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 **December 31, 2021**

or

☐ **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 **001-38416**

ORGENESIS INC.
(Exact name of registrant as specified in its charter)

Nevada	**98-0583166**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)

20271 Goldenrod Lane, Germantown, MD 20876
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(480) 659-6404**

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**ORGS**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

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 checkmark 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 ☒

The registrant had 24,820,756 shares of common stock outstanding as of March 30, 2022. The aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2021) was $109,567,091, as computed by reference to the closing price of such common stock on The Nasdaq Capital Market on such date.

ORGENESIS INC.
2021 FORM 10-K ANNUAL REPORT
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SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. Certain statements made in this discussion are "forward-looking statements" within the meaning of 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by the Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used herein, the words "anticipate," "believe," "estimate," "expect," "forecast," "future," "intend," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" or the negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this report.

Unless otherwise indicated or the context requires otherwise, the words "we," "us," "our," the "Company," "our Company" or "Orgenesis" refer to Orgenesis Inc., a Nevada corporation, and our majority or wholly-owned subsidiaries, Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"); Orgenesis Belgium SRL, a Belgian-based entity (the "Belgian Subsidiary"); Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"); Orgenesis Maryland Inc., a Maryland corporation (the "U.S. Subsidiary"); Orgenesis Switzerland Sarl, which was incorporated in October 2020 (the "Swiss Subsidiary"); Orgenesis Biotech Israel Ltd. ("OBI"); Koligo Therapeutics Inc., a Kentucky corporation, purchased in 2020 ("Koligo"); Orgenesis Germany GmbH which was incorporated in 2021 (the "German Subsidiary"); Orgenesis CA, Inc. which was incorporated in 2021 (the "California Subsidiary"); Masthercell Global Inc. ("Masthercell") and its wholly owned subsidiaries Cell Therapy Holdings S.A., MaSTherCell, S.A. ("MaSTherCell"), a Belgian-based subsidiary and a Contract Development and Manufacturing Organization ("CDMO") specialized in cell therapy development and manufacturing for advanced medicinal products, and Masthercell U.S., LLC ("Masthercell U.S."), a U.S.-based CDMO (collectively, "Masthercell"). The Company sold all of its equity interests in Masthercell and its subsidiaries on February 20, 2020.

Forward-looking statements made in this Annual Report on Form 10-K include statements about:

Corporate and Financial

- our ability to generate revenue from the commercialization of our point-of-care cell therapy ("POC") to reach patients and to increase such revenues;
- our ability to achieve profitability;
- our ability to manage our research and development programs that are based on novel technologies;
- our ability to grow the size and capabilities of our organization through further collaboration and strategic alliances to expand our point-of-care cell therapy business;
- our ability to control key elements relating to the development and commercialization of therapeutic product candidates with third parties;
- our ability to manage potential disruptions as a result of the continued impact of the coronavirus outbreak;
- our ability to manage the growth of our company;
- our ability to attract and retain key scientific or management personnel and to expand our management team;
- the accuracy of estimates regarding expenses, future revenue, capital requirements, profitability, and needs for additional financing; and
- our belief that our therapeutic related developments have competitive advantages and can compete favorably and profitably in the cell and gene therapy industry.

Cell & Gene Therapy Business ("CGT")

- our ability to adequately fund and scale our various collaboration, license, partnership and joint venture agreements for the development of therapeutic products and technologies;
- our ability to advance our therapeutic collaborations in terms of industrial development, clinical development, regulatory challenges, commercial partners and manufacturing availability;
- our ability to implement our POC strategy in order to further develop and advance autologous therapies to reach patients;
- expectations regarding our ability to obtain additional and maintain existing intellectual property protection for our technologies and therapies;
- our ability to commercialize products in light of the intellectual property rights of others;
- our ability to obtain funding necessary to start and complete such clinical trials;
- our ability to further our CGT development projects, either directly or through our JV partner agreements, and to fulfill our obligations under such agreements;
- our belief that our systems and therapies are as at least as safe and as effective as other options;
- our Subsidiary's relationship with Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") and the growing risk that THM may cancel or, at the very least continue to challenge, the License Agreement with Orgenesis Ltd. as we continue to expand our focus to other therapies;
- the outcome of certain legal proceedings that we become involved in;
- our license agreements with other institutions;
- expenditures not resulting in commercially successful products;
- our dependence on the financial results of our POC business;
- our ability to complete development, processing and then roll out Orgenesis Mobile Processing Units and Labs ("OMPULs"); and
- our ability to grow our POC business and to develop additional joint venture relationships in order to produce demonstrable revenues.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled "Risk Factors" set forth in this Annual Report on Form 10-K for the year ended December 31, 2021, any of which may cause our Company's or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks may cause the Company's or its industry's actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The Company is under no duty to update any forward-looking statements after the date of this report to conform these statements to actual results.

PART I

ITEM 1. BUSINESS

Business Overview

Orgenesis Inc., a Nevada corporation, is a global biotech company working to unlock the potential of cell and gene therapies ("CGTs") in an affordable and accessible format.

CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products ("ATMP"). We are mostly focused on autologous therapies, with processes and systems that are developed for each therapy using a closed and automated processing system approach that is validated for compliant production near the patient for treatment of the patient at the point of care ("POCare"). This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients (ultimately limiting the number of patients that can have access to, or can afford, these therapies).

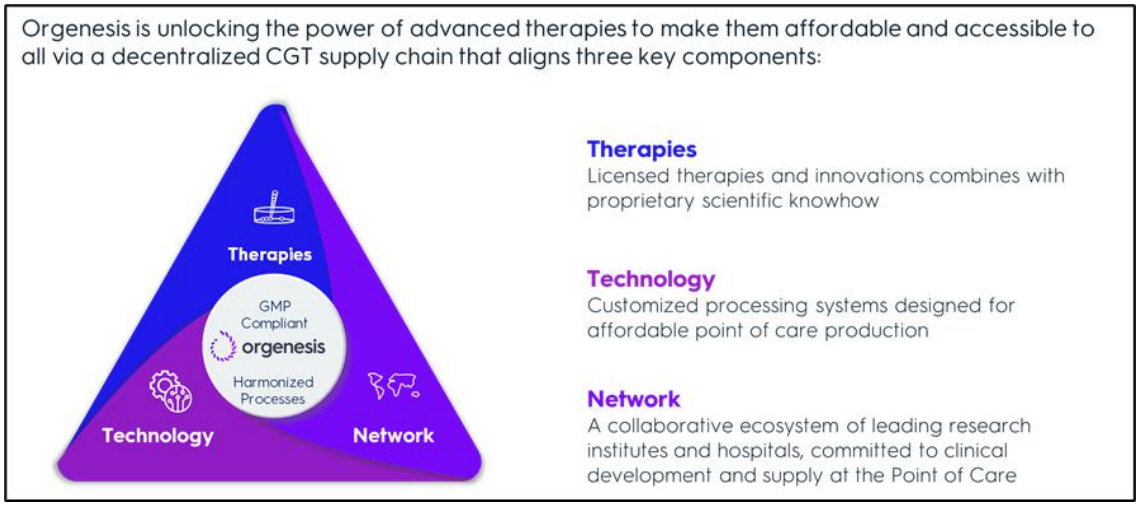
To achieve these goals, we have developed a Point of Care Platform ("POCare Platform") comprised of three enabling components: (i) a pipeline of licensed POCare advanced therapies that are designed to be processed and produced, (ii) automated closed POCare technology systems, and (iii) a collaborative worldwide network of POCare research institutes and hospitals ("POCare Network").

The POCare Platform relies, in particular, on the development of its own production capacity, known as "POCare Services", the goal of which is to ensure that therapies are accessible at the point of treatment (the "POCare Center"). POCare Services, which have been expanding worldwide, are based on a global approach and local adaptation that allows replication and expansion. Global harmonization of the POCare Services is ensured by a central quality system, replicability of infrastructure and equipment and centralized monitoring and data management.

The POCare Services include:

- Process development of therapies that are intended for use of the POCare Network;
- Adaptation of automation and closed systems to such therapies;
- Incorporation of the processing systems and the Good Manufacturing Practices ("GMP") in the Orgenesis Mobile Processing Units and Labs ("OMPULs");
- Tech transfers to required POCare Centers and training of local teams;
- Processing and supply of the therapies and required supplies under GMP conditions by the various POCare Centers, including required quality control testing; and
- Contract Research Organization ("CRO") services for clinical trials.

POCare Centers are the decentralized hubs that provide harmonized services to customers and partners. We are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. The workflow of a POCare Center is designed to allow rapid capacities expansion while integrating new technologies. We also draw upon extensive medical expertise to identify promising new autologous therapies to leverage within the POCare Platform either via ownership or licensing.



The POCare Network brings together patients, doctors and industry partners with a goal of achieving harmonized, regulated clinical development and production of POCare advanced therapies.

We have worked to develop and validate POCare technologies that can be combined within mobile production units for advanced therapies. We have made significant investments in the development of several types of OMPULs with the expectation of use and/or distribution through our POCare Network and/or partners, collaborators, and regional distributors. As of the date of this report, the OMPULs have been adapted for processing of chimeric antigen receptor (CAR) T-cell therapy ("CAR-T"), tumor infiltrating lymphocyte ("TIL") TILS and mesenchymal stem cell ("MSC") based products and are in the qualification stage for clinical use in various locations. Additional OMPULs are still in the development stage.

OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved advanced therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The OMPUL design delivers a potential industrial solution for us to deliver CGTs to practically any clinical institution at the point of care.

We have continued to grow our infrastructure and expand our processing sites into new markets and jurisdictions. In addition, we have continued investing manpower and financial resources to focus on developing, processing and rolling out several types of OMPULs to be used and/or distributed through our POCare Network and/or partners, collaborators, and regional distributors.

POCare Platform Operations via Subsidiaries

We currently conduct our core business operations ourselves and through our subsidiaries which are all wholly-owned except as otherwise stated below (collectively, the "Subsidiaries"). The Subsidiaries are as follows:

United States

- Orgenesis Maryland Inc. (the "U.S. Subsidiary") is the center of activity in North America and is currently focused on setting up and providing POCare Services to the POCare Network.

- Koligo Therapeutics, Inc. ("Koligo") is a Kentucky corporation that we acquired in 2020. Koligo is a regenerative medicine company, specializing in developing personalized cell therapies. It is currently focused on commercializing its metabolic pipeline via the POCare network throughout the United States and in international markets.

- Orgenesis CA, Inc. (the "California subsidiary") is a Californian subsidiary incorporated in 2021 and is currently focused on development of our technologies and therapies in California.

Europe

- Orgenesis Belgium SRL (the "Belgian Subsidiary") is currently focused on expanding our POCare network in Europe, process development and the preparation of European clinical trials.

- Orgenesis Switzerland Sarl (the "Swiss Subsidiary"), was incorporated in October 2020, and is currently focused on providing management services to us.

- Orgenesis Germany GmbH (incorporated in 2021) (the "German subsidiary") is currently focused on providing CRO services to the POCare Network.

Asia

- Korea: Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"), is a provider of processing and pre-clinical services in Korea. We own 94.12% of the Korean Subsidiary.

- Orgenesis Ltd. in Israel (the "Israeli Subsidiary") is a provider of regulatory, clinical and pre-clinical services in Israel.

- Orgenesis Biotech Israel Ltd. ("OBI") is a provider of process development and cell-processing services in Israel.

Discontinued Operations

In February 2020, we and GPP-II Masthercell LLC ("GPP") sold 100% of the outstanding equity interests of Masthercell Inc. (the "Masthercell Business"), which comprised the majority of our CDMO Business, to Catalent Pharma Solutions, Inc. We determined that the Masthercell Business ("Discontinued Operations") met the criteria to be classified as a discontinued operation as of the first quarter of 2020. The Discontinued Operation includes the vast majority of the previous CDMO Business, including majority-owned Masthercell Inc and its subsidiaries.

Advanced Therapy Medicinal Products Overview

ATMP means one of any of the following medicinal products that are developed and commercialized for human use:

- A *somatic cell therapy medicinal product* ("STMP") that contains cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body.
- A *tissue engineered product* ("TEP") that contains cells or tissues that have been modified so that they can be used to repair, regenerate, or replace human tissue.
- A *gene therapy medicinal product* ("GTMP") that engineers genes that lead to a therapeutic, prophylactic, or diagnostic effect and, in many cases, work by inserting "recombinant" genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer, or long-term diseases. In this case, a recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources.

It is important to note that although STMPs and GTMPs currently dominate the market, in order to access the market potential and trends in the future, other cell products are likely to be essential in all of these categories.

We believe that autologous therapies represent a substantial segment of the ATMP market. Autologous therapies are produced from a patient's own cells versus allogeneic therapies that are mass-cultivated from donor cells via the construction of master and working cell banks, are then produced on a large scale. Developers and manufacturers of ATMPs (both autologous and allogeneic) currently rely heavily on production using traditional centralized supply chains and manufacturing sites.

CGTs are costly and complex to produce. We also refer to CGTs as “living” drugs since they are based on maintaining the cells vitality. Therefore, there is no possibility to sterilize the products, since such a process involves killing any living organism. Many of these therapies require sourcing of the patient’s cells, engineering them in a sterile environment and then transplanting them back to the patient (so-called “autologous” CGT). This presents multiple logistic challenges as each patient requires its own production batch, and the current processes involve complex laboratory-based types of manipulations requiring highly trained lab technicians. We are leveraging a unique approach to therapy production using the POCare Platform to potentially overcome some of the development and supply chain challenges of affordably bringing autologous therapies to patients.

Allogeneic therapies are costly and complex to produce because autologous therapies are derived from the treated patient and manufactured through a defined protocol before re-administration. We are leveraging a unique approach to therapy production using the POCare Platform to potentially overcome some of the development and supply chain challenges of bringing autologous therapies to patients affordably.

Therapies in Development

The following table summarizes our therapies in development, which are discussed in detail below:

Ref	Therapy	Licensing/Joint Venture/Collaboration Partner	Indication
1	KYSLECEL	Own	TP-IAT
2 & 6	Tissue Genesis Icellator®	Own	Cell Assisted Lipotransfer, COVID-19, CLI-ED
3	Cartil-S	Licensed from Theracell	Osteoarthritis
4	Chondroseal	Licensed from Theracell	Cartilage Defects
5	RanTop, Ranpirnase Topical Formulation	Own	HPV-associated external anogenital warts (EGW)
7	Autologous Insulin-Producing Cells (AIPs) from Adult Liver Cells	ORG Ltd. Licensed from THM	Diabetes treatment
8	CAR-T CD19	ORG Inc. Licensed from Broaden Bioscience and Technology Corp	B-ALL, Lymphoma
9	Dual Cellular vaccine (DUVAC)	Licensed from Columbia University	Pancreatic Cancer
10	Metabolically Optimized T-Cells (MOTC): Therapy for melanoma and lung cancer	Own	Solid Tumors
11	Autologous Cell-Based Vaccine for protecting against SARS-CoV-2	Own	COVID -19, platform for the prevention of viral diseases
12	Bioxomes	Own	Various Indications
13	MSCP	Own	Wound healing and Psoriasis
14	Muscle-derived Mesenchymal Stem Cells for Human Regenerative Medicine	Licensed from Revitas	Urinary Incontinence
15	Kidney Disease	Own	CKD
16	KT-DM-103 and KT-CP-203 (3D-Printed Pancreatic Islets)	Own	Type 1 diabetes and chronic pancreatitis

Products in Clinical Use

1. *KYSLECEL® (Autologous Pancreatic Islets)*

KYSLECEL is made from a patient's own pancreatic islets – the cells that make insulin to regulate blood sugar. KYSLECEL is intended to preserve insulin secretory capacity in chronic or acute recurrent pancreatitis patients after total pancreatectomy (TP-IAT). KYSLECEL is a minimally manipulated autologous cell-based product available in the United States and regulated by the U.S. Food and Drug Administration ("FDA"). KYSLECEL is produced according to current good tissue practices (cGTP) and in compliance with federal and state regulations. We are planning on initiating an observational study in the US to gain insight into KYSLECEL patient outcomes. Substantial efforts are being invested in promoting the process development and the marketing of KYSLECEL in the European Union. In May 2021 we submitted a request for classification to Committee for Advanced Therapies (CAT) to the European Medicines Agency (EMA), who classified KYSLECEL as not being an Advanced Therapy Medicinal Product (ATMP). We have identified relevant Key Opinion Leaders (KOL) and established contact with islet transplantation/pancreas surgery centers in Germany and Switzerland. We are adjusting the KYSLECEL Good Manufacturing Practice (GMP) for European requirements for the initiation for the first clinical application. We are also monitoring the Chinese market for potential partners. Furthermore, we are training teams who will manage introduction into new markets by supporting the KYSLECEL tech transfer, as well as working on the OMPUlization process so as to manufacture via automated closed systems.

2. *Tissue Genesis Icellator® for Cell Assisted Lipotransfer*

The Tissue Genesis Icellator is a point-of-care medical device that isolates stromal and vascular fraction cells ("SVF") from a patient's own (autologous) adipose tissue (fat). The Icellator is commercially available in Korea through a medical device distributor. The SVF obtained from the Icellator is for use in cell-assisted lipotransfer, a plastic surgery procedure intended to improve fat engraftments.

3. *Cartil-S Autologous Products for the Treatment of Osteoarthritis*

Cartil-S is a cell therapy for Osteoarthritis. This product is produced by performing a minimally invasive biopsy of adipose (fat) tissue from a patient, followed by isolation and expansion of adipose-derived stem cells (ADSCs), to be injected arthroscopically. The autologous injectable product helps delay/stop the progression of osteoarthritis, involving the patient's own stem cells.

4. *Chondroseal Autologous Products for the Treatment of Cartilage Defects (Osteoarthritis)*

Chondroseal is a cell therapy for cartilage defects. Following collection of adipose tissue by minimally invasive biopsy that is composed of ADSCs, the cells are combined with a natural gel serving as a scaffold for local cartilage regeneration in the joint.

Products in Clinical Trials

5. *RanTop, Ranpirnase Topical Formulation*

We are currently developing a novel topical formulation of an active RNA-degrading enzyme, called Ranpirnase. Ranpirnase combats viral infections by targeting double-stranded RNA including miRNA precursors, via RNA degradation catalysis. It acts through a dual mechanism: 1) Inhibition of viral replication; and 2) induction of host cell apoptosis. Topical Ranpirnase demonstrated good tolerability and preliminary clinical efficacy in the treatment of HPV-associated external anogenital warts (EGW) in a Phase 2a clinical study conducted in Bolivia.

During 2021 we prepared a detailed pre-IND briefing package and received positive pre-IND feedback from the FDA on the development plan and proposed clinical study under an IND of topical Ranprinase for the treatment of EGW**.** The FDA generally confirmed that the proposed preclinical development plan should support a Phase 2b study of topical Ranprinase in EGW. The proposed plan included a dermal toxicology study using the gel formulation.

We have demonstrated in laboratory experiments the feasibility of Ranprinase encapsulation in the Orgenesis Bioxome delivery platform. Encapsulation enhanced Ranprinase anti-viral activity in an in-vitro test. We have also shown feasibility of producing an active recombinant Ranprinase. Recombinant production could in the future replace the sourced Ranprinase to improve manufacturing scalability, eliminate dependence on procurement of *rana pipiens* frog oocytes and potentially decrease production cost.

6. Tissue Geneseis Icellator® for Erectile Dysfunction and COVID-19 (SVF-CLI-ED)

The safety of the Tissue Genesis Icellator, and use of SVF produced by the Icellator, has previously been tested in a number of pilot clinical trials in the United States. Orgenesis has prioritized the clinical development of the Icellator for potential use in the treatment of erectile dysfunction and COVID-19 related respiratory complications. In 2021, the FDA approved our investigational device exemption (IDE) for a Pilot Clinical Trial of the Tissue Genesis Icellator to treat Acute Respiratory Distress Syndrome (ARDS) resulting from COVID-19 infection.

The Tissue Genesis Icellator is also being used by research collaborators in FDA-regulated clinical trials to test the use of SVF during rotator cuff surgery.

Products in IND Enabling Studies

7. Generation of Autologous Insulin-Producing Cells (AIPs) from Adult Liver Cells ("trans-differentiation technology")

Orgenesis Ltd. has trans-differentiation in-vitro technology that has demonstrated in animal models the capacity to induce a shift in the developmental fate of cells from the liver or other tissues, transdifferentiating them into "pancreatic beta cell-like" AIP cells for patients with Type 1 Diabetes ("T1D"), acute pancreatitis and other insulin deficient diseases. For the treatment of diabetes, cells are derived from the liver or other adult tissue and are trans-differentiated to become AIP cells. This technology has shown in relevant animal models that the human derived AIP cells produce insulin in a glucose-sensitive manner. No adverse effects were observed in any of the animal studies. This trans-differentiation technology is licensed by the Israeli Subsidiary and is based on the work of Prof. Sarah Ferber, a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") in Israel. The development plan calls for conducting additional pre-clinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating human clinical trials.

With respect to the trans-differentiation technology, we have exclusive rights to eight (8) United States and twenty four (24) foreign issued patents, two (2) pending patent applications in the United States, eleven (11) pending patent applications in foreign jurisdictions, including, Brazil, Canada, Europe, Israel, Panama, South Korea, and Singapore. These patents and patent applications relate, among others, to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis.

On June 11, 2019, the FDA granted Orphan Drug Designation for our AIP cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy ("TP") due to chronic pancreatitis.

On April 29, 2019, we received Institutional Review Board ("IRB") approval to collect liver biopsies from patients at Rambam Medical Center located in Haifa, Israel for a planned study to confirm the suitability of liver cells for personalized cell replacement therapy for patients with insulin-dependent diabetes resulting from total or partial pancreatectomy. The first patients were enrolled during 2020. The goal of the proposed study, entitled "Collection of Human Liver Biopsy and Whole Blood Samples from Type 1 Diabetes Mellitus (T1DM), Total or Partial Pancreatectomy Patients for Potential use as an Autologous Source for Insulin Producing Cells in Future Clinical Studies," is to confirm the suitability of the liver cells for personalized cell replacement therapy, as well as eligibility of patients to participate in a future clinical study, as defined by successful AIP cell production from their own liver biopsy. The secondary objective of the study is to evaluate patients' immune response to AIPs based on the patient's blood samples and followed by subcutaneous implantation into the patients' arm which would represent the first human trial.

We have invested substantial efforts in the feasibility of upscaling the manufacturing process for expansion of liver cells to the number required for clinical application (i.e. approximately two billion cells). We were successful in developing the expansion protocols while maintaining the liver cells' viability. However, the resulting cell expansion hampered the ability of the cells to efficiently transdifferentiate, as was determined in pre-clinical studies. Furthermore, combining the liver cells with alginate-based 3D scaffold failed to present significant potential of the scaffolds to support the cells' survival in pre-clinical studies. We will consider if other indications require a lower number of cells. To date, we have not been successful in in identification of such other relevant therapies.

The trans-differentiation technology is from a licensing agreement entered into as of February 2, 2012 by the Israeli Subsidiary and THM pursuant to which the Israeli Subsidiary, Orgenesis Ltd, was granted a worldwide royalty bearing and exclusive license (the "THM License Agreement"). By using therapeutic agents that efficiently convert a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. While we believe that this provides a major competitive advantage to the cell transformation technology of the Israeli Subsidiary, we also believe that our expanded focus to other therapies and business activities may continue to prompt THM to inquire of such activities as they may relate to our compliance with the terms or direction of the THM License Agreement. While we have not received any notice of cancellation of the THM License Agreement, we have received an allegation regarding the scope of the rights by THM that may present future challenges for our Israeli Subsidiary to continue to develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the development plan of the THM License Agreement. In addition, THM has filed a complaint against us in the Tel Aviv District Court relating to the scope of such THM License and the royalties and other payments that THM is entitled to thereunder. See "Legal Proceedings" in this Annual Report on Form 10-K.

8. CAR-T CD19

ORG-CAR19, Autologous anti CD19 CAR-T Chimeric antigen receptor T cells (known as CAR-T cells) are genetically engineered to express an artificial T-cell receptor for cancer immunotherapy. The promise of CAR-T immunotherapy is to engineer T cells to effectively recognize a specific antigen present on cancer cells to destroy those cells. CAR-T cells can be either derived from the patient's own T cells (autologous) or from T cells of a healthy donor (allogeneic). Once isolated from a person, these T cells are genetically engineered to express a specific CAR, which programs them to target an antigen present on the surface of tumors. After CAR-T cells are infused into a patient, they act as a "living drug" against cancer cells expressing the target antigen.

We are developing a new anti-CD19 CAR-T therapy for treating patients with B-cell malignancies including acute lymphoblastic leukemia (B-ALL) and non-Hodgkin lymphoma. Malignant B cells of these patients express the CD19 protein on their surface that is targeted by the CAR-T cells. Orgenesis anti-CD19 CAR-T is based on a clinically used CAR-T therapy licensed from Kecellitics Biotech.

9. Dual Cellular vaccine (DUVAC), Therapy for Pancreatic Cancer

The DUVAC cell-based immunotherapy, licensed from Columbia University, is based on autologous dendritic cells and macrophages. These cells are key coordinators of the innate and adaptive immune system and have critical roles in the induction of antitumor immunity. The cells are exposed to whole cancer cells and constitute the most comprehensive source of cancer antigens, which may boost the patient immune system and direct it against the tumor. We believe that a vaccine based on DUVAC vaccine can potentially be developed for a wide range of solid tumors, but our initial focus is on pancreatic cancer. We have signed a Material Transfer Agreement with a leading medical center in the US for their clinical grade pancreatic tumor cell lines to be used for proof-of concept

10. Metabolically Optimized T-Cells (MOTC): Therapy for melanoma and lung cancer

In the early stages of cancer, some lymphocytes successfully attack and infiltrate the tumor microenvironment, surround the tumor cells, and mount an anti-tumor response. TIL therapy is a clinically validated personalized cancer treatment based on infusion of autologous TILs expanded ex vivo from tumors. Once expanded, the TILs are infused back into the patient where they attack the cancer cells with a high degree of specificity.

We have recently licensed new technology to optimize the manufacturing process from the Yeda Research and Development Company Limited. The technology was developed as a synthetic immune niche technology. The technology will support and accelerate the expansion and function of TILs,

Products in Pre-Clinical Studies

11. Autologous Cell-Based Vaccine for protecting against SARS-CoV-2

We continue working on developing a cell-based vaccine platform for the prevention of viral diseases. The initial target for the platform is SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2, the causative agent of COVID-19). This cell-based vaccine platform utilizes an autologous approach. The goal is to enable the COVID-19 engineered cells will have the ability to activate an endogenous immune response and induce the production of neutralizing antibodies as well as cellular response.

12. Bioxomes

Exosomes are small, membrane-enclosed extracellular vesicles implicated in cell-to-cell communication. Exosomes may serve as a valuable therapeutic modality because of their ability to transfer a wide variety of therapeutic payloads among cells that can influence a cell in multiple ways, and they can be designed to reach specific cell types. Natural cell membranes (biomimetics) have recently emerged as a new source of materials for molecular delivery systems. Because cell membrane-derived vesicles contain the intrinsic functionalities and signaling networks of their parent cells, they can overcome various obstacles encountered by synthetic liposomes in vivo (including immunogenecity concerns)

To this end, we have developed a proprietary manufacturing process for preparation of the natural exosome-mimetic/liposome, termed BioxomeTM, a large-scale GMP-compatible production protocol that will potentially allow us to obtain Bioxome from various cell types, including human adipose cells, fibroblasts, blood cells, as well as plant cells. Various therapeutic cargos (including modified mRNA) can be encapsulated into the Bioxome during its manufacture. Once injected systemically, Bioxomes naturally fuse with the cell membrane and release therapeutic cargo.

In 2021, we assessed Bioxome biodistribution of the non-loaded Bioxome upon its systemic administration in rodents. This study had demonstrated a rapid and preferential uptake of the Bioxome by the liver, followed (to a lesser extent) by the kidney and lungs. Further biodistribution studies with Bioxome-encapsulated RNAse and Bioxome-encapsulated mRNA are planned for 2022.

In addition, accelerated anti-COVID19 efficacy was demonstrated for Bioxome-incorporated Ranprinase in an in vitro COVID-19 infection model, and we will conduct further studies to determine if Bioxome can be a vehicle for effective delivery of antiviral compounds.

13. .Mesenchymal stem cell Psoriasis (“MSCP”)

We are developing a personalized cell-based therapy product for wound healing and psoriasis. The product is based on allogeneic Adipose-Derived Stem Cells (ADSCs). Following expansion, the ADSCs are used for the extraction of BioxomeTM. We have established a process for encapsulation of Topiramate, a well-known substrate used in other indications, during the Bioxome manufacture. The Bioxome-encapsulated Topiramate (Biox-Top) will be further formulated in commercially available hyaluronic acid (HA), a well-known dermal filler, for topical application. Regulatory approval is required for this process.

The developed manufacture-encapsulation protocol is currently being scaled-up for the future production of the clinical grade Biox-Top for topical administration.

Promising anti-inflammatory efficacy of the Biox-Top was demonstrated in the human skin explants that were subjected to inflammation.

After demonstrating in vivo efficacy in the animal models of psoriasis, we plan to further advance this product to clinical development.

14. Muscle-derived Mesenchymal Stem Cells for Human Regenerative Medicine

An innovative and patented technology licensed from a licensing partner that enables the isolation of pluripotent adult Mesenchymal Stem Cells (MSCs) from a minimally invasive muscle micro-biopsy. The isolated autologously undifferentiated muscle-derived MSCs are developed for local administration into the muscle to correct muscle-related clinical indications, such as Stress Urinary Incontinence (SUI).

In 2021, promising results were obtained in an in-vivo model of SUI demonstrating robust therapeutic efficacy of locally injected human muscle-derived MSCs (MD-MSCs) in reversing the development of SUI in nude rats. Moreover, both nerve regeneration and functional restoration of the muscle tissue was observed.

In addition, we are working to establish the regulatory path and are preparing all relevant documentation for potential clinical implementation of MD-MSCs.

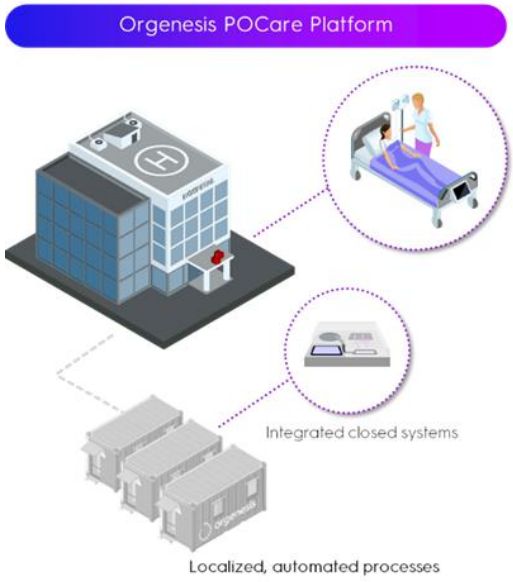
15. Kidney Disease

We are also developing multiple proprietary cell and cell derived products therapies for treating kidney failure and End-Stage Renal Disease (ESRD). We have made progress in the establishment of the enrichment process of extracellular vesicles (EV) replacement therapy for chronic kidney disease (CKD) patients.

16. KT-DM-103 and KT-CP-203 (3D-Printed Pancreatic Islets)

We, through our Koligo acquisition, have exclusively licensed patents and technology from the University of Louisville Research Foundation related to the revascularization and 3D printing of cell and tissue for transplant (“3D-V” technology platform). We are developing this technology for potential autologous and allogeneic pancreatic islet transplant to treat type 1 diabetes (KT-DM-103) and chronic pancreatitis (KT-CP-203). The 3D-V technology platform may also support improved transplantation of other cell and tissue types in additional to pancreatic islets.

POCare Platform Strategy



Our aim is to provide a pathway to bring ATMPs in the cell and gene therapy industry from research to patients worldwide through our POCare Platform. We define point of care as a process of collecting, processing, and administering cells as close as possible to the clinical setting. We believe that this approach is an attractive proposition for personalized medicine because of our strategic partnerships with suppliers that help us to customize closed systems into effective mobile clean room facilities. This will potentially help to minimize or eliminate the need for cell transportation, which is a high-risk and costly aspect of the supply chain, further allowing flexible production and patient treatment.

The POCare Platform is a unique globally harmonized and decentralized CGT-processing infrastructure that offers cost-effective processing capacities with ease for scalability and reproducibility. By producing personalized cell and gene therapies (CGTs) at the point of care, we are able to add new capacity within months instead of years.

Local decentralization: POCare Centers are set up in preferred regions, based on nearby hospitals' capacity needs, and support the POCare model by providing POCare Services for the POCare Network.

Global harmonization: the POCare Platform overcomes conventional processing challenges by enabling high quality standards and sterile, scalable onsite processing of CGTs orchestrated by the POCare centers to service local hospitals. Processing infrastructure is harmonized and reproducible using the Orgenesis Mobile Processing Unit and Lab technology ("OMPUL"). The use of an OMPUL can shorten implementation time from approximately 18-24 months to approximately 3-9 months, offers a more cost-effective environment and enables local scalability by connecting additional OMPULs. The network structure is supported and connected by the centralization of the harmonized best industry practices and standards to meet the highest quality standards ("QMS", Quality Management System). Further global harmonization is implemented through standardization of the training programs, centralized data management and a unified supply chain.

OMPULization of therapies: strong process development capabilities are critical for any CGT to scale. All therapeutic candidates must undergo some level of process development to move from the discovery phase to the clinical phase, if only to establish the same protocols under GMP. The POCare Platform takes process development to the next level, implementing a process we call OMPULization. OMPULization includes unitizing the process to the exact specifications of the OMPUL so it can be rapidly implemented in OMPULs around the world. In addition, OMPULization incorporates the latest technology solutions to close and automate the process whenever possible.

Integrated closed and automated processing systems require fewer Full Time Employees ("FTEs") to produce GMP batches, resulting in lower COGs and a process that has the ability to scale in sync with market demand. Full automation may not be necessary for all clinical phases, but it is important to plan for future incorporation. To this end, we have invested time and capital into evaluating relevant technology for CGT processing and have developed proprietary equipment that did not exist in the marketplace.

We aim to build value in various aspects of our company ranging from supply related processes including development and distribution systems, clinical and regulatory services, engineering and devices such as OMPULs discussed below, delivery systems, therapies including immuno-oncology, anti-aging, anti-viral, metabolic, nephrology, dermatology, orthopedic, as well as regenerative technologies.

Over time, we have worked to develop and validate POCare Technologies that can be combined within mobile production units for advanced therapies.

We have made significant investments in the development of several types of OMPULs and have made significant progress in the validation, risk analysis, regulatory and other related tasks relating to the OMPULs. We anticipate distributing and using the OMPULs through our POCare Network of partners, collaborators, and regional partners. OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved cell and gene therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The design delivers a potential industrial solution for us to deliver CGTs to most clinical institutions at the point of care.

