UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended **December 31, 2019**

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 **000-54329**

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 [**X**]

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 [**X**]

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 [**X**] 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 [**X**] 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 **[X]**
Non-accelerated filer [ ]	Smaller reporting company **[X]**
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 is a shell company (as defined in Rule 12b-2 of the Act).
Yes **[ ]** No [**X**]

The registrant had 18,361,050 shares of common stock outstanding as of March 9, 2020. 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 28, 2019) was $56,803,434, as computed by reference to the closing price of such common stock on The Nasdaq Capital Market on such date.

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PART IV

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" or "our Company" or "Orgenesis" refer to Orgenesis Inc., a Nevada corporation, and Orgenesis Belgium SRL, a Belgian-based entity which is engaged in development and manufacturing activities, together with clinical development studies in Europe (the "Belgian Subsidiary"), and its wholly-owned subsidiaries Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"), Orgenesis Maryland Inc., a Maryland corporation (the "Maryland Subsidiary"), and Cell Therapy Holdings S.A, Atvio Biotech Ltd. ("Atvio"), an Israeli-based CDMO, CureCell Co. Ltd. ("CureCell"), a Korea-based CDMO and, as of December 31, 2019, its majority-owned subsidiary, Masthercell Global Inc., a Delaware corporation ("Masthercell Global"), and Masthercell Global's subsidiaries including 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, a United States ("U.S.")-based CDMO. The Company sold all of its equity interests in Masthercell Global and its subsidiaries on February 10, 2020.

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

Corporate

- our ability to increase revenues;
- our ability to achieve profitability;
- 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 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;
- our belief that our therapeutic related developments have competitive advantages and can compete favorably and profitably in the cell and gene therapy industry;

POC Business

- 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 develop, through our Israeli Subsidiary and Belgian Subsidiary, to the clinical stage a new technology to transdifferentiate liver cells into functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- 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 the ability of our Maryland Subsidiary, Israeli Subsidiary and Belgian Subsidiary 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 belief that Diabetes Mellitus will be one of the most challenging health problems in the 21st century and will have staggering health, societal and economic impact;
- our belief that our diabetes-related treatment seems to be safer than other options;
- our relationship with Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") and the risk that THM may cancel the License Agreement;
- expenditures not resulting in commercially successful products;

Sale of Masthercell and the CDMO Business

- our dependence on the financial results of our POC business;
- our ability to grow our POC business and to develop additional joint venture relationships in order to produce demonstrable revenues;
- our ability to effectively utilize the proceeds from the sale of Masthercell;
- potential adverse effects to our POC business resulting from the announcement of the sale of Masthercell;
- the restriction on our ability to engage in the CDMO business outside Israel and Korea pursuant to a non-competition covenant in the Masthercell purchase agreement;
- our obligation to indemnify Catalent Pharma Solutions for certain losses and litigation resulting from breaches of certain representations and warranties set forth in the Purchase Agreement relating to the sale of Masthercell; and
- our ability to meet the continued listing requirements of the Nasdaq Capital Market.

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, 2019, 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

We are a biotechnology company specializing in the development, manufacturing and provision of cell and gene therapies ("CGTs") through point-of-care solutions. We have historically operated through two independent business platforms: (i) a point-of-care cell therapy ("POC") platform and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform, which provided contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). Through the POC platform, our aim is to further the development of CGTs, including Advanced Therapy Medicinal Products ("ATMPs"), through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. These therapies span a wide range of treatments including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration. We out-license these ATMPs, thus far primarily through joint venture ("JV") agreements, with regional partners including pharmaceutical and biotech companies as well as research institutions and hospitals These regional partners have cell therapies in clinical development and are to whom we also provide manufacturing know-how, assay services, licensing, regulatory assistance, pre-clinical studies, intellectual property services, and co-development services (collectively "POC Development Services") to support their activity in order to reach patients in a point-of-care hospital setting. Currently, our POC Development Services constitute the entirety of our revenue from the POC platform. Through the CDMO platform, we had focused on providing contract manufacturing and development services for biopharmaceutical companies, and we continue to provide such CDMO, or development, services in Israel and South Korea.

On February 2, 2020, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with GPP-II Masthercell LLC ("GPP" and together with the Company, 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.

