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, 2020**

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 24,199,674 shares of common stock outstanding as of March 9, 2021. 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, 2020) was $105,399,427, as computed by reference to the closing price of such common stock on The Nasdaq Capital Market on such date.

ORGENESIS INC.
2020 FORM 10-K ANNUAL REPORT
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FORWARD-LOOKING STATEMENTS

CAUTIONARY STATEMENT FOR PURPOSES OF THE "SAFE HARBOR" PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

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"), (formerly known as CureCell); 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. (formerly known as Atvio Biotech Ltd.) ("OBI"); Koligo Therapeutics Inc., a Kentucky corporation, purchased in 2020 ("Koligo"); 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 increase 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 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 point-of-care cell therapy ("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 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;
- our license agreements with other institutions;
- expenditures not resulting in commercially successful products;
- our dependence on the financial results of our POC business; 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, 2020, 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

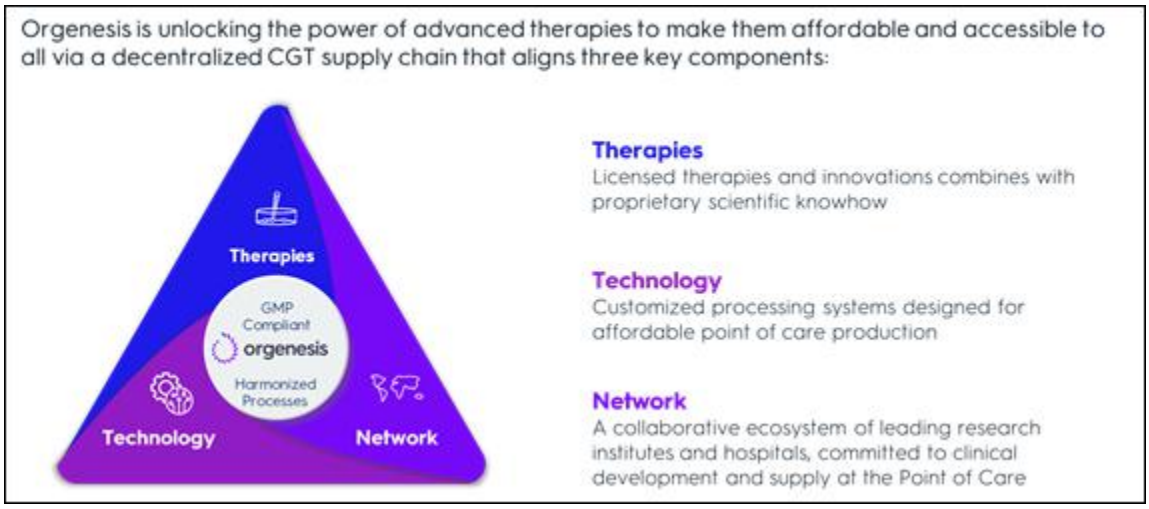
Business Overview

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

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 (ATMPs). We mostly focus 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 at their point of care for treatment of the patient. 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 the 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 comprised of three enabling components: a pipeline of licensed **POCare Therapies** that are designed to be processed and produced in closed, automated **POCare Technology** systems across a collaborative **POCare Network**. Via a combination of science, technology, engineering, and networking, we are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. 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, industry partners, research institutes and hospitals worldwide with a goal of achieving harmonized, regulated clinical development and production of the therapies.



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 the POCare Network.

- Koligo Therapeutics Inc. ("Koligo") is a Kentucky corporation that we acquired in 2020 and is currently focused on developing the POCare network and therapies. .

Europe

- Orgenesis Belgium SRL (the "Belgian Subsidiary") is the center of activity in Europe and is currently focused on 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.

Asia

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

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

- 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.

Discontinued Operations

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

Historically, the second separate business segment was operated as a Contract Development and Manufacturing Organization ("CDMO") platform, providing contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). The CDMO platform was historically operated mainly through majority owned Masthercell Global (which consisted of the following two subsidiaries: MaSTherCell S.A. in Belgium ("MaSTherCell"), and Masthercell U.S., LLC in the United States ("Masthercell U.S.") (collectively, the "Masthercell Global Subsidiaries")).

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"). After accounting for GPP's liquidation preference and equity stake in Masthercell as well as other investor interests in our Belgian subsidiary MaSTherCell, distributions to Masthercell option holders and transaction costs, we received approximately $126.7 million. We incurred an additional approximately $5.6 million in transaction costs.

We determined that the Masthercell Business ("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.

Since the Masthercell Sale, we entered into new joint venture agreements with new partners in various jurisdictions. This has allowed us to grow our infrastructure and expand our processing sites into new markets and jurisdictions. In addition, we have 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 have been investing 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.

The Chief Executive Officer ("CEO") is the Company's chief operating decision-maker who reviews financial information prepared on a consolidated basis. Effective from the first quarter of 2020, all of our continuing operations are in the point-of-care business via our POCare Platform. Therefore, no segment report has been presented.

Advanced Therapy Medicinal Products (ATMPs) Overview

Advanced Therapy Medicinal Product ("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.

Our Therapies

Products in Clinical Use

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 Food and Drug Administration ("FDA"). KYSLECEL is produced according to current good tissue practices (cGTP) and in compliance with federal and state regulations. Prior to being acquired by us, Koligo treated approximately 40 patients with KYSLECEL at six U.S. hospitals through a commercial pilot program.

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.

It is expected that the Icellator may also become commercially available in Japan in 2021 for use in cell assisted lipotransfer, pending review and approval by the Japanese Pharmaceuticals and Medical Devices Agency.

Cartil-S Autologous Products for the Treatment of Osteoarthritis

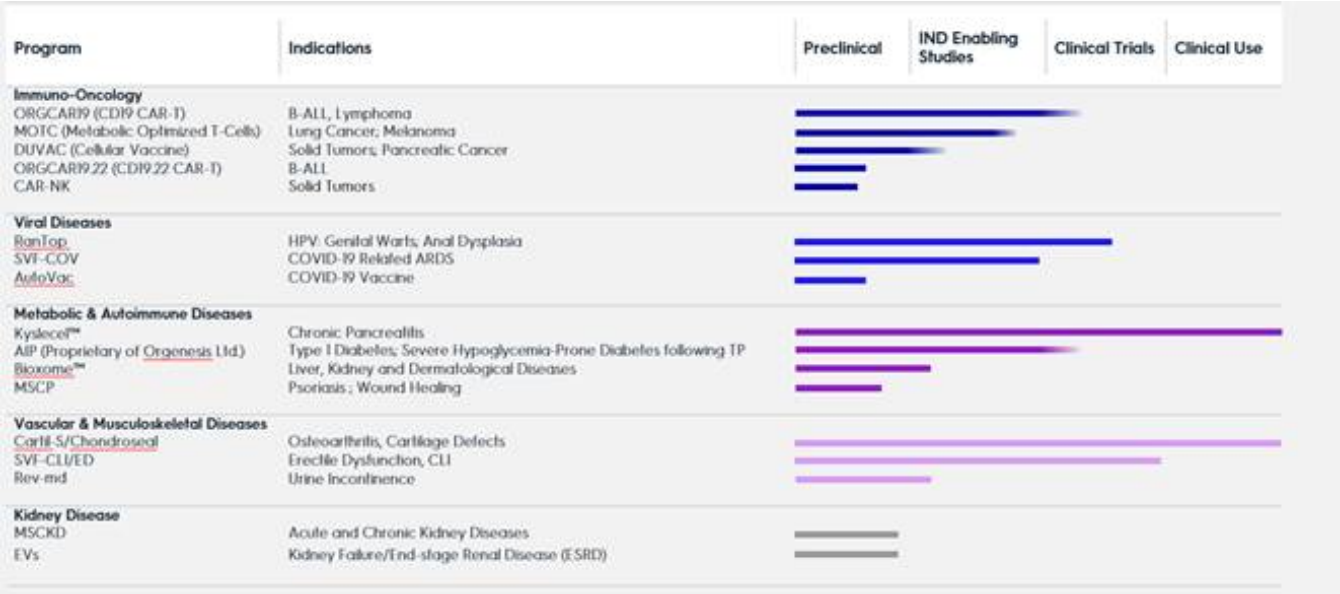
Cartil-S is a cell therapy for Osteoarthritis. This product is produced by performing a minimally invasive biopsy of adipose (fat) tissue from a patient, followed by isolation and expansion of adipose-derived stem cells (ADSCs), to be injected arthroscopically. The autologous injectable product helps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

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 Development

The following chart depicts our therapeutic development pipeline.



Products in Clinical Trials

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. Ranpirnase was previously developed for the treatment of human papillomavirus (HPV)-related pathologies such as external genital warts (EGW) and anal dysplasia. It has demonstrated clinical efficacy and good tolerability in a Phase IIa clinical study for the treatment of HPV-associated EGW. The initiation of a clinical Phase IIb for EGW is planned for 2021.

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. Pending review and approval of the FDA of the clinical trials, we expect to start a phase 2 trial in erectile dysfunction and a phase 1 trial for COVID -19 in 2021.

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. These trials are investigator sponsored initiatives that Orgenesis will continue to support.

Products in IND Enabling Studies

We are engaged in the following IND-enabling studies:

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, which has yet to be proven in human clinical trials, 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 seven (7) United States and twelve (12) foreign issued patents, five (5) pending patent applications in the United States, twenty four (24) pending patent applications in foreign jurisdictions, including, Australia, Brazil, Canada, China, Europe, India, 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. The incidence of diabetes following TP is 100%, resulting in immediate and lifelong insulin-dependence with the loss of both endogenous insulin secretion and that of the counter-regulatory hormone, glucagon. Glycemic control after TP is notoriously difficult with conventional insulin therapy due to complete insulin dependence and loss of glucagon-dependent counter-regulation. Patients with this condition experience both severe hyperglycemic and hypoglycemic episodes.

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.

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 in regards to 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.

ORG-CAR19, Autologous CD-19 CAR-T

Chimeric antigen receptor T cells (also known as CAR-T cells) are T cells that have been genetically engineered to produce an artificial T-cell receptor for use in immunotherapy. CAR-T cell therapy uses T cells engineered with CARs for cancer therapy. The premise of CAR-T immunotherapy is to modify T cells to recognize cancer cells in order to more effectively target and destroy them. Physicians harvest T cells from patients, genetically alter them, then infuse the resulting CAR-T cells into patients to attack their tumors. CAR-T cells can be either derived from T cells in a patient's own blood (autologous) or derived from the T cells of another 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 that is present on the surface of tumors. After CAR-T cells are infused into a patient, they act as a "living drug" against cancer cells. When they come in contact with their targeted antigen on a cell, CAR-T cells bind to it and become activated, then proceed to proliferate and become cytotoxic.

We are developing a new and advanced anti-CD19 CAR-T therapy for treating B-cell Acute lymphoblastic leukemia (B-ALL) and lymphoma patients, based on a clinically used CAR-T therapy licensed from Kecellitics Biotech. B-ALL is driven by malignant B-cell, expressing the B-cell surface protein, CD19. Orgenesis is also working on combining the CD19 with CD22 CAR on a single, bi-specific CD19/22 CAR-T that can target both antigens simultaneously for the treatment of blood cancers.

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 constitute the most comprehensive source of cancer antigens and by so boosting the patient immune system and direct it against the tumor. The DUVAC vaccine can be a developed for a wide range of solid tumor, but our initial focus is on pancreatic cancer.

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. Orgenesis is developing an advanced cellular biomanufacturing platform integrated with metabolic control. The expanded TILs possess an optimized metabolic state referred to as MOTC (Metabolically Optimized T-Cells), which can potentially lead to a more robust therapeutic response, especially for solid tumors such as lung cancer and melanoma.

Products in Pre-Clinical Studies

CAR-NK, Therapy for Solid Tumors

We have licensed from Caerus Therapeutics (a related party) a unique CAR platform that contains additional immunological effectors that aim to address significant challenges emerged in the development process of CAR technologies such as: safety, viability, immunosuppression by tumor microenvironment and dense desmoplastic stroma. Orgenesis aims target this CAR platform Natural Killer Cells (CAR-NK) platform for the treatment of solid tumors.

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

We are 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.

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. We are developing a proprietary manufacturing process for exosome like structures, termed Bioxomes. Bioxomes can carry specific therapeutic cargo into target cells. Orgenesis is developing this platform technology to treat liver fibrosis, dermatology, and other indications.

MSCP

Orgenesis is developing a personalized cell-based therapy product for wound healing and psoriasis. The product is based on Adipose-Derived Stem Cells (ADSCs). Following expansion, the ADSCs are formulated with Topiramate, a well-known substrate used in other indications, and a commercially available hyaluronic acid (HA), a well-known dermal filler, for topical treatment.

Muscle-derived Mesenchymal Stem Cells for Human Regenerative Medicine

An innovative and patented technology licensed by Revatis 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 to explore autologous therapeutics fields in humans such as Urine Incontinence

Kidney Disease

We are also developing multiple Proprietary cell and cell derived products therapies for treating kidney failure and End-Stage Renal Disease (ESRD).

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

Koligo had 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). Orgenesis is 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.

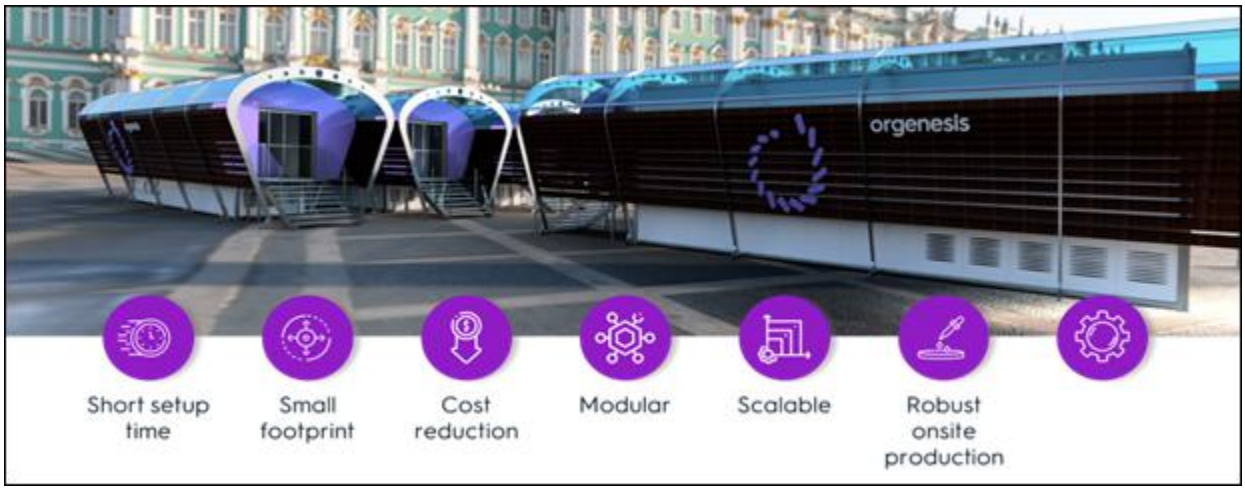
POCare Platform Strategy

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 within the patient care environment, namely through academic partnerships in a hospital 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.

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. In 2020, we 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 of partners, collaborators, and joint ventures.

In 2020 we 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 joint ventures. 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.



*For illustrative purposes only

Currently, we are finalizing the development over 30 OMPUL-based POC processing locations worldwide 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 to as many as 2,000 patients annually. The responsibility for setting up the OMPULS falls on the joint venture partners, who are also responsible for marketing and distribution worldwide. As we expand operations, the OMPUL setup cost is expected to decline proportionately. Most of our POC revenue to date is in support of the implementation of our technologies and therapies in our partners' POC activities, which will be the basis for future royalties and supply revenues.

We have embarked on a strategy of collaborative arrangements with strategically situated regional joint venture partners around the world. We believe that these parties 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 Mircod, , Cure Therapeutics, Columbia University in the City of New York, Caerus Therapeutics Corporation, Sescom Ltd., UC Davis, SBH Sciences, Inc., The Johns Hopkins University 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, the Middle East, and Australia.

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

CDMO Business

Regarding the Masthercell Sale, see Note 3 to Item 8 of this Annual Report.

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 3 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 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 the most favorable environment for the cell therapy industry in the world. 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 3 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.

Koligo

Koligo maintains commercial production facilities for KYSLECEL at an FDA-registered establishment in Indiana. The Tissue Genesis Icellators, and associated reagents and kits, are made by contract manufacturers and warehoused at our facility in Texas. Koligo also maintains development labs at the 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. 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 provides quality assurance and supply activities for the global POCare network. It has developed smart and agile methodologies to ensure compliant and harmonized decentralization operations at POCare.

Notable 2020 Activities

On April 7, 2020, we entered into an Asset Purchase Agreement (the "Tamir Purchase Agreement") with Tamir Biotechnology, Inc. ("Tamir" or "Seller"), pursuant to which we 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 ranpirnase and use for antiviral therapy (collectively, the "Purchased Assets and Assumed Liabilities" and such acquisition, the "Tamir Transaction"). The Tamir Transaction closed on April 23, 2020. We paid $2.5 million in cash and issued an aggregate of 3,400,000 shares (the "Shares") of our common stock to Tamir resulting in a total consideration of $20.2 million. In November 2020, we filed a registration statement on Form S-3 to register the resale of the Shares as required by the Tamir Purchase Agreement.