Above is a diagram of an OMPUL and partial interior for illustrative purposes only

We have finalized or are in the process of finalizing the development of several POCare centers and, with the assistance of our partners, we are adapting the local requirements of each partner with the target of achieving a capacity to process and supply CGTs per our existing manufacturing contracts. As we expand operations, we expect that the OMPUL setup costs will decline over time. Most of our POC revenue to date is in support of the implementation of our technologies and therapies in our partners' POC activities, which we expect will be the basis for future royalties and supply revenues.

We have embarked on a strategy of collaborative arrangements with strategically situated regional distributor partners around the world. We believe that these partners have the expertise, experience and strategic location to advance our POCare Platform.

Strategic CGT Therapeutics Collaborations

Collaborations, partnerships, joint ventures and license agreements are a key component of our POC strategy.

Our POC technology collaborators and partners include Ori Biotech, Accelix, Columbia University in the City of New York, Caerus Therapeutics Corporation, UC Davis, The Johns Hopkins University, The Weizman Institute of Science and others.

In addition, we have collaborations and joint ventures for setting up POCare Platform operations facilities in jurisdictions throughout the world, including various countries in North America, Europe, Latin America, Asia, and Australia. Such partnerships include in-licensing and out-licensing of therapies, service contracts from the partners under co-development agreements, and development and manufacturing agreements for POCare products supplied regionally. Such partners/customers include Broaden Bioscience & Technology Corp, Celleska Pty Ltd, Cure Therapeutics, Educell, Image Securities FZC, Med Centre for Gene and Cell Therapy FZ-LLC, MIDA Biotech B.V., Mircod Biotech LLC, Theracell, and SBH Sciences.

For more information, see Note 11, "Collaboration and Licensing Agreements" of the "Notes to the Financial Statements" included in Item 8.

Current Development Facilities

OBI

OBI is a specialized process and technology development wholly owned subsidiary focused on custom-made process development, upscaling design from lab to industry innovation and automation procedures, which are extremely essential in the cell therapy industry. OBI is located in Bar-Lev Industrial Park utilizing the exclusive Israeli innovative ecosystem and highly experienced and talented associates including Ph.D. holders and biotechnology engineers. The center provides end to end solutions to cell therapy industrialization, process development capabilities and proficiency, custom-made engineering and a unique platform for creative design and process optimization. OBI occupies 1300 square meters of labs and offices resulting in an efficient and unique environment for cell therapy development. In connection with the Masthercell Sale, for a period of three years in the European Union and five years in the United States and the rest of the world from the closing date of the Masthercell Sale, we agreed that OBI will not manufacture products on a contract basis for third-party customers in any jurisdiction other than the State of Israel, but it may conduct such CDMO business in the State of Israel, solely for customers located within the State of Israel or with respect to therapies intended for distribution solely within the State of Israel. The Masthercell sale agreement stipulated that OBI may also conduct, worldwide, (i) point-of-care system, point-of-care products, point-of-care systems, point-of-care processing, and point-of-care development services for the development, manufacturing or processing of therapeutics, processes, systems and technologies to treat patients in a point-of-care clinical, hospital or institutional setting, any future point-of-care services substantially related to the foregoing, and advanced therapy medicinal products either proprietary to us or our affiliates or proprietary to a third-party partner (including a joint venture partner) or collaborator, which includes research, development, systems, manufacturing and processing of therapeutic technology products, systems, and processes, methods or services and (ii) research, manufacturing, development and other activities related to the research, development, manufacturing, discovery and commercialization of therapeutic products or technologies, and processes, systems, methods or services thereof for its own account or in order to make such products or services available for the account of their third-party partners (including joint venture partners) or collaborators (including such therapeutic products, processes or technologies in which we or one of our affiliates has an economic interest or any relationship with any third-party or that are created, developed, manufactured or sold by a joint venture, partnership or collaboration between us or any of our affiliates and a third-party (individually and collectively, “Permitted Business”).

The Korean Subsidiary

The Korean Subsidiary has a particular focus on developing innovative cell therapies. Together, with promising in-house research programs, the technologies are currently under development for the rapidly growing Korean market offering a favorable environment for the cell therapy industry. Through close collaboration with leading medical and academic facilities, the Korean Subsidiary is accelerating the development of foreign technologies in Korea. In connection with the Masthercell Sale, for a period of three years in the European Union and five years in the United States and the rest of the world from the closing date of the Masthercell Sale, we agreed that the Korean Subsidiary will not manufacture cell and gene products on a contract basis for third-party customers in any jurisdiction other than South Korea, but it may conduct CDMO business in South Korea, solely for customers located within South Korea and with respect to therapies intended for distribution solely within South Korea, provided that the Korean Subsidiary may conduct Permitted Business.

Koligo

Koligo maintains commercial production facilities for KYSLECEL at an FDA-registered establishment in Indiana. Koligo is also developing new technologies such as bio-degradable 3D structure to deliver islets & other cell/tissue.

The Tissue Genesis Icellators, and associated reagents and kits, are made by contract manufacturers and warehoused at our facility in Texas. The Tissue Genesis Icellator is used to isolate stromal and vascular fraction cells (“SVF”) from a patient’s own (autologous) adipose tissue (fat). The SVF obtained from the Icellator is for use in cell-assisted lipotransfer, and other indication such as orthopedic and COVID-19-induced ARDS. Koligo also maintains development labs at its Indiana and Texas locations to support continued development.

The Belgian Subsidiary

The Belgian subsidiary specializes in developing and validating proprietary and licensed advanced cell and gene therapies such as the Muscle-derived Mesenchymal Stem Cells therapy for the treatment of SUI. The subsidiary benefits both from its central position in Europe and its being in the leading Walloon biotech cluster. Located near Namur, at Novalis Science Park, the Belgian subsidiary collaborates with leading medical and academic facilities which enables it to cover the drug product life cycle from research to clinical stage through pre-clinical and quality control. It occupies innovative facilities for the development and quality control of therapies in R&D and GMP grades.

Its talented and highly experienced staff and collaborators, including Ph.D. holders, quality assurance experts and biotechnology manufacturing engineers, contribute to the POCare platform development and roll-out. The subsidiary supports quality assurance and supply activities for the global POCare network.

Notable 2021 Activities

In 2021, we have focused on setting up our regional POCare activities. This included the setup of POCare Centers that oversee regional development and GMP services, local OMPUL deployment and supply of products to the local clinical centers. We are in the process of setting up POCare Centers in Maryland, Boston, California, Belgium, Greece, Slovenia, Israel, Italy, Spain and Korea. Future set-up plans include potential sites in the U.S. and EU where we already have initial activity such as in Germany and Texas, as well as in Australia and China.

As part of our POCare Services, we have developed the relevant GMP processes for a variety of therapies such as CAR-T, TILs, NK and MSC based therapies. We have developed OMPULs with the required systems for production of CAR-T, TILs and MSC products, and are working on several other therapies intended for clinical testing.

We have worked closely with technology partners to adapt various systems for closed system production of the above products and continue our collaboration efforts to develop fully automated systems for integration in the OMPULs.

We expanded our collaboration with UC Davis and have completed the first production batch of GMP grade lentivirus to be utilized for clinical grade production of CAR-Ts. We have expanded our partnership with Johns Hopkins University and are setting up a GMP facility with the support of a grant from Maryland. We are providing products to several hospitals in the U.S., are working closely with leading hospitals in Spain and Italy and are working closely with clinicians from hospitals in Israel, where we have deployed our OMPULs to set up additional clinical sites where we can provide POCare Services for our customers and partners. Based on the requests of our customers and partners, we have expanded our POCare Services to include CRO services.

We have collaborated closely with our Greek partner, Theracell, and have set up a partnership in Greece focusing on delivering advanced therapies to Greek hospitals. The Greek government has granted our Greek joint venture entity a “fast track” status and a supportive financial grant.

Our POCare Services are expanding to additional geographies, and we are providing services to the U.S., EU, and Asia.

Revenue Model, Business Development and Licenses

The Orgenesis Point of Care (POCare) Platform is comprised of three enabling components: a multitude of licensed cell based POCare Therapeutics to be produced in closed, automated POCare Technology systems across a collaborative POCare Network. Our therapies include, but are not limited to, autologous, cell-based immunotherapies, therapeutics for metabolic diseases, anti-viral diseases, and tissue regeneration. We are establishing and positioning the business to bring point-of-care therapies to patients in a scalable way working directly with hospitals and through regional JV partners and JVs active in autologous cell therapy product development, including facilities in various countries in North America, Europe, Asia, the Middle East, and Australia. The POCare Platform’s goal is to enable a rapid, globally harmonized pathway for these therapies to reach large numbers of patients at lowered costs through efficient, and decentralized production. The POCare Network brings together industry partners, research institutes and hospitals worldwide to achieve harmonized, regulated clinical development and production of the therapies.

We are focused on technology in licensing and therapeutic collaborations, and we out license therapies marketing rights and manufacturing rights to partners and/or to the JVs. In many cases, the JVs are responsible for the preparation of clinical trials, local regulatory approvals and regional marketing activities. Such licensing includes exclusive or nonexclusive, sublicensable, royalty bearing rights and license to the Orgenesis Background IP as required to manufacture, distribute and market and sell Orgenesis products within the relevant territories. In consideration of the rights and the licenses so granted, we receive a royalty in the range of ten percent of the net sales generated by the JV Entity and/or its sublicensees (as applicable) with respect to the Orgenesis products.

In addition, in many cases, once the JV entities become profitable, we are entitled (in addition to any of its rights as holder of the JV Entity and prior to any other distributions of dividends by the JV Entity to shareholders of the JV Entity) and in addition to any royalties to which we may be entitled pursuant to a Orgenesis License Agreement, to receive from the JV entity royalties at a range of 10 to 15 percent of the JV entity's audited US GAAP profit after tax.

Further to revenues generated from out licenses we generate revenues from POCare Services and sales which is comprised of:

- R&D services provided to out-licensing partners

We have signed POCare Master Services Agreements ("MSAs") with our JV partners. In terms of the MSAs, we provide certain broadly defined development services that relate to our licensed therapies designed to develop or enhance the therapy with the objective of preparing it for clinical use. Such services, per therapy, include regulatory services, pre-clinical studies, intellectual property services, development services, and GMP process translation. We also provide support services to our customers.

- Hospital supply

Hospital services includes the sale or lease of products and the performance of processing services to our POCare hospitals or other medical providers. We either work directly with hospitals or receive payments through our regional JV partnerships.

- Cell process development revenue

We provide cell process development services in some regions to third party customers. Those services are unique to the customers who retain the ownership of the intellectual property created through the process.

Our POCare therapy revenue is as follows:

Revenue stream:	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
POC and hospital services (Mainly POC)	$ 32,819	$ 6,068
Cell process development services	2,683	1,584
Total	$ 35,502	$ 7,652

Cost of Services and other Research and Development Expenses, net

We incurred $ 36,644and $83,986 thousand in cost of services and other research and development expenses, net in the fiscal years ended December 31, 2021 and December 31, 2020, respectively, of which $196 thousand was covered by grant funding in the fiscal year ended December 31, 2020. Part of the expense was funded by share issues. Our research and development scope was expanded to the evaluation and development of new cell therapies related technologies in the field of immuno-oncology, liver pathologies and tissue regeneration.

Competition in the Cell Therapy Field

The biopharmaceutical industry is intensely competitive. There is continuous demand for innovation and speed, and as the cell-based therapies market evolves, there is always the risk that a competitor may be able to develop other compounds or drugs that are able to achieve similar or better results for indications. Potential competition includes major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of these competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations with established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Currently, we are not aware of any other companies pursuing a business model similar to what we are developing under our POCare Platform. However, our competitors in the CGT field who are significantly larger and better capitalized than us could undertake strategies similar to what we are pursuing and even develop them at a much more rapid rate. These potential competitors include the same multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions that are operating in the CGT field. In that respect, smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Intellectual Property

We will be able to protect our technology and products from unauthorized use by third parties only to the extent it is covered by valid and enforceable claims of our patents or is effectively maintained as trade secrets. Patents and other proprietary rights are thus an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

In addition, we own or have exclusive rights to thirty-two (32) United States patents, fifty-seven (57) foreign-issued patents, twenty-six (26) pending patent applications in the United States, fifty-four (54) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, and South Korea, and six (6) international Patent Cooperation Treaty (“PCT”) patent applications. These patents and patent applications relate, among others, to (1) dendritic cell based (whole cell) vaccines, and their use for treating cancer and viral diseases; (2) compositions comprising Ranpirnase and other ribonucleases and their use for treating viral diseases; (3) tumor infiltrating lymphocytes (TILs) and their use for treating cancer; (4) compositions comprising immune cells, ribonucleases, or antibodies for treating COVID-19; (5) therapeutic compositions comprising exosomes, bioxomes, and redoxomes; (6) bioreactors for cell culture automated devices for supporting cell therapies and point-of-care systems; (7) chimeric antigen receptors (CARs); (8) adoptive immunotherapy using neurotransmitters; (9) Mobile Processing Units; (10) Axial Stem Cells; (11) Cell-delivery devices; (12) scaffolds, including alginate and sulfated alginate scaffolds, and bioconjugates comprising sulfated polysaccharides and diverse bioactive peptides, and uses thereof; and (13) skin diseases treatment and anti-aging compositions.

We have a granted U.S. patent, a pending U.S. patent application and pending U.S. provisional patent applications directed, among others, to dendritic cell-based (whole cell) vaccines, and their use for treating cancer and viral diseases. If issued, any patents based on these applications will expire between 2037 and 2043. The granted U.S. patent will expire in 2037.

We have pending U.S. patent applications directed, among others, to compositions comprising Ranpirnase and other ribonucleases for the treatment of viral diseases. If issued, any patents based on these applications will expire between 2031 and 2040. Counterpart patents applications were filed in Australia, Canada, China, Europe, Hong Kong, Japan, Israel, Mexico, New Zealand, South Korea, Russian Federation, Singapore, and South Africa. If issued, any patents based on these applications will expire between 2035 and 2041. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

We have pending U.S. patent applications directed, among others, to therapeutic compositions comprising exosomes, bioxomes, and redoxomes. If issued, any patents based on these applications will expire between 2029 and 2041. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, India, Israel, Japan and South Korea. If issued, any patents based on these applications will expire in 2039. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending International PCT application, pending U.S. patent applications, and pending U.S. provisional patent applications directed, among others, to bioreactors for cell culture, automated devices for supporting cell therapies, and point-of-care systems. If issued, any patents based on these applications will expire between 2035 and 2042.

We have pending U.S. provisional patent applications directed, among others, to tumor infiltrating lymphocytes (TILs) and their use for treating cancer. If converted into non-provisional applications and issued, any patents based on these applications will expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have pending International PCT applications directed, among others, to compositions comprising immune cells, ribonucleases, or antibodies for treating COVID-19. If converted into national phase applications and issued, any patents based on these applications will expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending U.S. provisional patent application and a pending U.S. patent application directed, among others, to chimeric antigen receptors (CARs), and their use for treating malignancies. If issued, any patents based on these applications would expire between 2041 and 2043, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a granted patent and a pending U.S. patent application directed, among others, to adoptive immunotherapy using neurotransmitters. If issued, any patent based on this application would expire in 2039. Counterpart patent applications were filed in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, Russian Federation, Singapore, and South Korea. If issued, any patents based on these applications would expire in 2039. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations. The granted U.S. patent will expire in 2024.

We have a pending U.S. provisional patent application directed, among others, to mobile processing laboratories configured for performing there within a cell therapy process. If converted into non-provisional applications and issued, any patents based on these applications would expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending International PCT application directed, among others, to Axial Stem Cells, their preparation, and uses in treatment or diagnostics of neurodegenerative diseases, bone or cartilage disorders, muscle disorders, and in regenerative treatment of tissues or organs. If converted into national phase applications and issued, any patents based on these applications would expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

Granted U.S. patents, which are directed among others to scaffolds, including alginate and sulfated alginate scaffolds, and to bioconjugates comprising sulfated polysaccharides and diverse bioactive peptides, allowing sustained release of the bioactive polypeptides and their uses will expire between 2025 and 2036. Counterpart patent applications and patents granted in Australia, France, Germany, Israel, Switzerland, and the United Kingdom, will expire between 2026 and 2035.

We have a pending U.S. provisional patent application directed, among others, to a composition comprising topiramate and bioxome, redoxome, HA, extracellular vesicles (EV), or PRP extracellular vesicles and its use for the treatment of a dermatological condition. If converted into national phase applications and issued, any patents based on these applications would expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have pending U.S. provisional patent applications directed, among others, to the use of a combination of natural products, such as anti-aging, anti-photoaging or anti-inflammatory combination. If converted into national phase applications and issued, any patents based on these applications would expire in 2042 and 2043, without including any patent term extensions that might be available following the grant of marketing authorizations.

Orgenesis Ltd, has exclusive rights to eight (8) United States patents, twenty-four (24) foreign-issued patents, two (2) pending patent applications in the United States, and eleven (11) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Panama, Singapore, and South Korea. These patents and patent applications relate, among others, to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis. Granted U.S. patents, which are directed to trans-differentiation to pancreatic β-cell-like phenotype and function cells and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis, will expire between 2024 and 2035. Counterpart patents granted in Australia, France, Germany, Israel, Switzerland, and the United Kingdom, will expire between 2024 and 2035.

Orgenesis Ltd, has pending U.S. patent applications directed, among others, to the trans-differentiation of cells, to cells having pancreatic β-cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis. If issued, any patents based on these applications will expire between 2038 and 2040. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, Japan, Israel, Mexico, Panama, Singapore, and South Korea. If issued, any patents based on these applications will expire between 2034 and 2039. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

Government Regulation

Development Business

We are required to comply with the regulatory requirements of various local, state, national and international regulatory bodies having jurisdiction in the countries or localities where we manufacture products, where our OMPULs are established or where we plan to supply products. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with GMPs, labeling and distribution, import and export, facility registration or licensing, and product registration and listing. As a result, our facilities are subject to regulation in Israel and South Korea. We are also required to comply with environmental, health and safety laws and regulations, as discussed below. These regulatory requirements impact many aspects of our operations, including manufacturing, developing, labeling, packaging, storage, distribution, import and export and record keeping related to customers' products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve facilities for manufacturing products or products for commercialization.

Our and our customers' products must undergo pre-clinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities that have jurisdiction in the countries in which our and our customers' products are intended to be marketed may delay or put on hold clinical trials, delay approval of a product or determine that the product is not approvable. The regulatory agencies can delay approval of a drug if our manufacturing facilities or OMPULs are not able to demonstrate compliance with cGTPs, pass other aspects of pre-approval inspections (i.e., compliance with filed submissions) or properly scale up to produce commercial supplies. The government authorities having jurisdiction in the countries in which our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product is deemed adulterated or misbranded. In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards or pay additional fees. This may require a change in our manufacturing techniques or additional capital investments in our facilities.

Certain products manufactured by us involve the use, storage and transportation of toxic and hazardous materials. Our operations are subject to extensive laws and regulations relating to the storage, handling, emission, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We maintain environmental and industrial safety and health compliance programs and training at our facilities.

Prevailing legislation tends to hold companies primarily responsible for the proper disposal of their waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, health and safety laws and regulations, and enforcement policies, could result in substantial costs and liabilities to us and could subject the handling, manufacture, use, reuse or disposal of substances or pollutants at our facilities to more rigorous scrutiny than at present.

Our development operations involve the controlled use of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our contract manufacturing operations, which could materially harm our business, financial condition and results of operations.

The costs associated with complying with the various applicable local, state, national and international regulations could be significant and the failure to comply with such legal requirements could have an adverse effect on our results of operations and financial condition. See “Risk Factors — Risks Related to Development and Regulatory Approval of Our Therapies and Product Candidates — Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.” for additional discussion of the costs associated with complying with the various regulations.

POCare Therapies Portfolio

Our therapeutic portfolio pipeline is diverse and addresses various unmet clinical needs. It is predominantly comprised of personalized autologous cell therapies, implying that patients receive cells that originate from their own body, virtually eliminating the risk of an immune response and rejection and thus easing various regulatory hurdles. In addition, by leveraging Orgenesis’ vast experience and proven track record in developing and optimizing cell processing, these selective therapies are adapted to be produced in closed, automated systems, reducing the need for high grade cleanroom environments. The systems enable each stage of the manufacturing process (cell sorting, expansion, genetic modifications, quality control) to be optimized in order to substantially reduce the cost burden for patients and making the therapies widely accessible. Notably, our therapeutic pipeline is developed by researchers from our network and are subsequently out-licensed and validated in multi-center clinical trials conducted across point of care partner sites leveraging the robustness of the Orgenesis network. Once approved these therapies are distributed to leading medical institutions globally within our network and thus granting the inventors a royalty-based commercialization horizon.

Regulatory Process in the United States

Our potential product candidates are subject to regulation as a biological product under the Public Health Service Act and the Food, Drug and Cosmetic Act. The FDA generally requires the following steps for pre-market approval or licensure of a new biological product:

- Pre-clinical laboratory and animal tests conducted in compliance with Good Laboratory Practice, or GLP, requirements to assess a drug’s biological activity and to identify potential safety problems, and to characterize and document the product’s chemistry, manufacturing controls, formulation, and stability;
- Submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before clinical testing in humans can start;
- Obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce biologic drug candidates into humans in clinical trials;
- Conducting adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with Good Clinical Practice, or GCP, requirements;
- Compliance with current GMP regulations and standards;
- Submission to the FDA of a Biologics License Application (“BLA”) for marketing that includes adequate results of pre-clinical testing and clinical trials;
- The FDA reviews the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses; and
- Obtaining FDA approval of the BLA, including inspection and approval of the product manufacturing facility as compliant with GMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent. The FDA may also require post marketing testing and surveillance of approved products or place other conditions on the approvals.

Regulatory Process in Europe

In the European Union ("EU") somatic cell and gene therapy products are called Advanced Therapy Medicinal Product (ATMPs). Since January 2022 the Clinical Trial Regulation (EU) 536/2014 regulates the application of medicinal products including ATMPs to humans immediately effective in all member states. In conjunction with Regulation 536/2014 the EU commission has released two delegated acts regulating manufacturing of investigational as well as marketed AMPs. For products that are regulated as an ATMP, the EU Regulation requires:

- Compliance with current GMP regulations and standards, as described in the delegated acts
- Filing a Clinical Trial Application ("CTA")
- in EU member states and EEA countries according to regulation 536/2014 via CTIS (Clinical Trial Information System) allowing a harmonized approval process among all member states (including multinational clinical trials)
- Obtaining approval by ethic committees responsible for medical institutions;
- Adequate and well-controlled clinical trials according to GCP standards protecting the well-being of a study participant and establishing the safety and efficacy of the product for its intended use;
- Centralized submission procedure for ATMPs via EMA for Marketing Authorization ("MA"); and
- Review and approval of the MAA ("Marketing Authorization Application").

As in the U.S., prior to the general regulatory process of a new biologic products, we will prosecute an Orphan Drug Designation for treatment of patients with Established "Diabetes Mellitus" ("DM") Induced by Total pancreatectomy. In the EU, in order to be qualified, the prevalence must be below 5 per 10,000 of the EU population, except where the expected return on investment is insufficient to justify the investment.

Authorized orphan medicines benefit from 10 years of protection from market competition with similar medicines with similar indications once they are approved. Companies applying for designated orphan medicines pay reduced fees for regulatory activities. This includes reduced fees for protocol assistance, marketing-authorization applications, inspections before authorization, applications for changes to marketing authorizations made after approval, and reduced annual fees.

Exemption from the centralized procedure was introduced into the ATMP Regulation to allow marketing of certain ATMPs in individual EU member states. The so-called "hospital exemption" can only be applied for custom-made ATMPs used in a hospital setting for a specific patient by a treating physician. In addition, a competent authority must authorize hospital exemption for ATMPs. Hospital exemption products must comply with the same national requirements concerning quality, traceability and pharmacovigilance that apply to authorized medicinal products. The "hospital exemption" has to be applied for individually in each EU member state according to national procedures and control measures.

Clinical Trials

Typically, both in the U.S. and the EU, clinical testing involves a three-phase process, although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers or patients and are designed to provide information about product safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. Phase III clinical trials are generally large-scale, multi-center, comparative trials conducted with patients afflicted with a target disease in order to provide statistically valid proof of efficacy, as well as safety and potency. In some circumstances, the FDA or EMA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, as well as clinical trial investigators. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Monitoring all aspects of the study to minimize risks is a continuing process. All adverse events must be reported to the FDA or EMA.

The FDA has granted Orphan Drug designation for our AIP cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from TP due to chronic pancreatitis. The FDA's Orphan Drug Designation Program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the United States. Orphan designation qualifies the sponsor of the drug for various development incentives, including eligibility for seven years of market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and other potential assistance in the drug development process.

Employees

As of December 31, 2021, we had an aggregate of 151 employees working at our company and subsidiaries. In addition, we retain the services of outside consultants for various functions including clinical work, finance, accounting and business development services. Most of our senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees are covered by collective bargaining agreements. We believe that we have good relations with our employees.

Corporate and Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are available free of charge though our website (*http://www.orgenesis.com*) as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (the "SEC"). Except as otherwise stated in these documents, the information contained on our website or available by hyperlink from our website is not incorporated by reference into this report or any other documents we file, with or furnish to, the SEC.

Our common stock is listed and traded on the Nasdaq Capital Market under the symbol "ORGS."

As used in this Annual Report on Form 10-K and unless otherwise indicated, the term "Company" refers to Orgenesis Inc. and its Subsidiaries. Unless otherwise specified, all amounts are expressed in United States Dollars.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- Our POC business has a limited operating history and an unproven business model and faces significant challenges as the cell therapy industry is rapidly evolving. Our prospects may be considered speculative and any failure to execute our business strategy could adversely impact our business.

- Our research and development efforts on novel technology using cell-based therapy and our future success is highly dependent on the successful development of that technology.

- We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

- Our success will depend on strategic collaborations with third parties to develop and commercialize therapeutic product candidates, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.

- Our business is affected by the ongoing COVID-19 pandemic and may be significantly adversely affected as the pandemic continues or if other events out of our control disrupt our business or that of our third party partners.

- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

- Our success depends on our ability to develop and roll out our OMPULs.

- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

- We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks.

- There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

- Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities.

- Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

- We currently have no marketing and sales organization and have no experience in marketing therapeutic products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

- There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

- We face significant competition from other biotechnology and pharmaceutical companies, many of which have substantially greater financial, technical and other resources, and our operating results will suffer if we fail to compete effectively.

- We are highly dependent on key personnel who would be difficult to replace, and our business plans will likely be harmed if we lose their services or cannot hire additional qualified personnel.

- Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

- Third parties to whom we may license or transfer development and commercialization rights for products covered by intellectual property rights may not be successful in their efforts and, as a result, we may not receive future royalty or other milestone payments relating to those products or rights.

Risk Factors

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our company and its business before purchasing shares of our company's common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. You could lose all or part of your investment due to any of these risks.

Risks Related to Our Company and POC Business

Our POC business has a limited operating history and an unproven business model and faces significant challenges as the cell therapy industry is rapidly evolving. Our prospects may be considered speculative and any failure to execute our business strategy could adversely impact our operations and the price of our common stock.

Our POC business has a limited operating history and an unproven business model. Our plans to continue to grow our POC cell therapy business and to further the development of ATMPs are subject to significant challenges. Although we have sufficient capital resources for the next 12 months and the foreseeable future, we may not be able to implement our POC business or commence clinical trials or respond to competitive pressures due to other non-financial factors beyond our control. Our failure to effectively execute our business strategy could adversely affect our ability to successfully grow our POC business and develop cell therapy product candidates, which could cause the value of your investment in our common stock to decline.

We are not profitable as of December 31, 2021, have limited cash flow and, unless we increase revenues and take advantage of any commercial opportunities that arise to expand our POC business, the perceived value of our company may decrease and our stock price could be affected accordingly.

For the fiscal year ended December 31, 2021 and as of the date of this report, we assessed our financial condition and concluded that we have sufficient resources for the next 12 months from the date of this report. Our auditor's report for the year ended December 31, 2021 does not include a going concern opinion on the matter. However, management is unable to predict if and when we will be able to generate significant revenues or achieve profitability. Our plan regarding these matters is to continue improving the net results in our POC business into fiscal year 2022. There can be no assurance that we will be successful in increasing revenues, improving our POC results or that the perceived value of our company will increase. In the event that we are unable to generate significant revenues in our POC business, our stock price could be adversely affected.

Our research and 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 cell therapy technology creates significant challenges with respect to product development and optimization, manufacturing, government regulation and approval, third-party reimbursement and market acceptance. For example, the FDA and EMA have relatively limited experience with the development and regulation of cell therapy products and, therefore, the pathway to marketing approval for our cell therapy product candidates may accordingly be more complex, lengthy and uncertain than for a more conventional product candidate. The indications of use for which we choose to pursue development may have clinical effectiveness endpoints that have not previously been reviewed or validated by the FDA or EMA, which may complicate or delay our effort to ultimately obtain FDA or EMA approval. Because this is a new approach to treating diseases, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA, EMA and other regulatory authorities that have very limited experience with the commercial development of our technology for treating different diseases;
- developing and deploying consistent and reliable processes for removing the cells from the patient engineering cells ex vivo and infusing the engineered cells back into the patient;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our products;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our products;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and
- maintaining a system of post marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process.

Our efforts to overcome these challenges may not prove successful, and any product candidate we seek to develop may not be successfully developed or commercialized.

Kyslecel may not achieve patient or market acceptance, which could have a material adverse effect on our business.

Our commercialization strategy for Kyslecel relies on medical specialists, medical facilities and patients adopting TP-IAT with Kyslecel as an accepted treatment for chronic pancreatitis. However, medical specialists are historically slow to adopt new treatments, regardless of perceived merits, when older treatments continue to be supported by established providers. Overcoming such resistance often requires significant marketing expenditure or definitive product performance and/or pricing superiority. The cost of allocating resources for such requirements might severely impact the potential for profitability of Kyslecel.

There is no guarantee that physician or patient acceptance of TP-IAT with Kyslecel will be substantial. Further, there is no guarantee that Koligo will be able to achieve patient acceptance or obtain enough customers (clinical providers) to meet its sales objectives. If we do not meet our sales objectives, our business prospects and financial performance will be materially and adversely affected.

Further, we are partially reliant on published clinical trials and scientific research conducted by third parties to justify the patient benefit and safety of TP-IAT with Kyslecel and, as such, we rely, in part, on the accuracy and integrity of those third-parties to have reported the results and correctly collected and interpreted the data from all clinical trials conducted to date. If published data turn out to later be incorrect or incomplete, our business prospects and financial performance may be materially and adversely affected.

The therapeutic efficacy of Ranpirnase and our other product candidates is unproven in humans, and we may not be able to successfully develop and commercialize Ranpirnase or any of our other product candidates.

Ranpirnase and our other product candidates are novel compounds and their potential benefit as antiviral drugs or immunotherapies is unproven. Ranpirnase and our other product candidates may not prove to be effective against the indications for which they are being designed to act and may not demonstrate in clinical trials any or all of the pharmacological effects that have been observed in preclinical studies. As a result, our clinical trial results may not be indicative of the results of future clinical trials.

Ranpirnase and our other product candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If Ranpirnase or any of our other product candidates is associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon the development of such product candidate or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Because of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop or commercialize Ranpirnase or any of our other product candidates, in which case our business will be harmed.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2021, we had 151 employees. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. This lack of long-term experience working together may adversely impact our senior management team's ability to effectively manage our business and growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

We may require additional capital to support our business, and this capital may not be available on acceptable terms or at all.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges and to grow our POC cell therapy business and to further the development of ATMPs. Accordingly, we may need to engage in equity or debt financings to secure additional funds.

Capital and credit market conditions, adverse events affecting our business or industry, the tightening of lending standards, rising interest rates, negative actions by regulatory authorities or rating agencies, or other factors also could negatively impact our ability to obtain future financing on terms acceptable to us or at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to support our business growth and respond to business challenges could be significantly limited. In addition, the terms of any additional equity or debt issuances may adversely affect the value and price of our common stock, our results of operations, financial condition and cash flows.

If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any financing secured by us in the future could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions.

In addition, on February 24, 2022, Russia launched a large-scale invasion of Ukraine. The conflict may adversely impact macroeconomic conditions and increase volatility in and affect our ability to access capital markets and external financing sources on acceptable terms or at all.

Our operations may be adversely affected by ongoing developments in the Ukraine and Russia.

The Company has signed agreements with a company whose principal place of business is in Russia that include collaboration in point of care development in Russia, as well as the development and commercialization of potential key technologies for the Company's clinical development and manufacturing projects. The United States, EU, UK, Canada and Japan have imposed sanctions against and export controls involving Russia, and other potential retaliatory measures could be taken by the United States and other countries. At this time, we cannot predict the outcome of developments in Russian and the Ukraine on these agreements.

Currency exchange fluctuations may impact the results of our operations.

The results of our operations are affected by fluctuations in currency exchange rates in both sourcing and selling locations. Our results of operations may still be impacted by foreign currency exchange rates, primarily, the euro-to-U.S. dollar exchange rate. In recent years, the euro-to-U.S. dollar exchange rate has been subject to substantial volatility which may continue, particularly in light of recent political events regarding the European Union, or EU. Because we do not hedge against all of our foreign currency exposure, our business will continue to be susceptible to foreign currency fluctuations.

We have entered into collaborations and joint ventures and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have entered into collaborations and joint ventures and may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners for which the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;

- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them and, in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. The success of our existing and future collaboration arrangements and strategic partnerships, which include research and development services by our collaborators to improve our intellectual property, will depend heavily on the efforts and activities of our collaborators and may not be successful. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Our success will depend on strategic collaborations with third parties to develop and commercialize therapeutic product candidates, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.

A key aspect of our strategy is to seek collaborations with partners, such as a large pharmaceutical organization, that are willing to further develop and commercialize a selected product candidate. To date, we have entered into a number of collaborative arrangements with cell therapy organizations. By entering into any such strategic collaborations, we may rely on our partner for financial resources and for development, regulatory and commercialization expertise. Our partner may fail to develop or effectively commercialize our product candidate because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture or obtain the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into additional collaborations on acceptable terms, if at all. We face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support. If we are not successful in attracting a partner and entering into a collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

Our business is affected by the ongoing COVID-19 pandemic and may be significantly adversely affected as the pandemic continues or if other events out of our control disrupt our business or that of our third party partners.