Activities in the POC platform include a multitude of cell therapies including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration. We are establishing and positioning our POC business in order to bring point-of-care therapies to patients in a scalable way through our JV partners active in autologous cell therapy product development, including facilities in Germany, Austria, Greece, the U.S., Korea, Japan, Singapore, Latin America, the UK, Spain, Israel, Russia and China. We believe that each of our regional JV partners represents a revenue and growth opportunity upon regulatory approval. Furthermore, our trans-differentiation technology, which demonstrates the capacity to induce a shift in the developmental fate of cells from the liver or other tissues and transdifferentiating them into "pancreatic beta cell-like" Autologous Insulin Producing ("AIP") cells for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases, represents a unique opportunity within our POC platform. This technology, which has yet to be proven in human clinical trials, has shown in pre-clinical animal models that the human derived AIP cells produce insulin in a glucose-sensitive manner. This trans-differentiation technology is licensed by Orgenesis Ltd. (the "Israeli Subsidiary") and is based on the work of Professor ("Prof.") Sarah Ferber, our Chief Scientific Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. 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 this trans-differentiation technology, we own or have exclusive rights to ten (10) United States and eight (8) foreign issued patents, five(5) pending applications in the United States, thirty-three (33) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and one (1) international Patent Cooperation Treaty ("PCT") patent applications. These patents and applications relate, among others, to (1) 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, and (2) scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, trans-differentiation, and transplantation in the treatment of autoimmune diseases, including diabetes.

We conduct the activities of our POC platform through our wholly-owned subsidiaries, including Orgenesis Maryland Inc. (the "U.S. Subsidiary"), Orgenesis Belgium SRL (the "Belgian Subsidiary") and Orgenesis Ltd. (the "Israeli Subsidiary").

We believe that, in-order to provide the optimal service to our customers, we need to have a global presence. Our POC platform is focused on providing our POC Development Services toward a goal of allowing us to be able to bring new products to patients faster and in a more cost-effective way. We target the international market as a key priority through our network of facilities that provide development, manufacturing and logistics services, utilizing our advanced quality management system and experienced staff. All of these capabilities offered to third-parties are utilized for our internal development projects, with the goal of allowing us to be able to bring new products to patients faster and in a more cost-effective way.

The CDMO platform was historically operated through (i) 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")), (ii) wholly-owned Atvio Biotech Ltd. in Israel ("Atvio"), and 94.12% owned CureCell Co., Ltd. in South Korea ("CureCell"). Each of these subsidiaries has unique know-how and expertise for manufacturing in a multitude of cell types.

We operated our POC and CDMO platforms as two separate business segments.

Overview for Advanced Therapy Medicinal Products (ATMPs)

Advanced Therapy Medicinal Product ("ATMP") means any of the following medicinal products for human use:

- a somatic cell therapy medicinal product ("STMP");
- a tissue engineered product ("TEP");
- a gene therapy medicinal product ("GTMP"); or
- a combined ATMP.

An STMP 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 TEP contains cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue. A GTMP contains genes that lead to a therapeutic, prophylactic or diagnostic effect and work by inserting "recombinant" genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer or long-term diseases. A recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources. Combined ATMPs contain one or more medical devices as an integral part of the medicine, such as cells embedded in a biodegradable matrix or scaffold. 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.

Furthermore, we believe that autologous therapies are a substantial segment of the ATMP market. Autologous therapies are produced from a patient's own cells, instead of mass-cultivated donor-cells, or allogeneic cells. Allogeneic therapies are derived from donor cells and, through the construction of master and working cell banks, are produced on a large scale. Autologous therapies are derived from the treated patient and manufactured through a defined protocol before re-administration and generally demand a more complex supply chain. Currently with the ATMP network relying heavily on production and supply chain of manufacturing sites, we believe our POC platform may help overcome some of the development and supply challenges with bringing these therapies to patients.

POC Business

Our therapeutic cell therapy development efforts underlying our POC platform are focused on advancing breakthrough scientific achievements in the field of autologous therapies which have a curative potential. We base our development on therapeutic collaborations and in-licensing with other pre-clinical and clinical-stage biopharma companies as well as direct collaboration with research and healthcare institutes. We are engaging in therapeutic collaborations and in-licensing with other academic centers and research centers in order to pursue emerging technologies of other ATMPs in cell and gene therapy in such areas as cell-based immunotherapies including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration. Each of these customers and collaborations represents a growth opportunity and future revenue potential as we out-license these ATMPs through regional partners to whom we also provide regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting.