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

Koligo's operations include (a) the manufacture and sale of KYSLECEL® (autologous pancreatic islets) for chronic and acute recurrent pancreatitis diseases in the United States; (b) development and commercialization of the Tissue Genesis Icellator® platform, a cell isolation system acquired by Koligo from Tissue Genesis, LLC prior to our acquisition of Koligo; and (c) preclinical development of the "3D-V" technology platform, a system exclusively licensed by Koligo from the University of Louisville Research Foundation intended for the revascularization and 3D printing of cell and tissue for transplant applications. Koligo maintains facilities in Indiana and Texas.

The Tissue Genesis assets acquired by Koligo included 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

Pursuant to the terms of the Merger Agreement, an aggregate of 2,061,713 shares of our common stock were issued to Koligo's Shareholders who were accredited investors (with certain Shareholders who were not accredited investors being paid solely in cash in the amount of approximately $20 thousand) in accordance with the terms of the Merger Agreement. In connection with the Merger, we assumed an aggregate of approximately $1.9 million of Koligo's liabilities, which were substantially all of Koligo's liabilities at the closing of the Merger. In addition, we issued 66,910 shares to Maxim Group LLC for advisory services in connection with the Merger. In November 2020, we filed a registration statement on Form S-3 to register the resale of 1,425,962 shares of our common stock as required by the Merger Agreement.

In addition, according to the agreement between the parties, we also 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. The Icellator device is already commercially available in Korea and the Bahamas, and is expected to gain regulatory approval in Japan during the first quarter of 2021, subject to completion of manufacturing tests requested by the Japanese Pharmaceutics and Medical Devices Agency. Tissue Genesis already initiated U.S. FDA IDE Phase 1 pilot trials SVF cells in the treatment of erectile dysfunction, critical limb ischemia, tissue repair, and other therapeutic indications.

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 that are 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, Latin America, 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 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 solely 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

The Company has signed POCare Master Services Agreements ("MSAs") with its 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.

- 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:

	Year Ended December 31,	
Revenue stream:	**2020**	**2019**
	(in thousands)	
POC and hospital services	$ 6,068	$ 3,109
Cell process development services	1,584	790
Total	$ 7,652	$ 3,899

Cost of Research and Development and Research and Development Services

We incurred $83,986 and $14,014 thousand in cost of sales, research and development and research and development services in the fiscal years ended December 31, 2020 and December 31, 2019, respectively, of which $196 and $812 thousand was covered by grant funding. 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 twenty eight (28) United States patents, thirty six (36) foreign-issued patents, twenty five (25) pending patent applications in the United States, forty five (45) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, North Korea, Russia, Singapore, South Africa, and South Korea, and two (2) international Patent Cooperation Treaty ("PCT") patent applications. These patents and patent applications relate, among others, to (1) dendritic and macrophages based vaccines, and their use for treating cancer and viral diseases; (2) compositions comprising ranpirnase and other ribonucleases 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) whole-cell antiviral vaccines; (6) therapeutic compositions comprising exosomes, bioxomes, and redoxomes; (7) bioreactors for cell cultureand automated devices for supporting cell therapies: and (8) scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, transplantations, and in the treatment of autoimmune diseases.

We have a pending U.S. patent applications directed, among others, to dendritic and macrophages based vaccines, and their use for treating cancer and viral diseases. If issued, this application would expire in 2038.

We have pending U.S. patent applications directed, among others, to compositions comprising ranpirnase and other ribonucleases for treating viral diseases. If issued, these applications would expire between 2039 and 2040. Counterpart patents applications were filed in Australia, Canada, China, Europe, Hong Kong, Japan, Mexico, New Zealand, North Korea, Russian Federation, Singapore, South Africa, and were also filed as International ("PCT") applications. If issued, these applications would expire between 2035 and 2037. 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, these applications would expire in 2040. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, India, Israel, India, Japan and South Korea. If issued, 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.

We have pending U.S. patent applications directed, among others, to automated devices for supporting cell therapies. If issued, these applications would expire between 2035 and 2038.

We have a pending U.S. provisional patent application directed, among others, to tumor infiltrating lymphocytes (TILs) and their use for treating cancer. If converted into a non-provisional application and issued, this application would expire in 2041, 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 compositions comprising immune cells, ribonucleases, or antibodies for treating COVID-19. If converted into a non-provisional application and issued, this application would expire in 2041, 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, polysaccharides thereof, and scaffolds for use for cell propagation, transplantations, and in the treatment of autoimmune diseases, will expire between 2025 and 2036. Counterpart patents granted in Australia, France, Germany, Israel, Switzerland, and the United Kingdom, will expire between 2026 and 2035. 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 bioconjugates comprising sulfated polysaccharides and diverse bioactive peptides, and their use in the treatment of inflammatory conditions. If issued, these applications would expire in 2038. Counterpart patents applications were filed in China, Europe, Israel, Japan, and South Korea. If issued, these applications would expire between 2026 and 2038. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations

Orgenesis Ltd, has exclusive rights to six (6) United States patents, fourteen (14) foreign-issued patents, five (5) pending patent applications in the United States, twenty six (26) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, India, 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 among others 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. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

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, these applications would expire between 2038 and 2040. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, India, Israel, Mexico, Panama, Singapore, South Korea, and were also filed as International (“PCT”) applications. If issued, these applications would 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 or where our customers’ products are distributed. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with cGMPs, 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 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 customers intend to market their products 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 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 novel 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 technology 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 outlicensed 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 the 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 the 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 a first human biologic drug candidate into humans in clinical trials;
- Conducting adequate and well-controlled human 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 Good Manufacturing Practices ("cGMP") 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 cGMP 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

The European Union ("EU") has approved a regulation specific to cell and tissue therapy products, the Advanced Therapy Medicinal Product ("ATMP") regulation. For products that are regulated as an ATMP, the EU directive requires:

- Compliance with current cGMP regulations and standards, pre-clinical laboratory and animal testing;
- Filing a Clinical Trial Application ("CTA") with the various member states or a centralized procedure;
- Voluntary Harmonization Procedure ("VHP"), a procedure which makes it possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries;
- Obtaining approval of ethic committees of research institutions or other clinical sites to introduce the AIP into humans in clinical trials;
- Adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use;
- Submission to EMEA for a 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.

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, 2020, we had an aggregate of 111 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.

- The failure to effectively utilize the proceeds from the sale of Masthercell to scale our POC business to show demonstrable revenue may adversely affect 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.

- The coronavirus outbreak has the potential to cause disruptions in our business, including our clinical development activities.

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

- 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

We will need to deploy our capital from the sale of Masthercell in a manner to scale our POC business to show demonstrable revenue and market value for our shareholders, the failure of which could adversely impact our operations and the price of our stock.

On February 2, 2020, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with GPP-II Masthercell LLC ("GPP" and together with Orgenesis, the "Sellers"), Masthercell Global Inc. ("Masthercell") and Catalent Pharma Solutions, Inc. (the "Buyer"). Pursuant to the terms and conditions of the Purchase Agreement, on February 10, 2020, the Sellers sold 100% of the outstanding equity interests of Masthercell to Buyer (the "Sale") for an aggregate nominal purchase price of $315 million, subject to customary adjustments. After accounting for GPP's liquidation preference and equity stake in Masthercell as well as SFPI - FPIM's interest in MaSTherCell S.A., distributions to Masthercell option holders and transaction costs, we received approximately $126.7 million at the closing of the Sale transaction, of which $7.2 million was used for the repayment of intercompany loans and payables.

The proceeds from the sale of Masthercell were received by us and not our shareholders. We used or will use a portion of the proceeds to repay certain outstanding indebtedness and to pay for certain additional transaction costs associated with the sale. We will also be paying taxes on the proceeds.

We expect to use the remainder of net proceeds from the sale of Masthercell, at the discretion of our Board of Directors, for working capital and other general corporate purposes, including to continue to grow our POC cell therapy business and to further the development of ATMPs. Although we now have sufficient capital resources for the next 12 months and the foreseeable future, we may not be able to implement our POC business and commence clinical trials for our diabetes solution or respond to competitive pressures due to other non-financial factors beyond our control. Our failure to effectively utilize the proceeds from the sale of Masthercell 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 Orgenesis to decline.

We are not profitable as of December 31, 2020, 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, 2020 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 the report as a result of the receipt of the net proceeds from the sale of Masthercell. Our auditor's report for the year ended December 31, 2020 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 2021. 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, 2020, we had 111 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.

Currency exchange fluctuations may impact the results of our operations.

The provision of services by our former subsidiary, Masthercell Global, were usually transacted in U.S. dollars and European currencies during the year ended December 31, 2020. Our results of 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 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.

The coronavirus outbreak has the potential to cause disruptions in our business, including our clinical development activities.

The outbreak of the novel strain of coronavirus, or COVID-19, has currently impacted and may continue to impact our business, including our preclinical studies and clinical trials. COVID-19 has spread to multiple countries, including the United States and Israel, where we conduct most of our operations.

Efforts to contain the spread of COVID-19 have intensified and the United States and Israel, among other countries, have implemented and may continue to implement severe travel restrictions, shelter in place orders, social distancing and delays or cancellations of elective surgeries. These and other disruptions have caused, and may continue to cause, a delay in the supply of consumable goods, which could result in further delays, increased costs to source alternative suppliers and affect our ability to commercialize and develop our product candidates.

The spread of an infectious disease, including COVID-19, may also result in a period of business disruption, and in reduced operations, including employee absenteeism and delays in payments from our customers, any of which could materially affect our business, financial condition and results of operations. Although, as of the date of this Annual Report on Form 10-K, we do not expect any material impact on our long-term activity, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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; automated devices for supporting cell therapies; immune cells, ribonucleases, or antibodies for treating COVID-19; chimeric antigen receptors (CARs); or cell-conditioned medium 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 type 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.

In addition, we own or have exclusive rights to twenty eight (28) United States patents, thirty six (36) foreign-issued patents, twenty five (25) pending patent applications in the United States, forty five (45) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, North Korea, Russia, Singapore, South Africa, and South Korea, and two (2) international Patent Cooperation Treaty (“PCT”) patent applications. These patents and patent applications relate, among others, to (1) dendritic and macrophages based vaccines, and their use for treating cancer and viral diseases; (2) compositions comprising ranpirnase and other ribonucleases 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) whole-cell antiviral vaccines; (6) therapeutic compositions comprising exosomes, bioxomes, and redoxomes; (7)bioreactors for cell culture and automated systems and devices for supporting cell therapies; and(8) scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, transplantations, and in the treatment of autoimmune diseases.

We have pending U.S. patent applications directed, among others, to dendritic and macrophages based vaccines, and their use for treating cancer and viral diseases. If issued, this application would expire in 2038.

We have pending U.S. patent applications directed, among others, to compositions comprising ranpirnase and other ribonucleases for treating viral diseases. If issued, these applications would expire between 2039 and 2040. Counterpart patents applications were filed in Australia, Canada, China, Europe, Hong Kong, Japan, Mexico, New Zealand, North Korea, Russian Federation, Singapore, South Africa, and were also filed as International ("PCT") applications. If issued, these applications would expire between 2035 and 2037. 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, these applications would expire in 2040. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, India, Israel, India, Japan and South Korea. If issued, 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.

We have pending U.S. patent applications directed, among others, to automated devices for supporting cell therapies. If issued, these applications would expire between 2035 and 2038.

We have a pending U.S. provisional patent application directed, among others, to tumor infiltrating lymphocytes (TILs) and their use for treating cancer. If converted into a non-provisional application and issued, this application would expire in 2041, 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 compositions comprising immune cells, ribonucleases, or antibodies for treating COVID-19. If converted into a non-provisional application and issued, this application would expire in 2041, 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, polysaccharides thereof, and scaffolds for use for cell propagation, transplantations, and in the treatment of autoimmune diseases, will expire between 2025 and 2036. Counterpart patents granted in Australia, France, Germany, Israel, Switzerland, and the United Kingdom, will expire between 2026 and 2035. 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 bioconjugates comprising sulfated polysaccharides and diverse bioactive peptides, and their use in the treatment of inflammatory conditions. If issued, these applications would expire in 2038. Counterpart patents applications were filed in China, Europe, Israel, Japan, and South Korea. If issued, these applications would expire between 2026 and 2038. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

Orgenesis Ltd, has exclusive rights to six (6) United States patents, fourteen (14) foreign-issued patents, five (5) pending patent applications in the United States, twenty six (26) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, India, 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 among others 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. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

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, these applications would expire between 2038 and 2040. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, India, Israel, Mexico, Panama, Singapore, South Korea, and were also filed as International ("PCT") applications. If issued, these applications would 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.

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.

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 Trans-Differentiation Technologies for Diabetes

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.

We have developed 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 from the FDA, EMA and other regulatory authorities that have very limited experience with the commercial development of our 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 good manufacturing practice ("cGMP") 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 expect that our early clinical work will help support the filing with the FDA of an IND for our product in fiscal 2020. However, we cannot be sure that we will be able to submit an IND in this time-frame, 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, 2020, our stock price has fluctuated from a low of $2.76 to a high of $7.84. 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**
	These are our principal offices:
Orgenesis Inc./Orgenesis Maryland Inc.	● Located at 20271 Goldenrod Lane, Germantown, MD 20876. ● Occupy office space at the Germantown Innovation Center. ● Cost is $200 per month on a month-to-month contract.
Orgenesis Ltd.	● The development lab is located in the Bar Lev Industrial Park M.P. MISGAV, Israel. ● Offices are in the science park of Ness Ziona. Monthly costs are approximately $5 thousand.
Orgenesis Korea	● Operational production and Office area represent approximately 2,234 square meters. ● Monthly costs are approximately 21,232 thousand KRW, or approximately $19 thousand. ● Lease agreement for the office and operational production area expires on January 1, 2023.
Koligo Therapeutics Inc.	● Production facility and development labs in New Albany, Indiana – approximately 4170 square feet (388 square meter) at monthly costs of about $5400 ● Medical device maintenance and development labs in Leander, Texas – approximately 2000 square feet (186 square meter) at monthly costs of about $2500
Orgenesis Biotech Israel (previously Atvio Biotech)	● Located in the Bar Lev Industrial Park M.P. MISGAV, Israel. ● Operational production and Office area represent +/-1,264 m^2. ● Monthly costs are approximately $10.5 thousand. ● Lease agreement for the office and operational production area expires on July 31, 2023.
Orgenesis Belgium	● Located near Namur, at Novalis Science Park, Orgenesis 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

We are not involved in any pending legal proceedings that we anticipate would result in a material adverse effect on our business or operations.

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 9, 2021, there were 205 holders of record of our common stock, and the last reported sale price of our common stock on the NasdaqCM on March 8, 2021 was $7.26. 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 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

During the fiscal year ended December 31, 2020, our financing activities consisted of the following:

On January 20, 2020, we entered into a Securities Purchase Agreement with certain investors pursuant to which we 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 and warrants to purchase up to 1,000,000 shares of Common Stock at an exercise price of $5.50 per share, which are exercisable between June 2021 and January 2023. We received gross proceeds of approximately $9.24 million before deducting related offering expenses in the amount of $0.8 million.

On April 7, 2020, we entered into an Asset Purchase Agreement (the "Tamir Purchase Agreement") with Tamir Biotechnology, Inc. ("Tamir"), pursuant to which we 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 ranpirnase and use for antiviral therapy (collectively, the "Purchased Assets and Assumed Liabilities" and such acquisition, the "Tamir Transaction"). The Tamir Transaction closed on April 23, 2020. As aggregate consideration for the acquisition, we paid $2.5 million in cash and issued an aggregate of 3,400,000 shares of common stock to Tamir resulting in a total consideration of $20.2 million.

On September 26, 2020, we 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, solely in its capacity as the representative, agent and attorney-in-fact of the Shareholders. The Merger Agreement provided 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 Merger closed on October 15, 2020.

Pursuant to the terms of the Merger Agreement, an aggregate of 2,061,713 shares of Company common stock were issued to Koligo's Shareholders who were accredited investors (with certain Shareholders who were not accredited investors being paid solely in cash in the amount of approximately $20 thousand) in accordance with the terms of the Merger Agreement. In connection with the Merger, the Company assumed an aggregate of approximately $1.9 million of Koligo's liabilities, which were substantially all of Koligo's liabilities at the closing of the Merger. In addition, we issued 66,910 shares to Maxim Group LLC for advisory services in connection with the Merger.

All of the securities issued in the transactions described above were issued without registration under the Securities Act in reliance upon the exemptions provided in Section 4(2) or Regulation S of the Securities Act. Except with respect to securities sold pursuant to Regulation S, the recipients of securities in each such transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Appropriate legends were affixed to the share certificates issued in all of the above transactions. Each of the recipients also represented that they were "accredited investors" within the meaning of Rule 501(a) of Regulation D under the Securities Act or had such knowledge and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in its common stock. All recipients had adequate access, through their relationships with the Company and its officers and directors, to information about the Company. None of the transactions described above involved general solicitation or advertising.