While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results. We have experienced and may in the future experience disruptions from COVID-19 to our business in a number of ways, including:

- Delays in supply chain and manufacturing, including the suspension of cell transport, limitations on transfer of technology, shutdown of manufacturing facilities and delays in delivery of supplies and reagents;

- Delays in discovery and preclinical efforts;

- Changes to procedures or shut down, or reduction in capacity, of clinical trial sites due to limited availability of clinical trial staff, reduced number of inpatient intensive care unit beds for patients receiving cell therapies, diversion of healthcare resources away from clinical trials and other business considerations;

- Limited patient access, enrollment and participation due to travel restrictions and safety concerns, as well as housing and travel difficulties for out of town patients and relatives; and

- Changes in regulatory and other requirements for conducting preclinical studies and clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance on conducting clinical trials during the pandemic, which was updated in July 2020, January 2021 and August 2021. The guidance describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report (or as a separate document) contingency measures implemented to manage the trial and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic-related trial disruptions by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or trial, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial. In its most recent update to this guidance, the FDA addressed questions received from clinical practitioners who are adapting their operations in a pandemic environment. These questions focused on, among other things, when to suspend, continue or initiate a trial and how to submit changes to protocols for INDs and handle remote site monitoring visits. There is no assurance that this guidance governing clinical trials during the pandemic will remain in effect or, even if it does, that it will help address the risks and challenges enumerated above.

Other potential impacts of the COVID-19 pandemic on our ongoing clinical trials include patient dosing and trial monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trial, interruption or delays in the operations of the FDA, or other reasons related to the COVID-19 pandemic.

If the COVID-19 pandemic continues, other aspects of our ongoing clinical trial and future planned clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, clinical trial site data monitoring and efficacy, safety and translational data collection, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our trials or we may have to pause enrollment or we may choose to or be required to pause enrollment and/or patient dosing in our ongoing or planned clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue. Patients may need to withdraw due to COVID-19 infections or experience increased adverse events and deaths in our clinical trials due to COVID-19 related infections, which may result in increased complications due to immune suppression in some of the patients being treated.

In addition, we currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials, ship investigation drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. If any such third party in our supply chain for materials is adversely impacted by effects from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted and our costs could be increased, limiting our ability to manufacture our product candidates for our clinical trials and planned future clinical trials and conduct our research and development operations as planned.

We previously closed our offices and requested that most of our personnel, including all of our administrative employees, work remotely, restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in any given research and development laboratory. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. Further, we and our third-party service providers, the clinical trial sites, our manufacturers and suppliers, may experience staffing shortages.

Our employees and contractors conducting research and development activities may not be able to access our laboratory for an extended period of time as a result of the closure of our offices and the possibility that governmental authorities further modify current restrictions. In addition, when our facilities are open, we could encounter delays in connection with implementing precautionary measures to mitigate the risk of exposing our facilities and employees to COVID-19 or otherwise in connection with addressing an actual or potential exposure to COVID-19 (for example, temporarily closing all or a portion of a facility or disinfecting all or a portion of a facility that may have been exposed to COVID-19). As a result, this could delay timely completion of preclinical activities, including completing IND/Clinical Trial Application (CTA)-enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for our other development programs.
Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA or foreign health authorities may have slower response times or be under-resourced to continue to monitor our ongoing clinical trial and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trial or delay in regulatory review resulting from such disruptions could materially affect the development of our product candidates.

The trading prices for shares of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the COVID-19 could materially and adversely affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve. The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, additional or modified government actions, and the actions taken to contain COVID-19 or address its impact, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

In addition, our business could be significantly adversely affected by other business disruptions to us or our third party partners or collaborators that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our partners and collaborators, contract manufacturing organizations (CMOs) and other contractors, consultants, and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredients are generally considered to offer the strongest protection of intellectual property and provide the broadest scope of patent protection for pharmaceutical products, as such patents provide protection without regard to any method of use or any method of manufacturing. While we have issued patents in the United States we cannot be certain that the claims in our issued patent will not be found invalid or unenforceable if challenged.

We cannot be certain that the claims in our issued United States methods of use patents will not be found invalid or unenforceable if challenged.

We cannot be certain that the pending applications covering among others the bioconjugates comprising sulfated polysaccharides; Ranpirnase and other ribonucleases for treating viral diseases; therapeutic compositions comprising exosomes, bioxomes, and redoxomes; bioreactors for cell culture, automated devices for supporting cell therapies, and point-of-care systems; immune cells, ribonucleases, or antibodies for treating COVID-19; or chimeric antigen receptors (CARs); will be considered patentable by the United States Patent and Trademark Office (USPTO), and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Even if our patent applications covering these inventions issue as patents, the patents protect specific products and may not be enforced against competitors making and marketing a product that has the same activity. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. These types of patents may not be enforced against competitors making and marketing a product that provides the same activity but is used for a method not included in the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating its trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of 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, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party’s intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when products are approved by the FDA, that certain third party may then seek to enforce its patents by filing a patent infringement lawsuit against us or our licensee(s). In such lawsuit, we or our licensees may incur substantial expenses defending our rights or our licensees rights to commercialize such product candidates, and in connection with such lawsuit and under certain circumstances, it is possible that we or our licensees could be required to cease or delay the commercialization of a product candidate and/or be required to pay monetary damages or other amounts, including royalties on the sales of such products. Moreover, any such lawsuit may also consume substantial time and resources of our management team and board of directors. The threat or consequences of such a lawsuit may also result in royalty and other monetary obligations being imposed on us, which may adversely affect our results of operations and financial condition.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. 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 and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. 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. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Because most of our products have not reached commercial stage, we do not currently need to carry clinical trial or extensive product liability insurance. In the future, our inability to obtain additional sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Such insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage.

It may be difficult to enforce a U.S. judgment against us, our officers and directors and the foreign persons named in this Annual Report on Form 10-K in the United States or in foreign countries, or to assert U.S. securities laws claims in foreign countries or serve process on our officers and directors and these experts.

While we are incorporated in the State of Nevada, currently a majority of our directors and executive officers are not residents of the United States, and the foreign persons named in this Annual Report on Form 10-K are located outside of the United States. The majority of our assets are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or foreign court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in foreign countries in which we operate. Foreign courts may refuse to hear a claim based on a violation of U.S. securities laws on the grounds that foreign countries are not necessary the most appropriate forum in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that foreign law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by foreign countries law. There is little binding case law in foreign countries addressing the matters described above.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information, including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, for example, effective May 25, 2018, the GDPR replaced the prior EU Data Protection Directive (95/46) that governed the processing of personal data in the European Union. The GDPR imposes significant obligations on controllers and processors of personal data, including, as compared to the prior directive, higher standards for obtaining consent from individuals to process their personal data, more robust notification requirements to individuals about the processing of their personal data, a strengthened individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data and increased requirements pertaining to health data, and strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes additional obligations on, and required contractual provisions to be included in, contracts between companies subject to the GDPR and their third-party processors that relate to the processing of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

Adoption of the GDPR increased our responsibility and liability in relation to personal data that we process and may require us to put in place additional mechanisms to ensure compliance. Any failure to comply with the requirements of GDPR and applicable national data protection laws of EU member states, could lead to regulatory enforcement actions and significant administrative and/or financial penalties against us (fines of up to Euro 20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher), and could adversely affect our business, financial condition, cash flows and results of operations.

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit confidential information, and it is critical that we do so in a secure manner in order to maintain the confidentiality and integrity of such confidential information. Our information technology systems are potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners, vendors, or from attacks by malicious third parties. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful access or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination or misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material effect on our business, financial position, results of operations and/or cash flow.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

A variety of risks associated with operating our business internationally could materially adversely affect our business. We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries, unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, and terrorism or disease outbreaks (such as the recent outbreak of COVID-19, or the novel coronavirus).

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we are unable to integrate acquired businesses effectively, our operating results may be adversely affected.

From time to time, we seek to expand our business through acquisitions. We may not be able to successfully integrate acquired businesses and, where desired, their product portfolios into ours, and therefore we may not be able to realize the intended benefits. If we fail to successfully integrate acquisitions or product portfolios, or if they fail to perform as we anticipate, our existing businesses and our revenue and operating results could be adversely affected. If the due diligence of the operations of acquired businesses performed by us and by third parties on our behalf is inadequate or flawed, or if we later discover unforeseen financial or business liabilities, acquired businesses and their assets may not perform as expected. Additionally, acquisitions could result in difficulties assimilating acquired operations and, where deemed desirable, transitioning overlapping products into a single product line and the diversion of capital and management's attention away from other business issues and opportunities. The failure to integrate acquired businesses effectively may adversely impact our business, results of operations or financial condition.

Risks Related to Our OMPULs

We may not be able to operate our OMPULs in all cities or desired locations and the sizes and use of our laboratories in such OMPULs may be restricted due to zoning, environmental, medical waste, or other licensing regulations.

We may be subject to local zoning ordinances or other similar restrictions that may limit where the OMPULs can be located and the extent of their size and use. In addition, international, federal, state and local environmental and other administrative and licensing regulations could restrict the ability of the OMPULs to connect with local power, water, sewer, and other infrastructure. Our success depends on our ability to develop and roll out our OMPULs which may become more difficult or more expensive by such applicable regulations. Changes in any of these regulations could require us to close or move our OMPULs which would affect our ability to conduct and grow our business.

If our existing OMPULs facilities become damaged or inoperable or if we are required to vacate our existing facilities, our ability to perform our tests and pursue our research and development efforts may be jeopardized.

We currently perform a majority of tests relating to our POCare services out of our OMPULs. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for us to operate for some period of time. In addition, since there is no lengthy history of use of OMPULs and the OMPULs are still in the development stage, we are unable to predict the normal wear and tear on such OMPULs or how many years each OMPUL will remain operational.

The inability to perform our tests or to reduce the backlog that could develop if our facilities are inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation. Furthermore, our OMPUL facilities and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facilities, or to locate and qualify new facilities.

We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facility and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

Changes in the price and availability of our raw materials could be detrimental to our OMPUL operations.

Supply chain issues, including limited supply of certain raw material or supply interruptions, delays or shortages of material may disrupt our daily operations as the OMPULs may be unable to retain an inventory of materials required to maintain operations or to build or repair OMPULs.

We are dependent on skilled human capital for our OMPULs.

Our ability to innovate and execute is dependent on the ability to hire, replace, and train skilled personnel. The employment market suffers from shortage of candidates that may continue in future years and cause delays and inabilities to execute our plans. Additionally, based on current trends in the US labor market, there could be a shortage of available trained staff for the OMPULs in the United States. Staff retention could also be a significant operational issue.

If we are unable to successfully secure our locations and premises, we may be unable to operate out of our OMPULs or keep our employees and laboratory equipment safe.

In certain cities and urban markets, homelessness, rising crime rates and decreased police funding, could impact the security of the OMPULs and the safety of employees and patients. If we are unable to successfully secure our OMPULs, our research and development could be negatively impacted.

Our OMPULs are operated in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition, and harm our business.

The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct our OMPUL business include, without limitation:

- federal and state laws governing laboratory testing, including CLIA, and state licensing laws;
- federal and state laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including laboratory developed tests, or LDTs;
- federal, state and local laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations; and
- European Union GMP approvals, which may be delayed because of the use OMPULs which could then delay manufacturing for clinical trials.

Risks Related to Our Trans-Differentiation Technologies for Diabetes and the THM License Agreement

THM is entitled to cancel the THM License Agreement.

Pursuant to the terms of the THM License Agreement with THM, Orgenesis Ltd, the Israeli Subsidiary, must develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the development plan. In the event the Israeli Subsidiary fails to fulfill the terms of the development plan under the THM License Agreement, THM shall be entitled to terminate the THM License Agreement by providing the Israeli Subsidiary with written notice of such a breach and if the Israeli Subsidiary does not cure such breach within one year of receiving the notice. THM may also terminate the THM License Agreement if the Israeli Subsidiary breaches an obligation contained in the THM License Agreement and does not cure it within 180 days of receiving notice of the breach. We also run the risk that THM may attempt cancel or, at the very least challenge, the License Agreement with Orgenesis Ltd. as we continue to expand our focus to other therapies and business activities. We believe that our expanded focus to such other therapies and business activities may continue to prompt THM to inquire of such activities as they may relate to our compliance with the terms or direction of resources toward the THM License Agreement. While we have not received any notice of cancellation of the THM License Agreement, we have received an allegation regarding the scope of the rights by THM that may present future challenges for our Israeli Subsidiary to continue to develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the development plan of the THM License Agreement. In addition, THM has filed a complaint against us in the Tel Aviv District Court relating to the scope of such THM license and the royalties and other payments that THM is entitled to thereunder. See “Legal Proceedings” in this Annual Report on Form 10-K. Such complaint may lead to further risk of cancellation of the THM License Agreement.

Orgenesis Ltd. licensed a technology that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and differentiating (converting) them into “pancreatic beta cell-like” insulin-producing cells for patients with diabetes. Our intention is to develop our technology to the clinical stage for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using therapeutic agents that efficiently convert a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his/her own therapeutic tissue and to start producing his/her own insulin in a glucose-responsive manner, thereby eliminating the need for insulin injections. Because this is a new approach to treating diabetes, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval regulatory authorities that have very limited experience with the commercial development of the trans-differentiating technology for diabetes;
- developing and deploying consistent and reliable processes for engineering a patient’s liver cells ex vivo and infusing the engineered cells back into the patient;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our products;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our products;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and
- maintaining a system of post marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process.

Risks Related to Development and Regulatory Approval of Our Therapies and Product Candidates

Research and development of biopharmaceutical products is inherently risky.

We may not be successful in our efforts to use and enhance our technology platform to create a pipeline of product candidates and develop commercially successful products. Furthermore, we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates will require substantial additional funding and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;

- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payers, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies are subject to extensive, complex, costly and evolving government regulation. For the U.S., this is principally administered by the FDA and to a lesser extent by the Drug Enforcement Administration ("DEA") and state government agencies, as well as by varying regulatory agencies in foreign countries where products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations, and similar foreign statutes and regulations, govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our future products. Under these regulations, we may become subject to periodic inspection of our facilities, procedures and operations and/or the testing of our future products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with current GMP and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or warning letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a warning letter is issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We may also be required to report adverse events associated with our future products to FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in labeling changes, recalls, market withdrawals or other regulatory actions.

The range of possible sanctions includes, among others, FDA issuance of adverse publicity, product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition and cash flows. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. If internal compliance programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business.

The European Medicines Agency ("EMA") will regulate our future products in Europe. Regulatory approval by the EMA will be subject to the evaluation of data relating to the quality, efficacy and safety of our future products for its proposed use. The time taken to obtain regulatory approval varies between countries. Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators.

Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

Further trials and other costly and time-consuming assessments of the product may be required to obtain or maintain regulatory approval. Medicinal products are generally subject to lengthy and rigorous pre-clinical and clinical trials and other extensive, costly and time-consuming procedures mandated by regulatory authorities. We may be required to conduct additional trials beyond those currently planned, which could require significant time and expense. In addition, even after the technology approval, both in the U.S. and Europe, we will be required to maintain post marketing surveillance of potential adverse and risk assessment programs to identify adverse events that did not appear during the clinical studies and drug approval process. All of the foregoing could require an investment of significant time and expense.

We have generated limited revenue from therapeutic product sales, and our ability to generate any significant revenue from product sales and become profitable depends significantly on our success in a number of factors.

We have a limited number of therapeutic products approved for commercial sale, and we have generated only limited revenue from product sales. Our ability to generate revenue of more significant scale and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if more of the product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

When we commence any clinical trials, we may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. We cannot be sure that we will be able to submit an IND, and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- the inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in establishing CMC (Chemistry, Manufacturing, and Controls) which is a cornerstone in clinical study submission and later on, the regulatory approval;
- the FDA not allowing us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical studies;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment;
- a result of a new safety finding that presents unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical study operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly;
- if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure to perform in accordance with the FDA's current good clinical practices, or cGCPs, requirements, or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of preclinical and clinical studies may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or our third-party manufacturers' facilities with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Further, failure to obtain approval for any of the above reasons may be made more likely by the fact that the FDA and other regulatory authorities have very limited experience with commercial development of our cell therapy for the treatment of Type 1 Diabetes.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

As with most biological drug products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Any of these occurrences may materially and adversely harm our business, financial condition and prospects.

Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities.

If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Our product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of liver cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, failures in process testing and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity and tractability of all reagents and viruses involved in the process with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Although we are working to develop commercially viable processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our subsidiaries and joint ventures will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents and viruses, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, viruses, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

There can be no assurance that we will be able to further develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

A variety of risks associated with operating our business internationally could materially adversely affect our business. We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries, unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry, and the rapidly evolving market for developing cell-based therapies is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our senior management, particularly our Chief Executive Officer, Vered Caplan. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, most these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of all of these individuals or the lives of any of our other employees.

Risks Related to our Common Stock

If we issue additional shares in the future, it will result in the dilution of our existing stockholders.

Our articles of incorporation authorizes the issuance of up to 145,833,334 shares of our common stock with a par value of $0.0001 per share. Our Board of Directors may choose to issue some or all of such shares to acquire one or more companies or products and to fund our overhead and general operating requirements. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change of control of our company.

Our stock price and trading volume may be volatile, which could result in losses for our stockholders.

The equity trading markets have recently experienced high volatility resulting in highly variable and unpredictable pricing of equity securities. If the turmoil in the equity trading markets continues, the market for our common stock could change in ways that may not be related to our business, our industry or our operating performance and financial condition. In addition, the trading volume in our common stock may fluctuate and cause significant price variations to occur. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include:

- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any;
- announcements relating to our business;
- conditions generally affecting the biotechnology industry;
- the success of our operating strategy; and
- the operating and stock performance of other comparable companies.

Many of these factors are beyond our control, and we cannot predict their potential effects on the price of our common stock. In addition, the stock market is subject to extreme price and volume fluctuations. During the past 52 weeks ended December 31, 2021, our stock price has fluctuated from a low of $2.61 to a high of $8.08. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

No assurance can be provided that a purchaser of our common stock will be able to resell their shares of common stock at or above the price that they acquired those shares. We can provide no assurances that the market price of common stock will increase or that the market price of common stock will not fluctuate or decline significantly.

We do not intend to pay dividends on any investment in the shares of stock of our company.

We have never paid any cash dividends, and currently do not intend to pay any dividends for the foreseeable future. The Board of Directors has not directed the payment of any dividends and does not anticipate paying dividends on the shares for the foreseeable future and intends to retain any future earnings to the extent necessary to develop and expand our business. Payment of cash dividends, if any, will depend, among other factors, on our earnings, capital requirements, and the general operating and financial condition, and will be subject to legal limitations on the payment of dividends out of paid-in capital. Because we do not intend to declare dividends, any gain on an investment in our company will need to come through an increase in the stock's price. This may never happen, and investors may lose all of their investment in our company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We do not own any real property. A description of the leased premises we utilize in several of our facilities is as follows:

Entity	Property Description
Orgenesis Inc.	• Our principal office is located at 20271 Goldenrod Lane, Germantown, MD 20876.
Orgenesis Maryland Inc.	• FastForward laboratory and office located at 1812 Ashland Ave, Baltimore, Maryland 21205.
Orgenesis Korea	• Operational production laboratory and office area located at Gwanggyo business centre 156, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea.
Koligo Therapeutics Inc.	• Production facility and development labs in New Albany, Indiana and medical device maintenance and development labs in Leander, Texas.
Orgenesis Biotech Israel	• Laboratories and offices located in the Bar Lev Industrial Park M.P. MISGAV, Israel.
Orgenesis Belgium	• Laboratories and offices located near Namur, at Novalis Science Park, Belgium

We believe that our facilities are generally in good condition and suitable to carry on our business. We also believe that, if required, suitable alternative or additional space will be available to us on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On January 18, 2022, a complaint (the "Complaint") was filed in the Tel Aviv District Court (the "Court") against us and our subsidiary Orgenesis Ltd., Prof. Sarah Ferber, Vered Caplan and Dr. Efrat Asa Kunik (collectively, the "defendants") by plaintiffs the State of Israel, as the owner of Chaim Sheba Medical Center at Tel HaShomer ("Sheba"), and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (collectively, the "plaintiffs"). In the Complaint, the plaintiffs are seeking that the Court issue a declaratory remedy whereby the defendants are required to pay royalties to the plaintiffs at the rate of 7% of the sales and 24% of any and all revenues in consideration for sublicenses related to any product, service or process that contain know-how and technology of Sheba and any and all know-how and technology either developed or supervised by Prof. Ferber in the field of cell therapy, including in the category of the point-of-care platform and any and all services and products in relation to the defendants' CDMO activity. In addition, the plaintiffs seek that the defendants provide financial statements and pay NIS 10 million to the plaintiffs due to the royalty provisions of the license agreement, dated February 2, 2012, between Orgenesis Ltd. and Tel Hashomer

Medical Research, Infrastructure and Services Ltd. (the "License Agreement"). The Complaint alleges that Orgenesis Inc. and Orgenesis Ltd. used know-how and technology of Sheba and know-how and technology either developed or supervised by Prof. Ferber while employed by Sheba in the field of cell therapy, including in the category of the point-of-care platform and the services and products in relation to the defendants' CDMO activity and are entitled to the payment of certain royalties pursuant to the terms of the License Agreement. The defendants are required to file their statement of defense responding to this Complaint by March 20, 2022. We believe that the allegations in this Complaint are without merit and intend to vigorously defend against the claims.

Except as described above, we are not involved in any pending material legal proceedings.

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

Market Information

Until March 13, 2018, our common shares were traded under OTC Market Group's OTCQB. Since March 13, 2018, our common stock has been listed for trading on the Nasdaq Capital Market ("Nasdaq CM") under the symbol "ORGS."

As of March 30, 2022, there were 185 holders of record of our common stock, and the last reported sale price of our common stock on the Nasdaq CM on March 29, 2022 was $3.35. A significant number of shares of our common stock are held in either nominee name or street name brokerage accounts, and consequently, we are unable to determine the total number of beneficial owners of our common stock.

Dividend Policy

To date, we have paid no dividends on our common stock and do not expect to pay cash dividends in the foreseeable future. We plan to retain all earnings to provide funds for the operations of our company. In the future, our Board of Directors will decide whether to declare and pay dividends based upon our earnings, financial condition, capital requirements, and other factors that our Board of Directors may consider relevant. We are not under any contractual restriction as to present or future ability to pay dividends.

Unregistered Sales of Equity Securities

On December 31, 2021, we issued 25,000 shares of common stock to a service provider. We relied upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Act") by virtue of Section 4(a)(2) thereof and/or Regulation S promulgated by the SEC under the Act with respect to the issuance of such shares in exchange for service provided to us.

Issuer Purchases of Equity Securities

On May 14, 2020, our Board of Directors approved the stock repurchase plan (the "Stock Repurchase Plan") pursuant to which we may, from time to time, purchase up to $10 million of our outstanding shares of common stock. The shares may be repurchased from time to time in privately negotiated transactions or the open market, including pursuant to Rule 10b5-1 trading plans, and in accordance with applicable regulations of the SEC. The timing and exact amount of any repurchases will depend on various factors including, general and business market conditions, corporate and regulatory requirements, share price, alternative investment opportunities and other factors. The Repurchase Plan commenced on May 29, 2020 and does not obligate us to acquire any specific number of shares in any period, and may be expanded, extended, modified, suspended or discontinued by the Board of Directors at any time.

The following table summarizes the share repurchase activity during the three months ended December 31, 2021.

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Value that May Yet Be Purchased Under the Plans or Programs
				(in thousands)
November 2021	24,477	4.32	105,806	8,734

ITEM 6. [RESERVED]

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the fiscal years ended December 31, 2021 and December 31, 2020 and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2021, as compared to the fiscal year ended December 31, 2020.

This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2021 and December 31, 2020 and related notes included elsewhere in this Annual Report on Form 10-K. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains numerous forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

See below for a discussion on the extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition.

Corporate Overview

Orgenesis Inc., a Nevada corporation, is a global biotech company working to unlock the potential of cell and gene therapies ("CGTs") in an affordable and accessible format.

CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products ("ATMP"). We are mostly focused on autologous therapies, with processes and systems that are developed for each therapy using a closed and automated processing system approach that is validated for compliant production near the patient for treatment of the patient at the point of care ("POCare"). This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients (ultimately limiting the number of patients that can have access to, or can afford, these therapies).

To achieve these goals, we have developed a Point of Care Platform ("POCare Platform") comprised of three enabling components: (i) a pipeline of licensed POCare advanced therapies that are designed to be processed and produced, (ii) automated closed POCare technology systems, and (iii) a collaborative worldwide network of POCare research institutes and hospitals ("POCare Network").

The POCare Platform relies in particular on the development of its own production capacity, known as "POCare Services", whose goal is to ensure that therapies are accessible at the point of treatment (the "POCare Center"). POCare Services, which have been expanding worldwide, are based on a global approach and local adaptation that allows replication and expansion. Global harmonization of the POCare Services is ensured by a central quality system, replicability of infrastructure and equipment and centralized monitoring and data management.

POCare Centers are the decentralised hubs that provide harmonized services to customers and partners. We are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. The workflow of a POCare Center is designed to allow rapid capacities expansion while integrating new technologies. We also draw on extensive medical expertise to identify promising new autologous therapies to leverage within the POCare Platform either via ownership or licensing.

The POCare Network brings together patients, doctors and industry partners with a goal of achieving harmonized, regulated clinical development and production of POCare advanced therapies.

We have worked to develop and validate POCare technologies that can be combined within mobile production units for advanced therapies. We have made significant investments in the development of several types of Orgenesis Mobile Processing Units and Labs ("OMPULs") with the expectation of use and/or distribution through our POCare Network and/or partners, collaborators, and regional distributors. As of the date of this report, the OMPULs have been adapted for processing of CAR-T, TILS and MSC based products and are in the qualification stage for clinical use in various locations. Additional OMPULs are still in the development stage.

OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved advanced therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The OMPUL design delivers a potential industrial solution for us to deliver CGTs to practically any clinical institution at the point of care.

The Chief Executive Officer is our chief operating decision-maker who reviews financial information prepared on a consolidated basis. All of our operations are in one segment, being the point-of-care business via our POCare Platform. Therefore, no segment information has been presented.

POCare Platform Operations via Subsidiaries

We currently conduct our core business operations ourselves and through our subsidiaries which are all wholly owned except as otherwise stated below (collectively, the "Subsidiaries"). The Subsidiaries are listed in this annual report in Item 8.

Discontinued Operations

Until December 31, 2019, we operated the POCare Platform as one of two business separate business segments.

The second separate business segment was operated as a Contract Development and Manufacturing Organization ("CDMO") platform, providing third party contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). The CDMO platform was historically operated mainly through majority owned Masthercell Global Inc.

In February 2020, we and GPP-II Masthercell LLC ("GPP") sold 100% of the outstanding equity interests of Masthercell (the "Masthercell Business"), which comprised the majority of our CDMO Business, to Catalent Pharma Solutions, Inc. for an aggregate nominal purchase price of $315 million, subject to customary adjustments (the "Masthercell Sale").

We determined that the Masthercell Business ("Discontinued Operations" or "Discontinued Operation") meets the criteria to be classified as a discontinued operation as of the first quarter of 2020. The Discontinued Operation includes the vast majority of the previous CDMO Business, including majority owned Masthercell, including MaSTherCell, Masthercell U.S. and all of the Masthercell Global Subsidiaries.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic continues to present substantial public health and economic challenges around the world, and to date has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures.

We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken steps to minimize the current environment's impact on our business and strategy, including devising contingency plans and securing additional resources from third party service providers. For the safety of our employees and families, we have introduced enhanced safety measures in our facilities.

Beyond the impact on our product development efforts, the extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain COVID-19 or treat its impact, including vaccination campaigns, among others. If we or any of the third parties with whom we engage, however, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, financial condition and results of operations. Although to date, our business has not been materially impacted by COVID-19, it is possible that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. See "Risk Factors" for additional discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

Developments During Fiscal 2021

License, Collaboration and Joint Venture Agreements

During 2021, we executed several license, collaboration and joint venture agreements, the most significant of which are summarized below. For a more complete description, see notes 11 and 12 to our consolidated financial statements included in Item 8 of this annual report on Form 10-K.

Description	Field / Territory
Neuro-immunotherapy exclusive license agreement	Neuro-immunotherapy.
Savicell Collaboration Agreement	Evaluation, continued development, validation, and use of Savicell's platform designed for the early detection and diagnosis of diseases and conditions and for quality control and monitoring purposes, in conjunction with our systems.
Stromatis Pharma Inc. Collaboration and Sublicense Agreement	Collaboration in refining methods for GMP manufacturing of CAR-T/CAR-NK CT109 and the development and validation of the Stromatis technology as it relates to the CAR-T/CAR-NK CT109 antibody up to and inclusive of filing of Investigational New Drug Application relating to Stromatis' CAR-T/CAR-NK CT109 antibody.
Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH) Exclusive License	Exclusive license to us in the field of human stem cells.
Celleska LTD Joint Venture Agreement	POCare in Australia.
Johns Hopkins University Sublease and Construction Agreement	Establishment of a clinical therapeutic development and point of care center in Maryland.
Deep Med IO Ltd Joint Venture Agreement	Development and commercialization of an AI-powered system to be used in the manufacturing and/or quality control of CGTs.

Theracell Laboratories Grant

In November 2021, Theracell Laboratories ("Theracell"), our joint venture entity in Greece, was designated as a "Priority Investment of Strategic National Importance" by Enterprise Greece, the official Greek national investment and trade promotion agency, which is responsible for the allocation of Greek government funding. As a result of this designation, Theracell will be inducted into Greece's fast-track licensing and approval process. This is expected to help advance development and clinical use of Theracell's CGT at POCare, subject to regulatory requirements.

Theracell has been approved to receive a grant of up to €32 million from the Greek government subject to compliance with budgetary conditions, spread over five years. The proceeds are expected to be used for:

- Installation of OMPULs throughout Greece (Point of Care Mode), which includes the completion of industrial research for the operation and automation of OMPULs intended for mass production of cell and gene therapies and experimental development of novel therapies through clinical trials towards regulatory approval.
- Clinical development, production and distribution of novel cell and gene therapies such as immunological therapies, CAR-T genetic modification therapies and Mesenchymal Stem Cells (MSCs) based therapies.

Revacel Joint Venture

During 2021, we, together with our joint venture partner, Revitas SA, incorporated our joint venture entity Revacel Srl in Belgium. Revacel will develop products in the field of muscle-derived mesenchymal stem/progenitor cells.

Results of Operations

Comparison of the Year Ended December 31, 2021 to the Year Ended December 31, 2020.

Our financial results for the year ended December 31, 2021 are summarized as follows in comparison to the year ended December 31, 2020:

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Revenues	$ 31,646	$ 6,177
Revenues from related party	3,856	1,475
Total revenues	35,502	7,652
Cost of services and other research and development expenses, net	36,644	83,986
Amortization of intangible assets	948	478
Selling, general and administrative expenses	14,710	18,973
Operating loss	16,800	95,785
Other income	(2,278)	(4)
Loss from extinguishment in connection with convertible loan (see note 7 a of Item 8)	1,865	-
Financial expense, net	1,292	1,061
Share in income of associated company	272	(106)
Loss from continuing operation before income taxes	17,951	96,736
Tax (income) expense	108	(1,609)
Net loss from continuing operation	18,059	95,127
Net income from discontinued operations, net of tax	-	(95,706)
Net loss (income)	$ 18,059	$ (579)

Revenues

The following table shows our revenues by major revenue streams:

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Revenue stream:		
POC and hospital services (Mainly POC)	$ 32,819	$ 6,068
Cell process development services	2,683	1,584
Total	$ 35,502	$ 7,652

Our revenues for the year ended December 31, 2021 were $35,502 thousand, as compared to $7,652 thousand for the year ended December 31, 2020, representing an increase of 364%. The increase in revenues for the year ended December 31, 2021 compared to the year ended December 31, 2020 was attributable to the increase in point-of-care services revenue as a result of increased activity under master service agreements with our customers.

POC services are mainly the result of agreements between us and our joint venture partners (See note 11 in Item 8). Pursuant to the agreements, we provide certain services in support of our joint venture partners' activity.

Of such $32,819 thousand of revenue during the year ended December 31, 2021, we recognized $3,856 thousand of point-of-care development service revenue from a related party as compared to $1,475 thousand during the year ended December 31, 2020, representing an increase of 161%. The increase is attributable to expanded activities and additional services provided in the territory.

A breakdown of the revenues per customer that constituted at least 10% of revenues is as follows:

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Revenue earned:		
Customer A (Korea)	$ 7,703	$ 2,857
Customer B (United Arab Emirates)	6,969	-
Customer C (China)	6,491	1,577
Customer D (India) – related party	3,856	1,475
Customer E (Greece)	4,693	1,412

Cost of services and other research and development expenses

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Salaries and related expenses	$ 10,977	$ 5,175
Stock-based compensation	729	481
Subcontracting, professional and consulting services	12,796	3,463
Lab expenses	3,513	2,348
Tamir Purchase Agreement (See Note 4)	-	19,225
Depreciation expenses, net	874	603
Other research and development expenses	7,755	52,887
Less – grant	-	(196)
Total	$ 36,644	$ 83,986

Cost of services and other research and development expenses for the year ended December 31, 2021 were $36,644 thousand, as compared to $83,986 thousand for the year ended December 31, 2020, representing a decrease of 56%.

The changes contributing to the net decrease were mainly attributable to the following:

- We experienced a significant decrease (in the amount of $45.3 million) in other research and development expenses during 2021. In 2020, we made significant investments in the development of several types of OMPULs, accounted for in other research and development expenses, with the expectation of use and/or distribution through our POCare Network of partners, collaborators, and joint ventures. The majority of our OMPUL development work was completed in 2021 and we expect that such OMPULs will be placed into service during 2022.

- Salaries and related expenses increased by $5,802 thousand, as a result of additional staff hired to continue the development of our CGT product pipeline as we expand our POC operations globally. We continue to invest in the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work with partners that address POCare needs.

- We experienced an increase in subcontracting, professional and consulting services of $9,333 thousand. As indicated above, we continue to invest in the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work with partners that address POCare needs.

Selling, General and Administrative Expenses

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Salaries and related expenses	$ 6,277	$ 3,379
Stock-based compensation	945	1,915
Accounting and legal fees	3,293	6,946
Professional fees	1,107	1,571
Rent and related expenses	249	407
Business development	577	3,477
Depreciation expenses, net	42	101
Other general and administrative expenses	2,220	1,177
Total	$ 14,710	$ 18,973

Selling, general and administrative expenses for the year ended December 31, 2021 were $14,710 thousand, as compared to $18,973 thousand for the year ended December 31, 2020, representing a decrease of 22%. The decrease for the year ended December 31, 2021 is primarily attributable to:

- A decrease in accounting and legal fees as a result of decreased corporate investment activities in 2021 compared to 2020; and

- A decrease in business development of $2,900 thousand as a result of reduced business development expenditures in 2021

Such decreases were countered by an increase in salaries and related expenses of $2,898 thousand, mainly as a result of a discretionary bonus to our Chief Executive Officer, Vered Caplan, in the amount of $3.6 million pursuant to the discretionary bonus provisions of the Personal Employment Agreement between Ms. Caplan and Orgenesis Services Sàrl

Financial Expenses, net

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Interest expense on convertible loans and loans	943	1,254
Foreign exchange loss, net	574	160
Other income	(225)	(353)
Total	$ 1,292	$ 1,061

Financial expenses, net for the year ended December 31, 2021 were $1,292 thousand, as compared to $1,061 thousand for the year ended December 31, 2020, representing an increase of 22%.