POC Revenue Model

We are establishing and positioning our POC platform in order to bring therapies to patients in a scalable way via a network of leading healthcare facilities active in autologous cell therapy product development, including facilities in Germany, Austria, Greece, the U.S., South Korea, Japan, Singapore, Latin America, the United Kingdom, Spain, Israel, Russia and China. We believe that our unique understanding of industry needs allows us to offer our clients a range of technologies and processes that potentially generate revenues from our POC Development Services. This may include:

- Technological Services - Industrial manufacturing know-how to the CGT arena, thus reducing cost of goods and facilitating regulatory scrutiny, higher automation level required to increase process robustness and reduce attrition rates, biological assay development, assay validation and assay optimization;
- Sub-Licensing Fees - Innovative technologies such as scaffolds and IoT sensors and closed system bioreactors that allow autologous cell manufacturing in lower grade clean rooms; and
- Regulatory and Partnership Services - Regulatory assistance and joint ventures with local partners who bring strong regional networks through (1) joint venture partnerships with local hospitals utilizing hospital networks for clinical development of therapies, (2) a global network of supply, (3) harmonized quality systems, (4) the provision of a comprehensive portfolio of ATMPs to hospitals via continuous in-licensing of autologous therapies from academia and research institutes, and (4) out-licensing hospital and academic-based therapies.

POC Strategy

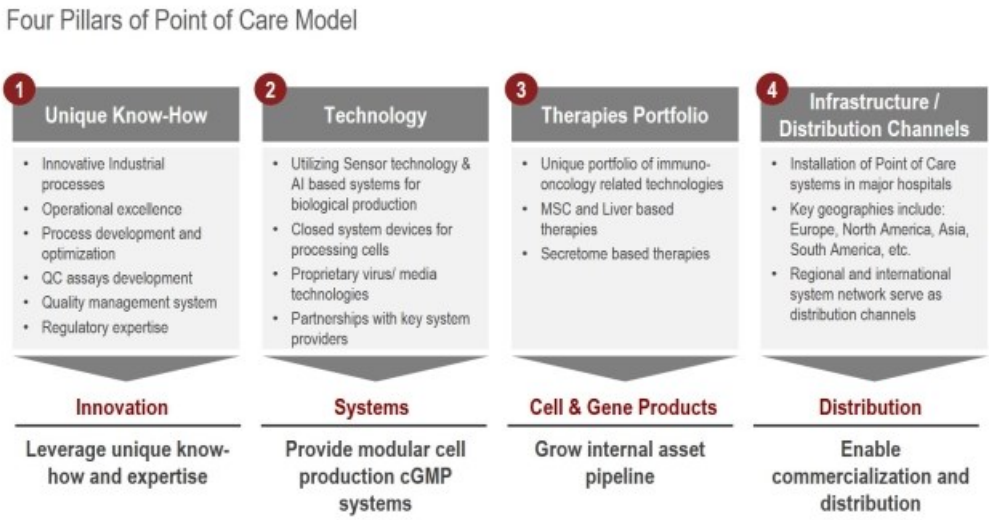
Our aim is to provide a pathway to bring ATMPs in the cell and gene therapy industry from research to patients worldwide through our POC platform. We define point-of-care CGT as a process of collecting, processing and administering cells within the patient care environment, namely through academic partnerships in a hospital setting. We believe this approach is an attractive proposition for personalized medicine because point-of-care therapy facilitates the development of technologies through our strategic partnerships and utilizes closed systems that have the potential of reducing the required grade of clean room facilities, thus substantially reducing manufacturing costs. Furthermore, cell transportation, which is a high-risk and costly aspect of the supply chain, could be minimized or eliminated. These therapies span a wide range of treatments including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration. Activities in the POC platform include a multitude of cell therapies, including autoimmune, oncologic, neurologic and metabolic diseases and other indications, including scaffolds for cell implantation, polypeptide conjugates for autoimmune diseases, and cancer vaccines.

While our POC business strategy is currently limited to early stage development to overcome certain industry challenges, we intend to continue developing a global point-of-care network, with the goal of developing ATMPs, and namely autologous cell therapies, via joint ventures with partners who bring strong regional networks. Such networks include partnerships with local hospitals which allows us to engage in continuous in-licensing of, namely, autologous therapies from academia and research institutes, co-development of hospital and academic-based therapies, and utilization of hospital networks for clinical development of therapies.