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 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

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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, 2020 and December 31, 2019 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, 2020, as compared to the fiscal year ended December 31, 2019. This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2020 and December 31, 2019 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."

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 have made estimates of the impact of COVID-19 within 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.

Corporate Overview

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

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 (ATMPs). We mostly focus 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 at their point of care for the treatment of patients. 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 the 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 comprised of three enabling components: a pipeline of licensed **POCare Therapies** that are designed to be processed and produced in closed, automated **POCare Technology** systems across a collaborative **POCare Network**. Via a combination of science, technology, engineering, and networking, we are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. 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, industry partners, research institutes and hospitals worldwide with a goal of achieving harmonized, regulated clinical development and production of the therapies.

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 the POCare Network.

- Koligo Therapeutics Inc. ("Koligo") is a Kentucky corporation that we acquired in 2020 and is currently focused on developing the POCare network and therapies. .

Europe

- Orgenesis Belgium SRL (the "Belgian Subsidiary") is the center of activity in Europe and is currently focused on 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.

Asia

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

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

- 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.

Corporate History

We were incorporated in the state of Nevada on June 5, 2008 under the name Business Outsourcing Services, Inc. Effective August 31, 2011, we completed a merger with our subsidiary, Orgenesis Inc., a Nevada corporation, which was incorporated solely to effect a change in its name. As a result, we changed our name from "Business Outsourcing Services, Inc." to "Orgenesis Inc."

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license from Tel Hashomer - Medical Research, Infrastructure and Services Ltd. ("THM"), a private company duly incorporated under the laws of Israel for the development of AIP (Autologous Insulin Producing) cells.

On November 6, 2014, we entered into an agreement with the shareholders of MaSTherCell S.A. to acquire MaSTherCell S.A. On March 2, 2015, we closed on the acquisition of MaSTherCell whereby it became an independent, and wholly-owned subsidiary of Orgenesis INC. Through MaSTherCell, we became engaged in the CDMO business.

On June 28, 2018, we, Masthercell Global, Great Point Partners, LLC, a manager of private equity funds focused on growing small to medium sized heath care companies ("Great Point"), and certain of Great Point's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand our CDMO business. In connection therewith, we, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company ("GPP-II") and an affiliate of Great Point, entered into a Stock Purchase Agreement (the "SPA") pursuant to which GPP-II purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the "Masthercell Global Preferred Stock"), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for cash consideration to be paid into Masthercell Global of up to $25 million, subject to certain adjustments (the "Consideration"). At such time, we held 622,000 shares of Masthercell Global's Common Stock, representing 62.2% of the issued and outstanding equity share capital of Masthercell Global. An initial cash payment of $11.8 million of the Consideration was remitted at closing by GPP-II, with a follow up payment of $6,600,000 made in each of years 2018 and 2019, or an aggregate of $13.2 million (the "Future Payments"), if (a) Masthercell Global achieved specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis' shareholders approved certain provisions of the Stockholders' Agreement referred to below on or before December 31, 2020. Both of these conditions were met and we received both milestone payments.

Contemporaneous with the execution of the SPA, we and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which we contributed to Masthercell Global our assets relating to the CDMO Business (as defined below), including the CDMO subsidiaries (the "Corporate Reorganization"). In furtherance thereof, Masthercell Global, as our assignee, acquired all of the issued and outstanding share capital of OBI, our Israel based CDMO partner since May 2016, and 94.12% of the share capital of the Korean Subsidiary, our Korea based CDMO partner since March 2016.

On August 7, 2019, we, Masthercell Global and GPP (the "Parties") entered into a Transfer Agreement (the "Transfer Agreement"). As a result of the Transfer Agreement, Masthercell Global transferred all of its equity interests of OBI and the Korean Subsidiary to us in exchange for one dollar ($1.00). The Transfer Agreement also contains agreements made with respect to certain intercompany loans. We accounted for the Transfer Agreement as a transaction with non-controlling interest.

Discontinued Operations

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

Historically, 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 (which consisted of the following two subsidiaries: MaSTherCell S.A. in Belgium ("MaSTherCell"), and Masthercell U.S., LLC in the United States ("Masthercell U.S.") (collectively, the "Masthercell Global Subsidiaries")).

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"). After accounting for GPP's liquidation preference and equity stake in Masthercell as well as other investor interests in our Belgian subsidiary MaSTherCell, distributions to Masthercell option holders and transaction costs, we received approximately $126.7 million. We incurred an additional approximately $5.6 million in transaction costs.

We determined that the Masthercell Business ("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.

Since the Masthercell Sale, we entered into new joint venture agreements with new partners in various jurisdictions. This has allowed us to grow our infrastructure and expand our processing sites into new markets and jurisdictions. In addition, we have 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 have been investing 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.

The Chief Executive Officer ("CEO") is our chief operating decision-maker who reviews financial information prepared on a consolidated basis. Effective from the first quarter of 2020, all of our continuing operations are in the point-of-care business via our POCare Platform. Therefore, no segment report has been presented.

Orgenesis Inc., a Nevada corporation, is a global biotech company working to unlock the potential of cell and gene therapies ("CGT"s) 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 mostly focus 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 at their point of care. 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 the 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 comprised of three enabling components: a pipeline of licensed **POCare Therapies** that are designed to be processed and produced in closed, automated **POCare Technology** systems across a collaborative **POCare Network**. Via a combination of science, technology, engineering, and networking, we are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. 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, industry partners, research institutes and hospitals worldwide with a goal of achieving harmonized, regulated clinical development and production of the therapies.

Material Developments During Fiscal 2020

Acquisitions and Dispositions

As mentioned above, on February 2, 2020, we entered into a Purchase Agreement with GPP, Masthercell and Catalent Pharma Solutions, Inc. pursuant to which the Sellers sold 100% of the outstanding equity interests of our Masthercell Business for an aggregate nominal purchase price of $315 million, subject to customary adjustments. After accounting for GPP's liquidation preference and equity stake in Masthercell as well as other investor interests in its Belgian subsidiary MaSTherCell, S.A. ("MaSTherCell"), distributions to Masthercell option holders and transaction costs, we received approximately $126.7 million. We incurred an additional approximately $5.6 million in transaction costs.

On April 7, 2020, we entered into an Asset Purchase Agreement (the "Tamir Purchase Agreement") with Tamir Biotechnology, Inc. ("Tamir" or "Seller"), pursuant to which we 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 ranpirnase and use for antiviral therapy (collectively, the "Purchased Assets and Assumed Liabilities" and such acquisition, the "Tamir Transaction"). The Tamir Transaction closed on April 23, 2020. As aggregate consideration for the acquisition, we 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.

On September 26, 2020, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among ourselves, 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 us through the merger of Merger Sub with and into Koligo, with Koligo surviving as our wholly-owned subsidiary (the "Merger"). The Merger was announced in a Current Report on Form 8-K filed with the Securities and Exchange Commission on October 1, 2020, to which a copy of the Merger Agreement, along with copies of certain other ancillary agreements, were annexed as exhibits. The Merger closed on October 15, 2020.

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.

In addition, according to the agreement between the parties, we also 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.

Private Placement

On January 20, 2020, we entered into a Securities Purchase Agreement with certain investors pursuant to which we issued and sold, in a private placement, 2,200,000 shares of Common Stock at a purchase price of $4.20 per share and warrants to purchase up to 1,000,000 shares of Common Stock at an exercise price of $5.50 per share which are exercisable between June 2021 and January 2023. We received gross proceeds of approximately $9.24 million before deducting related offering expenses in the amount of $0.8 million.

Other Developments and Agreements During Fiscal 2020

Joint Ventures, Collaborations and License Agreements During Fiscal 2020

During 2020, we entered into joint venture agreements ("JVA") or amended existing JVAs ("AJVA") (which superseded previous JVAs), master service agreements for POC development revenue ("MSA DEV") and master service agreements for procured services ("MSA PS"), with third parties as per the following table:

Name of Party (and country of origin)	Nature of Agreement	Territory	Notes
Theracell Advanced Biotechnology	AJVA	Greece, Turkey, Cyprus, Israel, and Balkans	(1)
Broaden Bioscience and Technology Corp	AJVA	Certain projects in China and the Middle East	(1)
Mircod LLC (US)	JVA	Russia	(2)
Image Securities FZC (UAE) (a related party)	AJVA & MSA PS	India	(1)
Cure Therapeutics	JVA	Korea and Japan	
Kidney Cure Ltd	JVA	N/A	(5)
Sescom Ltd	JVA	N/A	(6)
Educell D.O.O (Slovenia)	AJVA & MSA PS & MSA DEV	Croatia, Serbia and Slovenia	(1)
Med Centre for Gene and Cell Therapy FZ-LLC (UAE)	AJVA & MSA PS & MSA DEV	UAE	(1)
Mida Biotech B.V. (Netherlands)	AJVA & MSA PS & MSA DEV	Netherlands, Lithuania, Spain, Switzerland, Germany, Belgium and other countries within West Europe	(7)
Butterfly Biosciences Sarl	JVA	N/A	(8)

Notes:

(1) The parties will collaborate in POC processing, regulatory and therapy development including the setting up one or more point of care processing facilities in institutions or hospitals in the territory, the supply of our products and services within the Territory, and the clinical development and commercialization of the relevant third-party products worldwide.

(2) The parties will collaborate in POC processing, regulatory and therapy development including the setting up one or more point of care processing facilities in institutions or hospitals in the territory, the supply of our products and services within the Territory and clinical, regulatory, development and commercialization of cell and gene therapies in the Territory.

(5) The parties will collaborate 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.

(6) The parties will collaborate in (i) the assessment of relevant tools and technologies to be used in our information security system (the "ISS"); (ii) the implementation of the ISS within the Company and in our point-of-care network; and (iii) the operation and maintenance of the ISS.

(7) The parties will collaborate in POC processing, regulatory and therapy development including the setting up one or more point of care processing facilities in institutions or hospitals in the territory and the establishment of an induced pluripotent stem cells R&D and automation platforms and other early-stage development activities.

(8) We and Kidney Cure Ltd own 49% and 51%, respectively, of Butterfly Biosciences Sarl ("BB"). BB is the entity through which the Kidney Cure JVA activities will be completed.

Other License Agreements

We are now working on the completion of all the IND enabling requirements in order to get into Phase I studies under the Sponsored Research Agreement (the "SRA") and Exclusive License Agreement between ourselves and the Trustees of Columbia University in the City of New York, a New York corporation ("Columbia University"). In 2019, we entered into an SRA with Columbia University whereby we will provide financial support for studying the utility of serological tumor marker for tumor dynamics monitoring. Also in 2019, we and Columbia University entered into an Exclusive License Agreement (the "Columbia License Agreement") whereby Columbia University granted to us an exclusive license to discover, develop, manufacture and sell product in the field of cancer therapy. In consideration of the licenses granted under the Columbia License Agreement, we shall pay to Columbia University (i) a royalty of 5% of net sales of any patented product sold and (ii) 2.5% of net sales of other products.

On May 15, 2019, we entered into a Joint Venture Agreement with SBH Sciences, Inc., a Massachusetts corporation ("SBH"), for the establishment of a joint venture with SBH for the purpose of collaborating 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.

In October 2019, we concluded a license agreement with Caerus Therapeutics Corporation (a related party), a Virginia company ("Caerus"), pursuant to which Caerus granted us, among others, 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 us under this agreement, we shall pay Caerus feasibility fees, annual maintenance fees and royalties of sales of up to 5% and up to 18% of sub-license fees. Through this joint venture, the parties co-develop a novel CART and CAR-NK platform for the treatment of solid tumors. The development is at a pre-clinical stage.

On December 20, 2019, we 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, we 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.

During the third quarter of 2020, we purchased the IP and related EV technology from a service provider (the "Service Provider") pursuant to an EV agreement (the "EV agreement"). According to the EV agreement, the Service Provider sold to us all of its rights in the EV technology that it had produced, in the amount of $500 thousand, to be paid in installments over the next 12 months from September 2020. In addition, the Service Provider granted us an exclusive worldwide license to use the EV IP technology for any purpose.

Included in the purchased assets of the Tamir Biotechnology Inc. acquisition 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. This license fee and the right to receive future milestone payments (of up to $11 million assuming that certain milestones are reached) and royalties (of up to $35 million based on net sales milestones), were assumed by us in connection with the Tamir Purchase Agreement together with a less than 10% share interest. To date, no milestones have been reached.

As mentioned above, included in the Koligo acquisition were the assets of Tissue Genesis, LLC ("Tissue Genesis"). We are 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.

Results of Operations

Comparison of the Year Ended December 31, 2020 to the Year Ended December 31, 2019.

Our financial results for the year ended December 31, 2020 are summarized as follows in comparison to the year ended December 31, 2019:

	Year Ended December 31,	
	2020	**2019**
	(in thousands)	
Revenues	$ 6,177	$ 2,629
Revenues from related party	1,475	1,270
Research and development expenses and Research and development service expenses, net	83,986	14,014
Amortization of intangible assets	478	430
Selling, general and administrative expenses	18,973	11,451
Other income	(4)	(21)
Share in income of associated company	(106)	-
Financial expense, net	1,061	843
Loss from continuing operation before income taxes	$ 96,736	$ 22,818

Revenues

The following table shows our revenues by major revenue streams:

	Year Ended December 31,	
	2020	**2019**
	(in thousands)	
Revenue stream:		
POC and hospital services	$ 6,068	$ 3,109
Cell process development services	1,584	790
Total	$ 7,652	$ 3,899

Our revenues for the year ended December 31, 2020 were $7,652 thousand, as compared to $3,899 thousand for the year ended December 31, 2019, representing an increase of 96%. The increase in revenues for the year ended December 31, 2020 compared to the year ended December 31, 2019 is mainly attributable to increased POC services revenue.

POC services are mainly the result of agreements between us and our joint venture partners (See note 11). Pursuant to the agreements, we provide certain services in support of partners' activity. We have signed master services agreements partners in the aggregate amount of over $38 million for services to be provided from 2021 to 2022.

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

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Revenue earned:		
Customer A	$ 2,857	$ 1,420
Customer B	1,577	-
Customer C – related party	1,475	1,270
Customer D	1,412	857

Research and Development and Research and Development Services, net:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Salaries and related expenses	$ 5,175	$ 3,064
Stock-based compensation	481	776
Professional fees and consulting services	3,463	3,419
Lab expenses	2,348	3,229
First Choice JVA (See Note 11)	-	2,741
Tamir Purchase Agreement (See Note 4)	19,225	-
Depreciation expenses, net	603	521
Other research and development expenses	52,887	1,076
Less – grant	(196)	(812)
Total	$ 83,986	$ 14,014

Research and development expenses for the year ended December 31, 2020 were $83,986 thousand, as compared to $14,014 thousand for the year ended December 31, 2019, representing an increase of 499%.

The increase is mainly attributable to the following:

- expansion of our pipeline of licensed CGTs with a harmonized pathway for regulatory approval;
- expansion of our POC capacity globally;
- investment in automated processing units & processes;
- developing owned and licensed advanced therapies to enable commercial production;
- works with partners to enable efficient closed processing system technologies addressing POCare needs;
- an increase in salaries and related expenses and other research and development expenses. Additional R&D staff were hired as we expanded our research and development to the evaluation and development of new cell therapies and related technologies in the field of immune-oncology (our novel CD19 CAR-T and CD19.22 CAR-T programs, cellular vaccination for solid cancers, advanced tumor infiltrating lymphocyte, NK-based therapies, etc.), liver pathologies, stem cell-based therapies and other cell-based technologies such as the novel delivery system, Bioxomes. We invested in converting biological processes to GMP-compliant processes as these therapies progress to clinical stage;
- In 2020 we 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 of partners, collaborators, and joint ventures. 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 practically any clinical institution at the point of care; and
- The Tamir purchase agreement (See Note 4).

Selling, General and Administrative Expenses

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Salaries and related expenses	$ 3,379	$ 2,332
Stock-based compensation	1,915	1,855
Accounting and legal fees	6,946	2,388
Professional fees	1,571	1,553
Rent and related expenses	407	214
Business development	3,477	1,148
Expenses related to collaboration with Theracell	-	689
Depreciation expenses, net	101	113
Other general and administrative expenses	1,177	1,159
Total	$ 18,973	$ 11,451

Selling, general and administrative expenses for the year ended December 31, 2020 were $18,973 thousand, as compared to $11,451 thousand for the year ended December 31, 2019, representing an increase of 66%. The increase for the year ended December 31, 2020 is primarily attributable to:

(i) An increase in salaries and related expenses of $1,047 thousand, as a result of additional managerial appointments and increased salaries;

(ii) An increase in accounting and legal fees of $4,558 thousand, which is mainly attributable to additional legal fees incurred for recent business and collaboration agreements; and

(iii) An increase in business development of $2,329 thousand, as a result of increased activities to establish our presence in new markets.

Financial Expenses, net

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Decrease in fair value financial liabilities and assets measured at fair value	$ -	$ 63
Interest expense on convertible loans and loans	1,254	498
Foreign exchange loss, net	160	395
Other income	(353)	(113)
Total	$ 1,061	$ 843

Financial expenses, net for the year ended December 31, 2020 were $1,061 thousand, as compared to $843 thousand for the year ended December 31, 2019, representing an increase of 26%. The increase for the year ended December 31, 2020 is primarily attributable to an increase in interest expense on convertible loans and loans of $756 thousand.