Tax expense (income)

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Tax expense (income)	$ 108	$ (1,609)
Total	$ 108	$ (1,609)

Tax expenses (income), net for the year ended December 31, 2021 were $108 thousand, as compared to $1,609 thousand for the year ended December 31, 2020, representing an increase of 107%. The increase for the year ended December 31, 2021 is primarily attributable due to the release of a tax asset up to the amount of Koligo's net tax liability in the year ended December 31, 2020.

Discontinued Operations

Discontinued operations relate to the Masthercell Business. The following table presents the financial results associated with the Masthercell Business operation as reflected in our Consolidated Comprehensive loss:

OPERATIONS	Year Ended December 31,
	2020
	(in thousands)
Revenues	$ 2,556
Cost of revenues	1,482
Cost of services and other research and development expenses, net	7
Amortization of intangible assets	137
Selling, general and administrative expenses	1,896
Operating loss	966
Other expenses, net	305
Financial income, net	(29)
Loss before income taxes	1,242
Tax income	(30)
Net loss from discontinuing operation, net of tax	$ 1,212

Revenues are attributable to the extension of existing customer service contracts with biotechnology clients and from revenues generated from existing manufacturing agreements. Cost of revenues were in line with the growth in revenues and employment of additional operational staff. Selling, general and administrative expenses included additional managerial appointments, increased professional fees, additional rental space including in the U.S., and an increase of business development expenses.

Working Capital

	December 31,	
	2021	2020
	(in thousands)	
Current assets	$ 25,758	$ 50,077
Current liabilities	$ 15,365	$ 16,285
Working capital	$ 10,393	$ 33,792

Current assets decreased by $24,319 thousand between December 31, 2020 and December 31, 2021, which was primarily attributable to a decrease in cash and cash equivalents as the we continued to invest in the expansion of our POC operations globally and in the development of our CGT product pipeline and development of automated processing units and processes, and owned and licensed advanced therapies to enable commercial production; and an increase in accounts receivable as a result of increased POC revenues.

Current liabilities decreased by $920 thousand between December 31, 2020 and December 31, 2021, which was primarily attributable to the following: (i) an decrease in accounts payable and accrued expenses due to the reduction of certain expenses; and (ii) an increase in current maturities of convertible loans.

Liquidity and Capital Resources

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Net loss	$ (18,059)	$ 579
Net cash used in operating activities	(26,866)	(78,046)
Net cash provided by (used in) investing activities	(12,384)	105,610
Net cash provided by (used in) financing activities	(106)	5,881
Net change in cash and cash equivalents and restricted cash	$ (39,356)	$ 33,445

During year ended December 31, 2021, we funded our operations from existing funds.

Net cash used in operating activities for the year ended December 31, 2021 was approximately $27 million, as compared to net cash used in operating activities of approximately $78 million for the year ended December 31, 2020. Since the Masthercell Sale, and particularly in the year ended December 31, 2020, we entered into new joint venture agreements with new partners in various jurisdictions that allowed us to grow our infrastructure and expand our processing sites into new markets and jurisdictions. In addition, we engaged some of these joint venture partners to perform research and development services to further develop and adapt our systems and devices for specific purposes. We invested manpower and financial resources to focus on developing, manufacturing and rolling out several types of OMPULs to be used and/or distributed through our POCare Network of partners, collaborators, and joint ventures.

Net cash used in investing activities for the year ended December 31, 2021 was approximately $12 million, as compared to net cash provided by investing activities of approximately $106 million for the year ended December 31, 2020. The net cash provided in the year ended December 31, 2020 was mainly attributable to the Masthercell Sale.

Liquidity and Capital Resources Outlook

Through December 31, 2021, the Company had an accumulated deficit of $106.4 million as of December 31, 2021 and negative operating cashflows of $26.9 million in the year ended December 31, 2021. The Company’s activities have been funded by generating revenue, through offerings of the Company’s securities and selling its Contract Development and Manufacturing Organization (“CDMO”) business. There is no assurance that the Company’s business will generate sustainable positive cash flows to fund its business. See also note 21 with respect to an investment agreement in the amount of approximately $14.8 million (before deducting related offering expenses), which has been entered into subsequent to December 31, 2021.

Based on its current cash resources and commitments, including such investment agreement discussed in note 21, the Company believes it will be able to maintain its current planned development activities and expected level of expenditures for at least 12 months from the date of the issuance of these financial statements, although no assurance can be given that it will not need additional funds prior to such time.

If there are further increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, the Company will need to use mitigating actions as to seek additional financing or postpone expenses that are not based on firm commitments. In addition, in order to fund the Company's operations until such time that the Company can generate sustainable positive cash flows, the Company may need to raise additional funds.

In December 2018, we entered into a Controlled Equity Offering Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock having an aggregate offering price of up to $25.0 million. We will pay Cantor a commission rate equal to 3.0% of the aggregate gross proceeds from each sale. Shares sold under the Sales Agreement will be offered and sold pursuant to our Shelf Registration Statement on Form S-3 (Registration No. 333-223777) that was declared effective by the Securities and Exchange Commission on March 28, 2018, or the Shelf Registration Statement, and a prospectus supplement and accompanying base prospectus that we filed with the Securities and Exchange Commission on December 20, 2018. We have not yet sold any shares of our common stock pursuant to the Sales Agreement.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in the notes to our financial statements included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2021. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Income Taxes

Deferred income tax assets and liabilities are computed for differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

In addition, our management performs an evaluation of all uncertain income tax positions taken or expected to be taken in the course of preparing our income tax returns to determine whether the income tax positions meet a “more likely than not” standard of being sustained under examination by the applicable taxing authorities. This evaluation is required to be performed for all open tax years, as defined by the various statutes of limitations, for federal and state purposes.

Revenue from Contracts with Customers

Our agreements are primarily service contracts that range in duration. We recognize revenue when control of these services is transferred to the customer for an amount, referred to as the transaction price, which reflects the consideration to which we are expected to be entitled in exchange for those goods or services.

A contract with a customer exists only when:

- the parties to the contract have approved it and are committed to perform their respective obligations;
- we can identify each party’s rights regarding the distinct goods or services to be transferred (“performance obligations”);
- we can determine the transaction price for the goods or services to be transferred; and
- the contract has commercial substance and it is probable that we will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Nature of Revenue Streams

We have two main revenue streams being POC development services which includes hospital supplies, and cell process development services.

POC Development Services

Revenue recognized under contracts for POC development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages are not interrelated or the customer is able to complete the services performed.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices.

We recognize revenue when, or as, it satisfies a performance obligation. At contract inception, we determine whether the services are transferred over time or at a point in time. Performance obligations that have no alternative use and that we have the right to payment for performance completed to date, at all times during the contract term, are recognized over time. All other Performance obligations are recognized as revenues by us at point of time (upon completion).

Included in POC development services is hospital supplies revenue which is derived principally from the sale or lease of products and the performance of services to hospitals or other medical providers. Revenue is earned and recognized when product and services are received by the customer.

Significant Judgement and Estimates

Significant judgment is required to identifying the distinct performance obligations and estimating the standalone selling price of each distinct performance obligation, and identifying which performance obligations create assets with alternative use to us, which results in revenue recognized upon completion, and which performance obligations are transferred to the customer over time.

Cell Process Development Services

Revenue recognized under contracts for cell process development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages and milestones are not interrelated or the customer is able to complete the services performed independently or by using our competitors. In other contracts when the above circumstances are not met, the promises are not considered distinct and the contract represents one performance obligation. All performance obligations are satisfied over time, as there is no alternative use to the services it performs, since, in nature, those services are unique to the customer, which retain the ownership of the intellectual property created through the process.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices. For these contracts, the standalone selling prices are based on our normal pricing practices when sold separately with consideration of market conditions and other factors, including customer demographics and geographic location.

We measure the revenue to be recognized over time on a contract by contract basis, determining the use of either a cost-based input method or output method, depending on whichever best depicts the transfer of control over the life of the performance obligation.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by Item 8 is included following the “Index to Financial Statements” on page F-1 contained in this Annual Report on Form 10-K.

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act and regulations promulgated thereunder) as of December 31, 2021, or the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

Management’s Report on Internal Control over Financial Reporting

Our management, under the supervision of the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company’s assets that could have a material effect on the financial statements.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this evaluation, our management used the criteria set forth in the Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021 based on those criteria.

This annual report does not include an attestation report of our registered public accounting firm on internal control over financial reporting because we are a smaller reporting company and non-accelerated filer.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our each of our current Directors and Executive Officers as of March 30, 2022.

Name	Age	Position
Vered Caplan	53	Chief Executive Officer and Chairperson of the Board of Directors
Neil Reithinger	52	Chief Financial Officer, Secretary and Treasurer
Efrat Assa Kunik	47	Chief Development Officer
David Sidransky (1) (2) (4)	61	Director
Guy Yachin (1) (2) (3) (4)	54	Director
Yaron Adler (2) (3)	51	Director
Ashish Nanda (3)	56	Director
Mario Philips (1)	52	Director

(1) A member on the audit committee.
(2) A member on the compensation committee.
(3) A member on the nominating and corporate governance committee.
(4) A member of the research and development committee.

Our Executive Officers

Vered Caplan – Chief Executive Officer and Chairperson of the Board of Directors

Ms. Caplan has served as our CEO and Chairperson of the Board of Directors since August 14, 2014, prior to which she served as Interim President and CEO commencing on December 23, 2013. She joined our Board of Directors in February 2012. She has 26 years of industry experience, previously holding positions as CEO of Kamedis Ltd. from 2009 to 2014, CEO of GammaCan International Inc. from 2004 to 2007. She also served as a director of the following companies: Opticul Ltd., Inmotion Ltd., Nehora Photonics Ltd., Ocure Ltd., Eve Medical Ltd., and Biotech Investment Corp. Ms. Caplan holds a M.Sc. in biomedical engineering from Tel Aviv University specializing in signal processing; management for engineers from Tel Aviv University specializing in business development; and a B.Sc. in mechanical engineering from the Technion– Israel Institute of Technology specialized in software and cad systems.

Neil Reithinger – Chief Financial Officer, Secretary and Treasurer

Mr. Reithinger was appointed Chief Financial Officer, Secretary and Treasurer on August 1, 2014. Mr. Reithinger is the Founder and President of Eventus Advisory Group, LLC, a private, CFO-services firm incorporated in Delaware, which specializes in capital advisory and SEC compliance for publicly-traded and emerging growth companies. He is also the President of Eventus Consulting, P.C. Prior to forming Eventus, Mr. Reithinger was Chief Operating Officer & CFO from March 2009 to December 2009 of New Leaf Brands, Inc., a branded beverage company, CEO of Nutritional Specialties, Inc. from April 2007 to October 2009, a nationally distributed nutritional supplement company that was acquired by Nutraceutical International, Inc., Chairman, CEO, President and director of Baywood International, Inc. from January 1998 to March 2009, a publicly-traded nutraceutical company and Controller of Baywood International, Inc. from December 1994 to January 1998. Mr. Reithinger earned a B.S. in Accounting from the University of Arizona and is a Certified Public Accountant. He is a Member of the American Institute of Certified Public Accountants and the Arizona Society of Certified Public Accountants.

Efrat Assa-Kunik – Chief Development Officer

Dr. Assa-Kunik was appointed as our Chief Development Officer in December 2021. Dr. Assa-Kunik joined the Company in September 2016 as Head of Pre-Clinical Development. In August 2017, she was appointed General Manager of the Israeli subsidiary. Dr Assa-Kunik earned her PhD at the Weizmann Institute of Science in the fields of genetics and developmental biology and a Masters from the Ben-Gurion University in immunology and cancer research. Additionally, Dr Assa-Kunik was a postdoctoral fellow at the Weizmann Institute in the department of neural biology. After completing her postdoc, Dr. Assa-Kunik joined BioGenCell as a Senior Scientist. In 2012, she joined Pharmaseed as the director of the Business Development Unit, VP business development and manager of the business development activity in USA.

Our Directors

Dr. David Sidransky – Director

Dr. Sidransky has served as a director since his appointment on July 18, 2013. Dr. Sidransky is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine's Department of Otolaryngology and Professor of Oncology, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at the John Hopkins University School of Medicine. Dr. Sidransky is one of the most highly cited researchers in clinical and medical journals in the world in the field of oncology during the past decade, with over 600 peer reviewed publications. Dr. Sidransky is a founder of a number of biotechnology companies and holds numerous biotechnology patents. Dr. Sidransky has served as Vice Chairman of the board of directors, and was, until the merger with Eli Lilly, a director of ImClone Systems, Inc., a global biopharmaceutical company committed to advancing oncology care. He is currently on the board of Directors of Ascentage Pharma, Galmed and Champions Oncology. and chairs the board of directors of Advaxis and Ayala. Dr. Sidransky served as Director from 2005 until 2008 of the American Association for Cancer Research (AACR). He was the chairperson of AACR International Conferences during the years 2006 and 2007 on Molecular Diagnostics in Cancer Therapeutic Development: Maximizing Opportunities for Personalized Treatment. Dr. Sidransky is the recipient of a number of awards and honors, including the 1997 Sarstedt International Prize from the German Society of Clinical Chemistry, the 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians, and the 2004 Richard and Hinda Rosenthal Award from the American Association of Cancer Research. Dr. Sidransky received his BS in Chemistry from Brandies University and his medical degree from Baylor College of medicine where he also completed his residency in internal medicine. His specialty in Medical Oncology was completed at Johns Hopkins University and Hospital.

We believe Dr. Sidransky is qualified to serve on our Board of Directors because of his education, medical background, experience within the life science industry and his business acumen in the public markets.

Guy Yachin – Director

Mr. Yachin has served as a director since his appointment on April 2, 2012. Mr. Yachin serves, since November 2020, as the executive chairman of Xerient Pharma which develops a drug for the treatment of abdominal cancers. He served as the President and CEO of Serpin Pharma, a clinical stage Virginia-based company focused on the development of anti-inflammatory drugs, from April 2013 until October 2020. Prior to that, Mr. Yachin was the CEO of NasVax Ltd., a company focused on the development of improved immunotherapeutics and vaccines. Prior to joining NasVax, Mr. Yachin served as CEO of MultiGene Vascular Systems Ltd (a.k.a. Vessl), a cell therapy company focused on blood vessels disorders, leading the company through clinical studies in the U.S. and Israel, financial rounds, and a keystone strategic agreement with Teva Pharmaceuticals Industries Ltd. He was CEO and founder of Chiasma Inc., a biotechnology company focused on the oral delivery of macromolecule drugs, where he built the company's presence in Israel and the U.S., concluded numerous financial rounds, and guided the company's strategy and operation for over six years. Earlier, he was CEO of Naiot Technological Center Ltd., and provided seed funding and guidance to more than a dozen biomedical startups such as Remon Medical Technologies Ltd., Enzymotec Ltd. and NanoPass Technologies Ltd. He holds a BSc. in Industrial Engineering and Management and an MBA from the Technion – Israel Institute of Technology.

We believe Mr. Yachin is qualified to serve on our Board of Directors because of his education, experience within the life science industry and his business acumen in the public markets.

Yaron Adler – Director

Mr. Adler has served as a director since his appointment on April 17, 2012. Mr. Adler is the co-founder of a startup incubator, We Group Ltd. In 1999, Mr. Adler co-founded IncrediMail Ltd. and served as its CEO until 2008 and President until 2009. In 1999, prior to founding IncrediMail, Mr. Adler consulted Israeli startup companies regarding Internet products, services and technologies. Mr. Adler served as a product manager from 1997 to 1999, and as a software engineer from 1994 to 1997, at Tecnomatix Technologies Ltd., a software company that develops and markets production engineering solutions to complex automated manufacturing lines that fill the gap between product design and production, and which was acquired by UGS Corp. in April 2005. In 1993, Mr. Adler held a software engineer position at Intel Israel Ltd. He has a B.A. in computer sciences and economics from Tel Aviv University.

We believe Mr. Adler is qualified to serve on our Board of Directors because of his education, success with early-stage enterprises and his business acumen in the public markets.

Ashish Nanda – Director

Mr. Nanda has served as a director since his appointment on February 22, 2017. Since 1998, Mr. Nanda has been the Managing Director of Innovations Group, one of the largest outsourcing companies in the financial sector that employs close to 14,000 people working across various financial sectors. Since 1992, Mr. Nanda has served as the Managing Partner of Capstone Insurance Brokers LLC and, since 2009, has served as Managing Partner of Dive Tech Marine Engineering Services L.L.C. From 1991 to 1994, Mr. Nanda held the position of Asst. Manager Corporate Banking at Emirates Banking Group where he was involved in establishing relationships with business houses owned by UAE nationals and expatriates in order to set up banking limits and also where he managed portfolios of USD $26 billion. Mr. Nanda holds a Chartered Accountancy from the Institute of Chartered Accountants from India.

We believe that Mr. Nanda is qualified to serve on our Board of Directors because of his business experience and strategic understanding of advancing the valuation of companies in emerging industries.

There are no family relationships between any of the above executive officers or directors or any other person nominated or chosen to become an executive officer or a director. Pursuant to an agreement entered into between us and Image Securities fzc. ("Image"), for so long as Image's ownership of our company is 10% or greater, it was granted the right to nominate a director to our Board of Directors. Mr. Nanda was nominated for a directorship at the 2017 annual meeting in compliance with our contractual undertakings.

Mario Philips – Director

Mr. Philips has served as a director since his appointment on January 9, 2020. Since November 2020, Mr. Philips has been Chief Executive Officer of Polyplus, a leading Biotech supplier of transfection reagents for cell & gene therapy as well as the research life sciences market. Mario is also chairmen of the Board of PLL Therapeutics, a drug company based in France that has developed a diagnostic platform technology for neurodegenerative diseases in combination with a therapy to cure neurodegenerative diseases such as ALS and Parkinson's.

Prior to that Mario acted as VP/GM for Danaher Pall Biotech business with full P&L responsibility for a $1,3B business unit. Mario joined Pall in February 2014, as part of the Pall acquisition of ATMI Life Sciences, and was appointed to Vice President and General Manager to lead the Single-Use Technologies BU. In this role he was responsible for leading and executing an aggressive investment and growth strategy.

Mario joined ATMI in 1999 with ATMI's acquisition of MST Analytics, Inc., serving as European Sales Manager for ATMI Analytical Systems. In 2004, Mario was appointed to General Manager of ATMI Packaging, a role he held through 2010 when he was promoted to the position of Senior Vice President and General Manager, ATMI Life Sciences. In that role, he was responsible for developing and executing all business strategies, including the introduction of new products and service solutions for the Life Sciences industry. A strong leading innovative IP portfolio was created, Pall acquired the business in 2014.

Mario also held in the past several board member positions in the life sciences industry with Clean Biologics, Austar Life Sciences (China), Disposable Lab (France) and Artelis (Belgium).

We believe that Mr. Philips is qualified to serve on our Board of Directors because of his business experience and strategic understanding of advancing the valuation of companies in emerging industries.

Board of Directors

Our Board of Directors currently consists of six (6) members. All directors hold office until the next annual meeting of stockholders. At each annual meeting of stockholders, the successors to directors whose terms then expire are elected to serve from the time of election and qualification until the next annual meeting following election.

Management has been delegated the responsibility for meeting defined corporate objectives, implementing approved strategic and operating plans, carrying on our business in the ordinary course, managing cash flow, evaluating new business opportunities, recruiting staff and complying with applicable regulatory requirements. The Board of Directors exercises its supervision over management by reviewing and approving long-term strategic, business and capital plans, material contracts and business transactions, and all debt and equity financing transactions and stock issuances.

Director Independence

Our Board of Directors is comprised of a majority of independent directors. In determining director independence, we use the definition of independence in Rule 5605(a)(2) of the listing standards of The Nasdaq Stock Market.

The Board has concluded that each of Dr. Sidransky, and Messrs. Yachin, Adler, Philips and Nanda is "independent" based on the listing standards of the Nasdaq Stock Market, having concluded that any relationship between such director and our company, in its opinion, does not interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Board Committees

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, with each comprised of independent directors in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations. The members of the Audit Committee are Dr. Sidransky and Messrs. Yachin and Philips. The members of the Compensation Committee are Dr. Sidransky and Messrs. Adler and Yachin. The members of the Nominating and Corporate Governance Committee are Messrs. Nanda, Adler and Yachin. The members of the Research and Development Committee are Mr. Yachin and Dr. Sidransky. We have also established a Research and Development Committee.

Each committee operates under a written charter that has been approved by our Board of Directors. Copies of our committee charters are available on the investor relations section of our website, which is located at http://www.orgenesis.com.

Audit Committee

The Audit Committee (a) assists the Board of Directors in fulfilling its oversight of: (i) the quality and integrity of our financial statements; (ii) our compliance with legal and regulatory requirements relating to our financial statements and related disclosures; (iii) the qualifications and independence of our independent auditors; and (iv) the performance of our independent auditors; and (b) prepares any reports that the rules of the SEC require be included in our proxy statement for our annual meeting.

The Audit Committee held 7 meetings in fiscal 2021. In addition, the Audit Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2021. The Board has determined that each member of the Audit Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations. In addition, the Board has determined that Dr. Sidransky is an “audit committee financial expert” within the meaning of Item 407(d)(5) of Regulation S-K and has designated him to fill that role. See “Directors, Executive Officers and Corporate Governance – Directors” above for descriptions of the relevant education and experience of each member of the Audit Committee.

At no time since the commencement of our most recently completed fiscal year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board of Directors.

The Audit Committee is responsible for the oversight of our financial reporting process on behalf of the Board of Directors and such other matters as specified in the Audit Committee’s charter or as directed by the Board of Directors. Our Audit Committee is directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged by us for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us (or to nominate the independent registered public accounting firm for stockholder approval), and each such registered public accounting firm must report directly to the Audit Committee. Our Audit Committee must approve in advance all audit, review and attest services and all non-audit services (including, in each case, the engagement and terms thereof) to be performed by our independent auditors, in accordance with applicable laws, rules and regulations.

Compensation Committee

The Compensation Committee (i) assists the Board of Directors in discharging its responsibilities with respect to compensation of our executive officers and directors, (ii) evaluates the performance of our executive officers, and (iii) administers our stock and incentive compensation plans and recommends changes in such plans to the Board as needed.

The Compensation Committee held 5 meetings in fiscal 2021. In addition, the Compensation Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2021. The Board of Directors has determined that each member of the Compensation Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee assists the Board in (i) identifying qualified individuals to become directors, (ii) determining the composition of the Board and its committees, (iii) developing succession plans for executive officers, (iv) monitoring a process to assess Board effectiveness, and (v) developing and implementing our corporate governance procedures and policies.

The Nominating and Corporate Governance Committee held 4 meeting in fiscal 2021. In addition, the Nominating and Corporate Governance Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2021. The Board has determined that each member of the Nominating and Corporate Governance Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

Research and Development Committee

The Research and Development Committee assists the Board in fulfilling the Board's responsibilities to oversee our research and development programs, and strategies.

The Research and Development Committee was established in January 2021. The Research and Development Committee held 3 meeting in fiscal 2021.

DELINQUENT SECTION 16(a) REPORTS

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our officers and directors and persons who beneficially own more than ten percent (10%) of the Common Stock outstanding to file initial statements of beneficial ownership of Common Stock (Form 3) and statements of changes in beneficial ownership of Common Stock (Forms 4 or 5) with the SEC. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all such forms they file.

Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis, except that three reports, covering an aggregate of five transactions, were filed late by David Sidransky, one report on Form 3 was filed late by Efrat Assa-Kunik, one report was filed late by Yaron Adler, one report was filed late by Mario Philips, one report was filed late by Guy Yachin, and one report was filed late by Ashish Nanda.

Corporate Code of Conduct and Ethics

Our Board of Directors has adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Copies of our corporate code of conduct and ethics are available, without charge, upon request in writing to Orgenesis Inc., 20271 Goldenrod Lane, Germantown, MD, 20876, Attn: Secretary and are posted on the investor relations section of our website, which is located at www.orgenesis.com. The inclusion of our website address in this Annual Report on Form 10-K does not include or incorporate by reference the information on our website into this Annual Report on Form 10-K. We also intend to disclose any amendments to the Corporate Code of Conduct and Ethics, or any waivers of its requirements, on our website.

ITEM 11. EXECUTIVE COMPENSATION

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2021 to our Chief Executive Officer, Chief Financial Officer and Chief Development Officer. As of December 31, 2021, there were no other executive officers who earned more than $100,000 during the fiscal year ended December 31, 2021 and were serving as executive officers as of such date (the "named executive officers").

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensa-tion ($)	Non-qualified Deferred Compensation Earnings ($)	All Other Compensa-tion ($) (2)	Total ($)
Vered Caplan	2021	264,483	3,600,000	-	-	-	-	112,345	3,976,828
CEO(3)	2020	250,000	400,000	-	171,349	-	-	215,640	1,036,98
Neil Reithinger	2021	239,670	-	-	-	-	-	-	239,670
CFO, Treasurer & Secretary	2020	255,231	200,000	-	30,238	-	-	-	485,469
Efrat Assa-Kunik, *Chief Development Officer*	2021	169,533	-	-	-	-	-	46,387	215,919

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for us that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our Common Stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 15 to this Annual Report on Form 10-K for the year ended December 31, 2021. No executive officers received options awards in the year ended December 31, 2021. See below for a summary of options awarded in previous years.

(2) For 2021 and 2020, represents the compensation as described under the caption “All Other Compensation” below.

All Other Compensation

The following table provides information regarding each component of compensation for fiscal years 2021 and 2020 included in the All Other Compensation column in the Summary Compensation Table above. Represents amounts paid in New Israeli Shekels (NIS) or Swiss Franks and converted at average exchange rates for the year.

Name	Year	Automobile and Communication Related Expenses $ (1)	Social Benefits $ (2)	Total $
Vered Caplan	2021	-	112,345	112,345
	2020	13,172	202,468	215,640
Efrat Assa Kunik	2021	924	45,462	46,387

(1) Represents for Ms. Caplan, a leased automobile and communication expenses.

(2) These are comprised of contributions by us to savings, health, severance, pension, disability and insurance plans generally provided in Israel and Switzerland, including health, education, managerial insurance funds, and redeemed vacation pay. This amount represents Israeli and Swiss severance fund payments, managerial insurance funds, disability insurance, supplemental education fund contribution and social securities. See discussion below under “Narrative Disclosure to Summary Compensation Table – Vered Caplan.”

Outstanding Equity Awards at December 31, 2021

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of December 31, 2021.

Name	Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Vered Caplan	02-Feb-12[(1)]	278,191	-	0.012	02-Feb-22
	22-Aug-14[(1)]	230,189	-	0.0012	22-Aug-24
	09-Dec-16[(1)]	166,667	-	4.80	09-Dec-26
	06-Jun-17[(1)]	83,334	-	7.20	06-Jun-27
	28-Jun-18[(1)]	250,000	-	8.36	28-Jun-28
	22-Oct-18[(2)]	63,750	21,250	5.99	22-Oct-28
	19-Mar-20[(1)]	85,000	-	2.99	18-Mar-30
Neil Reithinger	09-Dec-16[(1)]	83,334	-	4.80	09-Dec-26
	08-Mar-19[(1)]	25,000	-	5.07	08-Mar-29
	19-Mar-20[(1)]	15,000	-	2.99	18-Mar-30
Efrat Assa Kunik	09-Dec-16[(1)]	16,667	-	4.8	09-Dec-26
	22-Oct-18[(2)]	11,250	3,750	5.99	22-Oct-28
	19-Mar-20[(1)]	15,000	-	2.99	18-Mar-30

(1) The options were fully vested as of December 31, 2021.

(2) The options vest on a quarterly basis over a period of four years from the date of grant.

There were no option exercises by our named executive officers during our fiscal year ended December 31, 2020 and 2021.

Narrative Disclosure to Summary Compensation Table

Vered Caplan

On August 14, 2014, our Board of Directors confirmed that Ms. Vered Caplan, who had served as our President and Chief Executive Officer on an interim basis since December 23, 2013, was appointed as our President and Chief Executive Officer.

On March 30, 2017, we and Ms. Caplan entered into an employment agreement replacing a previous employment agreement dated August 22, 2014 (the “Amended Caplan Employment Agreement”). Under the Amended Caplan Employment Agreement, which took effect April 1, 2017, Ms. Caplan’s annual salary continued at $160,000 per annum, subject to adjustment to $250,000 per annum upon the listing of the Company’s securities on an Exchange. On May 10, 2017, we and Ms. Caplan further amended the Amended Caplan Employment Agreement pursuant to which Ms. Caplan became entitled to a grant under the 2017 of options (the “Initial Option”) to purchase 83,334 shares of the Company’s common stock at a per share exercise price equal to the Fair Market Value (as defined in our 2017 Equity Incentive Plan (the “2017 Plan”)) of the Company’s common stock on the date of grant. The amendment further provided that beginning in fiscal 2018, subject to approval by the compensation committee, Ms. Caplan became entitled to an additional option (the “Additional Option”; together with the Initial Option, the “Options”) under the 2017 Plan for up to 250,000 shares of common stock of the Company to be awarded in such amounts per fiscal year as shall be consistent with the Plan, in each case at a per share exercise price equal to the Fair Market Value (as defined in the Plan) of the Company’s common stock on the date of grant. In 2018, following the listing of the Company’s securities on Nasdaq, Ms. Caplan’s annual salary was raised to $250,000.

For additional information regarding Ms. Caplan's stock options awards, see the Outstanding Equity Awards table above.

On November 19, 2020, we and Ms. Caplan entered into an executive directorship agreement, effective as of October 1, 2020 (the "Executive Directorship Agreement"), that supersedes and replaces the Amended Caplan Employment Agreement (the "Prior Agreement"). Pursuant to the Executive Directorship Agreement, Ms. Caplan will continue to serve the Company as its Chairperson of the Board of Directors (the "Board") and shall receive in consideration for her serving as Chairperson of the Board an annual regular Board fee in the amount of $75,000 payable by the Company in equal quarterly installments in advance. In addition, Ms. Caplan may be eligible for non-recurring special Board fees as reviewed and approved by the Compensation Committee of the Board (the "Compensation Committee") and then reviewed and ratified by the Board. In addition, Ms. Caplan may be granted option awards from time to time at the discretion of the Compensation Committee.

Ms. Caplan's position as Chairperson of the Board under the Executive Directorship Agreement may be terminated for any reason by either Ms. Caplan or the Company upon 90 days prior written notice (the "Notice Period"), provided that the Company may terminate such appointment as Chairperson at any time during the Notice Period subject to certain conditions. Such termination as Chairperson of the Board will be deemed a termination even if Ms. Caplan remains as a regular director of the Board. Upon termination by the Company of Ms. Caplan's employment other than for cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations (as defined therein) she shall be entitled to receive a lump sum payment equal to the sum of (i) the annual regular Board fee (the "Board Fee") and (ii) the greater of actual or target annual performance bonus to which she may have been entitled to as of the termination date (in each case, less all customary and required taxes and related deductions).

Ms. Caplan's position under the Executive Directorship Agreement may be terminated in the event of a Change of Control (as defined therein) by the Company other than for cause or by Ms. Caplan for any reason whatsoever. In the event of a Change of Control and if, within one year following such Change of Control, employment under the Executive Directorship Agreement is terminated by the Company other than for cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations, she shall be entitled to receive a lump sum payment equal to one and a half times the sum of (i) the Board Fee and (ii) the target annual performance remuneration to which she may have been entitled as of the termination date (in each case, less all customary and required taxes and related deductions).

In addition, on November 19, 2020, Orgenesis Services Sàrl, a Swiss corporation and wholly-owned, direct subsidiary of the Company ("Orgenesis Services"), and Ms. Caplan entered into a personal employment agreement (the "Swiss Employment Agreement" and together with the Executive Directorship Agreement, the "Agreements"), pursuant to which Ms. Caplan will serve as Chief Executive Officer, President and Chairperson of the Board of Directors of Orgenesis Services and will be a material provider of services to the Company pursuant to a services agreement between the Company and Orgenesis Services. The Swiss Employment Agreement provides that Ms. Caplan is entitled to a monthly base salary of CHF 13,345.05 (equivalent to $14,583 based on the current exchange rate at signing), and an annual representation fee of CHF 24,000 (equivalent to $26,226 based on the current exchange rate at signing), payable in monthly installments of CHF 2,000. Ms. Caplan is eligible to receive a bonus at the absolute discretion of Orgenesis Services and its compensation committee. Ms. Caplan may also be granted option awards from time to time, as per the recommendation of the compensation committee of Orgenesis Services as reviewed and approved by the Compensation Committee. Under the Swiss Employment Agreement, Ms. Caplan is entitled to be paid annual vacation days, monthly travel allowance, sick leave, expenses reimbursement and a mobile phone. The Swiss Employment Agreement has an effective date as of October 1, 2020.

Employment under the Swiss Employment Agreement may be terminated for any reason by Ms. Caplan or by Orgenesis Services other than for just cause (as defined therein) upon six months prior written notice or by Orgenesis Services other than for just cause in the event of a Change of Control (as defined therein) of the Company upon at least 12 months prior written notice. Upon termination by Orgenesis Services of Ms. Caplan's employment without just cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations (as defined therein), she shall be entitled to receive a lump sum payment equal to the sum of (i) her Base Salary (as defined therein) at the rate in effect as of the termination date and (ii) the greater of actual or target annual performance bonus to which she may have been entitled to for the year in which employment terminates (in each case, less all customary and required taxes and employment-related deductions). In the event of a Change of Control and if, within one year following such Change of Control, employment is terminated by Orgenesis Services other than for cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations she shall be entitled to receive a lump sum payment equal to one and a half times the sum of (i) her Base Salary and (ii) the target annual performance bonus to which she may have been entitled to for the year in which employment terminates (in each case, less all customary and required taxes and employment-related deductions).

The Swiss Employment Agreement provides for customary protections of Orgenesis' confidential information and intellectual property.

Ms. Caplan received an aggregate salary and board fee of $264,483 during 2021. On November 19, 2020, the Compensation Committee approved a special remuneration of $400,000 to Ms. Caplan for her outstanding service in the business development of the Company and its affiliates. The payment of such remuneration was made at the time of entry into the Agreements. On July 28, 2021, the Compensation Committee approved a discretionary bonus to Ms. Caplan in the amount of $3.6 million pursuant to the discretionary bonus provisions of the Personal Employment Agreement between Ms. Caplan and Orgenesis Services Sàrl. The bonus was paid during September 2021.