We consider the following to be the four pillars in order to advance our POC business strategy:

- Innovation - This leverages our unique know-how and expertise for industrial processes, operational excellence, process development and optimization, quality control assays development, quality management systems and regulatory expertise.

- Systems - We are developing cell production cGMP systems utilizing sensor technology and AI-based systems for biological production, closed system devices for processing cells, proprietary virus/ media technologies and partnerships with key system providers.
- Cell and Gene Products - We intend to grow our internal asset pipeline consisting of our unique portfolio of immuno-oncology related technologies, MSC and liver-based therapies and secretome-based therapies.
- Distribution - Our plan is to enable the industrialization, commercialization and distribution of point-of-care systems in major hospitals and key geographies, including Europe, Asia, North America, and South America.



POC Subsidiaries, Clinical Pipeline and Collaboration Agreements

We carry out our POC business through three wholly-owned and separate subsidiaries. We intend to devote significant resources to process development and manufacturing in order to optimize the safety and efficacy of our future product candidates, as well as our cost of goods and time to market. Our goal is to carefully manage our fixed cost structure, maximize optionality, and drive long-term cost of goods as low as possible. The subsidiaries related to this business are as follows:

- Orgenesis Maryland Inc. (the "U.S. Subsidiary"): This is the center of activity in North America currently focused on technology licensing, therapeutic collaborations and preparation for U.S. clinical trials.

- Orgenesis Belgium SRL (which changed its name and statutory designation in August 2019 from Orgenesis SPRL) (the "Belgian Subsidiary"): This is the center of activity in Europe currently focused on process development and preparation of European clinical trials.

- Orgenesis Ltd. (the "Israeli Subsidiary"): This is a research and technology center, as well as a provider of regulatory, clinical and pre-clinical services.

We have embarked on a strategy of collaborative arrangements with strategically situated regional JV partners around the world. We believe that these parties have the expertise, experience and strategic location to advance our POC platform. Activities in our POC platform include:

Strategic CGT Collaborations

Trans-differentiation Technology

Our trans-differentiation technology demonstrates the capacity to induce a shift in the developmental fate of cells from the liver or other tissues and transdifferentiating them into "pancreatic beta cell-like" AIP cells for patients with Type 1 Diabetes ("T1D"), acute pancreatitis and other insulin deficient diseases. The technology focuses on autologous cells that offer a low likelihood of rejection by the patient. We believe the long-term benefits of this treatment can best be achieved with an autologous product. For our purposes in the treatment of diabetes, our 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 our Israeli Subsidiary and is based on the work of Prof. Sarah Ferber, our Chief Scientific Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") in Israel. Our 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 and to complete, through our Israeli Subsidiary and Belgian Subsidiary the development of the closed loop system in order to effectively manufacture the cells in a point-of-care setting.

With respect to our trans-differentiation technology, we own or have exclusive rights to ten (10) United States and eight (8) foreign issued patents, five (5) pending applications in the United States, thirty-three (33) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and one (1) international PCT patent applications. These patents and applications relate, among others, to (1) 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, and (2) to scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, trans-differentiation, and transplantation in the treatment of autoimmune diseases, including diabetes.

On June 11, 2019, the United States Food & Drug Administration ("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 liver cells are intended to be bio-banked for potential future clinical use. The first patients are expected to be enrolled during this calendar year 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. 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 trans-differentiated 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, or point-of-care setting, under clinical grade/GMP level conditions.

In June 2019, we received additional Institutional Review Board ("IRB") approval to collect liver biopsies from patients at a leading medical center in United States 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 for potential future clinical use. In October 2019, a liver sample from the first recruited patient was collected and processed and stored at this same New York Blood Center in specialized, clinical grade, tissue banks for potential clinical use. Additional patients are expected to be enrolled during 2020.

We have broad patent claims on our process and have both issued and pending patents in the U.S. and internationally. The patent portfolio includes granted patent US 8119405, entitled "Methods of inducing regulated pancreatic hormone production in non-pancreatic islet tissues," which includes broad claims on trans-differentiating any mature, non-pancreatic cell type into an islet cell phenotype. Importantly, our IP portfolio is not dependent on processes owned by other companies, such as embryonic stem cell technologies, production of endodermal intermediates or reprogramming (iPS) technologies. As a result, we have both the freedom to operate and the ability to obstruct competitors in developing autologous cells for treatment of diabetes.