Tax income

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Tax income	$ 1,609	$ 229
Total	$ 1,609	$ 229

Tax income, net for the year ended December 31, 2020 were $1,609 thousand, as compared to $229 thousand for the year ended December 31, 2019, representing an increase of 603%. The increase for the year ended December 31, 2020 is primarily attributable due to the release of a tax asset up to the amount of Koligo's net tax liability. See Note 4.

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	2019
	(in thousands):	
Revenues	$ 2,556	$ 31,053
Cost of revenues	1,482	18,318
Cost of research and development and research and development services, net	7	54
Amortization of intangible assets	137	1,631
Selling, general and administrative expenses	1,896	13,886
Other (income) expenses, net	305	(207)
Operating loss	1,271	2,629
Financial expenses, net	(29)	31
Loss before income taxes	1,242	2,660
Tax expenses (income)	(30)	792
Net loss from discontinuing operation, net of tax	$ 1,212	$ 3,452

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,	
	2020	2019
	(in thousands)	
Current assets	$ 50,077	$ 78,348
Current liabilities	$ 16,285	$ 42,434
Working capital	$ 33,792	$ 35,914

Current assets decreased by $28,271 thousand between December 31, 2019 and December 31, 2020, which was primarily attributable to the following: (i) an increase in cash and cash equivalents due the Masthercell sale; and (ii) an increase in accounts receivable as a result of POC revenues.

Current liabilities decreased by $26,149 thousand between December 31, 2019 and December 31, 2020, which was primarily attributable to the following: (i) an increase in accounts payable and accrued expenses due to expanded operations, (ii) an increase in current maturities of convertible loans.

Liquidity and Capital Resources

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Net loss	$ 579	$ (26,041)
Net cash used in operating activities	(78,046)	(13,220)
Net cash provided by (used in) investing activities	105,610	(13,778)
Net cash provided by financing activities	5,881	24,098
Net change in cash and cash equivalents and restricted cash	$ 33,445	$ (2,900)

On February 2, 2020, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with GPP-II Masthercell LLC ("GPP" and together with us, the "Sellers"), Masthercell Global Inc. ("Masthercell") and Catalent Pharma Solutions, Inc. (the "Buyer"). Pursuant to the terms and conditions of the Purchase Agreement, on February 10, 2020 the Sellers sold 100% of the outstanding equity interests of Masthercell to Buyer (the "Masthercell Sale") for an aggregate nominal purchase price of $315 million, subject to customary adjustments. After accounting for GPP's liquidation preference and equity stake in Masthercell as well as SFPI – FPIM's interest in MaSTherCell S.A., distributions to Masthercell option holders and transaction costs, we received approximately $126.7 million, of which $7.2 million was used for the repayment of intercompany loans and payables.

Net cash used in operating activities for the year ended December 31, 2020 was approximately $78 million, as compared to net cash used in operating activities of approximately $13 million for the year ended December 31, 2019. Since the Masthercell Sale, we entered into new joint venture agreements with new partners in various jurisdictions. This has 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 provided by investing activities for the year ended December 31, 2020 was approximately $106 million, as compared to net cash used in investing activities of approximately $14 million for the year ended December 31, 2019. This was mainly attributable to the Masthercell sale.

Liquidity and Capital Resources Outlook

Based on our current cash resources and commitments, we believe that we will be able to maintain our current planned activities and expected level of expenditures for at least 12 months from the date of the issuance of the financial statements. If increases are incurred in operating costs in general and administrative expenses for facilities expansion, research and development, commercial and clinical activity or if we experience decreases in revenues from customers, we may need to seek additional financing. In addition, additional funds may be necessary to finance some of our collaborations and joint ventures.

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.

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, 2020. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Business Combination

We allocate the purchase price of an acquired business to the tangible and intangible assets acquired and liabilities assumed based upon our 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, brand name know, technology and IPR&D 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. We include the results of operations of the business that we have acquired in our 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 acquiree 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.

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, we manage 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.

Impairment of Long-lived Assets

We will periodically evaluate the carrying value of long-lived assets to be held and used when events and circumstances warrant such a review. The carrying value of a long-lived asset is considered impaired when the anticipated undiscounted cash flow from such asset is separately identifiable and is less than its carrying value. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Losses on long-lived assets to be disposed of are determined in a similar manner, except that fair values are reduced for the cost to dispose.

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.

ASC 606 - 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.

For the majority of our contracts, we receive non-refundable upfront payments. We do not adjust the promised amount of consideration for the effects of a significant financing component since we expect, 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. Our credit terms to customers are in average between thirty and ninety days.

We do not disclose the value of unsatisfied performance obligations for contracts with original expected duration of one year or less.

Disaggregation of Revenue

The following table disaggregates our revenues by major revenue streams:

	Year Ended December 31,	
Revenue stream:	**2020**	**2019**
	(in thousands)	
POC and hospital services	$ 6,068	$ 3,109
Cell process development services	1,584	790
Total	$ 7,652	$ 3,899

Nature of Revenue Streams

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

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 the company 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 (mainly discontinued operations)

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. Additionally, due to the non-refundable upfront payment the customer pays, together with the payment term and cancellation fine, it has a right to payment (which include 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 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.

Tech Transfer Services (discontinued operations)

Revenue recognized under contracts for tech transfer services are considered a single performance obligation, as all work packages (including data collection, GMP documentation, validation runs) and milestones are interrelated. Additionally, the customer is unable to complete services of work performed independently or by using our competitors. Revenue is recognized over time using a cost-based input method where progress on the performance obligation is measured by the proportion of actual costs incurred to the total costs expected to complete the contract.

Cell Manufacturing Services (discontinued operations)

Revenues from cell manufacturing services represent a single performance obligation which is recognized over time. The progress towards completion will continue to be measured on an output measure based on direct measurement of the value transferred to the customer (units produced).

Reimbursed Expenses

We include reimbursed expenses in revenues and costs of revenue as we are primarily responsible for fulfilling the promise to provide the specified service, including the integration of the related services into a combined output to the customer, which are inseparable from the integrated service. These costs include such items as consumable, reagents, transportation and travel expenses, over which we have discretion in establishing prices.

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.

Costs of Revenue (Discontinued Operations)

Costs of revenue include (i) compensation and benefits for billable employees and personnel involved in production, data management and delivery, and the costs of acquiring and processing data for our information offerings; (ii) costs of staff directly involved with delivering services offerings and engagements; (iii) consumables used for the services; and (iv) other expenses directly related to service contracts such as courier fees, laboratory supplies, professional services and travel expenses.

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:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Balance as of beginning of period	$ 1,831	$ 129
Acquisition of Koligo	228	-
Additions	6,997	2,079
Collections	(5,982)	(364)
Exchange rate differences	11	(13)
Balance as of end of period	$ 3,085	$ 1,831

The activity for contract liabilities is comprised of:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Balance as of beginning of period	$ 325	$ 56
Additions	597	1,126
Realizations	(862)	(854)
Exchange rate differences	(1)	(3)
Balance as of end of period	$ 59	$ 325

See note 2(z).

See note (x).

See note 2(y).

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.

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 such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2020, 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, the company’s principal executive and principal financial officers and effected by the company’s 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 the assets of the company; (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 management and directors of the company; 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.

The Koligo acquisition which was completed in October 2020 was excluded from management’s evaluation of internal control over financial reporting as of December 31, 2020 because the business was acquired in a transaction accounted for as a business combination during 2020. Koligo, represents approximately 2% of our total consolidated assets and approximately 3% of our total consolidated revenues as of and for the year ended December 31, 2020.

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, 2020. 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, 2020 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 is 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 quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our each of our current Directors and Executive Officers as of March 9, 2021.

Name	Age	Position
Vered Caplan	52	Chief Executive Officer and Chairperson of the Board of Directors
Neil Reithinger	51	Chief Financial Officer, Secretary and Treasurer
David Sidransky (1) (2) (4)	60	Director
Guy Yachin (1) (2) (3) (4)	53	Director
Yaron Adler (2) (3)	50	Director
Ashish Nanda (3)	55	Director
Mario Philips (1)	51	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 Arizona, 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., a registered CPA firm in Arizona. 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.

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 560 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 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 has served as the President and CEO of Serpin Pharma, a clinical stage Virginia-based company focused on the development of anti-inflammatory drugs, since April 2013. Mr. Yachin is the CEO of Oasis Management, a Maryland-based consulting company, since 2010. Mr. Yachin is 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 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. Mr. Yachin served on the board of Peak Pharmaceuticals, Inc. from March 2014 to April 2016.

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, the Company uses 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.

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 9 meetings in fiscal 2020. In addition, the Audit Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2020. 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 acted by unanimous written consent or held 5 meetings in fiscal 2020. In addition, the Compensation Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2019. 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 acted by unanimous written consent or held 4 meeting in fiscal 2020. 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 the Company's research and development programs, and strategies.

The Research and Development Committee was established in January 2021. The Board has determined that each member of the Research and Development Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

DELINQUENT SECTION 16(a) REPORTS

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires officers and directors of the Company 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 two reports, covering an aggregate of five transactions, were filed late by David Sidransky, one report, covering an aggregate of one transaction, was filed late by Yaron Adler, one report, covering an aggregate of one transaction, was filed late by Guy Yachin, and one report, covering an aggregate of one transaction, 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, 2020 to our Chief Executive Officer and Chief Financial Officer. As of December 31, 2020, there were no other executive officers who earned more than $100,000 during the fiscal year ended December 31, 2020 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	2020	250,000	400,000	-	163,239	-	-	215,640	1,028,879
CEO(3)	2019	250,000	200,000	-	871,036	-	-	77,020	1,398,056
Neil Reithinger *CFO, Treasurer &*	2020	255,231	200,000	-	57,331	-	-	-	512,562
Secretary	2019	213,653	-	-	22,970	-	-	-	236,623

(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 the Company 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, 2020.

(2) For 2020 and 2019, 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 2020 and 2019 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	2020	13,172	202,468	215,640
	2019	18,876	58,144	77,020

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

(2) These are comprised of contributions by the Company to savings, severance, pension, disability and insurance plans generally provided in Israel and Switzerland, including education funds and 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, 2020

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of December 31, 2020.

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[(3)]	42,500	42,500	5.99	22-Oct-28
	19-Mar-20[(2)]	31,875	53,125	2.99	18-Mar-30
Neil Reithinger	09-Dec-16[(1)]	83,334	-	4.80	09-Dec-26
	08-Mar-19[(2)]	6,250	18,750	5.07	08-Mar-29
	19-Mar-20[(2)]	5,625	9,375	2.99	18-Mar-30

(1) The options were fully vested as of December 31, 2020.
(2) The options vest on a quarterly basis over a period of two years from the date of grant.
(3) 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, 2019 and 2020.

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, (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 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 Services' confidential information and intellectual property.

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.

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 was paid prior to December 31, 2020. As of December 31, 2020, Eventus was owed $28 thousand for accrued and unpaid services under the financial consulting agreement.

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 the Company's executive officers had they been terminated as of December 31, 2020.

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, 2020 certain information concerning his or her compensation for the year ended December 31, 2020 and the December 2018 transition period:

Year Ended December 31, 2020

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	52,500	-	45,462 [2]	-	-	-	97,962
Yaron Adler	46,250	-	45,306 [3]	-	-	-	91,556
Dr. David Sidransky	75,000	-	45,518 [4]	-	-	-	120,518
Ashish Nanda	52,500	-	45,257 [5]	-	-	-	97,757
Mario Philips	37,500		27,514 [6]				65,014

(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 the Company 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) Aggregate number of option awards outstanding as of December 31, 2020 was 150,934 of which (i) 122,184 options are exercisable as of December 31, 2020, (ii) 12,500 options are exercisable on April 1, 2021 and (iii) 16,250 options are exercisable on December 17, 2021. Does not include $192 thousand related to options held by Caerus Therapeutics LLC over which Mr. Yachin does not have beneficial control.

(3) Aggregate number of option awards outstanding as of December 31, 2020 was 169,325 of which (i) 141,825 options are exercisable as of December 31, 2020, (ii) 12,500 options are exercisable as of April 1, 2021 and (iii) 15,000 options are exercisable on December 17, 2021.

(4) Aggregate number of option awards outstanding as of December 31, 2020 was 133,401 of which (i) 104,201 options are exercisable as of December 31, 2020, (ii) 12,500 options are exercisable on April 1, 2021 and (iii) 16,700 options are exercisable on December 17, 2021.

(5) Aggregate number of option awards outstanding as of December 31, 2020 was 66,700 of which (i) 39,600 options are exercisable as of December 31, 2020, (ii) 12,500 options are exercisable on April 1, 2021 and (ii) 14,600 options are exercisable on December 17, 2021.

(6) Aggregate number of option awards outstanding as of December 31, 2020 was 32,500 of which (i) 2,083 options are exercisable on January 9, 2021 (ii) 12,500 options are exercisable on April 1, 2021 (iii) 13,750 options are exercisable on December 17, 2021 (iv) 2,084 options are exercisable on January 9, 2022 and (v) 2,084 options are exercisable on January 9, 2023.

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 October 2018, the Board of Directors adopted a compensation policy for non-employee directors which replaced the non-employee director compensation terms discussed above. By its terms, the policy became effective November 2018. Under the adopted policy, each director is to receive an annual cash compensation of $30,000 and the Chairman and Vice Chairman is paid an additional $15,000 per annum. Each committee member will be paid an additional $7,500 per annum and each committee chairman 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 the Company’s common stock. All directors are entitled on 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 the Company’s ordinary

shares. In all cases, the options are granted at a per share exercise price equal to the closing price of the Company's 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, 2020.

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 9, 2021 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 9, 2021 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 24,199,674 shares of common stock outstanding on March 9, 2021.

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	3,126,434(2)	12.92%
Yehuda Nir c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	2,175,152(3)	8.99%
Gakasa Holding, LLC c/o Knoll Capital Management 5 East 44th Street New York, NY 10017	1,316,364(4)	5.44%

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	1,104,006(5)	4.56%
Neil Reithinger 14201 N. Hayden Road, Suite A-1 Scottsdale, AZ 85260	112,709(6)	<1%
Guy Yachin c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	134,684(7)	<1%
Dr. David Sidransky c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	116,701(8)	<1%
Yaron Adler c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	217,629(9)	<1%
Ashish Nanda c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	52,100(10)	<1%
Mario Philips c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	14,583(11)	<1%
Directors & Executive Officers as a Group (7 persons)	1,752,412	7.24%

Notes:

(1) Percentage of ownership is based on 24,167,784 shares of our common stock outstanding as of March 9, 2021. 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) 1,494,217 ordinary shares and (ii) 1,832,538 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) 309,464 ordinary shares issuable upon exercise of outstanding warrants at a price of $6.24 per share, exercisable until June 30, 2021, (ii) 153,846 ordinary shares issuable upon exercise of outstanding warrants at a price of $6.24 per share, exercisable until June 9, 2021, (iii) 50,000 ordinary shares issuable upon exercise of outstanding warrants at a price of $7.00 per share, exercisable until October 3, 2022, and (iv) 1,661,842 ordinary shares issuable upon exercise of convertible debt at a price of $7.00 per share.

(4) Consists of 1,316,364 ordinary shares.

(5) Consists of (i) 278,191 ordinary shares issuable upon exercise of outstanding options at a price of $0.012 per share, (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 $4.80 per share, (iv) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of $7.20 per share, (vi) 250,000 ordinary shares issuable upon exercise of outstanding options at a price of $8.36 per share and (v) 53,125 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and(vii) 42,500 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share. Does not include (i) options for 31,875 shares of common stock with an exercise price of $5.99 per share that are exercisable quarterly after April 22, 2021 and (ii) option for 42,500 shares of common stock with an exercise price of $2.99 per share that are exercisable quarterly after March 31, 2021.

(6) Consists of (i) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of $4.80 per share and (ii) 21,875 ordinary shares issuable upon exercise of outstanding options at a price of $5.07 per share (iii) 7,500 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share. Does not include (i) options for 3,125 shares of common stock with an exercise price of $5.07 per share that are exercisable quarterly after April 1, 2021 and (ii) option for 7,500 shares of common stock with an exercise price of $2.99 per share that are exercisable quarterly after March 31, 2021.

(7) Consists of (i) 39,267 ordinary shares issuable upon exercise of outstanding options at a price of $10.2 per share and (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.80 per share and (iii) 28,750 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and (iv) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share. Does not include 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 and (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.80 per share and (iii) 29,200 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and (iv) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share.

(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 and (iii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of $4.80 per share and (iv) 28,750 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and (iiv) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share.

(10) Consists of (i) 27,100 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share and (ii) 25,000 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share.

(11) Consists of (i) 2,083 ordinary shares issuable upon exercise of outstanding options at a price of $4.7 per share and (ii) 12,500 ordinary shares issuable upon exercise of outstanding options at a price of $2.99 per share. Does not include options for 4,167 shares of common stock with an exercise price of $4.70 per share that are exercisable in three equal instalments over three anniversaries starting on January 9, 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, 2020:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders [1]	2,503,002	$ 4.64	1,496,998
Equity compensation plans not approved by security holders	963,806	$ 3.55	141,668
Total	3,466,808	$ 4.34	1,638,666

(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 2020 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended December 31, 2020.