Neil Reithinger

Mr. Reithinger was appointed Chief Financial Officer, Treasurer and Secretary on August 1, 2014. Mr. Reithinger's employment agreement stipulates a monthly salary of $1,500; payment of an annual bonus as determined by the Company in its sole discretion, participation in the Company's pension plan; grant of stock options as determined by the Company; and reimbursement of expenses. In addition, on August 1, 2014, the Company entered into a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, of which Mr. Reithinger is the sole shareholder ("Eventus"), pursuant to which Eventus has agreed to provide financial consulting services to the Company. In consideration for Eventus' services, the Company agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement was for a period of one year from August 1, 2014 and automatically renews for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Mr. Reithinger. On December 16, 2020, the Compensation Committee of the Board of Directors of the Company, approved a special one-time bonus of $200,000 that was paid prior to December 31, 2020. As of December 31, 2021, Eventus was owed $56 thousand for accrued and unpaid services under the financial consulting agreement.

Efrat Assa-Kunik

Ms. Assa-Kunik was appointed Chief Development Officer in December 2021. According to the terms of Ms. Assa-Kunik's Employment Agreement Ms. Assa Kunik is entitled to a monthly salary of 45 thousand New Israeli Shekels, customary contributions to a pension and training fund, participation in cellphone expenses, and annual leave of 24 days.

Potential Payments upon Change of Control or Termination following a Change of Control

Our employment agreements with our named executive officers provide incremental compensation in the event of termination, as described herein. Generally, we currently do not provide any severance specifically upon a change in control nor do we provide for accelerated vesting upon change in control. Termination of employment also impacts outstanding stock options.

Due to the factors that may affect the amount of any benefits provided upon the events described below, any actual amounts paid or payable may be different than those shown in this table. Factors that could affect these amounts include the basis for the termination, the date the termination event occurs, the base salary of an executive on the date of termination of employment and the price of our common stock when the termination event occurs.

The following table sets forth the compensation that would have been received by each of our executive officers had they been terminated as of December 31, 2021.

Name	Salary Continuation
Vered Caplan	$ *

(*) Termination by Company without cause: $250,000
Termination without cause following a change in control: $375,000

Director Compensation

The following table sets forth for each non-employee director that served as a director during the year ended December 31, 2021:

Year Ended December 31, 2021

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	Non-equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Guy Yachin	100,000	-	34,518(2)	-	-	-	134,518
Yaron Adler	60,000	-	26,417(3)	-	-	-	86,417
Dr. David Sidransky	105,000	-	36,015(4)	-	-	-	141,015
Ashish Nanda	65,000	-	27,914(5)	-	-	-	92,914
Mario Philips	50,000	-	24,216(6)	-	-	-	74,216

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for us that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our common stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 15 (Stock Based Compensation) to our financial statements, which are included in this Annual Report on Form 10-K.

(2) In respect of 19,600 options which will vest on December 17, 2022.

(3) In respect of 15,000 options which will vest on December 17, 2022.

(4) In respect of 20,450 options which will vest on December 17, 2022.

(5) In respect of 15,850 options which will vest on December 17, 2022.

(6) In respect of 13,750 options which will vest on December 17, 2022.

All directors receive reimbursement for reasonable out of pocket expenses in attending Board of Directors meetings and for participating in our business.

Compensation Policy for Non-Employee Directors.

In January 2021, the Board of Directors adopted an updated compensation policy for non-employee directors which replaced the previous non-employee director compensation terms and which became effective January 2021. Under the policy, each director is to receive an annual cash compensation of $40,000 and the Chairman or lead director is paid an additional $20,000 per annum. Each committee member will be paid an additional $10,000 per annum and the committee chairman of the Audit and Research and Development committees is to receive $20,000 per annum while the chairman of the other committees is to receive $15,000 per annum. Cash compensation will be made on a quarterly basis.

All newly appointed directors also receive options to purchase up to 6,250 shares of our common stock. All directors are entitled to an annual bonus of options for 12,500 shares and each committee member is entitled to a further option to purchase up to 1,250 shares of common stock and each committee chairperson to options for an additional 2,100 shares of common stock. In addition, the Chairman and Vice Chairman shall be granted an option to purchase 4,200 shares of our ordinary shares. In all cases, the options are granted at a per share exercise price equal to the closing price of our publicly traded stock on the date of grant and the vesting schedule is determined by the compensation committee at the time of grant.

Compensation Committee Interlocks and Insider Participation

None of our executive officers has served as a member of the Board of Directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our Board of Directors or Compensation Committee during the fiscal year ended December 31, 2021.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 30, 2022 for (a) the named executive officers, (b) each of our directors, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of March 30, 2022 pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 24,820,756 shares of common stock outstanding on March 30, 2022.

Security Ownership of Greater than 5% Beneficial Owners

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership (1)	Percent(1)
Image Securities fzc. 2310, 23rd floor, Tiffany Towers, JLT Dubai, UAE	2,070,919(2)	8.34%
Yehuda Nir c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	2,182,164(3)	8.79%

Security Ownership of Directors and Executive Officers

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership (1)	Percent(1)
Vered Caplan c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	1,167,756(4)	4.70%

Neil Reithinger 14201 N. Hayden Road, Suite A-1 Scottsdale, AZ 85260	123,334(5)	<1%
Efrat Assa Kunik c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	44,792(6)	<1%
Guy Yachin c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	150,934(7)	<1%
Dr. David Sidransky c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	133,401(8)	<1%
Yaron Adler c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	232,629(9)	<1%
Ashish Nanda c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	66,700(10)	<1%
Mario Philips c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	30,417(11)	<1%
Directors & Executive Officers as a Group (8 persons)	1,949,963	7.86%

Notes:

(1) Percentage of ownership is based on 24,820,756 shares of our common stock outstanding as of March 30, 2022. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days, 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) Consists of (i) 1,830,534 ordinary shares and (ii) 240,385 ordinary shares issuable upon exercise of outstanding warrants at a price of $6.24 per share. The warrants are exercisable over a three-year period from the date of issuance.

(3) Consists of (i) 10,016 ordinary shares, (ii) 50,000 ordinary shares issuable upon exercise of outstanding warrants at a price of $7 per share, exercisable until, October 3, 2022, (iii) 453,294 ordinary shares issuable upon exercise of outstanding warrants at a price of $6.24 per share, exercisable until, June 30, 2023 and (iv) 1,668,854 ordinary shares issuable upon exercise of convertible debt at a price of $7 per share.

(4) Consists of (i) 278,191 ordinary shares, (ii) 230,189 ordinary shares issuable upon exercise of outstanding options at a price of $0.0012 per share, (iii)166,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.8 per share, (iv) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of $7.2 per share, (v) 250,000 ordinary shares issuable upon exercise of outstanding options at a price of $8.36 per share, (vi) 74,375 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and (vii) 85,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share. Does not include option for 10,625 shares of common stock with an exercise price of $5.99 per share that are exercisable quarterly after July 22, 2022.

(5) Consists of (i) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of $4.8 per share, (ii) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.07 per share and (iii) 15,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share.

(6) Consists of (i) 16,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.8 per share, (ii) 13,125 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and (iii) 15,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share. Does not include option for 1,875 shares of common stock with an exercise price of $5.99 per share that are exercisable quarterly after July 22, 2022.

(7) Consists of (i) 39,267 ordinary shares issuable upon exercise of outstanding options at a price of $10.2 per share, (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.8 per share, (iii) 28,750 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share, (iv) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share and (v) 16,250 ordinary shares issuable upon exercise of outstanding options at a price of $4.6 per share. Does not include (i) option for 19,600 shares of common stock with an exercise price of $2.89 per share that are exercisable on December 16, 2022 and options exercisable at a price per share of $7.00 into 70,000 ordinary shares held by Caerus Therapeutics LLC for which Mr. Yachin does not have beneficial control.

(8) Consists of (i) 20,834 ordinary shares issuable upon exercise of outstanding options at a price of $9 per share, (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.8 per share, (iii) 29,200 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share, (iv) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share and (v) 16,700 ordinary shares issuable upon exercise of outstanding options at a price of $4.6 per share. Does not include option for 20,450 shares of common stock with an exercise price of $2.89 per share that are exercisable on December 16, 2022.

(9) Consists of (i) 63,304 ordinary shares, (ii) 58,908 ordinary shares issuable upon exercise of outstanding options at a price of $9.48 per share, (iii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.8 per share, (iv) 28,750 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share, (v) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share and (vi) 15,000 ordinary shares issuable upon exercise of outstanding options at a price of $4.6 per share. Does not include option for 15,000 shares of common stock with an exercise price of $2.89 per share that are exercisable on December 16, 2022.

(10) Consists of (i) 27,100 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share, (ii) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share and (iii) 14,600 ordinary shares issuable upon exercise of outstanding options at a price of $4.6 per share. Does not include option for 15,850 shares of common stock with an exercise price of $2.89 per share that are exercisable on December 16, 2022. Does not include option for 15,850 shares of common stock with an exercise price of $2.89 per share that are exercisable on December 16, 2022.

(11) Consists of (i) 4,167 ordinary shares issuable upon exercise of outstanding options at a price of $4.7 per share, (ii) 12,500 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share and (iii) 13,750 ordinary shares issuable upon exercise of outstanding options at a price of $4.6 per share. Does not include (i) option for 2,083 shares of common stock with an exercise price of $4.7 per share that are exercisable in three equal instalments over three anniversaries starting on January 9, 2023 and (ii) option for 13,750 shares of common stock with an exercise price of $2.89 per share that are exercisable on December 16, 2022.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2021:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders [1]	3,030,916	$ 4.23	969,084
Equity compensation plans not approved by security holders	726,780	$ 4.68	-
Total	3,757,696	$ 4.31	1,347,778

(1) Consists of the 2017 Equity Incentive Plan and the Global Share Incentive Plan (2012). For a short description of those plans, see Note 15 to our 2021 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended December 31, 2021.

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

Transactions with Related Persons

Except as set out below, as of December 31, 2021, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds 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 any of the following persons had or will have a direct or indirect material interest:

- any director or executive officer of our company;
- any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our outstanding shares of common stock;
- any promoters and control persons; and
- any member of the immediate family (including spouse, parents, children, siblings and in laws) of any of the foregoing persons.

Pursuant to a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, of which Mr. Reithinger is the sole shareholder ("Eventus"), dated as of August 1, 2014, Mr. Reithinger received $240 thousand during the year ended December 31, 2021 and $255 thousand during the year ended December 31, 2020 for financial consulting services. Such amounts are included in Mr. Reithinger's executive compensation presented in the Summary Compensation Table in Item 11 of this Annual Report on Form 10-K. Eventus has agreed to provide financial consulting services to the Company and in consideration for Eventus' services, the Company agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement was for a period of one year from August 1, 2014 and automatically renews for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Mr. Reithinger

Pursuant to an agreement entered into between us and Image Securities fzc. ("Image"), so long as Image's ownership of our Common Stock is 10% or greater, it is entitled to nominate a director to our Board of Directors. Mr. Nanda was nominated for a directorship at the 2018 annual meeting in compliance with our contractual undertakings.

Pursuant to agreements with Image, we procured services from Image in the amount of $4.8 million during the year ended December 31, 2020, and earned revenues from Image in the amount of $3.9 million and $1.5 million for the years ended December 31, 2021 and December 31, 2020, respectively. In addition, we earned interest income in the amount of $64 thousand and $169 thousand for the years ended December 31, 2021 and December 31, 2020, respectively.

On August 24, 2021, we entered into a convertible loan agreement with Image whereby, pursuant to the terms of the Image joint venture agreement, we agreed to loan Image up to $5 million. The loan bears interest at the rate of 6% and is subject to repayment by August 21, 2022, unless we agree to an extension or the loan is converted into shares of Image or, if established, Image's Indian joint venture. As of December 31, 2021, we transferred $3 million to Image under the loan agreement, and this has been reflected as a short-term asset on our balance sheet. Such loan is senior to any and all other indebtedness of Image or, after its establishment, Image's joint venture entity. The Company shall have a first priority security interest on all of Image's or, if established, Image's joint venture entity's, present and future assets.

Pursuant to our Audit Committee charter adopted in March 2017, the Audit Committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us have or will have a direct or indirect material interest.

Named Executive Officers and Current Directors

For information regarding compensation for our named executive officers and current directors, see "Executive Compensation."

Director Independence

See "Directors, Executive Officers and Corporate Governance – Director Independence" and "Directors, Executive Officers and Corporate Governance – Board Committees" in Item 10 above.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our Board of Directors has appointed Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited ("PwC") as our independent registered public accounting firm for the fiscal year ended December 31, 2021. The following table sets forth the fees billed to us for professional services rendered by PwC for the years ended December 31, 2021 and December 31, 2020:

	Years Ended December 31,	
Services:	2021	2020
Audit Fees (1)	$ 228,188	$ 267,231
Audit-Related Fees (2)	16,634	67,405
Tax Fees (3)	29,863	12,500
All Other Fees	-	10,000
Total fees	$ 274,685	$ 357,136

(1) Audit fees consisted of audit work performed in the preparation of financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as statutory audits.

(2) Audit related fees consisted principally of audits of employee benefit plans and special procedures related to regulatory filings in 2021.

(3) The tax fees were paid for reviewing various tax related matters.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. ***Audit*** services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. ***Audit-Related*** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. ***Tax*** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. ***Other Fees*** are those associated with services not captured in the other categories. We generally do not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a)

c. Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

d. Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

e. Exhibits required by Regulation S-K

No.	Description
2.1	Stock Purchase Agreement, dated February 2, 2020, by and among Orgenesis, Inc., GPP-II Masthercell LLC, Masthercell Global Inc. and Catalent Pharma Solutions, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 3, 2020)
2.2	Agreement and Plan of Merger and Reorganization, dated as of September 26, 2020 by and among Orgenesis Inc., Orgenesis Merger Sub, Inc., Koligo Therapeutics Inc., the Shareholders of Koligo and Long Hill Capital V, LLC, solely in its capacity as representative of the Shareholders (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 2, 2020)
3.1	Articles of Incorporation, as amended (incorporated by reference to an exhibit to our registration statement on Form S-8, filed on August 7, 2020)
3.2	Amended and Restated Bylaws (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 21, 2011)
4.1	Description of Securities (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 9, 2020)
4.2	Form of Warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on January 22, 2020)
4.3	Form of Stock Option Agreement (incorporated by reference to an exhibit to our registration statement on Form S-8, filed on August 7, 2020)
4.4	Form of Warrant, dated as of September 13, 2021, issued in connection with Convertible Note Extension Agreements (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
4.5	Form of Warrant, dated as of September 13, 2021, issued in connection with Convertible Note Extension Agreements (incorporated by reference to an exhibit to our quarterly report filed on Form 10-Q, filed November 4, 2021)

No.	Description
10.1	Financial Consulting Agreement, dated August 1, 2014, with Eventus Consulting, P.C. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 5, 2014)
10.2	Personal Employment Agreement, dated August 1, 2014, by and between Orgenesis Inc. and Neil Reithinger (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 5, 2014)
10.3	2017 Equity Incentive Plan (incorporated by reference to an exhibit to our definitive proxy statement on Schedule 14A, filed on March 30, 2017)
10.4	Collaboration and License Agreement, dated as of June 8, 2018, between Orgenesis Inc. and Mircod Limited (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on October 12, 2018)
10.5	Controlled Equity Offering Sales Agreement, dated December 20, 2018, between Orgenesis Inc. and Cantor Fitzgerald & Co. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 20, 2018)
10.6	Joint Venture Agreement between the Company and First Choice International Company, Inc. dated March 12, 2019 (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on May 8, 2019)
10.7	Convertible Loan Agreement between Orgenesis Maryland Inc. and Yosef Ram dated April 12, 2019 (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on May 8, 2019)
10.8	Convertible Loan Agreement, dated April 10, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
10.9	Form of Subscription Agreement, dated May 17, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
10.10	Form of Subscription Agreement, dated May 30, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
10.11	Form of Subscription Agreement, dated June 6, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 7, 2019)
10.12	Transfer Agreement, dated as of August 7, 2019 by and among Masthercell Global, Orgenesis Inc. and GPP-II Masthercell, LLC (incorporated by reference to our current report on Form 8-K, filed on August 13, 2019)
10.13	Securities Purchase Agreement, dated January 20, 2020, by and among the Company and the Investors (incorporated by reference to an exhibit to our current report on Form 8-K, filed on January 22, 2020)
10.14	Registration Rights Agreement, dated January 20, 2020, by and among the Company and the Investors (incorporated by reference to an exhibit to our current report on Form 8-K, filed on January 22, 2020)
10.15	Asset Purchase Agreement by and between Orgenesis Inc. and Tamir Biotechnology, Inc, dated April 12, 2020 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 13, 2020)
10.16	Form of Registration Rights and Lock-Up Agreement between the Company, Long Hill Capital V, LLC and Maxim Group, LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 1, 2020)
10.17	Form of Shareholders Lock-Up Agreement between the Company and Shareholders other than Long Hill Capital V, LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 1, 2020)

No.	Description
10.18	Executive Directorship Agreement between the Company and Vered Caplan dated November 19, 2020 (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 9, 2021)
10.19	Swiss Employment Agreement between the Company and Vered Caplan dated November 19, 2020 (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 9, 2021)
10.20	Convertible Loan Agreement, dated as of August 24, 2021, between the Company and Image Securities FCZ (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.21	Convertible Credit Line and Unsecured Convertible Note Extension Agreement, dated as of September 13, 2021, between the Company and Yosef Dotan (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.22	Convertible Credit Line Extension Agreement, dated as of September 13, 2021, between the Company and Aharon Lukach (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.23	Unsecured Convertible Note Extension Agreement, dated as of September 13, 2021, between the Company and Yehuda Nir (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.24*	Employment Agreement, dated as of December 16, 2021, between the Company and Efrat Assa Kunik
21.1*	List of Subsidiaries of Orgenesis Inc.
23.1*	Consent of independent registered public accounting firm
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1**	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2**	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
99.1	Global Share Incentive Plan (2012) (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 31, 2012)
99.2	Appendix – Israeli Taxpayers Global Share Incentive Plan (2012) (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 31, 2012)

*Filed herewith
**Furnished herewith

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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.

ORGENESIS INC.

By: */s/ Vered Caplan*
Vered Caplan
Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)
Date: March 30, 2022

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
Date: March 30, 2022

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/ Vered Caplan*
Vered Caplan
Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)
Date: March 30, 2022

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
Date: March 30, 2022

By: */s/ Guy Yachin*
Guy Yachin
Director
Date: March 30, 2022

By: */s/ David Sidransky*
David Sidransky
Director
Date: March 30, 2022

By: */s/ Yaron Adler*
Yaron Adler
Director
Date: March 30, 2022

By: /*s/ Ashish Nanda*
Ashish Nanda
Director
Date: March 30, 2022

By: /*s/ Mario Philips*
Mario Philips
Director
Date: March 30, 2022

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2021

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and shareholders of Orgenesis Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orgenesis Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of comprehensive loss (income), changes in equity and 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 December 31, 2021 and 2020, 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.

Liquidity

As discussed in Note 1 to the consolidated financial statements, the Company had an accumulated deficit of $106.4 million as of December 31, 2021 and negative operating cashflows of $26.9 million in the year ended December 31, 2021. The Company's activities have been funded by generating revenue, through offerings of the Company's securities and selling its Contract Development and Manufacturing Organization ("CDMO") business.

The principal considerations for our determination that performing procedures related to liquidity is a critical audit matter are the estimation and execution uncertainty regarding the Company's future cash flows and management's judgments and assumptions in estimating these cash flows to conclude the Company would have sufficient liquidity to fund its operations for at least the next 12 months form the date of the issuance of the financial statements. This in turn led to a high degree of auditor subjectivity and judgment to evaluate the audit evidence supporting the liquidity conclusions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with our overall opinion on the consolidated financial statements. Our audit procedures included, among others, testing the reasonableness of the forecasted revenue, operating expenses, and uses and sources of cash used in management's assessment of whether the Company has sufficient liquidity to fund operations for at least the next 12 months form the date of the issuance of the financial statements. This testing included assessing the appropriateness of forecast assumptions by comparing prior period forecasts to actual results, comparing forecasted revenue to recent historical financial information and signed contracts, inquiring of management regarding the mitigating actions to reduce costs and manage cash flows and assessing whether the mitigating actions were within the Company's control, testing the underlying data generated to prepare the forecast scenarios and determining whether there was adequate support for the assumptions underlying the forecast, considering the terms of the Company's existing convertible loans, and evaluating management's analysis of the impact of the above assumptions on the forecasted cash flows.

We assessed the adequacy of the Company's liquidity disclosures included in Note 1 to the consolidated financial statements.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited
Tel-Aviv, Israel

March 30, 2022

We have served as the Company's auditor since 2012.

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ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
(U.S. Dollars, in thousands, except share and per share amounts)

	December 31,	
	2021	**2020**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,473	$ 44,923
Restricted cash	501	645
Accounts receivable, net	15,245	3,085
Prepaid expenses and other receivables	1,188	1,070
Convertible Loan to related parties	3,064	-
Grants receivable	169	169
Inventory	118	185
Total current assets	25,758	50,077
NON CURRENT ASSETS:		
Deposits	$ 363	$ 296
Investments in associates, net	152	175
Loan to associates	432	-
Loans receivable	821	-
Property, plants and equipment, net	10,271	3,073
Intangible assets, net	11,821	13,023
Operating lease right-of-use assets	1,015	1,474
Goodwill	8,403	8,745
Other assets	805	821
Total non-current assets	34,083	27,607
TOTAL ASSETS	$ 59,841	$ 77,684

ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
(U.S. Dollars, in thousands, except share and per share amounts)

	December 31,	
	2021	**2020**
Liabilities and equity		
CURRENT LIABILITIES:		
Accounts payable	$ 5,238	$ 8,649
Accrued expenses and other payables	485	792
Income tax payable	54	7
Employees and related payables	1,907	1,463
Advance payments on account of grant	1,238	692
Short-term loans and current maturities of long-term loans	-	145
Contract liabilities	59	59
Current maturities of finance leases	18	19
Current maturities of operating leases	481	485
Current maturities of convertible loans	5,885	3,974
TOTAL CURRENT LIABILITIES	15,365	16,285
LONG-TERM LIABILITIES:		
Non-current operating leases	$ 561	$ 1,020
Convertible loans	4,854	7,200
Retirement benefits obligation	101	74
Long-term debt and finance leases	41	64
Other long-term liabilities	288	313
TOTAL LONG-TERM LIABILITIES	5,845	8,671
TOTAL LIABILITIES	21,210	24,956
EQUITY:		
Common stock of $0.0001 par value: Authorized at December 31, 2021 and December 31, 2020: 145,833,334 shares; Issued at December 31, 2021 and December 31, 2020: 24,567,366 and 24,223,093 shares, respectively; Outstanding at December 31, 2021 and December 31, 2020: 24,280,799 and 24,167,784 shares, respectively.	3	3
Additional paid-in capital	145,916	140,397
Accumulated other comprehensive income	207	748
Treasury stock 231,258 shares and 55,309 as of December 31, 2021 and December 31, 2020	(1,266)	(250)
Accumulated deficit	(106,372)	(88,319)
Equity attributable to Orgenesis Inc.	38,488	52,579
Non-controlling interests	143	149
TOTAL EQUITY	38,631	52,728
TOTAL LIABILITIES AND EQUITY	$ 59,841	$ 77,684

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (INCOME)
(U.S. Dollars, in thousands, except share and per share amounts)

	Years ended December 31,	
	2021	**2020**
Revenues	$ 31,646	$ 6,177
Revenues from related party	3,856	1,475
Total revenues	35,502	7,652
Cost of services and other research and development expenses, net	36,644	83,986
Amortization of intangible assets	948	478
Selling, general and administrative expenses	14,710	18,973
Operating loss	16,800	95,785
Other income, net	(2,278)	(4)
Loss from extinguishment in connection with convertible loan	1,865	-
Financial expenses, net	1,292	1,061
Share in net loss (income) of associated companies	272	(106)
Loss from continuing operation before income taxes	17,951	96,736
Tax (income) expense	108	(1,609)
Net loss from continuing operation	18,059	95,127
Net income from discontinued operations, net of tax	-	(95,706)
Net loss (income)	$ 18,059	$ (579)
Net loss attributable to non-controlling interests from continuing operation	(6)	(39)
Net loss attributable to non-controlling interests from discontinued operations	-	(492)
Net loss (income) attributable to Orgenesis Inc.	$ 18,053	$ (1,110)
Loss (income) per share:		
Basic and diluted from continuing operation	$ 0.74	$ 4.46
Basic and diluted from discontinued operation	$ -	$ (4.75)
Basic and diluted	$ 0.74	$ (0.29)
Weighted average number of shares used in computation of Basic and Diluted loss per share:		
Basic and diluted	24,273,658	21,320,314
Comprehensive loss (income):		
Net loss from Continuing Operation	$ 18,059	$ 95,127
Net loss income from Discontinued Operation, Net of Tax	-	(95,706)
Other Comprehensive (income) loss – Translation adjustment	541	(341)
Release of translation adjustment due to sale of subsidiary	-	(194)
Comprehensive loss (income)	$ 18,600	$ (1,114)
Comprehensive loss attributed to non-controlling interests	(6)	(39)
Comprehensive loss attributed to non-controlling interests from discontinued operations	-	(492)
Comprehensive loss (income) attributed to Orgenesis Inc.	$ 18,594	$ (1,645)

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. Dollars, in thousands, except share amounts)

	Common Stock								
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Treasury Shares	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Par Value
Balance at January 1, 2020	16,140,962	$ 2	$ 94,691	$ 213	$ -	$ (89,429)	$ 5,477	$ 601	$ 6,078
Changes during the Year ended December 31, 2020:									
Stock-based compensation to employees and directors	-	-	1,470	-	-	-	1,470	-	1,470
Stock-based compensation to service providers	**270,174	1	1,376	-	-	-	1,377	-	1,377
Stock-based compensation for Tamir purchase agreement (See Note 4)	3,400,000	*	17,748	-	-	-	17,748	-	17,748
Exercise of options	83,334	*	300	-	-	-	300	-	300
Beneficial conversion feature of convertible loans	-	-	42	-	-	-	42	-	42
Issuance of shares and warrants	2,200,000	-	8,438	-	-	-	8,438	-	8,438
Issuance of shares related to acquisition of Koligo	2,128,623	*	11,172	-	-	-	11,172	-	11,172
Sale of subsidiaries	-	-	-	-	-	-	-	(413)	(413)
Adjustment to redemption value of redeemable non-controlling interest	-	-	5,160	-	-	-	5,160	-	5,160
Repurchase of treasury stock	(55,309)	-	-	-	(250)	-	(250)	-	(250)
Comprehensive income (loss) for the period	-	-	-	535	-	1,110	1,645	(39)	1,606
Balance at December 31, 2020	24,167,784	$ 3	$ 140,397	$ 748	$ (250)	$ (88,319)	$ 52,579	$ 149	$ 52,728

* Represents an amount lower than $1 thousand

** out of which 30,000 shares have additional restrictions on transfer until services have been provided.

The accompanying notes are an integral part of these consolidated financial statement

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. Dollars, in thousands, except share amounts)

	Common Stock								
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Treasury Shares	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Par Value
Balance at January 1, 2021	24,167,784	$ 3	$ 140,397	$ 748	$ (250)	$ (88,319)	$ 52,579	$ 149	$ 52,728
Changes during the Year ended December 31, 2021:									
Stock-based compensation to employees and directors	-	-	1,349	-	-	-	1,349	-	1,349
Stock-based compensation to service providers	25,000	*	396	-	-	-	396	-	396
Exercise of options	13,750	*	64	-	-	-	64	-	64
Extinguishment in connection with convertible loan restructuring	-	-	1,848	-	-	-	1,848	-	1,848
Issuance of Shares due to exercise of warrants	305,523	*	1,862	-	-	-	1,862	-	1,862
Repurchase of treasury stock	(231,258)	-	-	-	(1,016)	-	(1,016)	-	(1,016)
Comprehensive loss for the period	-	-	-	(541)	-	(18,053)	(18,594)	(6)	(18,600)
Balance at December 31, 2021	24,280,799	$ 3	$ 145,916	$ 207	$ (1,266)	$ (106,372)	$ 38,488	$ 143	$ 38,631

* Represents an amount lower than $1 thousand

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS(*)
(U.S. Dollars, in thousands)

	Years ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (18,059)	$ 579
Adjustments required to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	1,745	2,847
Stock-based compensation for Tamir Purchase Agreement (See Notes 4)	-	17,048
Capital loss (gain), net	25	22
Gain on disposal of subsidiaries	-	(96,918)
Share in loss (income) of associated company	272	(106)
Depreciation and amortization expenses	1,864	1,435
Effect of exchange differences on inter-company balances	341	(618)
Net changes in operating leases	(4)	14
Interest expense accrued on loans and convertible loans (including amortization of beneficial conversion feature)	482	927
Loss from extinguishment in connection with convertible loan restructuring	1,865	-
Changes in operating assets and liabilities:		
Increase in accounts receivable	(12,178)	(1,350)
Decrease (increase) in inventory	55	(84)
Increase in other assets	(18)	(24)
Increase in prepaid expenses, other accounts receivable	(173)	(1,073)
Increase (decrease) in accounts payable	(3,755)	1,985
Decrease in accrued expenses and other payable	(248)	(1,156)
Increase (decrease) in employee and related payables	487	(170)
Decrease in contract liabilities	-	(166)
Change in advance payments and receivables on account of grant, net	433	140
Decrease in deferred taxes	-	(1,378)
Net cash used in operating activities	$ (26,866)	$ (78,046)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in loan to JV partner, a related party	-	(500)
Repayment in loan to JV partner, a related party	-	3,000
Investment in convertible loan to related party	(3,000)	-
Loan to associate	(430)	-
Loan granted	(818)	-
Sale of property, plants and equipment	-	7
Purchase of property, plants and equipment	(7,866)	(1,525)
Acquisition of Koligo, net of cash acquired (See Note 4)	-	(955)
Proceed from sale of subsidiaries, net	-	105,634
Investment in associated company	(242)	(69)
Investment in deposits	(28)	-
Repayment from deposits	-	18
Net cash provided by (used in) investing activities	$ (12,384)	$ 105,610
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repurchase of treasury stock	(1,016)	(250)
Proceeds from issuance of shares, warrants and exercise of options (net of transaction costs)	1,926	8,738
Proceeds from issuance of convertible loans (net of transaction costs)	-	250
Repayment of convertible loans and convertible bonds	(1,000)	(2,400)
Repayment of short and long-term debt	(16)	(457)
Net cash provided by financing activities	$ (106)	$ 5,881
NET CHANGE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(39,356)	33,445
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (238)	$ 82
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	$ 45,568	$ 12,041
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 5,974	$ 45,568

SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES				
Finance Leases of property, plant and equipment	$	-	$	366
Right-of-use assets acquired in exchange for right-of-use liabilities	$	-	$	967
Purchase of property, plant and equipment included in accounts payable	$	331	$	241
Acquisition of other asset in exchange for common stocks	$	-	$	700
Issuance of common stocks in connection with the acquisition of Koligo	$	-	$	11,172
Extinguishment in connection with convertible loan restructuring		1,848	$	-

(*) See Note 3 for information regarding the discontinued operations.

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

NOTE 1 – DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc., a Nevada corporation, is a global biotech company working to unlock the potential of cell and gene therapies ("CGTs") in an affordable and accessible format.

CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products ("ATMP"). The Company mostly focused on autologous therapies, with processes and systems that are developed for each therapy using a closed and automated processing system approach that is validated for compliant production near the patient for treatment of the patient at the point of care ("POCare"). This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients (ultimately limiting the number of patients that can have access to, or can afford, these therapies).

To achieve these goals, the Company has developed a Point of Care Platform ("POCare Platform") comprised of three enabling components: (i) a pipeline of licensed POCare advanced therapies that are designed to be processed and produced, (ii) automated closed POCare technology systems, and (iii) a collaborative worldwide network of POCare research institutes and hospitals ("POCare Network").

The POCare Platform relies in particular on the development of its own production capacity, known as "POCare Services", whose goal is to ensure that therapies are accessible at the point of treatment (the "POCare Center"). POCare Services, which have been expanding worldwide, are based on a global approach and local adaptation that allows replication and expansion. Global harmonization of the POCare Services is ensured by a central quality system, replicability of infrastructure and equipment and centralized monitoring and data management.

The POCare Services include:

- Process development of therapies that are intended for use of the POCare Network,
- Adaptation of automation and closed systems to such therapies,
- Incorporation of the processing systems and the Good Manufacturing Processes ("GMP") in the OMPULs,
- Tech transfers to required POCare Centers and training of local teams,
- Processing and supply and of the therapies and required supplies under GMP conditions by the various POCare centers, including required quality control testing,
- CRO services for clinical trials.

POCare Centers are the decentralised hubs that provide harmonized services to customers and partners. The Company is working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. The workflow of a POCare Center is designed to allow rapid capacities expansion while integrating new technologies. The Company also draws on extensive medical expertise to identify promising new autologous therapies to leverage within the POCare Platform either via ownership or licensing.

The POCare Network brings together patients, doctors and industry partners with a goal of achieving harmonized, regulated clinical development and production of POCare advanced therapies.

The Company has worked to develop and validate POCare technologies that can be combined within mobile production units for advanced therapies. The Company has made significant investments in the development of several types of Orgenesis Mobile Processing Units and Labs ("OMPULs") with the expectation of use and/or distribution through the Company's POCare Network and/or partners, collaborators, and regional distributors. As of the date of this report, the OMPULs have been adapted for processing of CAR-T (chimeric antigen receptor T-cell) therapy, TIL (tumor infiltrating lymphocyte) and MSC (mesenchymal stem cell) based products, and are in the qualification stage for clinical use in various locations. Additional OMPULs are still in the development stage.

OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved advanced therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The OMPUL design delivers a potential industrial solution for us to deliver CGTs to practically any clinical institution at the point of care.

The Company has continued to grow its infrastructure and expand its processing sites into new markets and jurisdictions. In addition, the Company has continued investing manpower and financial resources to focus on developing, processing and rolling out several types of OMPULs to be used and/or distributed through its POCare Network and/or partners, collaborators, and regional distributors.

The Chief Executive Officer is the Company's chief operating decision-maker who reviews financial information prepared on a consolidated basis. All of our continuing operations are in one segment, being the point-of-care business via our POCare Platform. Therefore, no segment information has been presented.

The Company currently conducts its core CGT business operations through itself and its subsidiaries which are all wholly owned except as otherwise stated (collectively, the "Subsidiaries"). The Subsidiaries are as follows:

- Orgenesis Maryland Inc. (the "U.S. Subsidiary") is the center of activity in North America and is currently focused on setting up and providing POCare Services to the POCare Network.

- Koligo Therapeutics, Inc. ("Koligo") is a Kentucky corporation that we acquired in 2020. Koligo is a leading regenerative medicine company, specializing in developing personalized cell therapies. It is currently focused on commercialising its metabolic pipeline via the POCare network throughout the United States and in international markets.

- Orgenesis CA, Inc. (the "California subsidiary") is a Californian subsidiary incorporated in 2021 and is currently focussed on development of the Company's technologies and therapies in California.

- Orgenesis Belgium SRL (the "Belgian Subsidiary") is currently focused on expanding our POCare network in Europe, process development and the preparation of European clinical trials.