Our trans-differentiation technology derives from a licensing agreement entered into as of February 2, 2012 by Orgenesis Ltd., our Israeli Subsidiary, and THM pursuant to which our Israeli Subsidiary was granted a worldwide royalty bearing and exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells as a treatment for diabetes (the "THM License Agreement"). By using therapeutic agents (i.e., PDX-1, and additional pancreatic transcription factors in an adenovirus-vector) 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. We believe that this provides major competitive advantage to the cell transformation technology of our Israeli Subsidiary.

As consideration for the license, our Israeli Subsidiary has agreed to 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 $15,000, which commenced on January 1, 2012 and is due once every year thereafter (the "Annual Fee"). The Annual Fee is non-refundable, but it shall be credited each year due, against the royalty noted above, to the extent that such are payable, during that year; and
4) Milestone payments as follows:

    a) $50,000 on the date of initiation of phase I clinical trials in human subjects;
    b) $50,000 on the date of initiation of phase II clinical trials in human subjects;
    c) $150,000 on the date of initiation of phase III clinical trials in human subjects;
    d) $750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA; and
    e) $2,000,000, when worldwide net sales of products have reached the amount of $150,000,000 for the first time (the "Sales Milestone").

As of December 31, 2019, our Israeli Subsidiary has not reached any of these milestones.

In the event of an acquisition of all of the issued and outstanding share capital of the Israeli Subsidiary or of us and/or consolidation of the Israeli Subsidiary or us into or with another corporation ("Exit"), under the THM License Agreement, THM is entitled to elect, at its sole option, whether to receive from us a one-time payment based, as applicable, on the value at the time of the Exit of either 463,651 shares of our common stock or the value of 1,000 ordinary shares of the Israeli Subsidiary at the time of the Exit. If THM elects to receive the consideration as a result of an Exit, the royalty payments will cease.

If THM elects to not receive any consideration as a result of an Exit, THM is entitled under the THM License Agreement to continue to receive all the rights and consideration it is entitled to pursuant to the THM License Agreement (including, without limitation, the exercise of the rights pursuant to future Exit events), and any agreement relating to an Exit event shall be subject to the surviving entity's and/or the purchaser's undertaking towards THM to perform all of the Israeli Subsidiary's obligations pursuant to the THM License Agreement.

The Israeli Subsidiary agreed to submit to THM a commercially reasonable plan which shall include all research and development activities as required for the development and manufacture of the products, including preclinical and clinical activities until an FDA or any other equivalent regulatory authority's approval for marketing and including all regulatory procedures required to obtain such approval for each product candidate (a "Development Plan"), within 18 months from the date of the THM License Agreement. Under the THM License Agreement, the Israeli Subsidiary undertook to develop, manufacture, sell and market the products pursuant to the milestones and time-frame schedule specified in the Development Plan. The Israeli Subsidiary submitted the Development Plan in May 2014.

Under the THM License Agreement, THM is entitled to terminate the THM License Agreement under certain conditions relating to a material change in the business of our Israeli Subsidiary or a breach of any material obligation thereunder or to a bankruptcy event of our Israeli Subsidiary. Under certain conditions, our Israeli Subsidiary may terminate the THM License Agreement and return the licensed information to THM.

Collaboration Agreement with Hemogenyx Pharmaceuticals Plc

On October 18, 2018, we entered into a collaboration agreement with Hemogenyx to collaborate on the development and commercialization of Hemogenyx's Human Postnatal Hemogenic Endothelial (Hu-PHEC) technology, a cell replacement product candidate that is being designed to generate cancer-free, patient-matched blood stem cells after transplantation into the patient.

Collaboration Agreement with Immugenyx, LLC

On October 16, 2018, we entered into a collaboration agreement with Immugenyx, LLC ("Immugenyx"), a wholly owned subsidiary of Hemogenyx Pharmaceuticals Plc ("Hemogenyx"), to collaborate with us to further the development and commercialization of its advanced hematopoietic chimeras, which is a new type of humanized mouse with a functional human immune system that is being developed by Immugenyx as an in vivo platform for disease modelling, drug and cell therapy development.

Collaboration Agreement with Tarus Therapeutics, Inc.

On February 27, 2019, we entered into a collaboration agreement with Tarus Therapeutics Inc., a Delaware corporation ("Tarus"), in connection with 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. The parties plan to enter into pre-clinical studies as part of the preparations to clinical studies submission during 2020.