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

Transactions with Related Persons

Except as set out below, as of December 31, 2020, 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.

On September 15, 2014, the Company received a loan in the principal amount of $100,000 from Yaron Adler Investments (1999) Ltd., an entity of which Mr. Yaron Adler, one of the Company's non-employee director, is the sole shareholder. The loan, with an original interest rate of 6% per annum, was repayable on or before March 15, 2015. The Loan currently bears a default interest rate of 24% per annum and, as of November 30, 2017, the outstanding balance on the note was $166,581. The loan was converted into our common stock in 2018.

In January 2017, the Company entered into definitive agreements with Image Securities fzc. ("Image") for the private placement of 2,564,115 units of the Company's securities for aggregate subscription proceeds to the Company of $16 million at $6.24 price per unit. In July 2018, the Company entered into definitive agreements with assignees of Image whereby these assignees remitted $4.6 million in respect of the units available under the original subscription agreement that have not been subscribed for, entitling such investors to 702,307 units, with each unit being comprised of (i) one share of the Company's common stock and (ii) one three-year warrant to purchase up to an additional one share of the Company's common stock at a per share exercise price of $6.24.

In July 2018, the Company entered into definitive agreements with assignees of Image whereby these assignees remitted $4.6 million in respect of the units available under the original subscription agreement that have not been subscribed for, entitling such investors to 702,307 units, with each unit being comprised of (i) one share of the Company's common stock and (ii) one three-year warrant to purchase up to an additional one share of the Company's common stock at a per share exercise price of $6.24.

During 2018, the Company raised $6.9 million from Image entitling it to 1,111,380 shares of Common Stock and three-year warrants for an additional 1,111,380 shares of the Company's Common Stock at a per share exercise price of $6.24. Following this remittance and those referred to in the previous paragraph, the Company received a total of $16 million out of the committed $16 million subscription proceeds under such agreement

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

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.

Pursuant to agreements with Image, the Company 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 $1.5 million and $1.3 million for the years ended December 31, 2020 and December 31, 2019, respectively. In addition, the company earned interest income in the amount of $169 thousand and $112 thousand for the years ended December 31, 2020 and December 31, 2019, respectively.

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

The Board of Directors of the Company has appointed Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited ("PwC") as our independent registered public accounting firm (the "Independent Auditor") for the fiscal year ended December 31, 2020. The following table sets forth the fees billed to the Company for professional services rendered by PwC for the years ended December 31, 2020 and December 31, 2019:

	Year Ended December 31,	
Services:	**2020**	**2019**
Audit Fees (1)	$ 267,231	$ 426,040
Audit-Related Fees (2)	67,405	26,900
Tax Fees (3)	12,500	18,300
All Other Fees	10,000	49,500
Total fees	$ 357,136	$ 520,740

(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 2020.

(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. The Company generally does 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 current report on Form S-8, filed on August 7, 2020)
10.1	Convertible Loan Agreement, dated December 6, 2013, with Mediapark A.G. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 16, 2013)
10.2	Investment Agreement, dated December 13, 2013, with Kodiak Capital Group, LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 16, 2013)
10.3	Registration Rights Agreement, dated December 13, 2013, with Kodiak Capital Group, LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 16, 2013)
10.4	Form of subscription agreement (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 4, 2014)
10.5	Form of warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 4, 2014)
10.6	Consulting Agreement, dated April 3, 2014, with Aspen Agency Limited (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 7, 2014)
10.7	Stock Option Agreement, dated April 3, 2014, with Aspen Agency Limited (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 7, 2014)
10.8	Form of subscription agreement with form of warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 28, 2014)
10.9	Convertible Loan Agreement, dated May 29, 2014, with Nine Investments Limited (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 30, 2014)
10.10	Service Agreement between Orgenesis SPRL and MaSTherCell S.A., dated July 3, 2014 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on July 7, 2014)
10.11	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)
10.12	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)
10.13	Executive Employment Agreement, dated March 30, 2017, between Orgenesis Inc. and Vered Caplan (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on July 24, 2017)
10.14	Amendment No. 1, dated May 10, 2017, to Executive Employment Agreement, dated as of March 30, 2017, between Orgenesis Inc. and Vered Caplan (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on July 24, 2017)

No.	Description
10.15	Share Exchange Agreement, dated November 3, 2014, by and between Orgenesis Inc. and MaSTherCell S.A. and Cell Therapy Holding SA (collectively "MaSTherCell") and each of the shareholders of MaSTherCell (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 10, 2014)
10.16	Addendum No. 1, dated March 2, 2015, to Share Exchange Agreement, dated November 3, 2014, by and between Orgenesis Inc., MaSTherCell, and each of the shareholders of MaSTherCell (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 5, 2015)
10.17	Escrow Agreement, dated February 27, 2015, by and between Orgenesis Inc., the shareholders of MaSTherCell S.A. and Cell Therapy Holding SA, the bondholders of MaSTherCell S.A. and Securities Transfer Corporation (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 5, 2015)
10.18	Orgenesis Inc. Board of Advisors Consulting Agreement, dated March 16, 2015 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 17, 2015)
10.19	Addendum No. 2, dated November 12, 2015, to Share Exchange Agreement, dated November 3, 2014, by and between Orgenesis Inc., MaSTherCell, and each of the shareholders of MaSTherCell (incorporated by reference to an exhibit our current report on Form 8-K, filed on November 13, 2015)
10.20	Joint Venture Agreement, dated March 14, 2016, by and between Orgenesis Inc. and CureCell Co., Ltd. (incorporated by reference to an exhibit to our annual report on Form 10-K, filed on February 28, 2017)
10.21	Joint Venture Agreement, dated May 10, 2016, by and between Orgenesis Inc. and Atvio Biotech Ltd. (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on April 19, 2017)
10.22	Private Placement Subscription Agreement, dated January 26, 2017, between Orgenesis Inc. and Image Securities FZC (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on April 19, 2017)
10.23	Amendment No. 1, dated February 9, 2017, to the Private Placement Subscription Agreement, dated January 26, 2017, between Orgenesis Inc. and Image Securities FZC (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on April 19, 2017)
10.24	2017 Equity Incentive Plan (incorporated by reference to an exhibit to our definitive proxy statement on Schedule 14A, filed on March 30, 2017)
10.25	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)
10.26	Private Placement Subscription Agreement, dated November 13, 2018, between Orgenesis Inc. and Avner Sonnino (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 20, 2018)
10.27	Private Placement Subscription Agreement, dated November 21, 2018, between Orgenesis Inc. and an accredited investor (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 28, 2018)
10.28	Private Placement Subscription Agreement, dated November 30, 2018, between Orgenesis Inc. and an accredited investor (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 6, 2018)
10.29	Private Placement Subscription Agreement, dated December 10, 2018, between Orgenesis Inc. and an accredited investor (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 14, 2018)
10.30	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)
10.31	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)

No.	Description
10.32	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)
10.33	Joint Venture Agreement between the Company and KinerjaPay Corp. dated May 6, 2019 (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on May 8, 2019)
10.34	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)
10.35	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)
10.36	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)
10.37	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)
10.38	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)
10.39	2017 Equity Incentive Plan (incorporated by reference to an exhibit to our definitive proxy statement on Schedule 14A, filed on March 30, 2017)
10.40	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)
10.41	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)
10.42	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)
10.43	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)
10.44	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)
10.45*	Executive Directorship Agreement between the Company and Vered Caplan dated November 19, 2020
10.46*	Swiss Employment Agreement between the Company and Vered Caplan dated November 19, 2020
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)
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

*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 9, 2021

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
Date: March 9, 2021

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

By: */s/ Vered Caplan*
Vered Caplan
Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)
Date: March 9, 2021

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
Date: March 9, 2021

By: */s/ Guy Yachin*
Guy Yachin
Director
Date: March 9, 2021

By: */s/ David Sidransky*
David Sidransky
Director
Date: March 9, 2021

By: */s/ Yaron Adler*
Yaron Adler
Director
Date: March 9, 2021

By: */s/ Ashish Nanda*
Ashish Nanda
Director
Date: March 9, 2021

By: */s/ Mario Philips*
Mario Philips
Director
Date: March 9, 2021

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2020

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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, 2020 and 2019, 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, 2020 and 2019, 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.

Changes in Accounting Principle

As discussed in Note 2(x) to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

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.

Revenue Recognition - Point-of-Care ("POC") Cell Therapy Platform

As described in Notes 1 and 2(w) to the consolidated financial statements, the Company generated approximately $5.9 million in revenue from POC services for the year ended December 31, 2020. The transaction price from those POC services is allocated by management to each distinct performance obligation based on its relative standalone selling price. 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. Revenue related to 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. Revenue from all other performance obligations are recognized as revenues by the Company at point of time (upon completion).

The principal considerations for our determination that performing procedures relating to revenue recognition - POC cell therapy platform is a critical audit matter are that there was significant judgment by management in (1) identifying the distinct performance obligations and estimating the standalone selling price of each distinct performance obligation, and (2) 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. This in turn led to significant auditor judgment and effort in performing procedures to evaluate management's significant judgment in identifying distinct performance obligations and determining whether those performance obligations create assets with alternative use to the Company.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process. These procedures also included, among others, on a test basis, testing the completeness and accuracy of management's identification of the distinct performance obligations by evaluating customer arrangements; and testing management's process for determining the appropriate amount of revenue recognition based on the performance obligations identified in relevant contracts.

/s/ Kesselman & Kesselman

Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 9, 2021

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

ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
(U.S. Dollars, in thousands)

	December 31,	
	2020	**2019**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 44,923	$ 107
Restricted cash	645	467
Accounts receivable, net	3,085	1,831
Prepaid expenses and other receivables	1,070	382
Grants receivable	169	204
Inventory	185	136
Current assets of discontinued operations (See Note 3)	-	75,221
Total current assets	50,077	78,348
NON CURRENT ASSETS:		
Deposits	$ 296	$ 299
Loan to related party	-	2,623
Investments in associates, net	175	-
Property, plants and equipment, net	3,073	2,305
Intangible assets, net	13,023	3,348
Operating lease right-of-use assets	1,474	725
Goodwill	8,745	4,812
Other assets	821	35
Total non-current assets	27,607	14,147
TOTAL ASSETS	$ 77,684	$ 92,495

ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
(U.S. Dollars, in thousands)

	December 31,	
	2020	**2019**
Liabilities and equity		
CURRENT LIABILITIES:		
Accounts payable	$ 8,649	$ 5,549
Accrued expenses and other payables	792	1,615
Income tax payable	7	-
Employees and related payables	1,463	1,672
Advance payments on account of grant	692	523
Short-term loans and current maturities of long-term loans	145	391
Contract liabilities	59	325
Current maturities of finance leases	19	-
Current maturities of operating leases	485	357
Current maturities of convertible loans	3,974	416
Current liabilities of discontinued operations (See Note 3)	-	31,586
TOTAL CURRENT LIABILITIES	16,285	42,434
LONG-TERM LIABILITIES:		
Non-current operating leases	$ 1,020	$ 455
Convertible loans	7,200	12,143
Retirement benefits obligation	74	41
Deferred taxes	-	58
Long-term debt and finance leases	64	-
Other long-term liabilities	313	331
TOTAL LONG-TERM LIABILITIES	8,671	13,028
TOTAL LIABILITIES	24,956	55,462
COMMITMENTS		
REDEEMABLE NON CONTROLLING INTEREST OF DISCONTINUED OPERATIONS (See Note 3)	-	30,955
EQUITY:		
Common stock of $0.0001 par value, 145,833,334 shares authorized, 24,223,093 and 16,140,962 shares issued as of December 31, 2020 and December 31, 2019, respectively	3	2
Additional paid-in capital	140,397	94,691
Accumulated other comprehensive income	748	213
Treasury stock at December 31, 2020 55,309 shares	(250)	-
Accumulated deficit	(88,319)	(89,429)
Equity attributable to Orgenesis Inc.	52,579	5,477
Non-controlling interests	149	601
TOTAL EQUITY	52,728	6,078
TOTAL LIABILITIES AND EQUITY	$ 77,684	$ 92,495

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)

	Year ended December 31,	
	2020	**2019**
Revenues	$ 6,177	$ 2,629
Revenues from related party	1,475	1,270
Total revenues	7,652	3,899
Cost of research and development and research and development services, net	83,986	14,014
Amortization of intangible assets	478	430
Selling, general and administrative expenses	18,973	11,451
Other income, net	(4)	(21)
Operating loss	95,781	21,975
Financial expenses, net	1,061	843
Share in net income of associated companies	(106)	-
Loss from continuing operation before income taxes	96,736	22,818
Tax income	(1,609)	(229)
Net loss from continuing operation	95,127	22,589
Net loss (income) from discontinued operations, net of tax	(95,706)	3,452
Net loss (income)	$ (579)	$ 26,041
Net loss attributable to non-controlling interests (including redeemable) from continuing operation	(39)	(99)
Net loss attributable to non-controlling interests (including redeemable) from discontinued operations	(492)	(1,821)
Net loss (income) attributable to Orgenesis Inc.	$ (1,110)	$ 24,121
Loss (income) per share:		
Basic and diluted from continuing operations	$ 4.46	$ 1.41
Basic and diluted from discontinued operations	$ (4.75)	$ 0.36
Basic and diluted	$ (0.29)	$ 1.77
Weighted average number of shares used in computation of Basic and Diluted loss per share:		
Basic and diluted	21,320,314	15,907,995
Comprehensive loss (income):		
Net loss from Continuing Operation	$ 95,127	$ 22,589
Net loss (income) from Discontinued Operations, Net of Tax	(95,706)	3,452
Other Comprehensive (income) loss – Translation adjustment	(341)	456
Release of translation adjustment due to sale of subsidiary	(194)	-
Comprehensive loss (income)	$ (1,114)	$ 26,497
Comprehensive loss attributed to non-controlling interests (including redeemable)	(39)	(99)
Comprehensive loss attributed to non-controlling interests (including redeemable) from discontinued operations	(492)	(1,821)
Comprehensive loss (income) attributed to Orgenesis Inc.	$ (1,645)	$ 24,577

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			Accumulated Other		Equity Attributable		
	Number	Par Value	Additional Paid-in Capital	Comprehensive Income (loss)	Accumulated Deficit	to Orgenesis Inc.	Non-Controlling Interest	Total
BALANCE AT JANUARY 1, 2019	15,540,333	$ 2	$ 90,597	$ 669	$ (65,163)	$ 26,105	$ 645	$ 26,750
Changes during the Year ended December 31, 2019:								
Stock-based compensation to employees and directors	-	-	2,106	-		2,106	58	2,164
Stock-based compensation to service providers	75,629	*-	893	-	-	893	-	893
Stock-based compensation to strategic collaborations	525,000	*-	2,641			2,641	-	2,641
Issuance and modification of warrants and Beneficial conversion feature of convertible loans	-	-	515	-	(145)	370	-	370
Transaction with non-controlling interest GPP (See Note 1)	-	-	2,034	-		2,034	-	2,034
Adjustment to redemption value of redeemable non-controlling interest	-	-	(4,095)	-	-	(4,095)	-	(4,095)
Comprehensive loss for the year		-	-	(456)	(24,121)	(24,577)	(102)	(24,679)
BALANCE AT DECEMBER 31, 2019	16,140,962	$ 2	$ 94,691	$ 213	$ (89,429)	$ 5,477	$ 601	$ 6,078

* Represents an amount lower than $1 thousand

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		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Treasury Shares	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Par Value
	Number	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	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 statements.