- Orgenesis Switzerland Sarl (the "Swiss Subsidiary"), was incorporated in October 2020, and is currently focused on providing management services to us.

- Orgenesis Germany GmbH (incorporated in 2021) (the "German subsidiary") is currently focused on providing CRO services to the POCare Network.

- Korea: Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"), is a provider of processing and pre-clinical services in Korea. The Company owns 94.12% of the Korean Subsidiary.

- Orgenesis Ltd. in Israel (the "Israeli Subsidiary") is a provider of regulatory, clinical and pre-clinical services in Israel.
-
- Orgenesis Biotech Israel Ltd. ("OBI") is a provider of process development and cell-processing services in Israel.

These consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries including the Discontinued Operations.

The Company's common stock, par value $0.0001 per share (the "Common Stock") is listed and traded on the Nasdaq Capital Market under the symbol "ORGS."

As used in this report and unless otherwise indicated, the term "Company" refers to Orgenesis Inc. and its Subsidiaries. Unless otherwise specified, all amounts are expressed in United States Dollars.

b. Liquidity

Through December 31, 2021, the Company had an accumulated deficit of $106.4 million as of December 31, 2021 and negative operating cashflows of $26.9 million in the year ended December 31, 2021. The Company's activities have been funded by generating revenue, through offerings of the Company's securities and selling its Contract Development and Manufacturing Organization ("CDMO") business. There is no assurance that the Company's business will generate sustainable positive cash flows to fund its business. See also note 21 with respect to an investment agreement in the amount of approximately $14.8 million (before deducting related offering expenses), which has been entered into subsequent to December 31, 2021.

Based on its current cash resources and commitments, including such investment agreement discussed in note 21, the Company believes it will be able to maintain its current planned development activities and expected level of expenditures for at least 12 months from the date of the issuance of these financial statements, although no assurance can be given that it will not need additional funds prior to such time. If there are further increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, the Company will need to use mitigating actions as to seek additional financing or postpone expenses that are not based on firm commitments. In addition, in order to fund the Company's operations until such time that the Company can generate sustainable positive cash flows, the Company may need to raise additional funds.

The estimation and execution uncertainty regarding the Company's future cash flows and management's judgments and assumptions in estimating these cash flows to conclude that the Company would have sufficient liquidity to fund its operations for at least the next 12 months is a significant estimate. Those assumptions include reasonableness of the forecasted revenue, operating expenses, and uses and sources of cash.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

a. Use of Estimates in the Preparation of Financial Statements

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity, the amount of revenues and expenses and determining whether an acquisition is a business combination or a purchase of asset. Actual results could differ from those estimates.

The full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We examined the impact of COVID-19 on our financial statements, and although there is currently no major impact, there may be changes to those estimates in future periods. Actual results may differ from these estimates.

b. Business Combination

The Company allocates the purchase price of an acquired business to the tangible and intangible assets acquired and liabilities assumed based upon their estimated fair values on the acquisition date. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Acquired in-process backlog, customer relations, technology, IPR&D, brand name and know how are recognized at fair value. The purchase price allocation process requires management to make significant estimates and assumptions, especially at the acquisition date with respect to intangible assets. Direct transaction costs associated with the business combination are expensed as incurred. The allocation of the consideration transferred in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date. The Company includes the results of operations of the business that it has acquired in its consolidated results prospectively from the date of acquisition.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer's previously held equity interest in the acquire is re-measured to fair value at the acquisition date; any gains or losses arising from such re-measurement are recognized in profit or loss.

c. Discontinued operations

Upon divestiture of a business, the Company classifies such business as a discontinued operations, if the divested business represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. For disposals other than by sale such as abandonment, the results of operations of a business would not be recorded as a discontinued operations until the period in which the business is actually abandoned.

The Masthercell Business divestiture qualifies as a discontinued operations and therefore has been presented as such.

The results of businesses that have qualified as a discontinued operations have been presented as such for all reporting periods. Results of discontinued operations include all revenues and expenses directly derived from such businesses; general corporate overhead is not allocated to discontinued operations. Any loss or gain that arose from the divestiture of a business that qualifies as discontinued operations is included within the results of the discontinued operations. The Company included information regarding cash flows from discontinued operations (See Note 3).

d. Cash Equivalents

The Company considers cash equivalents to be all short-term, highly liquid investments, which include money market instruments, that are not restricted as to withdrawal or use, and short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

e. Cost of services and other research and development expenses, net

Cost of services and other research and development expenses, net include costs directly attributable to the conduct of research and development activities, including the cost of salaries, stock-based compensation expenses, payroll taxes and other employees' benefits, lab expenses, consumable equipment, courier fees, travel expenses, professional fees and consulting fees. All costs associated with research and developments are expensed as incurred. Participation from government departments and from research foundations for development of approved projects is recognized as a reduction of expense as the related costs are incurred. Research and development in-process acquired as part of an asset purchase, which has not reached technological feasibility and has no alternative future use, is expensed as incurred.

f. Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its Subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

g. Non-Marketable Equity Investments

The Company's investments in certain non-marketable equity securities in which it has the ability to exercise significant influence, but it does not control through variable interests or voting interests. These are accounted for under the equity method of accounting and presented as Investment in associates, net, in the Company's consolidated balance sheets. Under the equity method, the Company recognizes its proportionate share of the comprehensive income or loss of the investee. The Company's share of income and losses from equity method investments is included in share in losses of associated company.

The Company reviews its investments accounted for under the equity method for possible impairment, which generally involves an analysis of the facts and changes in circumstances influencing the investments.

For other investments, the Company applies the measurement alternative upon the adoption of ASU 2016-01, and elected to record equity investments without readily determinable fair values at cost, less impairment, adjusted for subsequent observable price changes. In this measurement alternative method, changes in the carrying value of the equity investments are reflected in current earnings. Changes in the carrying value of the equity investment are required to be made whenever there are observable price changes in orderly transactions for the identical or similar investment of the same issuer.

h. Functional Currency

The currency of the primary economic environment in which the operations of the Company and part of its Subsidiaries are conducted is the U.S. dollar ("$" or "dollar"). The functional currency of the Belgian Subsidiaries is the Euro ("€" or "Euro"). The functional currency of Orgenesis Korea is the Won ("KRW"). Most of the Company's expenses are incurred in dollars, and the source of the Company's financing has been provided in dollars. Thus, the functional currency of the Company and its other subsidiaries is the dollar. Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for nonmonetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions – exchange rates at transaction dates or average rates and (2) for other items (derived from nonmonetary balance sheet items such as depreciation) – historical exchange rates. The resulting transaction gains or losses are recorded as financial income or expenses. The financial statements of the Belgian Subsidiaries and Orgenesis Korea are included in the consolidated financial statements, translated into U.S. dollars. Assets and liabilities are translated at year-end exchange rates, while revenues and expenses are translated at yearly average exchange rates during the year. Differences resulting from translation of assets and liabilities are presented as other comprehensive income.

i. Inventory

The Company's inventory consists of raw material for use for the services provided. The Company periodically evaluates the quantities on hand. Cost of the raw materials is determined using the weighted average cost method. The inventory is recorded at the lower of cost or net realizable value.

j. Property, plant and Equipment

Property, plant and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the related assets.

Annual rates of depreciation are presented in the table below:

	Weighted Average Useful Life (Years)
Production facility	5 – 10
Laboratory equipment	2 – 10
Office equipment and computers	3 – 17

k. Intangible assets

Intangible assets and their useful lives are as follows:

	Useful Life (Years)	**Amortization Recorded at Comprehensive Loss Line Item**
Customer Relationships	10	Amortization of intangible assets
Know-How	12	Amortization of intangible assets
Technology	15	Amortization of intangible assets
In-process research and development	Indefinite	

Intangible assets are recorded at acquisition less accumulated amortization and impairment. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the asset are expected to be generated. The Company capitalizes IPR&D projects acquired as part of a business combination. On successful completion of each project, IPR&D assets are reclassified to developed technology and amortized over their estimated useful lives.

l. Goodwill

Goodwill represents the excess of consideration transferred over the value assigned to the net tangible and identifiable intangible assets of businesses acquired. Goodwill is allocated to reporting units expected to benefit from the business combination. Goodwill is not amortized but rather tested for impairment at least annually in the fourth quarter, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Following the sale of Masthercell the Company manages the business as one operating segment and one reporting unit. Goodwill impairment is recognized when the quantitative assessment results in the carrying value exceeding the fair value, in which case an impairment charge is recorded to the extent the carrying value exceeds the fair value.

There were no impairment charges to goodwill during the periods presented.

m. Impairment of Long-lived Assets

The Company reviews its property, plants and equipment, intangible assets subject to amortization and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset class may not be recoverable. Indicators of potential impairment include: an adverse change in legal factors or in the business climate that could affect the value of the asset; an adverse change in the extent or manner in which the asset is used or is expected to be used, or in its physical condition; and current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of the asset. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted cash flows. There were no impairment charges in the years ended December 31, 2021 and 2020. For indefinite life intangible assets, The Company performs an impairment test annually in the fourth quarter and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. The Company determines the fair value of the asset based on discounted cash flows and records an impairment loss if its book value exceeds fair value.

n. Income Taxes

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

3) Taxes that would apply in the event of disposal of investment in Subsidiaries and associated companies have not been taken into account in computing the deferred income taxes, as it is the Company’s intention to hold these investments and not realize them.

o. Stock-based Compensation

The Company recognizes stock-based compensation for the estimated fair value of share-based awards. The Company measures compensation expense for share-based awards based on estimated fair values on the date of grant using the Black-Scholes option-pricing model. This option pricing model requires estimates as to the option’s expected term and the price volatility of the underlying stock. The Company amortizes the value of share-based awards to expense over the vesting period on a straight-line basis.

p. Redeemable Non-controlling Interest

Non-controlling interests with embedded redemption features, whose settlement is not at the Company's discretion, are considered redeemable non-controlling interest. Redeemable non-controlling interests are considered to be temporary equity and are therefore presented as a mezzanine section between liabilities and equity on the Company's consolidated balance sheets. Subsequent adjustment of the amount presented in temporary equity is required only if the Company's management estimates that it is probable that the instrument will become redeemable. Adjustments of redeemable non-controlling interest to its redemption value are recorded through additional paid-in capital.

q. Loss (income) per Share of Common Stock

Basic net loss (income) per share is computed by dividing the net loss (income) for the period by the weighted average number of shares of common stock outstanding for each period. Diluted net loss (income) per share is based upon the weighted average number of common shares and of common shares equivalents outstanding when dilutive. Common share equivalents include: (i) outstanding stock options and warrants which are included under the treasury share method when dilutive, and (ii) common shares to be issued under the assumed conversion of the Company's outstanding convertible loans and debt, which are included under the if-converted method when dilutive (See Note 14).

r. Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of principally cash and cash equivalents, bank deposits and certain receivables. The Company held these instruments with highly rated financial institutions and the Company has not experienced any significant credit losses in these accounts and does not believe the Company is exposed to any significant credit risk on these instruments apart of accounts receivable. The Company performs ongoing credit evaluations of its customers for the purpose of determining the appropriate allowance for doubtful accounts. An appropriate allowance for doubtful accounts is included in the accounts and netted against accounts receivable. In the year ended December 31, 2021 the Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

Bad debt allowance is created when objective evidence exists of inability to collect all sums owed it under the original terms of the debit balances. Material customer difficulties, the probability of their going bankrupt or undergoing economic reorganization and insolvency, material delays in payments and other objective considerations by management that indicate expected risk of payment are all considered indicative of reduced debtor balance value.

s. Treasury shares

The Company repurchases its ordinary shares from time to time on the open market and holds such shares as treasury stock. The Company presents the cost to repurchase treasury stock as a reduction of shareholders' equity. The Company did not reissue nor cancel treasury shares during the year ended December 31, 2021 and December 31, 2020.

t. Beneficial Conversion Feature ("BCF")

When the Company issues convertible debt, if the stock price is greater than the effective conversion price (after allocation of the total proceeds) on the measurement date, the conversion feature is considered "beneficial" to the holder. If there is no contingency, this difference is treated as issued equity and reduces the carrying value of the host debt; the discount is accreted as deemed interest on the debt (See Note 7).

u. Other Comprehensive Loss

Other comprehensive loss represents adjustments of foreign currency translation.

v. Revenue from Contracts with Customers

The Company recognizes revenue from contracts with customers according to ASC 606, *Revenue from Contracts with Customers* and the related amendments ("New Revenue Standard") to all contracts.

The Company's agreements are primarily service contracts that range in duration from a few months to one year. The Company recognizes revenue when control of these services is transferred to the customer for an amount, referred to as the transaction price, which reflects the consideration to which the Company is expected to be entitled in exchange for those goods or services.

A contract with a customer exists only when:

- the parties to the contract have approved it and are committed to perform their respective obligations;
- the Company can identify each party's rights regarding the distinct goods or services to be transferred ("performance obligations");
- the Company can determine the transaction price for the goods or services to be transferred; and
- the contract has commercial substance and 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.

The Company does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between the time of transfer of the promised goods or services to the customer and the time the customer pays for these goods or services to be generally one year or less. The Company's credit terms to customers are in average between thirty and one hundred and fifty days.

Nature of Revenue Streams

The Company's main revenue streams from continuing operations are POC development services and Cell Process Development Services.

POC Development Services

Revenue recognized under contracts for POC development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages are not interrelated or the customer is able to complete the services performed.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices.

The Company recognizes revenue when, or as, it satisfies a performance obligation. At contract inception, the Company determines whether the services are transferred over time or at a point in time. Performance obligations that have no alternative use and that the Company has the right to payment for performance completed to date, at all times during the contract term, are recognized over time. All other performance obligations are recognized as revenues by the Company at point of time (upon completion). In addition, during 2021, the Company started providing support services to its customers. These revenues are recognized as and when the services are provided because the customer simultaneously receives and consumes the benefits provided.

Also included in POC development services is Hospital supplies revenue which is derived principally from the performance of services to hospitals or other medical providers. Revenue is earned and recognized when product and services are received by the customer.

Significant Judgement and Estimates

Significant judgment is required to identifying the distinct performance obligations and estimating the standalone selling price of each distinct performance obligation and identifying which performance obligations create assets with alternative use to the Company, which results in revenue recognized upon completion, and which performance obligations are transferred to the customer over time.

Cell Process Development Services

Revenue recognized under contracts for cell process development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages and milestones are not interrelated or the customer is able to complete the services performed independently or by using competitors of the Company. In other contracts when the above circumstances are not met, the promises are not considered distinct and the contract represents one performance obligation. All performance obligations are satisfied over time, as there is no alternative use to the services it performs, since, in nature, those services are unique to the customer, which retain the ownership of the intellectual property created through the process. Additionally, due to the non-refundable upfront payment feature which may exist in certain contracts and which the customer pays together with the payment term and cancellation fine, Company has a right to payment (which includes a reasonable margin), at all times, for work completed to date, which is enforceable by law.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices. For these contracts, the standalone selling prices are based on the Company's normal pricing practices when sold separately with consideration of market conditions and other factors, including customer demographics and geographic location.

The Company measures the revenue to be recognized over time on a contract-by-contract basis, determining the use of either a cost-based input method or output method, depending on whichever best depicts the transfer of control over the life of the performance obligation.

Change Orders

Changes in the scope of work are common and can result in a change in transaction price, equipment used and payment terms. Change orders are evaluated on a contract-by-contract basis to determine if they should be accounted for as a new contract or as part of the existing contract. Generally, services from change orders are not distinct from the original performance obligation. As a result, the effect that the contract modification has on the contract revenue, and measure of progress, is recognized as an adjustment to revenue when they occur.

w. Leases

The Company recognizes lease expenses according to the lease standard ASC 842 and related amendments.

The Company determines if an arrangement is a lease at inception. Lease classification is governed by five criteria in ASC 842-10-25-2. If any of these five criteria is met, The Company classifies the lease as a finance lease; otherwise, the Company classifies the lease as an operating lease. When determining lease classification, the Company's approach in assessing two of the mentioned criteria is: (i) generally 75% or more of the remaining economic life of the underlying asset is a major part of the remaining economic life of that underlying asset; and (ii) generally 90% or more of the fair value of the underlying asset comprises substantially all of the fair value of the underlying asset.

Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the consolidated balance sheet.

ROU assets represent Orgenesis' right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments.

The standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. This means that for those leases, the Company does not recognize ROU assets or lease liabilities, including not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition, but recognizes lease expenses over the lease term on a straight-line basis.

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

x. Recently issued accounting pronouncements, not yet adopted

In June 2016, the FASB issued ASU 2016-13 “Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments.” This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for Smaller Reporting Companies (SRCs, as defined by the SEC) for the fiscal year beginning on January 1, 2023, including interim periods within that year. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In August 2020, the FASB issued Accounting Standards Update (“ASU”) 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40)-Accounting For Convertible Instruments and Contracts in an Entity’s Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after December 15, 2021, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company expects to apply modified retrospective basis adoption of this guidance, which will not have a significant impact on the Company’s consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815- 40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (“ASU 2021-04”). The guidance is effective for the Company on January 1, 2022. The Company expects that this guidance, will not have a significant impact on the Company’s consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08 “Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers”, which requires contract assets and contract liabilities acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606, Revenue from Contracts with Customers. The guidance will result in the acquirer recognizing contract assets and contract liabilities at the same amounts recorded by the acquiree. The guidance should be applied prospectively to acquisitions occurring on or after the effective date. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, including in interim periods, for any financial statements that have not yet been issued. The Company is currently evaluating this guidance to determine the impact it may have 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. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

NOTE 3 – DISCONTINUED OPERATION

On February 2, 2020, the Company entered into a Purchase Agreement with GPP, Masthercell and the Buyer. Pursuant to the terms and conditions of the Purchase Agreement, Sellers agreed to sell 100% of the outstanding equity interests of Masthercell to Buyer for an aggregate nominal purchase price of $315 million. The Company has determined that the Masthercell Business meets the criteria to be classified as discontinued operations.

On February 10, 2020, the Masthercell Sale was consummated in accordance with the terms of the Purchase Agreement. After accounting for GPP's liquidation preference and equity stake in Masthercell, as well as SFPI – FPIM's interest in MaSTherCell, distributions to Masthercell option holders and transaction costs, the Company received approximately $126.7 million at the closing of the Masthercell Sale, of which $7.2 million was used for the repayment of intercompany loans and payables, including $4.6 million of payables to MaSTherCell.

Due to the sale of the controlling interest in Masthercell, the Company retrospectively reclassified the assets and liabilities of these entities as assets and liabilities of discontinued operations and included the financial results of these entities as discontinued operations in the Company's consolidated financial statements.

Discontinued operations relate to the Masthercell Business. The comprehensive loss and balance sheet for this operation are separately reported as discontinued operations for all periods presented.

The financial results of the Masthercell Business are presented as income (loss) from discontinued operations, net of income taxes on the Company's consolidated statement of comprehensive loss. The following table presents the financial results associated with the Masthercell Business operation as reflected in the Company's Consolidated Comprehensive loss (in thousands):

	Year Ended December 31, 2020
OPERATIONS	
Revenues	$ 2,556
Cost of revenues	1,482
Cost of services and other research and development expenses, net	7
Amortization of intangible assets	137
Selling, general and administrative expenses	1,896
Operating loss	966
Other expenses, net	305
Financial income, net	(29)
Loss before income taxes	1,242
Tax income	(30)
Net loss from discontinuing operation, net of tax	$ 1,212
DISPOSAL	
Gain on disposal before income taxes	$ 96,918
Provision for income taxes	-
Gain on disposal	$ 96,918
Net profit from discontinuing operation, net of tax	$ 95,706

The following table represents the components of the cash flows from discontinued operations (in thousands):

	Year Ended December 31, 2020
Net cash flows used in operating activities	$ (2,409)
Net cash flows used in investing activities	$ (579)
Net cash flows used in financing activities	$ (51)

Disaggregation of Revenue

The following table disaggregates the Company's revenues by major revenue streams related to discontinued operations (in thousands):

	Year Ended December 31, 2020
Revenue stream:	
Cell process development services	$ 2,556
Total	$ 2,556

Redeemable Non-Controlling Interest of Discontinued Operations

a. *Subscription and Shareholders Agreement with Belgian Sovereign Funds Société Fédérale de Participations et d'Investissement ("SFPI(".*

On November 15, 2017, the Company, MaSTherCell and SFPI entered into a Subscription and Shareholders Agreement ("SFPI Agreement") pursuant to which SFPI made an equity investment in MaSTherCell.

Due to the embedded redemption feature of the SFPI agreement whose settlement was not at the Company discretion, the Company had accounted for the investment made by GPP as a redeemable non-controlling interest.

b. *Stock Purchase Agreement and Stockholders' Agreement with Great Point Partners, LLC ("GPP")*

On June 28, 2018, the Company, Masthercell Global GPP, and certain of GPP's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business.

Due to the embedded redemption feature of the GPP agreement whose settlement was not at the Company discretion, the Company had accounted for the investment made by GPP as a redeemable non-controlling interest.

NOTE 4 – ACQUISITION AND REORGANIZATION

Tamir Biotechnology, Inc.

On April 7, 2020, the Company entered into the Tamir Purchase Agreement with Tamir, pursuant to which the Company agreed to acquire certain assets and liabilities of Tamir related to the discovery, development and testing of therapeutic products for the treatment of diseases and conditions in humans, including all rights to Ranprinase and use for antiviral therapy. The Tamir Transaction closed on April 23, 2020.

As aggregate consideration for the acquisition, the Company paid $2.5 million in cash and issued an aggregate of 3,400,000 shares (the "Shares") of Common Stock to Tamir resulting in a total consideration of $20.2 million based on the Company's share price at the closing date. $4.5 million of the consideration was attributable to research and development related inventory and most of the remaining amount reflected the cost of intangible assets. The Shares were registered for resale by the Company in November 2020.

The Company's acquired right to Tamir's intellectual property represents a single identifiable asset sourced from the agreement. Because substantially all (more than 90%) of the fair value of the gross assets acquired are concentrated in a single asset being the right to Tamir's intellectual property and related assets ("IPR&D"), the Company determined that the acquisition is not considered a business in accordance with ASC 805-10-55-5A. Therefore, the Company accounted the transaction as an asset acquisition. The fair value associated with Tamir's IPR&D in the amount of $19.5 million was charged to research and development expenses under ASC 730. The remaining amount was attributed to the above-mentioned share in a private company, which is presented in the balance sheet as long term "other assets".

Included in the purchased assets of Tamir was the assumption by us of a worldwide license to a private company of certain Tamir technologies in the field of treatment, amelioration, mitigation or prevention of diseases or conditions of the eye and its adnexa in return for certain development and sales milestone payments to be paid to Tamir. We also received a less than 10% share interest in said private company in addition to the license fee and right to receive future milestone payments and royalties.

Koligo Therapeutics Acquisition

On September 26, 2020, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among the Company, Orgenesis Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), Koligo Therapeutics Inc., a Kentucky corporation ("Koligo"), the shareholders of Koligo (collectively, the "Shareholders"), and Long Hill Capital V, LLC ("Long Hill"), solely in its capacity as the representative, agent and attorney-in-fact of the Shareholders. The Merger Agreement provides for the acquisition of Koligo by the Company through the merger of Merger Sub with and into Koligo, with Koligo surviving as a wholly-owned subsidiary of the Company (the "Merger"). The acquisition was completed on October 15, 2020 (the "Effective Time").

Koligo was a privately-held US regenerative medicine company. Koligo's first commercial product is KYSLECEL® (autologous pancreatic islets) for chronic and acute recurrent pancreatitis. Koligo's 3D-V technology platform incorporates the use of advanced 3D bioprinting techniques and vascular endothelial cells to support development of transformational cell and tissue products for serious diseases.

Pursuant to the terms of the Merger Agreement, at the Effective Time, the shares of capital stock of Koligo that were issued and outstanding immediately prior to the Effective Time were automatically cancelled and converted into the right to receive, subject to customary adjustments, an aggregate of 2,061,713 shares of Company common stock which have been issued to Koligo's accredited investors (with certain non-accredited investors being paid solely in cash in the amount of approximately $20 thousand). In addition, the Company issued 66,910 shares to Maxim Group LLC for advisory services in connection with the Merger. The share price was $5.26 at the day of the closing.

As partial security for the indemnification and purchase price adjustment obligations of Koligo shareholders under the Merger Agreement, $7 thousand in cash and 328,587 shares of Company common stock of the merger consideration otherwise payable in the Merger to the Shareholders were placed in a third party escrow account until April 2022. The aggregate indemnification obligations of the Koligo shareholders under the Merger Agreement is capped at the amounts in escrow, subject to certain limited exceptions.

In addition, according to the agreement between the parties, the Company funded an additional cash consideration of $500 thousand (with $100 thousand of such reducing the ultimate consideration payable to Koligo) for the acquisition of the assets of Tissue Genesis, LLC ("Tissue Genesis") by Koligo that was consummated on October 14, 2020. The Tissue Genesis assets include the entire inventory of Tissue Genesis Icellator® devices, related kits and reagents, a broad patent portfolio to protect the technology, registered trademarks, clinical data, and existing business relationships for commercial and development stage use of the Icellator technology.

In connection with the Merger Agreement, the Company, Long Hill and Maxim Group LLC ("Maxim") entered into a Registration Rights and Lock-Up Agreement. All of the shares required to be registered by the Company pursuant to the Registration Rights and Lock-Up Agreement were registered by the Company in November 2020.

In addition, pursuant to separate Lock-Up Agreements entered into by the Shareholders other than Long Hill with the Company (the "Shareholders Lock-Up Agreement"), such Shareholders agreed that they will not transfer any of their shares received in the Merger except in accordance with the following lock-up release schedule whereby one fifth of such holder's respective shares will be released from such restriction every six months, starting six months from the closing of the Merger. Each holder's sales of such shares are subject to a resale limit of its pro rata portion of 10% of the average daily trading volume, allocated to the Shareholders other than Long Hill pro-rata.

The acquisition was accounted in accordance with Accounting Standards Codification Topic 805, “Business Combinations”. The allocation of the consideration transferred in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date. The Company includes the results of operations of the business that it has acquired in its consolidated results prospectively from the date of acquisition.

Fair Value of Consideration Transferred

The following table summarizes the allocation of purchase price to the fair values of the assets acquired and liabilities assumed as of the transaction date:

	(in thousands)
Fair value of 8.8% of shared issued *	11,172
Cash payment	1,115
Total consideration transferred	$ 12,287

* Fair value of the consideration is based on the company’s market share price.

Total assets acquired:	
Cash and cash equivalents	$ 8
Restricted Cash	152
Accounts Receivable	228
Inventory	34
Other assets	25
Property, plants and equipment, net	482
Kyslecel Technology (a)	9,340
IPR&D (a)	641
Operating lease right-of-use assets	238
Goodwill (b)	3,704
Total assets	14,852
Total liabilities assumed:	
Operating leases	238
Accounts Payable	216
Accrued Expenses	4
Orgenesis Inc loan	651
Deferred taxes	1,293
Notes Payable	162
Other liabilities	1
Total liabilities	2,565
Total consideration transferred	$ 12,287

a. The allocation of the purchase price to the net assets acquired and liabilities assumed resulted in the recognition of other intangible assets which comprised of: Kyslecel Technology of $9,340 and IPR&D of 641. Kyslecel Technology has a useful life of 15 years. The useful life of these intangible assets for amortization purposes was determined considering the period of expected cash flows generated by the assets used to measure the fair value of the intangible assets adjusted as appropriate for the entity-specific factors, including legal, regulatory, contractual, competitive, economic or other factors that may limit the useful life of intangible assets.

These intangible assets were estimated using a discounted cash flow method with the application of the multi-period excess earnings method. Under this method, an intangible asset’s fair value is equal to the present value of the incremental after-tax cash flows attributable only to the subject intangible asset after deducting contributory asset charges. An income and expenses forecast were built based upon revenue and expense estimates.

b. The primary items that generate goodwill include the value of the synergies between the acquired company and the Company and the acquired assembled workforce, neither of which qualifies for recognition as an intangible asset. The Goodwill is not deductible for tax purposes.

Pro forma Impact of Business Combination

The unaudited pro forma financial results have been prepared using the acquisition method of accounting and are based on the historical financial information of the Company and Koligo. The unaudited pro forma condensed financial results have been prepared for illustrative purposes only and do not purport to be indicative of the results of operations that actually would have resulted had the acquisition of Koligo occurred at the beginning of the fiscal year, or of future results of the combined entities. The unaudited pro forma condensed financial information does not reflect any operating efficiencies and expected realization of cost savings or synergies associated with the acquisition.

Unaudited supplemental pro forma combined results of operations (in thousands):

	Year ended December 31, 2020
Revenues	$ 8,239
Net loss	$ 318
Loss per share:	
Basic	$ 0.05

Koligo's related actual results from the date of acquisition to December 31, 2020 resulted in a loss of $513 thousand.

Koligo's Acquisition-related Costs

Acquisition-related expenses consist of transaction costs which represent external costs directly related to the acquisition of Koligo and primarily include expenditures for professional fees such as legal, accounting and other directly related incremental costs incurred to close the acquisition by both the Company and Koligo.

Acquisition-related expenses for the year ended December 31, 2020 were $682 thousand. These expenses were recorded to selling and general administrative expense in the consolidated statements of comprehensive loss.

Extracellular Vesicle ("EV") Technology License

During the third quarter of 2020, the Company purchased IP and related EV technology pursuant to an EV agreement (the "EV agreement"). According to the EV agreement, the Company received all of the rights in the EV technology purchased, in the amount of $500 thousand, which was paid during 2020 and 2021. The $500 thousand was recorded in R&D expenses. In addition, the Company received an exclusive worldwide license to use the EV IP technology for any purpose.

NOTE 5 – PROPERTY, PLANTS AND EQUIPMENT

The following table represents the components of property, plants and equipment:

	December 31,	
	2021	2020
	(in thousands)	
Cost:		
Production facility	$ 4,040	$ 2,801
Office furniture and computers	555	697
Lab equipment	2,435	1,483
Advance payment	6,181	281
Subtotal	13,211	5,262
Less – accumulated depreciation	(2,940)	(2,189)
Total	$ 10,271	$ 3,073

Depreciation expense for the years ended December 31, 2021 and December 31, 2020 were $916 thousand and $705 thousand, respectively.

Property, plants and equipment, net by geographical location were as follows:

	December 31,	
	2021	2020
	(in thousands)	
Belgium	$ 1,149	$ 358
Korea	694	839
Israel	2,602	1,386
U.S.	5,826	490
Total	$ 10,271	$ 3,073

NOTE 6 – INTANGIBLE ASSETS AND GOODWILL

Changes in the carrying amount of the Company's goodwill for the years ended December 31, 2021 and 2020 are as follows:

	(in thousands)
Goodwill as of December 31, 2019	$ 4,812
Goodwill as acquired, (Koligo) see note 4	3,704
Translation differences	229
Goodwill as of December 31, 2020	$ 8,745
Translation differences	(342)
Goodwill as of December 31, 2021	$ 8,403

Goodwill Impairment

See Note 2(l) for the Company's goodwill impairment analysis.

Other Intangible Assets

Other intangible assets consisted of the following:

	December 31,	
	2021	2020
	(in thousands)	
Gross Carrying Amount:		
Know How	$ 2,904	$ 3,170
Customer relationships	811	886
Kyslecel Technology	9,340	9,340
IPR&D	641	641
Subtotal	13,696	14,037
Less – Accumulated amortization	(1,875)	(1,014)

Net carrying amount of other intangible assets	$ 11,821	$ 13,023

Intangible assets amortization expenses were approximately $948 thousand and $478 thousand for the years ended December 31, 2021 and December 31, 2020, respectively.

Estimated aggregate amortization expenses for the five succeeding years ending on December 31st are as follows:

	2022	2023 to 2026
	(in thousands)	
Amortization expenses	$ 323	$ 1,390

NOTE 7 – CONVERTIBLE LOANS

a. Long term convertible loans outstanding as of December 31, 2021 and December 31, 2020 are as follows:

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	NOTE	BCF
(in thousands)			(Years)			
Convertible Loans Outstanding as of December 31, 2021						
$ 750	*2018	2%	5	7.00	(1)+(4)	39
8,750	*2019	6%-8%	3-5	7.00	(2)+(4)	-
250	*2020	8%	3	7.00	(3)	-
$ 9,750						

* **Extended during the year ended December 31, 2021**

Convertible Loans Outstanding as of December 31, 2020

$ 1,000	2018	2%	3	7.00	(1)+(4)	71
9,500	2019	6%-8%	2-5	7.00	(2)+(4)	-
250	2020	8%	2	7.00	(3)	-
$ 10,750						

Convertible Loans repaid during the year ended December 31, 2021

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF
750	2019	8%	2	$ 7	31
250	2018	2%	3	7	-
1,000					

Convertible Loans repaid during the year ended December 31, 2020

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF
500	2018	2%	2	$ 7	53
500	2019	6%	2	7	-
1,400	2019	8%	3	7	-
2,400					

Apart from the items mentioned below there were no repayments of convertible loans during the fiscal years ended December 31, 2020 and December 31, 2021. In addition, there were no conversions during the fiscal years ended December 31, 2020 and December 31, 2021.

(1) The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 113,775 shares and 113,775 three-year warrants to purchase up to an additional 113,775 shares of the Company's common stock at a per share exercise price of $7. As of December 31, 2021, the loans are presented in current maturities of convertible notes in the balance sheet (See Notes 10(f) and 10(g)).

(2) The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 1,363,206 shares and 1,070,176 three-year warrants to purchase up to an additional 1,070,176 shares of the Company's common stock at a per share exercise price of $7. As of December 31, 2021, $3,750 thousand of the principal amount is included in current maturities of convertible loans in the balance sheet and the remainder in long-term convertible loans. See also Notes 7(b), 7(c), 7(d) and 7(e).

(3) The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 41,416 shares at a per share exercise price of $7. As of December 31, 2021, all the principal amount is included in short-term convertible loans in the balance sheet. See also Notes 7(f).

(4) During the year ended December 31, 2021, the Company and certain convertible loan holders (including certain credit line investors, see note 7 (e)) agreed to extend the maturity date on loans due during the fourth quarter of 2021 to June 30, 2023. The principal amount extended was $2.25 million excluding the credit line investors. The loan holders may request that the Company repay them on November 21, 2022 (the "Early Redemption Option"). In consideration for the extension, including for the credit line investors, warrants to purchase 926,413 shares of common stock of the Company were issued to the loan holders at an exercise price of $6.24 per share. If the Early Redemption Option is exercised, the warrants will be cancelled. The latest date to exercise the warrants is June 30, 2023. During March 2022 the loan holders waived the early redemption option.

