 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).
- 10.23 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).
- 10.24 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).
- 10.25+ Letter agreement by and between Pluristem Ltd. and Rose High Tech Ltd., dated September 13, 2021 (incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K filed on September 13, 2021).
- 10.26+ Letter agreement by and between Pluristem Ltd. and Yaky Yanay, dated September 13, 2021 (incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K filed on September 13, 2021).
- 10.27+ Consulting Agreement by and between Pluristem Ltd. and Mr. Zalman (Zami) Aberman, dated January 1, 2022 (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on January 3, 2022).
- 10.28^ Share Purchase Agreement, dated January 5, 2022, by and among Tnuva Food-Tech Incubator (2019), Limited Partnership, Plurinuva Ltd. and Pluri-Biotech Ltd. (formerly Pluristem Ltd.) (incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q filed on May 9, 2022).
- 10.29^ Technology License Agreement, dated January 5, 2022, by and between Pluri-Biotech Ltd. (formerly Pluristem Ltd.) and Plurinuva Ltd. (incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q filed on May 9, 2022).
- 21.1\* List of Subsidiaries of the Company.
- 23.1\* Consent of Kesselman & Kesselman, Independent Registered Public Accounting Firm.
- 31.1\* Certification pursuant to Rule 13a-14(a)/15d-14(a) of Yaky Yanay.
- 31.2\* Certification pursuant to Rule 13a-14(a)/15d-14(a) of Chen Franco-Yehuda.
- 32.1\*\* Certification pursuant to 18 U.S.C. Section 1350 of Yaky Yanay.
- 32.2\*\* Certification pursuant to 18 U.S.C. Section 1350 of Chen Franco-Yehuda.
- 101\* The following materials from our Annual Report on Form 10-K for the fiscal year ended June 30, 2022 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.
- 104\* Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

\* 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 the registrant if publicly disclosed. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

#### 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.

Pluri Inc.

By: /s/ Yaky Yanay Dated: September 21, 2022  
Yaky Yanay, Chief Executive Officer

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 Dated: September 21, 2022  
Yaky Yanay, Chief Executive Officer,  
President and Director  
(Principal Executive Officer)

By: /s/ Chen Franco-Yehuda Dated: September 21, 2022  
Chen Franco-Yehuda, Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)

By: /s/ Zami Aberman Dated: September 21, 2022  
Zami Aberman, Chairman of the Board of Directors

By: /s/ Doron Birger Dated: September 21, 2022  
Doron Birger, Director

By: /s/ Rami Levi Dated: September 21, 2022  
Rami Levi, Director

By: /s/ Prof. Varda Shalev Dated: September 21, 2022  
Prof. Varda Shalev, Director

By: /s/ Mital Shemesh-Rasmussen Dated: September 21, 2022  
Mital Shemesh-Rasmussen, Director



## **CORPORATE INFORMATION**

### ***Executive Officers***

Yaky Yanay  
Chief Executive Officer and President

Chen Franco-Yehuda  
Chief Financial Officer, Treasurer and Secretary

### ***Directors***

Zami Aberman  
Chairman of the Board

Yaky Yanay  
Chief Executive Officer and President

Rami Levi  
A leading expert in international affairs, global market development, strategic planning and government regulatory management

Maital (Shemesh) Rasmussen  
Health Sciences commercial executive.  
Chief Commercial Officer at Octave Bioscience

Doron Birger  
Active in variety of technology companies as interim CEO, director and chairman of the board

Professor Varda Shalev\*  
Professor at the department of epidemiology at the school of public health. A Managing Partner Team8 Health

### ***Corporate Address***

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

### ***Independent Auditors for 2023 Fiscal Year***

Kesselman & Kesselman Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited

### ***Counsel***

Sullivan & Worcester LLP  
1633 Broadway, 32<sup>nd</sup> Floor  
New York, New York 10019  
U.S.A.

### ***Transfer Agent***

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

### ***Stock Market Information***

Pluri's shares of common stock are traded on the Nasdaq Global Market and the Tel Aviv Stock Exchange under the symbol 'PLUR'.

### ***Annual Meeting***

The Annual Meeting of Stockholders will be held at 5 p.m., local time, on April 20, 2023, at Pluri's offices in Haifa, Israel.

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

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

### ***Website***

<http://www.pluri-biotech.com>

\* Not a nominee for re-election at the 2023 Annual Meeting of Stockholders