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

	Year ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 579	$ (26,041)
Adjustments required to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	2,847	3,057
Stock-based compensation for strategic collaborations	-	2,641
Stock-based compensation for Tamir Purchase Agreement (See Notes 4)	17,048	-
Capital loss (gain), net	22	(29)
Gain on disposal of subsidiaries	(96,918)	-
Share in income of associated company	(106)	-
Depreciation and amortization expenses	1,435	3,806
Effect of exchange differences on inter-company balances	(618)	214
Net changes in operating leases	14	(339)
Interest expense accrued on loans and convertible loans (including amortization of beneficial conversion feature)	927	387
Changes in operating assets and liabilities:		
Increase in accounts receivable	(1,350)	(5,308)
Increase in inventory	(84)	(414)
Increase in other assets	(24)	(46)
Increase in prepaid expenses, other accounts receivable	(1,073)	(112)
Increase in accounts payable	1,985	4,626
Increase (decrease) in accrued expenses and other payable	(1,156)	271
Increase (decrease) in employee and related payables	(170)	474
Increase (decrease) in contract liabilities	(166)	3,536
Change in advance payments and receivables on account of grant, net	140	(247)
Increase (decrease) in deferred taxes	(1,378)	304
Net cash used in operating activities	$ (78,046)	$ (13,220)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in loan to JV partner, a related party	(500)	(1,500)
Repayment in loan to JV partner, a related party	3,000	-
Sale of property, plants and equipment	7	79
Purchase of property, plants and equipment	(1,525)	(12,129)
Acquisition of Koligo, net of cash acquired (See Note 4)	(955)	-
Proceed from sale of subsidiaries, net	105,634	-
Investment in associated company	(69)	-
Repayment (investment) in short term deposits	18	(228)
Net cash provided by (used) in investing activities	$ 105,610	$ (13,778)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repurchase of treasury stock	(250)	-
Increase in redeemable non-controlling interests received from GPP	-	13,200
Proceeds from issuance of shares, warrants and exercise of options (net of transaction costs)	8,738	-
Proceeds from issuance of convertible loans (net of transaction costs)	250	11,400
Repayment of convertible loans and convertible bonds	(2,400)	-
Repayment of short and long-term debt	(457)	(772)
Proceeds from issuance of loans payable	-	270
Net cash provided by financing activities	$ 5,881	$ 24,098
NET CHANGE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	33,445	(2,900)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ 82	$ (58)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	$ 12,041	$ 14,999
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 45,568	$ 12,041

SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:				
Interest paid in cash during the year	$	-	$	157
Income taxes, net of refunds paid in cash during the year	$	-	$	156
SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES				
Finance Leases of property, plant and equipment	$	366	$	355
Right-of-use assets acquired in exchange for right-of-use liabilities	$	967	$	8,229
Purchase of property, plant and equipment included in accounts payable	$	241	$	1,584
Transaction costs of issuance of convertible loans	$	-	$	546
Acquisition of other asset in exchange for common stocks	$	700	$	-
Issuance of common stocks in connection with the acquisition of Koligo	$	11,172	$	-

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

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

ORGENESIS INC.
NOTES TO 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 in an affordable and accessible format ("CGTs").

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 focusses 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 at their point of care for treatment of the patient. 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 the 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 comprised of three enabling components: a pipeline of licensed **POCare Therapies** that are designed to be processed and produced in closed, automated **POCare Technology** systems across a collaborative **POCare Network**. Via a combination of science, technology, engineering, and networking, the Company is working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. 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, industry partners, research institutes and hospitals worldwide with a goal of achieving harmonized, regulated clinical development and production of the therapies.

Over time, the Company has worked to develop and validate POCare Technologies that can be combined within mobile production units for advanced therapies. In 2020, the Company 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 of partners, collaborators, and joint ventures. As of the date of this report, the 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 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 the Company to deliver CGTs to practically any clinical institution at the point of care.

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

Historically, the second separate business segment was operated as a Contract Development and Manufacturing Organization ("CDMO") platform, providing contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). The CDMO platform was historically operated mainly through majority owned Masthercell Global (which consisted of the following two subsidiaries: MaSTherCell S.A. in Belgium ("MaSTherCell"), and Masthercell U.S., LLC in the United States ("Masthercell U.S.") (collectively, the "Masthercell Global Subsidiaries")).

In February 2020, the Company and GPP-II Masthercell LLC ("GPP") sold 100% of the outstanding equity interests of Masthercell (the "Masthercell Business"), which comprised the majority of the Company's CDMO Business, to Catalent Pharma Solutions, Inc. for an aggregate nominal purchase price of $315 million, (the "Masthercell Sale"). After accounting for GPP's liquidation preference and equity stake in Masthercell as well as other investor interests in our Belgian subsidiary MaSTherCell, distributions to Masthercell option holders and transaction costs, the company received approximately $126.7 million. The Company incurred an additional approximately $5.6 million in transaction costs.

The Company determined that the Masthercell Business ("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.

Since the Masthercell Sale, the Company has entered into new joint venture agreements with new partners in various jurisdictions. This has allowed the Company to grow its infrastructure and expand its processing sites into new markets and jurisdictions. In addition, the Company has engaged some of these joint venture partners to perform research and development services to further develop and adapt its systems and devices for specific purposes. The Company has been investing 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.

The Chief Executive Officer ("CEO") is the Company's chief operating decision-maker who reviews financial information prepared on a consolidated basis. Effective from the first quarter of 2020, all of our continuing operations are in one segment, being the point-of-care business via our POCare Platform. Therefore, no segment report 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:

- United States: Orgenesis Maryland Inc. (the "U.S. Subsidiary") is the center of activity in North America currently focused on setting up of the POCare Network.

- Koligo Therapeutics Inc. ("Koligo") is a Kentucky corporation that was acquired in 2020 and is currently focused on developing the POCare network and therapies (See Note 4 for the acquisition of Koligo).

- European Union: Orgenesis Belgium SRL (the "Belgian Subsidiary") is the center of activity in Europe currently focused on process development and preparation of European clinical trials.

- Orgenesis Switzerland Sarl (the "Swiss subsidiary) incorporated in October 2020 is currently focused on providing management services to the Company.

- Israel: Orgenesis Ltd. (the "Israeli Subsidiary") is a provider of regulatory, clinical and pre-clinical services, and Orgenesis Biotech Israel Ltd. ("OBI") previously known as Atvio Biotech Ltd. ("Atvio") is a provider of cell-processing services in Israel.

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

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

On April 7, 2020, the Company entered into an Asset Purchase Agreement (the "Tamir Purchase Agreement") with Tamir Biotechnology, Inc. ("Tamir" or "Seller"), 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 Ranpirnase and use for antiviral therapy (collectively, the "Purchased Assets and Assumed Liabilities" and such acquisition, the "Tamir Transaction"). 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 (See Note 4).

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

As of December 31, 2020 ,the Company has accumulated losses of approximately $88 Million.

On February 10, 2020, the Company received approximately $126.7 million, of which $7.2 million was used for the repayment of intercompany loans and payables, from the Masthercell Sale (See Note 3). In addition, on January 20, 2020, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company received gross proceeds of approximately $9.24 million before deducting related offering expenses.

The Company invested significant resources in research and development and research and development services in 2020. The Company believes that these investments will enable it to substantially increase revenues in the next 12 months. Based on its current cash resources and commitments, 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. 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 may decide to seek additional financing.

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. Other 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.

d. Discontinued operations

Upon divestiture of a business, the Company classifies such business as a discontinued operation, 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 operation until the period in which the business is actually abandoned.

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

The results of businesses that have qualified as a discontinued operation 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).

e. 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.

f. Cost of research and development and research and development services, net

Cost of research and development and research and development services 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.

g. 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.

h. 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.

i. 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.

j. 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.

k. 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 - 7
Office equipment and computers	3 - 17

l. 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

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.

m. 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.

n. 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 year ended December 31, 2020 and 2019.

o. 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 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.

p. 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.

q. 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.

r. 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).

s. 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, 2020 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 or material delays in payments are all considered indicative of reduced debtor balance value.

t. 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. During the years ended December 31, 2020, the Company repurchased 55,309 shares. The Company did not reissue nor cancel treasury shares during the year ended December 31, 2020.

u. 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).

v. Other Comprehensive Loss

Other comprehensive loss represents adjustments of foreign currency translation.

w. 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 operation 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).

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 the Company, which results in revenue recognized upon completion, and which performance obligations are transferred to the customer over time.

Practical Expedients

As part of ASC 606, the Company has adopted several practical expedients including the Company's determination that it need 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 when the Company transfers a promised service to the customer and when the customer pays for that service will be one year or less.

Cell Process Development Services (mainly discontinued operations)

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 the customer pays, together with the payment term and cancellation fine, it has a right to payment (which include 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.

Tech Transfer Services (discontinued operations)

Revenue recognized under contracts for tech transfer services are considered a single performance obligation, as all work packages (including data collection, GMP documentation, validation runs) and milestones are interrelated. Additionally, the customer is unable to complete services of work performed independently or by using competitors of the Company. Revenue is recognized over time using a cost-based based input method where progress on the performance obligation is measured by the proportion of actual costs incurred to the total costs expected to complete the contract.

Cell Manufacturing Services (discontinued operations)

Revenues from cell manufacturing services represent a single performance obligation which is recognized over time. The progress towards completion will continue to be measured on an output measure based on direct measurement of the value transferred to the customer (units produced).

Reimbursed Expenses (discontinued operations)

The Company includes reimbursed expenses in revenues and costs of revenue as the Company is primarily responsible for fulfilling the promise to provide the specified service, including the integration of the related services into a combined output to the customer, which are inseparable from the integrated service. These costs include such items as consumable, reagents, transportation and travel expenses, over which the Company has discretion in establishing prices.

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.

Costs of Revenue (discontinued operations)

Costs of revenue include (i) compensation and benefits for billable employees and personnel involved in production, data management and delivery, and the costs of acquiring and processing data for the Company's information offerings; (ii) costs of staff directly involved with delivering services offerings and engagements; (iii) consumables used for the services; and (iv) other expenses directly related to service contracts such as courier fees, laboratory supplies, professional services and travel expenses.

x. Leases

The Company adopted the new lease standard ASC 842 and all the related amendments on January 1, 2019.

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's 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.

y. 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 is currently evaluating the impact that this new guidance will have on its consolidated financial statements.

z. *Newly issued and recently adopted accounting pronouncements*

The Company early adopted ASU 2019-12 on January 1, 2020, which did not have a material impact on the Consolidated Financial Statements except for the removal of the exception related to intra-period tax allocations. Commencing from January 1, 2020, the Company followed the general intra-period allocation of tax expenses. The Company had incurred a loss from continuing operations and subsequent to the adoption of ASU 2019-12, the Company determined the amount attributable to continuing operations without regard to the tax effect of other items. The ASU 2019-12 amendment related to the intra-period tax allocation was applied prospectively.

Had the Company not adopted ASU 2019-12, an approximately $20 million tax benefit would have been recognized along with corresponding decreases to net loss from continuing operations with a corresponding increase in tax expenses and decrease in net income resulting from discontinued operations. The Company had no intra-period tax allocation items in prior years.

aa. Reclassifications

Certain reclassifications have been made to the prior years' financial statements to conform to the current year presentation. These reclassifications had no net effect on previously reported results of operations.

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	2019
OPERATIONS		
Revenues	$ 2,556	$ 31,053
Cost of revenues	1,482	18,318
Cost of research and development and research and development services, net	7	54
Amortization of intangible assets	137	1,631
Selling, general and administrative expenses	1,896	13,886
Other (income) expenses, net	305	(207)
Operating loss	1,271	2,629
Financial expenses (income), net	(29)	31
Loss before income taxes	1,242	2,660
Tax expenses (income)	(30)	792
Net loss from discontinuing operation, net of tax	$ 1,212	$ 3,452
DISPOSAL		
Gain on disposal before income taxes	$ 96,918	$ -
Provision for income taxes	-	-
Gain on disposal	$ 96,918	$ -
Net profit (loss) from discontinuing operation, net of tax	$ 95,706	$ (3,452)

The following table is a summary of the assets and liabilities of discontinued operations (in thousands):

	December 31, 2019
Assets	
CURRENT ASSETS:	
Cash and cash equivalents	$ 11,281
Restricted cash	186
Accounts receivable, net	6,654
Prepaid expenses and other receivables	845
Grants receivable	1,979
Inventory	1,907
Deposits	326
Property and equipment, net	22,149
Intangible assets, net (mainly Know How)	10,858
Operating lease right-of-use assets	8,860
Goodwill	10,129
Other assets	47
TOTAL CURRENT ASSETS OF DISCONTINUED OPERATIONS	$ 75,221

	December 31, 2019
CURRENT LIABILITIES:	
Accounts payable	$ 5,756
Accrued expenses and other payables	372
Employees and related payables	2,047
Advance payments on account of grant	2,227
Short-term loans and current maturities of long- term loans	372
Contract liabilities	8,301
Current maturities of long-term finance leases	291
Current maturities of operating leases	1,365
Non-current operating leases	7,069

Loans payable	1,230
Deferred taxes	1,868
Long-term finance leases	688
TOTAL CURRENT LIABILITIES OF DISCONTINUED OPERATIONS	$ 31,586

Property, plants and equipment, net and right-of-use assets by geographical location were as follows:

	December 31, 2019
United States	$ 16,707
Belgium	14,302
Total	$ 31,009

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

	Year Ended December 31,	
	2020	2019
Net cash flows used in operating activities	$ (2,409)	$ (1,248)
Net cash flows used in investing activities	$ (579)	$ (11,621)
Net cash flows (used in) provided by financing activities	$ (51)	$ 12,570

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	2019
Revenue stream:		
Cell process development services	$ 2,556	$ 20,834
Tech transfer services	-	5,396
Cell manufacturing services	-	4,823
Total	$ 2,556	$ 31,053

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 SPFI 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 Ranpirnase 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. $59 thousand and 340,000 Shares are being held in an escrow account for a period of 18 months from closing to secure indemnification obligations of Tamir pursuant to the terms of the Tamir Purchase Agreement. $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.

Description of Koligo Acquisition during 2020

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 is 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, we 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.

The Merger Agreement contains customary indemnification provisions whereby the Shareholders of Koligo will indemnify the Company and certain affiliated parties for any losses arising out of breaches of the representations, warranties and covenants of Koligo and the Shareholders under the Merger Agreement. 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. 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 has also 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 pursuant to which Long Hill will have one demand registration right to require the registration of the shares of Company common stock received by Long Hill in the Merger and Long Hill and Maxim will have certain piggyback registration rights. In addition, Long Hill agreed with the Company that, during the applicable Restriction Period (as defined below), it shall not sell or transfer, subject to certain limited exceptions, the portion of the shares received in the Merger during the applicable Restriction Period, subject to a limitation on the number of shares sold per any trading day not to exceed 10% of the average daily trading volume of the Common Stock, as reported by Bloomberg Financial L.P. "Restriction Period" means (a) in relation to 70% of all of the shares received in the Merger that Long Hill is entitled to receive under or in connection with the Merger Agreement, the period beginning on the date of the closing and ending on the date that is the four month anniversary thereof, and (b) in relation to the remaining 30% of all of the shares received in the Merger that Long Hill is entitled to receive under or in connection with the Merger Agreement, the period beginning on the date of the closing and ending on the date that is the twelve month anniversary thereof. 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	**2019**
Revenues	$ 8,239	$ 4,398
Net loss	$ 318	$ 27,263
Loss per share:		
Basic	$ 0.05	$ 1.91

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.

Cooperate reorganization, description of the Transactions Korea and OBI during 2019

On August 7, 2019, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company ("GPP-II"), (the "Parties") entered into a Transfer Agreement (the "Transfer Agreement"). As a result of the Transfer Agreement, Masthercell Global transferred all of its equity interests of OBI and the Korean Subsidiary to Orgenesis Inc in exchange for one dollar ($1.00). The Transfer Agreement also contained agreements made with respect to certain intercompany loans. The Company accounted for the Transfer Agreement as a transaction with non-controlling interest.

NOTE 5 – PROPERTY, PLANTS AND EQUIPMENT

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

	December 31,	
	2020	**2019**
	(in thousands)	
Cost:		
Production facility	$ 2,801	$ 2,481
Office furniture and computers	697	606
Lab equipment	1,483	656
Advance payment	281	-
Subtotal	5,262	3,743
Less – accumulated depreciation	(2,189)	(1,438)
Total	$ 3,073	$ 2,305

Depreciation expense for the years ended December 31, 2020 and December 31, 2019 were $ 705 thousand and $634 thousand, respectively.

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

	December 31,	
	2020	**2019**
	(in thousands)	
Belgium	$ 358	$ -
Korea	839	983
Israel	1,386	1,322
U.S.	490	-
Total	$ 3,073	$ 2,305

NOTE 6 – INTANGIBLE ASSETS AND GOODWILL

Changes in the carrying amount of the Company's goodwill for the years ended December 31, 2020 and 2019 are as follows:

	(in thousands)
Goodwill as of December 31, 2018	$ 4,942
Translation differences	(130)
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

Goodwill Impairment

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

Other Intangible Assets

Other intangible assets consisted of the following:

	December 31,	
	2020	2019
	(in thousands)	
Gross Carrying Amount:		
Know How	$ 3,170	$ 2,991
Customer relationships	886	895
Kyslecel Technology	9,340	-
IPR&D	641	-
Subtotal	14,037	3,886
Less – Accumulated amortization	(1,014)	(538)
Net carrying amount of other intangible assets	$ 13,023	$ 3,348

Intangible assets amortization expenses were approximately $478 thousand and $430 thousand for the years ended December 31, 2020 and December 31, 2019, respectively.

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

	2021	2022 to 2025
	(in thousands)	
Amortization expenses	$ 965	$ 3,910

NOTE 7 – CONVERTIBLE LOANS

a. Long term convertible loans outstanding as of December 31, 2020 and December 31, 2019 are as follows:

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF
(in thousands)			(Years)		
Convertible Loans Outstanding as of December 31, 2020					
$ 1,000	2018	2%	3	7.00(1)	71
9,500	2019	6%-8%	2-5	7.00(2)	-
250	2020	8%	2	7.00(3)	-
$ 10,750					
Convertible Loans Outstanding as of December 31, 2019					
$ 1,500	2018	2%	3	7.00(1)	124
11,400	2019	6%-8%	2-5	7.00(2)	-
$ 12,900					

Convertible Loans repaid during the year ended December 31, 2020

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF
500	2018	2%	0.87	$ 7	53
500	2019	6%	0.28	7	-
1,400	2019	8%	0.76	7	-
2,400					

Apart from the items mentioned below there were no repayments of convertible loans during the fiscal years ended December 31, 2019 and December 31, 2020. In addition, there were no conversions during the fiscal years ended December 31, 2019 and December 31, 2020.