The Company concluded that the change in the terms (including for the credit line investors extension) does not constitute a troubled debt restructuring. The Company therefore applied the guidance in ASC 470-50, Modifications and Extinguishments. The accounting treatment is determined by whether terms of the new debt and original debt are substantially different. The new debt and the old debt are considered "substantially different" pursuant to ASC 470-50 when the change in the fair value of the embedded conversion option is at least 10% of the carrying amount of the original debt instrument immediately before the modification or exchange or the value of the cash flows under the terms of the new debt instrument is at least 10% different from the present value of the remaining cash flows under the terms of the original instrument (including the incremental fair value resulting from issuing new warrants held by the lender). If the original and new debt instruments are substantially different, the original debt is derecognized and the new debt should be initially recorded at fair value, with the difference recognized as an extinguishment gain or loss. Based on the analysis, the Company concluded that the change in terms should be accounted for as an extinguishment. The extinguishment resulted in a loss of $1,865 thousand. The Company concluded that, since the warrants cannot be exercised prior to the expiry date of the Early Redemption Option, the warrants are considered embedded in the convertible loan and not freestanding instruments. It also concluded that the prepayment option and the embedded warrants should not be bifurcated from the debt host. In accordance with ASC 470-20-25-13, if a convertible debt instrument is issued at a substantial premium, there is a presumption that such premium represents paid-in capital. Since the fair value of the new convertible loan instrument issued as part of the change in terms are higher than the par value of the loan and the premium is substantial, the Company allocated the premium to paid in capital and the reminder to the convertible loan.

The fair value of the conversion feature was estimated using the binomial model. The total fair value of the new instruments is $4.4M (including the credit line agreements).

Following are the main estimates and assumptions that were used for the valuation of the new instruments as of the valuation date:

Parameter	8% Note	2% Note	Warrants
Notional (USD)	1,500,000	750,000	926,413
Accrued Coupon (USD)	224,603	41,945	-
Coupon Rate	8.00%	2.00%	-
Conversion Ratio (USD)	7.00	7.00	-
Exercise Price (USD)	-	-	6.24
Stock Price (USD)	5.02	5.02	5.02
Expected Term (years)	1.79	1.79	1.79
Risk Free Rate	0.20%	0.20%	0.20%
Volatility	72.84%	72.84%	72.84%
Yield	7.87%	7.84%	-

b. During May 2019, the Company entered into a private placement subscription agreement with an investor for $5 million. The lender shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share.

The transaction costs were approximately $497 thousand, out of which $97 thousand are stock-based compensation due to issuance of warrants.

c. In June 2019, the Company entered into private placement subscription agreements with investors for an aggregate amount of $2 million. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share.

d. During October 2019, the Company entered into a Private Placement Subscription Agreement and Convertible Credit Line Agreement (collectively, the "Credit Line Agreements") with four non-U.S. investors (the "Lenders"), pursuant to which the Lenders furnished to the Company access to an aggregate $5.0 million credit line (which consists of $1.25 million from each Lender) (collectively, the "Credit Line"). Pursuant to the Credit Line Agreements, the Company was entitled to draw down an aggregate of $1 million (consisting of $250 thousand from each Lender) of the Credit Line in each of October 2019 and November 2019. In each of December 2019, January 2020 and February 2020, the Company may draw down an additional aggregate of $1 million (consisting of $250 thousand from each Lender), until the total amount drawn down under the Credit Line reaches an aggregate of $5 million (consisting of $1.25 million from each Lender), subject to the approval of the Lenders.

Pursuant to the terms of the Credit Line Agreements and the Notes, the total loan amount, and all accrued but unpaid interest thereon, became due and payable on the second anniversary of the Effective Date (the "Maturity Date"). The Maturity Date may be extended by each Lender in its sole discretion and shall be in writing signed by the Company and the Lender. Interest on any amount that has been drawn down under the Credit Line accrues at a per annum rate of eight percent (8%). At any time prior to or on the Maturity Date, by providing written notice to the Company, each of the Lenders is entitled to convert its respective drawdown amounts and all accrued interest, into shares of the Company's common stock, par value $0.0001 per share (the "Common Stock"), at a conversion price equal to $7.00 per share.

Furthermore, upon the drawdown of $500 thousand from each Lender and, together with the other Lenders, a drawdown of an aggregate of $2 million under the Credit Line, the existing warrants of the Lenders to purchase shares of Common Stock shall be amended to extend their exercise date to June 30, 2021 and the Company will issued to each of the Lenders warrants to purchase 50,000 shares of Common Stock at an exercise price of $7.00 per share. The new warrants will be exercisable for three (3) years from the Effective Date. During October 2019, such drawdown was reached and the warrants were issued.

During the year ended December 2020, the Company repaid principal amount of $2,400 thousand and a total interest amount of $372 thousand to certain of the credit line investors.

During the year ended December 2021, the company repaid principal amount of $1,000 thousand and a total interest amount of $140 thousand to certain of the credit line investors.

See note 7 (a) (4) regarding the extension of certain of the Credit Line Agreements.

e. In December 2019, the Company entered into private placement subscription agreements with investors for an aggregate amount of $250 thousand. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of 1 share of common stock of the Company at a conversion price per share equal to $7.00. In addition, the Company granted the investors 183,481 warrants to purchase an equal number of additional shares of Common Stock at a price of $7.00 per share. The fair value of the warrants was $124 thousand using the fair value of the shares on the grant date. During 2021, the Company and the investors agreed to extend the maturity of the loans to December 2022. Based on the analysis, the Company concluded that the change in terms should be accounted for as a modification.

f. On January 2, 2020, the Company entered into private placement subscription agreements with investors for an aggregate amount of $250 thousand of convertible loans. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into shares of Common Stock of the Company at a conversion price per share equal to $7.00. In addition, the Company granted the investors 151,428 warrants to purchase an equal number of additional shares of Common Stock at a price of $7.00 per share. During 2021, the Company and the investors agreed to extend the maturity of the loans to December 2022. Based on the analysis, the Company concluded that the change in terms should be accounted for as a modification.

h . On November 2, 2016, the Company entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of NIS 1 million ($280 thousand). The loan bears a monthly interest rate of 2% and mature on May 1, 2017, unless converted earlier. On April 27, 2017 and November 2, 2017, the Company entered into extension agreements through November 2, 2017 and May 2, 2018, respectively.

In March 2018, the investor submitted a notice of its intention to convert into shares of the Company’s common stock the principal amount and accrued interest of approximately $383 thousand outstanding. A related party of such investor at the same time, exercised warrants issued in November 2016 to purchase shares of the Company’s Common Stock. The exercise price of the warrants and conversion price were fixed at $0.52 per share (pre-reverse stock split implemented by the Company in November 2017). There is a significant disagreement between the Company and these two entities as to the number of shares of Common Stock issuable to these entities, and they contend that the number of shares of Common Stock issuable to them should not consider the reverse stock split. The Company rejects these contentions in their entirety and, based on the advice of specially retained counsel, believes that these claims are without legal merit and not made in good faith. The Company intends to vigorously defend its interests and pursue other avenues of legal address. Through its counsel, the Company has advised these entities that unless they withdraw their request within a specified period, the Company will cancel the above referenced agreements and these parties’ right to receive any shares of the Company’s Common Stock. In April 2018, the Company withdrew the agreements and deposited the shares in total amount of 107,985 issued under those agreements and the principal amount and accrued interest of the loan in escrow account. The deposit of the principal amount and accrued interest presented as restricted cash in the balance sheet as of December 31, 2021.

NOTE 8 – LOANS

Terms of Short-term Loans

	Currency	Interest Rate	December 31, 2021	December 31, 2020
			(in thousands)	
Short term loans	USD	1.00%	-	145
			$ -	$ 145

NOTE 9 – LEASES

The Company leases research and development facilities, equipment and offices under finance and operating leases. For leases with terms greater than 12 months, the Company record the related asset and obligation at the present value of lease payments over the term. Many of the leases include rental escalation clauses, renewal options and/or termination options that are factored into the determination of lease payments when appropriate.

The Company's leases do not provide a readily determinable implicit rate. Therefore, the Company estimated the incremental borrowing rate to discount the lease payments based on information available at lease commencement.

Manufacturing facilities

The Company leases space for its manufacturing facilities in Israel under operating lease agreements. The leasing contracts are for a period of 3 – 5 years.

Research and Development facilities

The Company leases space for its research and development facilities in South Korea under an operating lease agreement. The leasing contracts are for a period of 2 – 5 years.

Offices

The Company leases space for offices in Israel under operating leases. The leasing contracts are valid for terms of 5 years. These contracts are considered as operational leasing and under operating lease right-of-use assets.

Lease Position

The table below presents the lease-related assets and liabilities recorded on the balance sheet:

	December 31,	
	2021	**2020**
Assets		
Operating Leases		
Operating lease right-of-use assets	$ 1,015	$ 1,474
Finance Leases		
Property, plants and equipment, gross	91	99
Accumulated depreciation	(33)	(17)
Property and equipment, net	$ 58	$ 82
Liabilities		
Current liabilities		
Current maturities of operating leases	$ 481	$ 485
Current maturities of long-term finance leases	$ 18	$ 19
Long-term liabilities		
Non-current operating leases	$ 561	$ 1,020
Long-term finance leases	$ 41	$ 64
Weighted Average Remaining Lease Term		
Operating leases	2.3 years	3.4 years
Finance leases	3.2 years	4.2 years
Weighted Average Discount Rate		
Operating leases	6.9%	6.7%
Finance leases	2.0%	2.0%

Lease Costs

The table below presents certain information related to lease costs and finance and operating leases:

	Years ended December 31, 2021	2020
Operating lease cost:	$ 514	547
Finance lease cost:		
Amortization of leased assets	20	17
Interest on lease liabilities	1	3
Total finance lease cost	$ 21	20

The table below presents supplemental cash flow information related to lease:

	Years ended December 31, 2021	2020
	(in Thousands)	
Cash paid for amounts included in the measurement of leases liabilities:		
Operating leases	$ 526	$ 515
Finance leases	$ 20	$ 42
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ -	$ 967
Finance leases	-	366

Undiscounted Cash Flows

The table below reconciles the undiscounted cash flows for each of the first five years and total of the remaining years to the finance lease liabilities and operating lease liabilities recorded on the balance sheet.

	Operating Leases	Finance Leases
Year ended December 31,		
2022	$ 516	$ 19
2023	338	19
2024	181	19
2025	54	4
Total minimum lease payments	1,089	61
Less: amount of lease payments representing interest	(47)	(2)
Present value of future minimum lease payments	1,042	59
Less: Current leases obligations	(481)	(18)
Long-term leases obligations	$ 561	$ 41

Right-of-use assets by geographical location were as follows:

	December 31,	
	2021	2020
	(in thousands)	
Korea	$ 432	$ 683
Israel	365	496
U.S.	218	295
Total	$ 1,015	$ 1,474

NOTE 10 – COMMITMENTS AND LICENSE AGREEMENTS

See Note 11 for additional commitments for funding of the ventures of the company.

a. *Tel Hashomer Medical Research, Infrastructure and Services Ltd ("THM")*

On February 2, 2012, the Company's Israeli Subsidiary entered into a licensing agreement with THM. According to the agreement, the Israeli Subsidiary was granted a worldwide, royalty bearing, exclusive license to trans-differentiation of cells to insulin producing cells, including the population of insulin producing cells, methods of making this population, and methods of using this population of cells for cell therapy or diabetes treatment developed by Dr. Sarah Ferber of THM.

As consideration for the license, the Israeli Subsidiary will pay the following to THM:

1) A royalty of 3.5% of net sales;
2) 16% of all sublicensing fees received;
3) An annual license fee of $15 thousand, which commenced on January 1, 2012 and shall be paid once every year thereafter. The annual fee is non-refundable, but it shall be paid each year against the royalty noted above, to the extent that such are payable, during that year; and
4) Milestone payments as follows:
    a. $50 thousand on the date of initiation of Phase I clinical trials in human subjects;
    b. $50 thousand on the date of initiation of Phase II clinical trials in human subjects;
    c. $150 thousand on the date of initiation of Phase III clinical trials in human subjects;
    d. $750 thousand on the date of initiation of issuance of an approval for marketing of the first product by the FDA; and
    e. $2 million when worldwide net sales of Products (as defined in the agreement) have reached the amount of $150 million for the first time, (the "Sales Milestone").

As of December 31, 2021, the Israeli Subsidiary had not reached any of these milestones.

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Israeli Subsidiary and/or consolidation of the Israeli Subsidiary or the Company into or with another corporation ("Exit"), the THM shall be entitled to choose whether to receive from the Israeli Subsidiary a one-time payment based, as applicable, on the value of either 463,651 shares of common stock of the Company at the time of the Exit or the value of 1,000 shares of common stock of the Israeli Subsidiary at the time of the Exit.

b. Department De La Gestion Financiere Direction De L'analyse Financiere ("DGO6")

(1) On November 17, 2014, the Belgian Subsidiary, received the formal approval from the DGO6 for a Euro 2 million ($2.4 million) support program for the research and development of a potential cure for Type 1 Diabetes. The financial support was composed of Euro 1.085 million (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of Euro 930 thousand (60% of budgeted costs) of the experimental development part of the research program. In December 2014, the Belgian Subsidiary received advance payment of Euro 1.209 million under the grant. The grants are subject to certain conditions with respect to the Belgian Subsidiary's work in the Walloon Region. In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. In 2017 the Company received by the DGO6 final approval for Euro 1.8 million costs invested in the project out of which Euro 1.2 million funded by the DGO6. As of December 31, 2021, the Company repaid to the DGO6 a total amount of approximately $145 thousand and amount of $264 thousand was recorded in other payables.

(2) In April 2016, the Belgian Subsidiary received the formal approval from DGO6 for a Euro 1.3 million ($1.5 million) support program for the development of a potential cure for Type 1 Diabetes. The financial support was awarded to the Belgium Subsidiary as a recoverable advance payment at 55% of budgeted costs, or for a total of Euro 717 thousand ($800 thousand). The grant will be paid over the project period. The Belgian Subsidiary received advance payment of Euro 438 thousand ($537 thousand). Up through December 31, 2021, an amount of Euro 358 thousand ($406 thousand) was recorded as deduction of research and development expenses and an amount of Euro 74 thousand was recorded as advance payments on account of grant.

(3) On October 8, 2016, the Belgian Subsidiary received the formal approval from the DGO6 for a Euro 12.3 million ($12.8 million) support program for the GMP production of AIP cells for two clinical trials that will be performed in Germany and Belgium. The project will be conducted during a period of three years commencing January 1, 2017. The financial support is awarded to the Belgium subsidiary at 55% of budgeted costs, a total of Euro 6.8 million ($7 million). The grant will be paid over the project period. On December 19, 2016, the Belgian Subsidiary received a first payment of Euro 1.7 million ($2 million). As of December 31, 2021 the program is pending for extension approval.

(4) In December 2020, the Belgian Subsidiary received the formal approval from DGO6 for a Euro 2.9 million ($3.5 million) support program for research on Dermatitis Treatments and Wound Healing Using Cell Regenerative Technologies. The financial support was awarded to the Belgium Subsidiary as a recoverable advance payment at 60% of budgeted costs, or for a total of Euro 1.7 million ($2.1 million). The grant will be paid over the project period. The Belgian Subsidiary received advance payments of Euro 301 thousand ($366 thousand) in 2020 and of Euro 392 thousand ($445 thousand) in 2021. The research program started in 2021.

c. Israel-U.S. Binational Industrial Research and Development Foundation ("BIRD")

On September 9, 2015, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with BIRD and Pall Corporation, a U.S. company. BIRD awarded a conditional grant of up to $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use of Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the "Project"). Company received a total of $299 thousand under the grant. The project was completed in 2019. The grant is to be repaid at the rate of 5% of gross sales generated from the Project. To date no sales have been generated.

d. Korea-Israel Industrial Research and Development Foundation ("KORIL")

On May 26, 2016, the Israeli Subsidiary and the Korean Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with KORIL. KORIL will make a conditional grant of up to $400 thousand to each company (according to terms defined in the agreement), for a joint research and development project for the use of AIP Cells for the Treatment of Diabetes (the "Project"). The Project started on June 1, 2016. The project was completed in 2021 and the Company is currently awaiting the grant audit report from KORIL. The grant is to be repaid at the yearly rate of 2.5% of gross sales. To date no sales have been generated. As of December 31, 2021, the Israeli Subsidiary and the Korean Subsidiary received $440 thousand under the grant.

e. BIRD Secant

On July 30, 2018, Orgenesis Inc and OBI entered into a collaboration agreement with Secant Group LLC ("Secant"). Under the agreement, Secant will engineer and prototype 3D scaffolds based on novel biomaterials and technologies involving bioresorbable polymer microparticles, while OBI will provide expertise in cell coatings, cell production, process development and support services. Under the agreement, Orgenesis is authorized to utilize the jointly developed technology for its autologous cell therapy platform, including its Autologous Insulin Producing ("AIP") cell technology for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases. In 2018, OBI entered into a Cooperation and Project Funding Agreement (CPFA) with the BIRD fund, which provided certain grant funding, and Secant.

As of December 31, 2021, OBI had received a total amount of $425 thousand under the grant and the project was completed. The grant is to be repaid at the yearly rate of 5% of gross sales. To date no sales have been generated.

f. Hemogenyx Pharmaceuticals PLC.

On October 18, 2018, the Company and Hemogenyx Pharmaceuticals PLC., a corporation with its registered office in the United Kingdom and Hemogenyx-Cell ("H-Cell"), a corporation with its registered office in Belgium (together "Hemo"), who are engaged in the development of cell replacement bone marrow therapy technology, entered into a Collaboration Agreement (the "Hemo Agreement") pursuant to which the parties will collaborate in the funding, continued development, and commercialization of the Hemo technology via Hemo. Pursuant to the Hemo agreement the Company and Hemogenyx LLC ("Hemo-LLC") (a wholly owned US subsidiary of Hemo) entered into a loan agreement on November 7, 2018 according to which the Company agreed to loan Hemo-LLC not less than $1 million by way of a convertible loan. On November 25, 2018 the Company and Hemo entered into a License and Distribution agreement according to which Company received the worldwide rights to market the products under the agreement in consideration for the payment of a 12% royalty all subject to the terms of the agreement. As of December 31, 2021, no royalty incurring sales were made. On November 25, 2018, the Company and H-Cell signed an Exclusive Manufacturing agreement according to which the Company will receive the exclusive right to manufacture certain of H-Cell products. The Company recorded the loan amounts as research and development expenses under ASC 730-10-50 and 20-50 in 2018 and 2019. The loan amounts were repaid in 2021 and presented as other income.

g. Immugenyx LLC.

On October 16, 2018, the Company and Immugenyx LLC., a corporation with its registered office in the USA ("Immu"), which is engaged in the development of technology related to the production and use of humanized mice entered into a Collaboration Agreement (the "Immu Agreement") pursuant to which the parties will collaborate in the funding, continued development, and commercialization of the Immu technology. Pursuant to the agreement, the Company received the worldwide rights to market the products under the agreement in consideration for the payment of a 12% royalty all subject to the terms of the agreement. As of December 31, 2021 no royalty incurring sales were made. Pursuant to the Immu agreement the Company and Immu entered into a loan agreement on November 7, 2018 according to which the Company agreed to loan Immu not less than US$1 million by way of a convertible loan. The Company recorded the loan amounts as research and development expenses under ASC 730-10-50 and 20-50 in 2018 and 2019. The loan amounts were repaid in 2021 and were presented as other income.

h. BG Negev Technologies and Applications ("BGN").

On August 2, 2018, Company entered into a licensing agreement with BGN. According to the agreement, the Company was granted a worldwide, royalty bearing, exclusive license to develop and commercialize a novel alginate scaffold technology for cell transplantation focused on autoimmune diseases.

On November 25, 2018, the Company entered into a further licensing agreement with BGN. According to the agreement, the U.S. Subsidiary was granted a worldwide, royalty bearing, exclusive license to develop and commercialize technology directed to RAFT modification of polysaccharides and use of a bioreactor for supporting cell constructs.

As of December 31, 2021 no royalty incurring sales were made.

In January 2022, the Company terminated both of the licensing agreements with BGN effective April 26, 2022.

i. Sponsored Research and Exclusive License Agreement with Columbia University

Effective April 2, 2019, the Company and The Trustees of Columbia University in the City of New York, a New York corporation, ("Columbia") entered into a Sponsored Research Agreement (the "SRA") whereby the Company will provide financial support for studying the utility of serological tumor marker for tumor dynamics monitoring. Under the terms of the SRA, the Company shall pay $300 thousand per year for three years, or for a total of $900 thousand, with payments of $150 thousand due every six months.

Effective April 2, 2019, the Company and Columbia entered into an Exclusive License Agreement (the "Columbia License Agreement") whereby Columbia granted to the Company an exclusive license to discover, develop, manufacture, sell, and otherwise distribute certain product in the field of cancer therapy. In consideration of the licenses granted under the Columbia License Agreement, the Company shall pay to Columbia (i) a royalty of 5% of net sales of any product sold which incorporates a licensed Columbia patent and (ii) 2.5% of net sales of other products. In addition, the Company shall pay a flat $100 thousand fee to Columbia upon the achievement of each regulatory milestone. As of December 31, 2021, no royalty incurring sales were made.

j. Regents of the University of California

In December 2019, the Company and the Regents of the University of California ("University") entered into a joint research agreement in the field of therapies and processing technologies according to an agreed upon work plan. According to the agreement, the Company will pay the University royalties of up to 5% (or up to 20% of sub-licensing sales) in the event of sales that includes certain types of University owned IP. As of December 31, 2021, no royalty incurring sales were made.

k. Caerus Therapeutics Inc

In October 2019, the Company and Caerus Therapeutics ("Caerus"), a Virginia company, concluded a license agreement whereby Caerus granted the Company an exclusive license to all Caerus IP relating to Advance Chemeric Antigen Vectors for Targeting Tumors for the development and/or commercialization of certain licensed products. In consideration for the License granted to the Company under this Agreement, the Company shall pay Caerus annual maintenance fees and royalties of sales of up to 5% and up to 18% of sub-license fees. As of December 31, 2021, no royalty incurring sales were made.

l. Tissue Genesis, LLC ("Tissue Genesis")

Included in the Koligo acquisition (See Note 4) were the assets of Tissue Genesis. The Company is committed to paying the previous owners of Tissue Genesis up to $500 thousand upon the achievement of certain performance milestones and earn-out payments on future sales provided that in no event will the aggregate of the earn-out payments exceed $4 million. To date, no milestones have been reached.

m. University of Louisville research foundation ("ULRF")

Koligo had exclusively licensed patents and technology from the ULRF related to the revascularization and 3D printing of cell and tissue for transplant ("ULRF licensed products"). The Company is committed to utilizing commercial reasonable efforts to achieving certain milestones regarding the ULRF licensed products. Pursuant to the license, Company will pay ULRF royalties of 3.5% of sales and certain performance milestones. During the year ended December 31, 2021, Company paid $40 thousand under its obligations.

n. Neuro-Immunotherapy Exclusive License Agreement

During the twelve months ended December 31, 2021, the Company entered into an exclusive license agreement in the field of neuro-immunotherapy. Pursuant to the agreement, the Company received an exclusive, worldwide, sublicensable, royalty-bearing license of certain technology and patents for the purpose of developing, manufacturing, using, and commercializing the licenced technology. Royalties of between 0.5% and 5% on royalty-bearing sales are payable for up to 15 years from the date of first sale in any country in which licensed products are sold, and sublicense fees are payable at the rate of 12% on sublicense income (but no less than two percent (2.0%) of sublicenses' net sales). Pursuant to the agreement, the Company is required to invest within thirty-six (36) months of the effective date an aggregate amount of at least $2 million in its efforts to develop the licensed technology.

o. Savicell

On June 14, 2021, the Company and Savicell Ltd ("Savicell") entered into a collaboration agreement (the "Savicell Agreement") to collaborate in the evaluation, continued development, validation, and use of Savicell's platform designed for the early detection and diagnosis of diseases and conditions and for quality control and monitoring purposes, in conjunction with the Company's systems. Pursuant to the Savicell Agreement, the Company will provide to Savicell funding for the performance of certain tasks agreed upon by the parties in a work plan. In consideration for such funding, Savicell will supply the Company with products developed under the Savicell Agreement at preferential rates and grant to the Company a worldwide exclusive licence to sell such products in the Company's point-of-care network of hospitals, clinics and institutions for quality control and monitoring of manufacturing and processing of autologous immune cells manipulated by cell and gene therapies. The Company will be required to pay a 10% royalty for all gross sales of such products developed under the Savicell Agreement. As of December 31, 2021, no royalty incurring sales were made.

p. Stromatis Pharma

On June 15, 2021, the Company and Stromatis Pharma Inc. ("Stromatis") entered into a Collaboration and Sublicense Agreement (the "Stromatis Agreement") to collaborate in refining methods for GMP manufacturing of CAR-T/CAR-NK CT109; and the development and validation of the Stromatis technology as it relates to the CAR-T/CAR-NK CT109 antibody up to and inclusive of filing of Investigational New Drug Application relating to Stromatis' CAR-T/CAR-NK CT109 antibody ("Licensed Product"), in accordance with the agreed project plan ("Project"). The Company will fund the Project by providing Stromatis an amount of $1.2 million such funding to be provided based on approved projects. Stromatis will grant the Company certain perpetual, irrevocable royalty free and fully paid-up exclusive rights to manufacture, process and supply the Licensed Product ("Manufacturing Rights") and perpetual, irrevocable, royalty bearing exclusive rights to market and sell and offer for sale the Licensed Product within the Company's point of care network ("Marketing Rights"). As of December 31, 2021, no royalty incurring sales were made.

Stromatis has the option to convert the exclusive Manufacturing Rights to non-exclusive rights subject to repayment by Stromatis of an amount equal to funding provided by the Company and an additional payment by Stromatis of an ongoing revenue share of five percent (5%) of revenues of any kind received by Stromatis or its affiliates from the sale or transfer of Licensed Products or license of rights under the licensed technology in relation to the Licensed Products. The Company shall pay Stromatis in consideration for the Marketing Rights and royalties equal to 12% of net revenues of Licensed Products received by the Company. The Company advanced to Stromatis an initial sum of $500 thousand under the Stromatis Agreement, which was recorded as cost of services and other research and development expenses, net.

q. Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)) ("HMGU")

During September 2021, HMGU granted an exclusive licence under HGMU owned patent rights and non-exclusive license under HGMU know how and licensed materials, to the Company in the field of certain human stem cells. The Company incurred a one-time up-front payment of approximately $60 thousand and annual license maintenance fees of between $18 thousand and $36 thousand. In addition, payments will be due by the Company upon certain milestones. The agreement also includes payment of royalties of between 3% and 4% on net sales of licensed product (with a minimum annual royalty of Euro 200,000, creditable against royalties on net sales incurred during such contract year) and 5% in service revenues and payment of between 10% and 18% on sublicense revenues.

NOTE 11 – COLLABORATIONS

a. Adva Biotechnology Ltd.

On January 28, 2018, the Company and Adva Biotechnology Ltd. ("Adva"), entered into a Master Services Agreement ("MSA"), pursuant to which the Company and/or its affiliates provided certain services relating to development of products for Adva.

In consideration for and subject to the fulfillment by the Company of certain funding commitments which were completed in 2019, Adva agreed that upon completion of the development of the products, the Company and/or its affiliates and Adva shall enter into a supply agreement pursuant to which for a period of eight (8) years following execution of such supply agreement, the Company and/or its affiliates (as applicable) is entitled (on a non-exclusive basis) to purchase the products from Adva at a specified discount pricing from their then standard pricing. The Company and/or its affiliates were also granted a non-exclusive worldwide right to distribute such products, directly or indirectly. The MSA shall remain in effect for 10 years unless earlier terminated in accordance with its terms.

b. IRB Approval for Liver Cell Collection

On April 29, 2019, the Company received Institutional Review Board ("IRB") approval to collect liver biopsies from patients at Rambam Medical Center located in Haifa, Israel for a planned study to confirm the suitability of liver cells for personalized cell replacement therapy for patients with insulin-dependent diabetes resulting from total or partial pancreatectomy. The liver cells are intended to be bio-banked for potential future clinical use.

The goal of the proposed study, entitled "Collection of Human Liver Biopsy and Whole Blood Samples from Type 1 Diabetes Mellitus (T1DM), Total or Partial Pancreatectomy Patients for Potential use as an Autologous Source for Insulin Producing Cells in Future Clinical Studies," is to confirm the suitability of the liver cells for personalized cell replacement therapy, as well as eligibility of patients to participate in a future clinical study, as defined by successful AIP cell production from their own liver biopsy. The secondary objective of the study is to evaluate patients' immune response to AIPs based on the patient's blood samples and followed by subcutaneous implantation into the patients' arm which would represent the first human trial. The Company has developed a novel technology based on technology licensed from Tel Hashomer Medical Research Infrastructure and Services Ltd., utilizing liver cells as a source for AIP cells as replacement therapy for islet transplantation.

During the study, liver samples will be collected and then processed and stored in specialized, clinical grade, tissue banks for potential clinical use. The propagated cells will be maintained in a tissue bank and are intended to be utilized in a future clinical study, in which the cells will be transdifferentiated and administered back to the patients as a potential treatment. This personalized autologous process will be performed under our POC platform in which the patient liver samples are processed, cryopreserved and potentially re-injected, all in the medical center under clinical grade/GMP level conditions.

In June 2019, the Company received additional Institutional Review Board ("IRB") approval to collect liver biopsies from patients at a leading medical center in USA for a planned study to confirm the suitability of liver cells for personalized cell replacement therapy for patients with insulin-dependent diabetes resulting from total pancreatectomy (the granted Orphan Drug Designation indication). Two liver samples have been processed and stored for potential clinical use.

c. FDA Approval for Orphan Drug Designation for AIP Cells

On June 11, 2019, the FDA granted Orphan Drug Designation for the Company's AIP cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy ("TP") due to chronic pancreatitis.

d. Johns Hopkins University

During the year ended December 31, 2021, the Company and Johns Hopkins University entered into a sublease and construction agreement for the establishment of a clinical therapeutic development and point of care center in Maryland of approximately 6,830 rentable square feet. Pursuant to the agreement, the Company will pay for certain leasehold improvements in the premises according to plans and specifications to be agreed upon. The Company advanced an initial $510 thousand for this purpose. The costs of the leasehold improvements will be offset by up to $5 million pursuant to a grant from the Board of Public Works of the State of Maryland to Johns Hopkins University. The annual base rent is initially $260 thousand per year, increasing to $324 thousand per year over the 10-year initial lease term. The Company has an option to renew the sublease for two additional periods of five years each under the same terms and conditions. The Company is expected to gain occupancy of the premises during the second quarter of 2022.

e. Joint venture agreements

The Company has entered into joint venture agreements ("JVAs") with its joint venture partners (Company and partner are referred to as "Parties") to facilitate the collaboration in the field of CGT development and development of the Company's worldwide POCare network. During 2021, the Company and / or JV partner continued the POCare network expansion in each of the territories as relevant. The provisos and the table below summarize the major agreements. CGT and POCare activities covered by the JVAs include the development, marketing, clinical development, and commercialization of the Company's and / or partner's products within defined territories. The extent of the collaboration is set out in each agreement.

Unless otherwise stated in the table below the JVAs include the following provisos ("Provisos"):

1. The incorporation of a joint venture entity ("JVE") in which the Company will hold between 49% and 51% of the equity.
2. The partner will manage the joint venture activities until the JVE is incorporated.
3. The JVE will be managed by a steering committee consisting of 3 members which will act as the entity's board of directors. The Company is entitled to appoint 1 member, the partner is entitled to appoint 1 member, and Company and partner will jointly appoint the third member.
4. The Company has the right to exercise a call option to acquire the partner's share in the JVE based on the occurrence of certain events and according to an agreed upon mechanism.
5. The funding of the parties' investment in the joint venture share may be made in the form of cash investment and / or in-kind services. The Company's cash investment may be in the form of additional shares, a convertible loan, and/or procured services.
6. Each of the parties may agree to provide additional funding to the JVE to cover the operation costs and such additional funding may be in the form of in-kind contributions. The Company's investments may be made in the form of a cash investment for additional shares, a convertible loan, and/or procured services. Procured services refer to certain services that the Company has engaged the partner or the JVE to provide the Company with, in support of Company's activity. All results of these procured services shall be owned by Company.
7. As appropriate, the parties will grant to the JVE an exclusive or nonexclusive, sublicensable, royalty-bearing, right and license to the relevant party's background IP as required solely to manufacture, distribute and market and sell the party's products within the territory. Each party shall receive royalties in an amount of ten percent (10%) of the net sales generated by the JVE and/or its sublicensees.
8. Once the JVE is profitable, the Company will be entitled (in addition to any of its rights as the holder of the JVE) to an additional share of fifteen percent (15%) of the JVE's GAAP profit after tax, over and above all rights granted pursuant to Company's participating interest in the JVE.
9. Unless otherwise stated, the relevant JVE had not been incorporated by December 31, 2021.

Name of party (and country of origin)	**POC Territory**	**Notes**
Theracell Advanced Biotechnology SA (Greece)	Greece, Turkey, Cyprus, Israel and Balkans	(1)
Broaden Bioscience and Technology Corp (USA)	Certain projects in China and the Middle East	
Mircod LLC (US)	Russia	(2)
Image Securities FZC (UAE) (a related party)	India	(3)
Cure Therapeutics (Korea)	Korea and Japan	
Kidney Cure Ltd (Israel)	N / A	(4)
Sescom Ltd (Israel)	N / A	(5)
Educell D.O.O (Slovenia)	Croatia, Serbia and Slovenia	(6)
Med Centre for Gene and Cell Therapy FZ-LLC (UAE)	UAE	
Mida Biotech B.V. (Netherlands)	Netherlands, Lithuania, Spain, Switzerland, Germany, Belgium or any other countries within West Europe	(7)
First Choice International Company, Inc (USA)	Panama and certain other Latin American countries	(8)
SBH Sciences Inc (USA)	N / A	(9)
Celleska Pty Ltd (Australia)	Australia	(10)
Revitas SA (Belgium)	N / A	(11)
Deep Med IO Ltd. (UK)	N / A	(12)

(1) The Theracell JVE was incorporated in Greece under the name of Theracell Laboratories Ltd. (See Note 12). In November 2021, the Company loaned approximately $800 thousand to Theracell the proceeds of which will be used to by Theracell to guarantee its obligations under a lease agreement for a biopark facility in Greece which may also be used for the Company's POC activities. The loan bears 8% annual interest and will be repaid at the termination of the lease. The lease period is 20 years. The loan is shown as a long-term asset on the balance sheet. The Company also loaned approximately $287 thousand as part of its obligations under the JVA to Theracell Laboratories Ltd. The 3-year loan bears interest at the annual rate of 8% and has been shown as a long-term asset on the balance sheet.

(2) Under the Mircod JVA, provisos 7 and 8 do not apply. Subject to payment by the Company of the contribution amount, the JVA will grant Company an exclusive, perpetual, irrevocable, royalty free and fully paid up and sublicensable license to use the Project IP for research and development and for the manufacturing, processing, supplying, and use of products based on point of care manufacturing and/or processing of treatments for patients and for use in hospitals, medical centers and academic institution settings solely outside the territory. In order for the Company to fulfil its obligations pursuant to proviso 6, the Parties concluded a convertible loan agreement pursuant to which Company shall lend to Mircod Biotech Inc up to $5 million. Mircod Biotech Inc., performs technological development work ordered by Company. The loan bears simple interest in the amount of 6% annually. During 2021, the Company had transferred $1,640 thousand under the loan agreement. The Company recorded the loan amounts as research and development expenses under ASC 730.

(3) On August 24, 2021, the Company entered into a convertible loan agreement with Image whereby, pursuant to the terms of the Image joint venture agreement, the Company agreed to loan Image up to $5 million. The loan bears interest at the rate of 6% and is subject to repayment by August 21, 2022, unless the Company agrees to an extension or the loan is converted into shares of Image or, if established, Image's Indian joint venture. As of December 31, 2021, the Company transferred $3 million to Image under the loan agreement, and this has been reflected as a short-term asset on the Company's balance sheet.

(4) The Kidney Cure JVE was incorporated in Switzerland under the name of Butterfly Biosciences Sarl ("BB") (See Note 12). The Company recorded the expenses paid to BB as research and development expenses under ASC 730.

(5) Under the Sescom JVA, the parties will collaborate in the field of the assessment of relevant tools and technologies to be used in the Company's information security system (the "ISS"); (ii) the implementation of the ISS within the Company and in the Company's point-of-care network; and (iii) the operation and maintenance of the ISS. Provisos 7 and 8 do not apply to this JVA. Company has agreed to provide the Sescom JVE with: (a) a non-exclusive, not transferable and non-sublicensable worldwide royalty-free license to use its background IP to the extent required for carrying out certain activities by the Sescom JVE; and (b) access to its point-of-care network and relevant data to be used for the certain activities. The Company recorded the expenses paid to Sescom under the JVA as research and development expenses under ASC 730.

(6) During 2021, the Company and Educell entered into a convertible loan agreement whereby the Company, pursuant to its obligations under the JVA, agreed to loan up to $1.2 million. As at December 31, 2021, the Company had transferred $970 thousand under the loan agreement. The Company recorded the loan amounts as research and development expenses under ASC 730. The loan bears interest at the annual rate of 4.5% and is repayable after 5 years. At Company's election, the loan is convertible into equity of borrower, or JVE entity if incorporated, at a valuation to be determined by an independent third party.

(7) See note 21.

(8) Under the First Choice JVA, each party shall, subject to fulfilment of the party's JVA, grant the Panama JV Entity an exclusive license to certain intellectual property of the part to develop and commercialize the party's products in the territory, subject to minimum sales obligations. In consideration of such license, the Panama JV shall pay the relevant part royalties at the rate of 15% of the Panama JVE net sales of party's products sold in the territory. The First Choice JVE will be managed by a steering committee consisting of 5 members which will act as the entity's board of directors. Each of the Partners is entitled to appoint 2 members, and Company and partner will jointly appoint the fifth member. Under the First Choice JVA, provisos 5,6,7 and 8 do not apply. There was no material activity under the First Choice JVA during 2021.

(9) Pursuant to the SBH JVA the parties will collaborate in the field of gene and cell therapy development, process and services of bio-exosome therapy products and services in the areas of diabetes, liver cells and skin applications, including wound healing. According to the JVA, the board of directors of the SBH JVE shall be comprised of three directors with one appointed by SBH and two appointed by the Company. Provisos 7 and 8 do not apply to the SBH JVA. There was no material activity under the SBH JVA during 2021.

(10) The Celleska JVA was signed in 2021.

(11) The Revitas JVE was incorporated in Belgium under the name of RevaCel Srl during 2021 (See Note 12). The Company holds 51% of the share capital of RevaCel and has the right to appoint two members to the RevaCel board of directors. The Company's partner, Revatis SA, (a Belgian entity) holds the remaining 49% and has the right to appoint two members to the Revacel board of directors. The fifth RevaCel board member will be an independent industry expert appointed with the mutual agreement of the Company and Revatis SA. The Company recorded the expenses paid to Revitas and RevaCel under the JVA as research and development expenses under ASC 730.

(12) In November 2021, Deep Med IO Ltd ("Deep Med") and Company entered into a JVA. The parties agreed to collaborate in the development and commercialization of an AI-powered system to be used in the manufacturing and/or quality control of CGTs, in accordance with an agreed upon work plan. Under the JVA, the Company committed to provide Deep Med with funding in the amount of up to $3 million at an agreed upon valuation (the "Funding"), for carrying out the Project in accordance with the work plan. Company was granted an option, during the period ending upon the earlier of (i) three years after the effective date of the JVA or (ii) the next financing round of the Deep Med (in which at least $1 million is invested in the capital of Deep Med), to invest additional amounts of up to $3 million in Deep Med based on a pre-money valuation of $6 million. The Company recorded the expenses paid to Deep Med under the JVA as research and development expenses under ASC 730.

NOTE 12 – INVESTMENTS IN ASSOCIATES, NET

a. Theracell Laboratories Private Company

During 2020, the Company and Theracell, pursuant to the Greek JVA (See Note 11) incorporated the Greek JVA entity known as Theracell Laboratories Private Company ("TLABS"). The Theracell Project activities will be run through TLABS. The Company and Theracell each hold a 50% participating interest in TLABS. Due to the Company's significant influence over the JVE the Company applies the equity method of accounting.

b. Butterfly Biosciences Sarl

During 2020, the Company and Kidney Cure ("KC"), pursuant to the Kidney Cure JVA (See Note 11) incorporated the KC JV Entity known as Butterfly Biosciences Sarl ("BB") in Switzerland. BB will be involved in the (i) implementation of a point-of-care strategy; (ii) assessment of the options for development and manufacture of various cell-based types (including kidney derived cells, MSC cells, exosomes, gene therapies) development; and (iii) development of protocols and tests for kidney therapies (the "BB Project"). The Company holds a 49% participating interest in BB and Kidney Cure holds the remaining 51%. Due to the Company's significant influence over the JVE the Company applies the equity method of accounting.

c. RevaCel

During 2021, the Company and Revatis S.A ("Revatis"), pursuant to the Revatis JVA (See Note 11) incorporated the Revatis JV Entity known as RevaCel Srl ("RevaCel") in Belgium. RevaCel will develop products in the field of muscle-derived mesenchymal stem/progenitor cells. The Company holds a 51% participating interest in RevaCel and Revatis holds the remaining 49% and is entitled to appoint 2 of the 5 members of RevaCel's board. Due to the Company's significant influence over the JVE the Company applies the equity method of accounting.

d. The table below sets forth a summary of the changes in the investments for the years ended December 31, 2021 and December 31, 2020:

	December 31,	
	2021	2020
	(in thousands)	
Opening balance	$ 175	$ -
Investments during the period	260	69
Share in net loss of associated companies	(272)	106
Exchange rate differences	(11)	-
Total	$ 152	$ 175

NOTE 13 – EQUITY

a. *Financings*

On January 20, 2020, the Company entered into a Securities Purchase Agreement (the "January Purchase Agreement") with certain investors pursuant to which the Company issued and sold, in a private placement (the "Offering"), 2,200,000 shares of Common Stock at a purchase price of $4.20 per share (the "Shares") and warrants to purchase up to 1,000,000 shares of Common Stock at an exercise price of $5.50 per share (the "Warrants") which are exercisable between June 2021 and January 2023. The Company received gross proceeds of approximately $9.24 million before deducting related offering expenses in the amount of $0.8 million. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was $1.911 million.

b. Tamir Biotechnology, Inc.

For the acquisition of Tamir, see Note 4.

As aggregate consideration for the acquisition, the Company issued an aggregate of 3,400,000 shares of Common Stock to Tamir.

c. Koligo Therapeutics Inc.

For the acquisition of Koligo, see Note 4.

Pursuant to the terms of the Merger Agreement, at the Effective Time, the shares of capital stock of Koligo that were issued and outstanding immediately prior to the Effective Time were automatically cancelled and converted into the right to receive, subject to customary adjustments, an aggregate of 2,063,713 shares of Company common stock which have been issued to Koligo's accredited investors (with certain non-accredited investors being paid solely in cash in the amount of approximately $20 thousand). In addition, the Company issued 66,910 shares to Maxim Group LLC for advisory services in connection with the Merger.

d. Warrants

A summary of the Company's warrants granted to investors and as finder's fees as of December 31, 2021, and December 31, 2020 and changes for the periods then ended is presented below:

	December 31,			
	2021		2020	
	Number of Warrants	Weighted Average Exercise Price $	Number of Warrants	Weighted Average Exercise Price $
Warrants outstanding at the beginning of the period	7,070,241	6.20	6,010,087	6.35
Changes during the period:				
Issued	926,413	6.24	1,344,606	5.64
Exercised	(319,811)	6.19	-	-
Expired	(4,634,323)	6.29	(284,452)	6.53
Warrants outstanding and exercisable at end of the period*	3,042,521	6.09	7,070,241	6.20

During the year ended December 31, 2021, the Company received approximately $1.9 million from the exercise of warrants for the purchase of the Company's Common Stock at a weighted average price of $6.24, and 305,523 shares were issued accordingly.

As of December 31, 2021 and December 31, 2020, there are no warrants that are subject to exercise price adjustments.

e. Treasury shares

During the year ended December 31, 2021, the Company repurchased its shares under a stock repurchase plan (the "Stock Repurchase Plan"). The following table summarizes the share repurchase activity pursuant to the Stock Repurchase Plan during the year ended December 31, 2021.

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Value that May Yet Be Purchased Under the Plans or Programs
				(in thousands)
January 2021	2,306	$ 4.45	$ 10,255	$ 9,740
April 2021	8,850	4.49	39,730	9,699
May 2021	195,625	4.34	848,234	8,841
November 2021	24,477	4.32	105,806	8,734
	231,258	$ 4.34	$ 1,004,025	$ 8,734

The following table summarizes the share repurchase activity from the inception of the Stock Repurchase Plan through December 31, 2020.

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Value that May Yet Be Purchased Under the Plans or Programs
				(in thousands)
October 2020	$ 8,807	$ 4.47	$ 8,807	$ 9,960
November 2020	101	4.50	101	9,960
December 2020	46,401	4.47	46,401	9,750
	55,309	$ 4.47	$ 55,309	$ 9,750

g. *Controlled Equity Offering Sales Agreement* In December 2018, the Company entered into a Controlled Equity Offering Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which the Company may offer and sell, from time to time through Cantor, shares of its common stock having an aggregate offering price of up to $25.0 million. The Company will pay Cantor a commission rate equal to 3.0% of the aggregate gross proceeds from each sale. Shares sold under the Sales Agreement will be offered and sold pursuant to the Company's Shelf Registration Statement on Form S-3 (Registration No. 333-223777) that was declared effective by the Securities and Exchange Commission on March 28, 2018, or the Shelf Registration Statement, and a prospectus supplement and accompanying base prospectus that the Company filed with the Securities and Exchange Commission on December 20, 2018. The Company has not yet sold any shares of its common stock pursuant to the Sales Agreement.

NOTE 14 – INCOME (LOSS) PER SHARE

The following table sets forth the calculation of basic and diluted loss per share for the periods indicated:

	Years ended December 31,	
	2021	**2020**
	(in thousands, except per share data)	
Basic and diluted:		
Net loss from continuing operations attributable to Orgenesis Inc.	$ 18,053	$ 95,088
Net income from discontinued operations attributable to Orgenesis Inc. for loss per share	-	(96,198)
Adjustment of redeemable non-controlling interest to redemption amount	-	(5,160)
	-	(101,358)
Net (income) loss attributable to Orgenesis Inc. for loss per share	18,053	(6,270)
Weighted average number of common shares outstanding	24,273,658	21,320,314
Loss per common share from continuing operations	$ 0.74	$ 4.46
Net income common share from discontinued operations	$ -	$ (4.75)
Net (income) loss per share	$ 0.74	$ (0.29)

For the year ended December 31, 2021, and December 31, 2020, all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive. Diluted loss per share does not include 5,919,739 shares underlying outstanding options and warrants and 1,518,397 shares upon conversion of convertible loans for the year ended December 31, 2021, because the effect of their inclusion in the computation would be anti-dilutive. Diluted loss per share does not include 10,212,789 shares underlying outstanding options and warrants and 1,630,857 shares upon conversion of convertible loans for the year ended December 31, 2020, because the effect of their inclusion in the computation would be antidilutive.

NOTE 15 – STOCK-BASED COMPENSATION

a. *Global Share Incentive Plan*

The Company's stockholders have approved the 2017 Equity Incentive Plan (the "2017 Plan") under which, the Company had reserved a pool of 3,000,000 shares of the Company's common stock, which may be issued at the discretion of the Company's board of directors from time to time. Under this Plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years. As of December 31, 2021, total options granted under this plan are 2,470,283 and the total options that are available for grants under this plan are 900,901.

On May 23, 2012, the Company's board of directors adopted the Global Share Incentive Plan 2012 (the "2012 Plan") under which, the Company had reserved a pool of 1,000,000 shares of the Company's common stock, which may be issued at the discretion of the Company's board of directors from time to time. Under this plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years. As of December 31, 2021, total options granted under this plan are 1,415,008 and the total options that are available for grants under this plan are 16,198.

b. *Options Granted to Employees and Directors*

Below is a table summarizing all of the options grants to employees and Directors made during the years ended December 31, 2021, and December 31, 2020:

	Year Ended	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Employees	December 31, 2021	277,000	$2.96-$5.12	Quarterly over a period of two years	$ 812	10 years
Directors	December 31, 2021	84,650	$ 2.89	On the one-year anniversary	$ 149	10 years
Employees	December 31, 2020	531,450	$2.99-$6.84	Quarterly over a period of two years	$ 1,312	10 years
Directors	December 31,2020	145,050	$ 2.99-$4.7	96% on the one-year anniversary, and the remaining 4% in three equal instalments on the first, second and third year anniversaries	$ 377	10 years

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for past periods based on expected term. The expected option term is calculated using the simplified method, as the Company concludes that its historical share option exercise experience does not provide a reasonable basis to estimate its expected option term. The fair value of each option grant is based on the following assumptions:

	Years Ended December 31,	
	2021	2020
Value of one common share	$2.89-$5.12	$2.99-$6.84
Dividend yield	0%	0%
Expected stock price volatility	71%-77%	80%-86%
Risk free interest rate	0.96%-1.34%	0.36%-1.71%
Expected term (years)	5.5-5.56	5.50-6.00

A summary of the Company's stock options granted to employees and directors as of December 31, 2021 and December 31, 2020 is presented below:

	Years Ended December 31			
	2021		2020	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the period	2,917,667	4.05	2,465,522	4.44
Changes during the period:				
Granted	361,650	4.19	676,500	3.74
Exercised	*(13,750)	4.63	-	-
Expired	(20,813)	5.67	(11,876)	7.88
Forfeited	(34,749)	4.67	(57,042)	4.52
Cancelled	-	-	(155,437)	8.38
Options outstanding at end of the period	3,210,005	4.05	2,917,667	4.05
Options exercisable at end of the period	2,777,563	4.00	2,299,937	4.03

* During the year ended December 31, 2021, the Company received $64 thousand from the exercise of employee options for the purchase of 13,750 shares of the Company's Common Stock at a weighted average price of $4.63.

The following table presents summary information concerning the options granted and exercisable to employees and directors outstanding as of December 31, 2021 (in thousands, except per share data):

Exercise Price $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value $	Number of Exercisable Options	Aggregate Exercisable Options Value $
			(in thousands)		(in thousands)
0.0012	230,189	2.64	663	230,189	-
0.012	510,017	0.09	1,463	510,017	6
2.89	84,650	9.96	-	-	-
2.96	63,500	9.96	-	-	-
2.99	432,200	8.15	-	431,638	1,291
3.14	2,500	7.91	-	2,500	8
4.42	50,000	5.93	-	50,000	221
4.5	34,000	7.17	-	34,000	153
4.6	174,800	8.68	-	112,488	517
4.7	6,250	8.03	-	2,083	10
4.8	483,337	4.94	-	483,337	2,320
5.02	78,500	9.71	-	-	-
5.07	52,500	7.00	-	52,500	266
5.1	60,500	8.34	-	44,750	228
5.99	327,050	6.61	-	297,425	1,782
6	16,667	2.59	-	16,667	100
6.84	15,125	6.79	-	12,453	85
7.2	83,334	5.43	-	83,334	600
8.36	250,001	6.50	-	250,001	2,090
8.91	15,000	6.46	-	15,000	134
9	20,834	1.54	-	20,834	187
9.48	58,908	0.52	-	58,908	558
10.2	39,267	0.42	-	39,267	401
	3,210,005	5.45	2,126	2,777,563	11,111

Costs incurred with respect to stock-based compensation for employees and directors for the years ended December 31, 2021 and December 31, 2020 were $1,349 thousand and $1,470 thousand, respectively, out of which $450 thousand related to options granted to employees of Masthercell Global, for the years ended December 31, 2020, and presented as part of net loss from discontinued operations in the consolidated statements of comprehensive loss. As of December 31, 2021, there was $1,093 thousand

of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 1.75 years.

c. Options Granted to Consultants and service providers

Below is a table summarizing all the compensation granted to consultants and service providers during the years ended December 31, 2021 and December 31, 2020:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employees	2021	7,500	$ 2.96	Quarterly over a period of two years	$ 22	10 years
Non-employees	2020	62,500	$2.99-$6.84	Quarterly over a period of two years	$ 209	10 years

The fair value of options granted during 2021 and 2020 to consultants and service providers, was computed using the Black-Scholes model. The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for past periods based on the expected term period, the expected term is the contractual term of each grant. The underlying data used for computing the fair value of the options are as follows:

	Years Ended December 31,	
	2021	2020
Value of one common share	$ 2.96	$ 2.99-$6.84
Dividend yield	0%	0%
Expected stock price volatility	145%	86%-89%
Risk free interest rate	1.47%	0.73%-1.12%
Expected term (years)	10	10

A summary of the Company's stock options granted to consultants and service providers as of December 31, 2021, and December 31, 2020 is presented below:

	Years Ended December 31,			
	2021		2020	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	549,141	5.89	598,310	5.76
Changes during the year:				
Granted	7,500	2.96	62,500	3.97
Exercised	-	-	(83,334)	3.60
Forfeited	(8,950)	3.88	(8,335)	5.99
Cancelled	-	-	(20,000)	5.30
Options outstanding at end of the year	547,691	5.89	549,141	5.89
Options exercisable at end of the year	467,689	6.20	450,972	6.28

The following table presents summary information concerning the options granted and exercisable to consultants and service providers outstanding as of December 31, 2021 (in thousands, except per share data):

Exercise Price $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value* $	Number of Exercisable Options	Aggregate Exercisable Options Value $
			(in thousands)		(in thousands)
2.96	7,500	9.96	-	-	-
2.99	35,000	8.22	-	-	-
3.14	11,250	7.91	-	11,250	35
3.36	136,775	4.32	-	136,775	459
4.09	25,000	7.76	-	25,000	102
4.42	5,125	5.93	-	5,125	23
4.5	13,335	7.53	-	5,000	23
4.6	20,000	8.96	-	4,000	18
4.8	16,668	4.94	-	16,668	80
5.07	5,000	7.19	-	1,000	5
5.3	15,000	6.70	-	15,000	80
5.99	16,670	6.81	-	16,670	100
6	90,000	2.59	-	90,000	540
6.84	7,500	8.38	-	-	-
7	70,000	7.83	-	70,000	490
7.32	8,334	0.89	-	8,334	61
8.34	8,600	6.52	-	8,600	72
8.43	8,333	6.05	-	6,666	56
11.52	8,334	1.26	-	8,334	96
16.8	39,267	0.28	-	39,267	660
	547,691	5.22	-	467,689	2,900

Costs incurred with respect to options granted to consultants and service providers for the years ended December 31, 2021 and December 31, 2020 were $122 thousand and $113 thousand, respectively. As of December 31, 2021, there was $109 thousands of unrecognized compensation costs related to non-vested consultants and service providers, to be recorded over the next 3.58 years.

d. Warrants and Shares Issued to Non-Employees

The fair value of Common Stock issued was the share price of the shares issued at the day of grant.

1) On January 2, 2020, the Company entered into private placement subscription agreements with investors for an aggregate amount of $250 thousand of convertible loans. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into shares of Common Stock of the Company at a conversion price per share equal to $7.00. In addition, the Company granted the investors 151,428 warrants to purchase an equal number of additional shares of the Company's Common Stock at a price of $7.00 per share. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was $210 thousand.

2) During the year ended December 31, 2020, the Company granted to several consultants 193,178 warrants each exercisable between $3.14 and $5.34 per share for three years. The fair value of those options as of the date of grant using the Black-Scholes valuation model was $378 thousand, out of which $350 thousand is related to 179,428 warrants granted as a success fee with respect to the issuance of the convertible notes and private Investment.

3) During the twelve months ended December 31, 2021, the Company issued 25,000 shares of common stock to a service provider. As of December 31, 2021, 25,000 shares have restrictions on transfer until such services have been provided.

NOTE 16 – TAXES

a. Corporate taxation in the U.S.

The corporate U.S. Federal Income tax rate applicable to the Company and its US subsidiaries is 21%.

As of December 31, 2021, the Company has an accumulated tax loss carryforward of approximately $29 million (as of December 31, 2020, approximately $18 million).

For U.S. federal income tax purposes, net operating losses ("NOLs") arising in tax years beginning after December 31, 2017, the Internal Revenue Code of 1986, as amended (the "Code") limits the ability to utilize NOL carryforwards to 80% of taxable income in tax years beginning after December 31, 2020. In addition, NOLs arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and twenty-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods as well as the new limitation on use of NOLs may significantly impact the Company's valuation allowance assessments for NOLs generated after December 31, 2017.

In addition, utilization of the NOLs may be subject to substantial annual limitation under Section 382 of the Code due to an "ownership change" within the meaning of Section 382(g) of the Code. An ownership change subjects pre-ownership change NOL carryforwards to an annual limitation, which significantly restricts the ability to use them to offset taxable income in periods following the ownership change. In general, the annual use limitation equals the aggregate value of the Company's stock at the time of the ownership change multiplied by a specified tax-exempt interest rate.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was enacted into law. The CARES Act is aimed at providing emergency relief and health care for individuals and businesses affected by the COVID-19 pandemic. The CARES Act, among other things, includes provisions related to refundable payroll tax credits, deferral of the employer portion of social security payments, expanded net operating loss application, modifications to the net interest deduction limitations, and technical corrections to tax depreciation methods for qualified improvement property. The CARES act allowed the Company to utilize 100% of NOLs arising in tax years after December 31, 2017 and before January1, 2021. The Company has assessed all other provisions of the CARES Act and notes no other material impact to the Company.

b. Corporate taxation in Israel

The Israeli Subsidiaries are taxed in accordance with Israeli tax laws. The corporate tax rate applicable to 2021 and 2020 are 23%.

As of December 31, 2021, the Israeli Subsidiaries has an accumulated tax loss carryforward of approximately $11 million (as of December 31, 2020, approximately $11 million). Under the Israeli tax laws, carryforward tax losses have no expiration date.

c. Corporate taxation in Belgium

The Belgian Subsidiary are taxed according to Belgian tax laws. The corporate tax rates applicable to 2021, 2020 are 25%.

As of December 31, 2021, the Belgian Subsidiary has an accumulated tax loss carryforward of approximately $8 million (€7 million), (as of December 31, 2020 $8 million). Under the Belgian tax laws there are limitation on accumulated tax loss carryforward deductions of Euro 1 million per year.

d. Corporate taxation in Korea

The basic Korean corporate tax rates are currently: 10% on the first KRW 200 million of the tax base, 20% up to KRW 20 billion, 22% up to KRW 300 billion and 25% for tax base above KRW 300 billion. In addition, the local income tax rate is 1% on the first KRW 200 million of taxable income, 2% on taxable income over KRW 200 million up to KRW 20 billion, 2.2% of taxable income over KRW 20 billion up to 300 billion and 2.5% on taxable income over KRW 300 billion.

As of December 31, 2021, the Korean subsidiary has an accumulated tax loss carryforward of approximately $3 million (KRW 3,023 million), (as of December 31, 2020, approximately $4 million). Under the Korean tax laws accumulated tax loss can be carry forwarded for 15 years.

e. Deferred Taxes

The following table presents summary of information concerning the Company's deferred taxes as of the years ending December 31, 2020 and December 31, 2020 (in thousands):

	December 31,	
	2021	**2020**
	(U.S. dollars in thousands)	
Deferred tax assets (liabilities), net:		
Net operating loss carry forwards	$ 11,451	$ 9,606
Research and development expenses	1,273	1,684
Equity compensation	2,631	2,747
Employee benefits	197	252
Property, plant and equipment	(206)	-
Leases asset	186	533
Lease liability	(134)	(324)
Loans	26	-
Intangible assets	(2,738)	(2,863)
Other	119	297
Total	12,805	11,932
Valuation allowance	(12,805)	(11,932)
Net deferred tax liabilities	$ -	$ -

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forwards losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not considered more likely than not achievable, the Company and all its subsidiaries except the Korean Subsidiary have recorded full valuation allowance.

The changes in valuation allowance are comprised as follows:

	December 31,	
	2021	2020
	(U.S dollars in thousands)	
Balance at the beginning of year	$ (11,932)	$ (14,939)
Change during the year	(873)	3,007
Balance at end of year	$ (12,805)	$ (11,932)

f. Reconciliation of the Theoretical Tax Expense to Actual Tax Expense

The main reconciling item between the statutory tax rate of the Company and the effective rate is the provision for valuation allowance with respect to tax benefits from carry forward tax losses.

g. Uncertain Tax Provisions

ASC Topic 740, “Income Taxes” requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company. As of December 31, 2021, the Company has not accrued a provision for uncertain tax positions.

NOTE 17 – REVENUES

Disaggregation of Revenue

The following table disaggregates the Company's revenues by major revenue streams.

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Revenue stream:		
POC and hospital services (Mainly POC)	$ 32,819	$ 6,068
Cell process development services	2,683	1,584
Total	$ 35,502	$ 7,652

POC development services are the result of agreements between Company and its partners (See Note 11).

A breakdown of the revenues per customer what constituted at least 10% of revenues is as follows:

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Revenue earned:		
Customer A (Korea)	$ 7,703	$ 2,857
Customer B (United Arab Emirates)	6,969	-
Customer C (China)	6,491	1,577
Customer D (India) – related party	3,856	1,475
Customer E (Greece)	4,693	1,412

Contract Assets and Liabilities

Contract assets are mainly comprised of trade receivables net of allowance for doubtful debts, which includes amounts billed and currently due from customers.

The activity for trade receivables is comprised of:

	Years Ended December 31,	
	2021	**2020**
	(in thousands)	
Balance as of beginning of period	$ 3,085	$ 1,831
Acquisition of Koligo	-	228
Additions	34,570	6,997
Collections	(22,333)	(5,982)
Exchange rate differences	(77)	11
Balance as of end of period	$ 15,245	$ 3,085

The activity of the related party included in the trade receivables activity above is comprised of:

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Balance as of beginning of period	$ 744	$ -
Additions	3,856	1,244
Collections	(2,628)	(500)
Balance as of end of period	$ 1,972	$ 744

The activity for contract liabilities is comprised of:

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Balance as of beginning of period	$ 59	$ 325
Additions	-	597
Realizations	-	(862)
Exchange rate differences	-	(1)
Balance as of end of period	$ 59	$ 59

The activity of the related party included in the contract liabilities activity above is comprised of:

	Year Ended December 31,
	2020
	(in thousands)
Balance as of beginning of period	$ -
Additions	231
Collections	(231)
Balance as of end of period	$ -

NOTE 18 – COST OF SERVICES AND OTHER RESEARCH AND DEVELOPMENT EXPENSES, NET

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Total expenses	$ 36,644	$ 84,182
Less grants	-	(196)
Total	$ 36,644	$ 83,986

NOTE 19 – FINANCIAL EXPENSES, NET

	Years Ended December 31,	
	2021	2020
	(in thousands)	
Interest expense on convertible loans	$ 943	$ 1,254
Foreign exchange loss, net	574	160
Other income	(225)	(353)
Total	$ 1,292	$ 1,061

NOTE 20 – RELATED PARTIES TRANSACTIONS

a. Related Parties presented in the consolidated statements of comprehensive loss

	Years ended December 31,	
	2021	2020
	(in thousands)	
Continuing operations:		
Stock-based compensation expenses to executive officers	$ 247	$ 221
Stock-based compensation expenses to Board Members	$ 265	$ 209
Compensation of executive officers	$ 4,422	$ 1,321
Management and consulting fees to Board Members	$ 380	$ 264
Revenues from customer	$ 3,856	$ 1,475
Cost of services and other research and development expenses, net	$ -	$ 4,772
Financial income	$ 64	$ 169

b. *Related Parties presented in the consolidated balance sheets*

	December 31,	
	2021	2020
	(in thousands)	
Executive officers' payables	$ 51	$ 170
Non-executive directors' payable	$ 178	$ 13
Loan to Related Party	$ 3,064	$ -
Accounts receivable, net	$ 1,972	$ 744

NOTE 21 – SUBSEQUENT EVENTS

a) On January 18, 2022, a complaint (the "Complaint") was filed in the Tel Aviv District Court (the "Court") against us and the Israeli subsidiary, Prof. Sarah Ferber, Vered Caplan and Dr. Efrat Asa Kunik (collectively, the "defendants") by plaintiffs the State of Israel, as the owner of Chaim Sheba Medical Center at Tel HaShomer ("Sheba"), and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (collectively, the "plaintiffs"). In the Complaint, the plaintiffs are seeking that the Court issue a declaratory remedy whereby the defendants are required to pay royalties to the plaintiffs at the rate of 7% of the sales and 24% of any and all revenues in consideration for sublicenses related to any product, service or process that contain know-how and technology of Sheba and any and all know-how and technology either developed or supervised by Prof. Ferber in the field of cell therapy, including in the category of the point-of-care platform and any and all services and products in relation to the defendants' CDMO activity. In addition, the plaintiffs seek that the defendants provide financial statements and pay NIS 10 million to the plaintiffs due to the royalty provisions of the license agreement, dated February 2, 2012, between the Israeli subsidiary and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (the "License Agreement"). The Complaint alleges that the Company and the Israeli subsidiary used know-how and technology of Sheba and know-how and technology either developed or supervised by Prof. Ferber while employed by Sheba in the field of cell therapy, including in the category of the point-of-care platform and the services and products in relation to the defendants' CDMO activity and are entitled to the payment of certain royalties pursuant to the terms of the License Agreement. The defendants were required to file their statement of defense responding to this Complaint by March 20, 2022. The Company believes that the allegations in this Complaint are without merit and intend to vigorously defend itself against the claims. Since a loss is not considered probable, no provision was made in the financial statements.

b) License and research agreement Yeda Research and Development Company Limited

On January 25, 2022, the Company and Yeda Research and Development Company Limited ("Yeda"), an Israeli corporation, entered into a license and research agreement. Pursuant to the agreement, Yeda granted to the Company an exclusive, worldwide license to its licensed information and the licensed patents, for the development, manufacture, use, offer for sale, sale and import of products in the Field a field of tumor-infiltrating lymphocytes (TIL) and Chimeric antigen receptor (CAR) T cell immunotherapy platforms (excluding CAR-Cytokine Induced Killer cell immunotherapy). The Company undertakes to make commercially reasonable efforts to develop and commercialize products in the field, and to achieve certain milestones. In consideration for the grant of the License, the Company shall pay Yeda:

A non-refundable annual license fee of $10 thousand;

Royalties of up to 2% on sales of licensed products;

25% of all Other Receipts received in respect of a Sublicense first granted or an assignment of rights made prior to the achievement of the dosing of a first patient in a Phase I Clinical Trial; and (ii) 12.5% of all Other Receipts received in respect of a Sublicense first granted or an assignment of rights made on or after the date described in subclause (i)

Milestone Events payments:

$50 thousand upon the dosing of a first patient in a Phase I Clinical Trial;

$500 thousand upon the receipt of FDA marketing approval in respect of a product 350 thousand upon receipt of marketing approval from a non-FDA regulatory agency in a major market territory (namely, a regulatory agency in Europe, Japan, China or Canada);

$250 thousand upon receipt of marketing approval from an additional non-FDA major regulatory agency (namely, a regulatory agency in Europe, Japan, China or Canada);

Patent fees already incurred by Yeda in connection with the Licensed Patents in the amount of $27 thousand, and all future costs and fees relating to the filing, prosecution, and maintenance of the Licensed Patents, Research related expenses based on an agreed research budget.

c) Joint venture agreement with Proterna Inc

On January 26, 2022, the Company and Proterna, Inc. a Delaware corporation, ("Proterna") (together, the "Parties"), entered into a joint venture agreement ("JVA"). Pursuant to the JVA, the Parties agreed to collaborate with each other and expand their activities in the development and commercialization of mRNA based vaccines and cellular immunotherapies for respiratory diseases, including, without limitation, COVID-19. The JVA provides that Proterna will grant to the JV Entity ("JVE"), under a separate license agreement, an exclusive, sublicensable right and license to its background IP as required to carry out the terms of the JVA including to develop, manufacture, distribute and market and sell mRNA vaccines and cellular immunotherapies for respiratory diseases, including COVID-19. In consideration for such license, the JVE will pay Proterna a 5% royalty on sales. The Company will provide funding for the joint venture of up to $5 million, based on a work plan to be approved, of which $2.5 million will be in the form of services to be procured from Proterna. Until the JVE is formed, the activities of the collaboration will be performed by

Proterna. The Parties will each hold 50% of the JVE. In addition, once JVE is profitable, Company shall have the rights to additional profit share. The Board of the JVE will be comprised of three directors, one to be appointed by the Company, one to be appointed by Proterna, and a third board member to be appointed upon mutual agreement of the Parties. Company shall have the right to purchase all of Proterna's then issued and outstanding equity interests in the JVE in return for, at Company's option: payment of cash and/or issuance of shares of common stock of Company. In the event that Company seeks to exercise this right, JVE's valuation shall be determined by an independent third-party expert to be mutually selected by the Parties, provided that in no event may such valuation be lower than US $2,000,000. As at the date of this report the JVE has not been incorporated.

d) On February 22, 2022, the Company, pursuant to the joint venture agreement between itself and Mida Biotech BV, purchased all the issued shares in the latter for a consideration of $100 thousand. The consideration will be paid via Company shares to be issued to Mida Biotech BV;s shareholders.

e) On March 30, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors (collectively, the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a private placement (the "Offering"), an aggregate of 4,933,333 shares of the Company's Common Stock at a purchase price of $3.00 per share and warrants to purchase up to an aggregate of 1,000,000 shares of Common Stock at an exercise price of $4.50 per share. The warrants are not exercisable until after six months and expire three years from the date of issuance. The Company expects to receive gross proceeds of approximately $14.8 million before deducting related offering expenses. The Offering is expected to close on or about April 30, 2022, subject to customary closing conditions.