(1)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 148,838 shares and 148,838 three-year warrants to purchase up to an additional 148,838 shares of the Company's common stock at a per share exercise price of $7. In the initial two years, the holders have the right to convert the outstanding principal amount and accrued interest into shares of capital stock of Hemogenyx-Cell or Immugenyx, LLC according under the relevant note agreement, subsidiaries of Hemogenyx Pharmaceuticals Plc, at a price per share based on a pre-money valuation of Hemogenyx-Cell or Immugenyx, LLC of $12 million and $8 million, respectively, pursuant to the collaboration agreement with Hemogenyx Pharmaceuticals Plc and Immugenyx, LLC. As of December 31, 2020, the loans are presented in current maturities of convertible notes in the balance sheet (See Notes 11(c) and 11(d).

(2)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 1,443,734 shares and 1,053,503 three-year warrants to purchase up to an additional 1,053,503 shares of the Company's common stock at a per share exercise price of $7. As of December 31, 2020, $2,500 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(e), 7(f) and 7(g).

(3)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 38,559 shares at a per share exercise price of $7. As of December 31, 2020, all the principal amount is included in long-term convertible loans in the balance sheet See also Notes 7(h).

b. During April 2019, the Company entered into a convertible loan agreement with an offshore investor for an aggregate amount of $500 thousand into the U.S. Subsidiary. The investor, at its option, may convert the outstanding principal amount and accrued interest under this note into shares and three-year warrants to purchase shares of the Company's common stock at a per share exercise price of $7.00; or into shares of the U.S. Subsidiary at a valuation of the U.S. Subsidiary of $50 million. During February 2020 the company repaid this convertible loan to the investor in full.

c. 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.

d. In May 2019, the Company had agreed to enter into a 6% convertible loan agreement with an investor for an aggregate amount of $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 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. As of the date of the filing of this Annual Report on Form 10-K, the loan had not yet been received by the Company.

e. 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.

f. 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 is 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, shall become 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 issue 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. The modification of the existing warrants in the amount of $145 thousands was recorded against the accumulated deficit and the value of the new warrants in the amount of $370 thousands was offset against the convertible loan amount.

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 shares of common stock of the Company at a conversion price per share equal to $7.00.

As at December 31, 2019, the Company had received $3.65 million from the Convertible Credit Line investment comprised of $1.15 million from one investor, $1 million from a second investor, and $750 thousand from two of the other lenders.

The transaction costs were approximately $145 thousand.

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.

g. 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 and warrants to purchase 183,481 additional shares of the Company's 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.

h. 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.

i. 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.

j. 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, 2020.

NOTE 8 – LOANS

Terms of Short-term Loans

	Currency	Interest Rate	December 31, 2020	December 31, 2019
			(in thousands)	
Short term loans	KRW	3.61%	$ -	$ 260
Short term loans	KRW	6.00%	-	131
Short term loans	USD	1.00%	145	-
			$ 145	$ 391

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, 2020
Assets	
Operating Leases	
Operating lease right-of-use assets	$ 1,474
Finance Leases	
Property, plants and equipment, gross	99
Accumulated depreciation	(17)
Property and equipment, net	$ 82
Liabilities	
Current liabilities	
Current maturities of operating leases	$ 485
Current maturities of long-term finance leases	$ 19
Long-term liabilities	
Non-current operating leases	$ 1,020
Long-term finance leases	$ 64
Weighted Average Remaining Lease Term	

Operating leases	3.4 years
Finance leases	4.2 years
Weighted Average Discount Rate	
Operating leases	6.7%
Finance leases	2.0%

Lease Costs

The table below presents certain information related to lease costs and finance and operating leases during the year ended December 31, 2020.

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

The table below presents supplemental cash flow information related to leases during the year ended December 31, 2020:

	Year ended December 30, 2020
	(in Thousands)
Cash paid for amounts included in the measurement of leases liabilities:	
Operating leases	$ 515
Finance leases	$ 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,		
2021	$ 526	$ 20
2022	528	20
2023	342	20
2024	188	20
2025	59	4
Total minimum lease payments	1,643	84
Less: amount of lease payments representing interest	(138)	(1)
Present value of future minimum lease payments	1,505	83
Less: Current leases obligations	(485)	(19)
Long-term leases obligations	$ 1,020	$ 64

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

	December 31,	
	2020	2019
	(in thousands)	
Korea	$ 683	$ 145
Israel	496	580
U.S.	295	-
Total	$ 1,474	$ 725

NOTE 10 – COMMITMENTS

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

a. *Maryland Technology Development Corporation*

On June 30, 2014, the Company's U.S. Subsidiary entered into a grant agreement with Maryland Technology Development Corporation ("TEDCO"). TEDCO was created by the Maryland State Legislature in 1998 to facilitate the transfer and commercialization of technology from Maryland's research universities and federal labs into the marketplace and to assist in the creation and growth of technology-based businesses in all regions of the State. Under the agreement, TEDCO paid to the U.S Subsidiary an amount of $406 thousand (the "Grant"). On June 21, 2016 TEDCO has approved an extension until June 30, 2017.

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 thousand (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 thousand 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, 2020, the Company repaid to the DGO6 a total amount of $118 thousand (Euro 96 thousand) and amount of $106 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, 2020, an amount of Euro 358 thousand ($437 thousand) was recorded as deduction of research and development expenses and an amount of Euro 80 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). Up through December 31, 2020, an amount of Euro 1.7 million was recorded as deduction of research and development expenses and an amount of Euro 53 thousand was recorded as receivable on account of grant.

(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 an advance payment of Euro 301 thousand ($366 thousand) in December 2020. The research program is to be 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 $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the "Project"). The Project started on March 1, 2015. Upon the conclusion of product development, the grant shall be repaid at the rate of 5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting on March 1, 2015. On July 28, 2016, BIRD approved an extension for the project period until May 31, 2017 and the final report was submitted to BIRD. As of December 31, 2020, the Israeli Subsidiary received a total amount of $299 thousand under the grant and the project was completed.

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 give 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 AIP Cells for the Treatment of Diabetes (the "Project"). The Project started on June 1, 2016. Upon the conclusion of product development, the grant shall be repaid at the yearly rate of 2.5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting. On July 26, 2018 KORIL approved extension for the project period till May 31, 2019 and was further extended to May 2020. During 2019, the grant was assigned to Cure Therapeutics from the Korean Subsidiary. As of December 31, 2020, 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 the beginning of 2018, OBI entered into a Cooperation and Project Funding Agreement (CPFA) with BIRD and Secant. BIRD will give a conditional grant up to $450 thousand each to support the joint project (according to terms defined in the agreement).

As of December 31, 2020, OBI received a total amount of $425 thousand under the grant. For the year ended December 31, 2020, an amount of $28 thousand was recorded as deduction of research and development expenses.

NOTE 11 – COLLABORATION AND LICENSE AGREEMENTS

a. *Adva Biotechnology Ltd.*

On January 28, 2018, the Company and Adva Biotechnology Ltd. ("Adva"), entered into a Master Services Agreement ("MSA"), under which the Company and/or its affiliates are to provide certain services relating to development of products to Adva, as may be agreed between the parties from time to time. Under the MSA, the Company undertook to provide Adva with in kind funding in the form of materials and services having an aggregate value of approximately $760 thousand at the Company's own cost in accordance with a project schedule and related mutually acceptable project budget. The Company entered into an agreement with Orgenesis Biotech Israel (previously Atvio), to fulfill its obligations pursuant this MSA and it completed its contractual obligations under the contract during 2019.

In consideration for and subject to the fulfillment by the Company of such in-kind funding commitment, 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. *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, 2020, 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.

c. *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. 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. During 2018 and 2020 the Company advanced $0.75 million and $0.25 million, respectively, to Hemo as a convertible loan and the entire loan was charged to expenses under ASC 730-10-50 and 20-50 and presented as research and development costs.

See Note 7.

d. *Immugenyx LLC.*

On October 16, 2018, the Company and Immugenyx LLC., a corporation with its registered office in the USA ("Immu"), who 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. 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. During 2018 and 2020 the Company advanced $0.75 million and $0.25 million, respectively, to Immu as a convertible loan and the entire loan was charged to expenses under ASC 730-10-50 and 20-50 and presented as research and development

e. *BG Negev Technologies and Applications ("BGN").*

On August 2, 2018, the Company's U.S. Subsidiary entered into a licensing agreement with BGN. According to the agreement, the U.S. Subsidiary 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's U.S. Subsidiary 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 consideration for the licenses, the U.S. Subsidiary will pay royalties of between 4% and 7% (subject to rate reductions to 5% and 4%, respectively, in specific circumstances) of net sales of the licensed product, sub-license fees of 20% of sub-license income received, license fees of $10,000 per year per license, and milestone and budget payments according to agreed upon work plans to BGN.

f. *Collaboration Agreement with Tarus Therapeutics, Inc.*

On February 27, 2019, the Company and Tarus Therapeutics Inc., a Delaware corporation, ("Tarus") entered into a Collaboration Agreement (the "Tarus Agreement") for the collaboration in the funding, development and commercialization of certain technologies, products and patents of Tarus in the areas of therapeutics for cancer and other diseases in the field of cell therapies and their combination with checkpoint inhibitors comprised of Adenosine Receptor Antagonists. Under the terms of the Tarus Agreement and subject to final due diligence and approved financing of the Company, the Company and/or one or more qualified investors (the "Investors") shall advance to Tarus a convertible loan in an amount of not less than $1,750 thousand and up to $3,000 thousand (the "Loan Agreement"). As of December 31, 2020, the loan agreements have not been concluded, nor has any financing been made to Tarus. As part of such Loan Agreement, and subject to approval by the board of directors of the Company, the Investors shall have the right, within two years of the date of the Loan Agreement, to convert the outstanding convertible loan into either (i) shares of Tarus at a price per share based on a pre- money valuation of $12,500 thousand or (ii) shares of the Company's common stock at a price per share set in accordance with an approved financing of the Company, with such terms as approved by the Company in its sole discretion. In the event the Investors elect to convert into shares of the Company's common stock, the Company shall have the right upon notice to Tarus to receive the same number of shares of capital stock of Tarus that the Investors would have received had the Investors converted their convertible loans into shares of Tarus. Further, as part of the Loan Agreement, the Company shall advance to Tarus up to $500 thousand within fourteen days of execution of the Loan Agreement. Subject to the closing of the Loan Agreement, the Company and/or the Investors shall have an option, exercisable by sending written notice to Tarus at any time through the second anniversary of the closing of the Loan Agreement, to invest additional funds in an amount of up to $1,250 thousand and not less than $500 thousand in Tarus. The Company will also have the right to appoint and/or replace one member of board of directors of Tarus. Upon and subject to the execution of a definitive development and manufacturing agreement between the Company and Tarus ("Manufacturing and Supply Agreement"), the Company, or one or more of its affiliates, shall manufacture and supply to Tarus and any of its affiliates, licensees, assignees of interest all requirements for all cell therapy elements of any combination therapy incorporating the technology of Tarus. Following the conclusion of the clinical development stage of each product emanating from the technology of Tarus, the cell therapy component of any such product borne out of the technology of Tarus shall be exclusively supplied by the Company under the Manufacturing and Supply Agreement. If the Company and Tarus fail to sign such Manufacturing and Supply Agreement for any given Tarus product, Tarus shall pay the Company an amount equal to four percent (4%) of gross revenues derived by Tarus from such Tarus products.

Apart from the above, there was no activity in the Tarus collaboration.

g. *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.

h. *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). The liver cells are intended to be bio-banked at the New York Blood Center, NYC for potential future clinical use. In October 2019, a liver sample from the first recruited patient was collected and processed and stored at the New York Blood Center, NYC in specialized, clinical grade, tissue banks for potential clinical use.

i. 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. The incidence of diabetes following TP is 100%, resulting in immediate and lifelong insulin-dependence with the loss of both endogenous insulin secretion and that of the counter-regulatory hormone, glucagon. Glycemic control after TP is notoriously difficult with conventional insulin therapy due to complete insulin dependence and loss of glucagon-dependent counter-regulation. Patients with this condition experience both severe hyperglycemic and hypoglycemic episodes.

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.

k. Caerus Therapeutics Inc (a related party)

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 feasibility fees (including the grant to purchase 70,000 options in the Company, annual maintenance fees and royalties of sales of up to 5% and up to 18% of sub-license fees. Expenses in the amount of approximately $200 thousand including the fair value of the options granted were recorded as research and development expenses. The Company also has the right to instruct Caerus to transfer the license, development, development results and any other rights and licenses granted to the Company to a joint venture ("JV") in which Company shall have a 51% controlling ownership stake in the JV Entity. Upon Company's election of such option, the development shall be carried out by Caerus for the JV and the royalty, sublicense fees and annual maintenance fee shall be terminated. Company may provide requisite funding for the JV Entity as determined by the Company and Caerus.

l. Extracellular Vesicle ("EV") Technology License

During the third quarter of 2020, the Company purchased the IP and related EV technology from a service provider (the "Service Provider") pursuant to an EV agreement (the "EV agreement"). According to the EV agreement, the Service Provider sold to the Company all of its rights in the EV technology that it had produced, in the amount of $500 thousand, to be paid in installments over the next 12 months from September 2020. The $500 thousand was recorded in R&D expenses. In addition, the Service Provider granted the Company an exclusive worldwide license to use the EV IP technology for any purpose.

m. Tamir Biotechnology acquisition

Included in the purchased assets of the Tamir Biotechnology Inc acquisition (See Note 4) was the assumption by the Company 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. This license fee and the right to receive future milestone payments (of up to $11 million assuming that certain milestones are reached) and royalties (of up to $35 million based on net sales milestones), were assumed by the Company in connection with the Tamir Purchase Agreement together with a less than 10% share interest. To date, no milestones have been reached.

n. 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.

o. Joint venture agreements

Additionally, 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. 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 50 % 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.

Name of party (and country of origin)	Territory	Notes
Theracell Advanced Biotechnology	Greece, Turkey, Cyprus, Israel and Balkans	(1)
Broaden Bioscience and Technology Corp	Certain projects in China and the Middle East	
Mircod LLC (US)	Russia	(2)
Image Securities FZC (UAE) (a related party)	India	
Cure Therapeutics	Korea and Japan	
Kidney Cure Ltd	Worldwide	(3)
Sescom Ltd	Worldwide	(4)
Educell D.O.O (Slovenia)	Croatia, Serbia and Slovenia	
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	(5)
First Choice International Company, Inc	Panama and certain other Latin American countries	(6)
KinerjaPay Corp	Singapore	(7)
SBH Sciences Inc	Worldwide	(8)
HekaBio KK	Japan	(9)

(1) The Theracell JVE was incorporated in Greece under the name of Theracell Laboratories Ltd. (See Note 12).

(2) Under the Mircod JVA, provisos 7 and 8 do not apply. Subject to payment by the Company ORGS 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. The parties also, following proviso 6, concluded a convertible loan agreement pursuant to which Company shall lend Mircod up to $5 million based upon a development plan to be agreed upon. The loan bears simple interest in the amount of 6% annually. As at December 31, 2020, the development plan had not been finalized and no transfers under the loan agreement were made.

(3) Pursuant to the Kidney Cure JVA, the parties will collaborate 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 "Project"). Provisos 7 and 8 do not apply to the Kidney Cure JVA. The Kidney Cure JVE was incorporated in Switzerland under the name of Butterfly Biosciences Sarl (See Note 12).

(4) 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.

(5) Under the Mida JVA, commencing January 1, 2022 and thereafter Mida shall have the right to sell to Company its then issued and outstanding shares in the JVA, and if the JVA was not yet set up, its assets, contracts and liabilities relating to the project, for a consideration to be agreed between the parties in good faith, provided that such consideration is not lower than $500 thousand.

(6) 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.

(7) No activities have taken place since the JVA was signed. According to the JVA, Company was eligible to receive 51% of the equity and 10% royalties on sales of products. The steering committee was to compromise 5 members of which Company could appoint 2, and a third member to be an industry expert, to be appointed by Orgenesis. The JVA did not include the proviso 8.

(8) 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. The SBH JVE has not yet been incorporated. 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. All intellectual property conceived or developed resulting from the business of the SBH JV Entity, that is not SBH's or the Company's background intellectual property, shall be owned exclusively by the SBH JV Entity, although the Company shall be granted the right to exclusively license any intellectual property arriving from the development activities of the SBH JV Entity, or exclusively distribute products based thereon. Provisos 7 and 8 do not apply to the SBH JVA.

During the third quarter of 2019, the Company transferred $50 thousand to SBH. Apart from the above, there was no material activity in the SBH Collaboration and the SBH JV entity had not been incorporated as at December 31, 2020.

(9) During the third quarter of 2020, the Company and HB agreed to terminate the license agreement. As of December 31, 2020, no activity had begun in the said JV and no investments were made therein.

NOTE 12 – INVESTMENTS IN ASSOCIATES, NET

a. Theracell Laboratories Private Company

During October 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.

b. Butterfly Biosciences Sarl

During October 2020, the Company and Kidney Cure, 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 on BB and Kidney Cure holds the remaining 51%.

c. The table below sets forth a summary of the changes in the investments for the year ended December 31, 2020:

	December 30, 2020
	(In thousands)
Opening balance	$ -
Investments during the period	69
Share in net income of associated companies	106
	$ 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.

b. Tamir Biotechnology, Inc.

For the acquisition of Tamir, see Note 4.

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. $59 thousand and 340,000 Shares are being held in an escrow account for a period of 18 months from closing to secure indemnification obligations of Tamir pursuant to the terms of the Tamir Purchase Agreement. The share price was $5.26 at the day of the closing.

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, we 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, 2020, and December 31, 2019 and changes for the periods then ended is presented below:

	December 31,			
	2020		2019	
	Number of Warrants	Weighted Average Exercise Price $	Number of Warrants	Weighted Average Exercise Price $
Warrants outstanding at the beginning of the period	6,010,087	6.35	6,286,351	6.29
Changes during the period:				
Issued	1,344,606	5.64	471,980	6.95
Expired	(284,452)	6.53	(748,244)	6.24
Warrants outstanding and exercisable at end of the period*	7,070,241	6.20	6,010,087	6.35

*As of December 31, 2020 and December 31, 2019, there are no warrants that are subject to exercise price adjustments.

e. Treasury shares

A summary of the Company's treasury shares purchased as of December 31, 2020 and changes for the period then ended is presented below:

	December 31, 2020	
	Number of Treasury Shares	Weighted Average Price Paid $
Treasury Shares at the beginning of the period	-	-
Changes during the period:		
Purchased	55,309	4.47
Shares at end of the period	53,309	4.47

NOTE 14 – INCOME (LOSS) PER SHARE

The following table sets forth the calculation of basic and diluted loss per share for the periods indicated:

	Year ended December 31,	
	2020	2019
	(in thousands, except per share data)	
Basic and diluted:		
Net loss from continuing operations attributable to Orgenesis Inc.	$ 95,088	$ 22,490
Net (income) loss from discontinued operations attributable to Orgenesis Inc. for loss per share	(96,198)	1,631
Adjustment of redeemable non-controlling interest to redemption amount	(5,160)	4,095
	(101,358)	5,726
Net (income) loss attributable to Orgenesis Inc. for loss per share	(6,270)	28,216
Weighted average number of common shares outstanding	21,320,314	15,907,995
Loss per common share from continuing operations	$ 4.46	$ 1.41
Net (income) loss common share from discontinued operations	$ (4.75)	$ 0.36
Net (income) loss per share	$ (0.29)	$ 1.77

For the year ended December 31, 2020, and December 31, 2019, 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 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 anti-dilutive.

NOTE 15 – STOCK-BASED COMPENSATION

a. *Global Share Incentive Plan*

On May 11, 2017, the annual meeting of the Company's stockholders approved the 2017 Equity Incentive Plan (the "2017 Plan") under which, the Company had reserved a pool of 1,750,000 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. At the Company's annual meeting of stockholders on November 26, 2019 the Company's stockholders approved an amendment to increase the number of shares authorized for issuance of awards under the Company's 2017 Equity Incentive Plan from 1,750,000 shares to an aggregate of 3,000,000 shares of Common Stock. As of December 31, 2020, total options granted under this plan are 1,362,133 and the total options that are available for grants under this plan are 1,724,966.

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, 2020, total options granted under this plan are 1,183,182 and the total options that are available for grants under this plan are 248,024.

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, 2020, and December 31, 2019:

	Year Ended	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
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
Employees	December 31, 2019	94,500	$3.14-$5.07	Quarterly over a period of two years	$ 322	10 years
Directors	December 31, 2019	50,000	$ 2.99	One-year anniversary	$ 103	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:

	Year Ended December 31,	
	2020	2019
Value of one common share	$ 2.99-$6.84	$ 2.99-$5.07
Dividend yield	0%	0%
Expected stock price volatility	80%-86%	83%-88%
Risk free interest rate	0.36%-1.71%	1.45%-2.47%
Expected term (years)	5.50-6.00	5.38-5.56

A summary of the Company's stock options granted to employees and directors as of December 31, 2020 and December 31, 2019 is presented below:

	Year Ended December 31			
	2020		2019	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the period	2,465,522	4.44	2,376,427	4.51
Changes during the period:				
Granted	676,500	3.74	144,500	4.15
Expired	(11,876)	7.88	(16,750)	6.01
Forfeited	(57,042)	4.52	(38,655)	7.11
Cancelled	(155,437)	8.38	-	-
Options outstanding at end of the period	2,917,667	4.05	2,465,522	4.44
Options exercisable at end of the period	2,299,937	4.03	2,112,567	4.21

The following table presents summary information concerning the options granted and exercisable to employees and directors outstanding as of December 31, 2020 (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	3.64	1,036	230,189	-
0.012	510,017	1.09	2,289	510,017	6
2.99	445,013	9.15	672	174,208	521
3.14	3,750	6.27	5	1,875	6
4.42	50,000	6.93	4	50,000	221
4.5	34,000	8.47	-	23,938	108
4.6	185,300	9.96	-	-	-
4.7	6,250	9.03	-	-	-
4.8	483,337	5.94	-	483,337	2,320
5.07	53,250	8.08	-	39,750	202
5.1	63,000	9.68	-	7,875	40
5.99	352,550	7.26	-	290,488	1,740
6	16,667	3.59	-	16,667	100
6.84	17,000	9.38	-	4,250	29
7.2	83,334	6.43	-	83,334	600
8.36	250,001	7.50	-	250,001	2,090
8.91	15,000	7.46	-	15,000	134
9	20,834	2.54	-	20,834	187
9.48	58,908	1.52	-	58,908	558
10.2	39,267	1.42	-	39,267	401
	2,917,667	5.98	4,006	2,299,937	9,263

Costs incurred with respect to stock-based compensation for employees and directors for the years ended December 31, 2020 and December 31, 2019 were $1,470 thousand and $2,107 thousand, respectively, out of which $450 thousand and $360 thousand related to options granted to employees of Masthercell Global, respectively, and presented as part of net loss from discontinued operations in the consolidated statements of comprehensive loss. As of December 31, 2020, there was $1,594 thousands of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 2.02 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, 2020 and December 31, 2019 and for the one-month period ended December 31, 2019:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employees	2020	62,500	$2.99-$6.84	Quarterly over a period of two years	$ 209	10 years
Non-employees	2019	128,336	$ 3.14-$7	Vest immediately-5 years	$ 394	10 years

The fair value of options granted during 2020 and 2019 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:

	Year Ended December 31,	
	2020	2019
Value of one common share	$ 2.99-$6.84	$ 3.14-$5.07
Dividend yield	0%	0%
Expected stock price volatility	86%-89%	89%-92%
Risk free interest rate	0.73%-1.12%	1.52%-2.62%
Expected term (years)	10	10

A summary of the Company's stock options granted to consultants and service providers as of December 31, 2020, and December 31, 2019 is presented below:

	Year Ended December 31,			
	2020		2019	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	598,310	5.76	469,974	5.75
Changes during the year:				
Granted	62,500	3.97	128,336	5.65
Exercised	(83,334)	3.60	-	-
Forfeited	(8,335)	5.99	-	-
Cancelled	(20,000)	5.30	-	-
Options outstanding at end of the year	549,141	5.89	598,310	5.76
Options exercisable at end of the year	450,972	6.28	539,515	5.88

The following table presents summary information concerning the options granted and exercisable to consultants and service providers outstanding as of December 31, 2020 (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)
2.99	35,000	9.22	53	-	-
3.14	15,000	8.91	20	-	-
3.36	136,775	5.32	156	136,775	460
4.09	25,000	8.76	10	25,000	102
4.42	10,325	6.93	1	10,325	46
4.5	13,335	8.53	-	-	-
4.6	20,000	9.96	-	-	-
4.8	16,668	5.94	-	16,668	80
5.07	5,000	8.19	-	1,000	5
5.3	15,000	7.70	-	15,000	80
5.99	16,670	7.81	-	16,670	100
6	90,000	3.59	-	90,000	540
6.84	7,500	9.38	-	-	-
7	70,000	8.83	-	70,000	490
7.32	8,334	1.89	-	8,334	61
8.34	8,600	7.52	-	8,600	72
8.43	8,333	7.05	-	4,999	42
11.52	8,334	2.26	-	8,334	96
16.8	39,267	1.28	-	39,267	660
	549,141	6.18	240	450,972	2,834

Costs incurred with respect to options granted to consultants and service providers for the years ended December 31, 2020 and December 31, 2019 were $113 thousand and $330 thousand, respectively. As of December 31, 2020, there was $231 thousands of unrecognized compensation costs related to non-vested consultants and service providers, to be recorded over the next 4.58 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 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 $9.2 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 thousand.

2) 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.

3) 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.

4) During the year ended December 31, 2019, the Company granted to several consultants 88,499 warrants each exercisable between $4.3 and $7.00 per share for three years. The fair value of those options as of the date of grant using the Black-Scholes valuation model was $155 thousand, out of which $97 thousand is related to 57,142 warrants granted as a success fee with respect to the issuance of the convertible notes.

5) In September 2019, the Company entered into an investor relation services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to issue the consultant 40,174 shares of restricted common stock, of which the first 20,087 shares will be held in escrow by the Company until the six months anniversary of the agreement and 20,087 shares will be issued on the six months anniversary of the agreement to be held in escrow by the company until the one-year anniversary of the agreement. The fair value of the shares was $178 thousand using the fair value of the shares on the grant date. $96 and 82 thousand was recognized during the year ended December 31, 2020 and December 31, 2019, respectively.

6) In March 2019, the Company issued First Choice 525,000 shares of Common Stock. The value of Common Stock issued in the amount of $2.6 million were charged to research and development expenses during the year ended December 31, 2019.

7) In December 2018, the Company entered into an investor relation services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to issue the consultant 10,000 shares of restricted common stock, of which the first 2,500 shares vested on the signing date, and 7,500 shares are to vest monthly over 3 months commencing January 2019. As of December 31, 2019, 10,000 shares were fully vested. The fair value of the shares was $51 thousand using the fair value of the shares on the vesting dates. $37 thousand was recognized during the year ended December 30, 2019.

8) In December 2018, the Company entered into a separate investor relations services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to issue the consultant 40,000 shares of restricted common stock, of which the first 6,667 shares vested on the signing date, and 33,333 shares vested monthly over five months commencing January 2019. As of December 31, 2019, 40,000 shares were fully vested. The fair value of the shares was $200 thousand using the fair value of the shares at the vesting dates. $163 thousand was recognized during the year ended December 30, 2019.

9) During the year ended November 30, 2018, the Company granted to several consultants 78,782 warrants each exercisable between $6.24 and $15.41 per share for three years. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was $350 thousand. The warrants granted as a success fee with respect to private placement and the issuance of convertible loans.

10) In January 2018, the Company entered into a consulting agreement with a financial advisor for a period of one year. Under the terms of the agreement, the consultant was entitled to receive $60 thousand and 19,000 units of the Company securities. Each unit is comprised of (i) one share of the Company's common stock and (ii) a three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of $6.24. The fair value of the units as of the date of grant was $171 thousand, out of which $62 thousand reflect the fair value of the warrants using the Black-Scholes valuation model. In July 2018, the board approved an additional issuance of 6,629 shares and three-year warrants to purchase up to 6,629 shares of the Company's Common Stock at a per share exercise price of $6.24. The fair value of the units as of the date of grant was $88 thousand.

11) In December 2017, the Company entered into investor relations services, marketing and related services agreements. Under the terms of the agreement, the Company agreed to grant the consultants a total of 195,000 shares of restricted common stock, out of which the first 50,000 shares will vest after 30 days from the signing date, and 145,000 shares are to vest monthly over 15 months commencing February 2018. As of December 31, 2019, all shares were vested. The fair value of the shares as of the date of grant was $1,439 thousand.

12) During the twelve months ended December 31, 2020, the Company issued 270,174 shares of common stock to service providers. As of December 31, 2020, 30,000 shares have additional restrictions on transfer until such services have been provide.

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, 2020, the Company has an accumulated tax loss carryforward of approximately $ 18 million (as of December 31, 2019, approximately $34 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 NOLs 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. The Company assess 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 2020 and 2019 are 23%.

As of December 31, 2020, the Israeli Subsidiaries has an accumulated tax loss carryforward of approximately $11 million (as of December 31, 2019, approximately $10 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 2020, 2019 are 25% and 29.58%, respectively.

As of December 31, 2020, the Belgian Subsidiary has an accumulated tax loss carryforward of approximately $ 8 million (€ 6 million), (as of December 31, 2019 $6 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, 2020, the Korean subsidiary has an accumulated tax loss carryforward of approximately $ 4 million (KRW 3,813 million), (as of December 31, 2019, approximately $3 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, 2019 and December 31, 2019 (in thousands):

	December 31,	
	2020	**2019**
	(U.S. dollars in thousands)	
Net operating loss carry forwards	$ 9,606	$ 14,033
Research and development expenses	1,684	1,358
Equity compensation	2,747	-
Employee benefits	252	228
Leases asset	533	-
Lease liability	(324)	-
Intangible assets	(2,863)	(737)
Other	297	(1)
Less: Valuation allowance	(11,932)	(14,939)
Net deferred tax liabilities	$ -	$ (58)

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 (previously CureCell) have recorded full valuation allowance.

The changes in valuation allowance are comprised as follows:

	December 31,	
	2020	**2019**
	(U.S dollars in thousands)	
Balance at the beginning of year	$ (14,939)	$ (10,254)
Change during the year	3,007	(4,685)
Balance at end of year	$ (11,932)	$ (14,939)

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, 2020, 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.

	Year Ended December 31,	
	2020	**2019**
	(in thousands)	
Revenue stream:		
POC and hospital services	$ 6,068	$ 3,109
Cell process development services	1,584	790
Total	$ 7,652	$ 3,899

POC development services are the result of agreements between Company and its partners (See Note 11). The Company provides certain services in support of the partners' clinical activity. The Company has signed Master Services Agreements with joint venture partners in the aggregate amount of over $38 million for services to be provided from 2021 to 2022.

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

	Year Ended December 31,	
	2020	**2019**
	(in thousands)	
Revenue earned:		
Customer A	$ 2,857	$ 1,420
Customer B	1,577	-
Customer C – related party	1,475	1,270
Customer D	1,412	857

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:

	Year Ended December 31,	
	2020	**2019**
	(in thousands)	
Balance as of beginning of period	$ 1,831	$ 129
Acquisition of Koligo	228	-
Additions	6,997	2,079
Collections	(5,982)	(364)
Exchange rate differences	11	(13)
Balance as of end of period	$ 3,085	$ 1,831

The activity for contract liabilities is comprised of:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Balance as of beginning of period	$ 325	$ 56
Additions	597	1,126
Realizations*	(862)	(854)
Exchange rate differences	(1)	(3)
Balance as of end of period	$ 59	$ 325

* Out of which $ 325 thousand were realized from the beginning of the period for the year ended December 31, 2020.

NOTE 18 – COST OF RESEARCH AND DEVELOPMENT AND RESEARCH AND DEVELOPMENT SERVICES, NET

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Total expenses	$ 84,182	$ 14,826
Less grants	(196)	(812)
Total	$ 83,986	$ 14,014

NOTE 19 – FINANCIAL EXPENSES, NET

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Increase in fair value of warrants and financial liabilities measured at fair value	$ -	$ 63
Interest expense on convertible loans	1,254	498
Foreign exchange loss, net	160	395
Other income	(353)	(113)
Total	$ 1,061	$ 843

NOTE 20 – RELATED PARTIES TRANSACTIONS

a. *Related Parties presented in the consolidated statements of comprehensive loss*

	Year ended December 31,	
	2020	2019
	(in thousands)	
Continuing operations:		
Stock-based compensation expenses to executive officers	$ 221	$ 898
Stock-based compensation expenses to Board Members*	$ 209	$ 414
Compensation of executive officers	$ 1,321	$ 812
Management and consulting fees to Board Members	$ 264	$ 233
Revenues from customer	$ 1,475	$ 1,270
Cost of research and development and research and development services, net	$ 4,772	$ -
Financial income	$ 169	$ 112

* Does not include $192 thousand for the year ended December 31, 2019 related to Stock Based Compensation expenses for options exercisable at an exercise price of $7.00 per share into 70,000 ordinary shares held by Caerus Therapeutics LLC for which the director does not have beneficial control.

	Year ended December 31, 2019
	(in thousands)
Discontinued operations:	
Stock-based compensation expenses to executive officers	$ 76
Compensation of executive officers	$ 685

b. *Related Parties presented in the consolidated balance sheets*

	December 31,	
	2020	2019
	(in thousands)	
Continuing operations:		
Executive officers' payables	$ 170	$ 1,251
Non-executive directors' payable	$ 13	$ 202
Loan to Related Party	$ -	$ 2,623
Accounts receivable, net	$ 744	$ -
Contract liabilities	$ -	$ 230