Joint Venture Agreement with Theracell Advanced Biotechnology

On February 14, 2019, we entered into a joint venture agreement with Theracell Advanced Biotechnology, a corporation organized under the laws of Greece ("Theracell"), pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products in Greece, Turkey, Cyprus and Balkan countries and the clinical development and commercialization of Theracell's products worldwide. On February 14, 2019, we entered into a master service agreement with Theracell whereby, subject to mutually agreed timing and definition of the scope of services, we provide regulatory services, pre-clinical studies, intellectual property services, GMP process translation services and co-development services to Theracell.

During the year ended December 31, 2019, we recognized POC development service revenue in the amount of $857 thousand, and Theracell invoiced us in the amount of $698 thousand for expenses related to activities in the territory.

Joint Venture Agreement with First Choice International Company, Inc.

On March 12, 2019, we entered into a joint venture agreement with First Choice International Company, Inc., a corporation organized under the laws of Delaware ("First Choice"), pursuant to which the parties will collaborate in the clinical development and commercialization of our products in Panama and certain other Latin American countries as agreed by the parties (the "Territory") and the clinical development and commercialization of First Choice's products worldwide (other than in the Territory).

Joint Venture Agreement with KinerjaPay Corp.

On May 6, 2019, we entered into a joint venture agreement with KinerjaPay Corp., a Delaware corporation ("KinerjaPay"), pursuant to which the parties will collaborate in the clinical development and commercialization of our products in Singapore and the introduction of KinerjaPay products to be offered for sale by us globally outside Singapore.

Master Services Agreement with Adva Biotechnology Ltd.

On January 28, 2018, we entered into a Master Services Agreement with Adva Biotechnology Ltd. ("Adva") pursuant to which we/and or our affiliates are to provide certain services relating to development of products and in-kind funding to Adva, and upon completion of the development of the products, Adva agreed to enter into supply agreements with us and/or our affiliates to purchase the products at a specified discount pricing from their then standard pricing.

Collaboration and License Agreement with Mircod Limited

On June 19, 2018, we entered into a Collaboration and License Agreement ("Mircod Collaboration Agreement") with Mircod Limited, a company formed under the laws of Cyprus ("Mircod"), for the adaptation of Mircod's background technologies related to biological sensing for use for the Company's clinical development and manufacturing projects (the "Development Project"). In October 2019, the Mircod Collaboration Agreement was amended to include, among other things, the formation of a wholly owned U.S. subsidiary to perform the duties of Mircod under the Mircod Collaboration Agreement. During 2018 and 2019, we transferred $104 and $108 thousand respectively to Mircod under the Development plan, and Mircod completed certain aspects thereof but the Development Project was not completed at December 31, 2019.

Joint Venture Agreement with Image Securities Ltd (a related party)

On July 11, 2018, we entered into a joint venture agreement with Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Cayman Islands ("India Partner"), pursuant to which we agreed to collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products in India. The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products in India. Effective January 1, 2019, the Company entered into a master service agreement for the provision of certain POC services. Payments of $1.5 million for these POC services were received during 2019. Total amount of $1,270 thousand was recognized as income during the year ended December 31, 2019. Prior to the establishment of the JV Entity, all activities are being carried out by the India Partner.

Research and License Agreement with B.G. Negev Technologies and Applications Ltd. and The National Institute of Biotechnology in the Negev Ltd.

On August 2, 2018 and November 25, 2018, respectively, we entered into research and license agreements (the "BGN Agreements") with B.G. Negev Technologies and Applications Ltd. ("BGN") and/or The National Institute of Biotechnology in the Negev Ltd. Under the terms of the BGN Agreements, we will collaborate on the research and development of BGN's dissolvable carriers for cell culturing and for developing and commercializing technology directed to RAFT modification of polysaccharides and use of a bioreactor for supporting cell constructs. We have received the exclusive, worldwide rights to make, develop and commercialize technologies utilizing the dissolvable carriers for cell culturing, with an initial focus on autoimmune diseases. This unique technology has the potential to allow us to reduce the cost and complexity of manufacturing of our cell therapy programs.

Joint Venture Agreement with HekaBio K.K.

On July 10, 2018, we entered into a joint venture agreement with HekaBio K.K., a corporation organized under the laws of Japan, pursuant to which we agreed to collaborate in the clinical development and commercialization of cell and gene therapeutic products in Japan (the "HB JVA"). The parties intend to pursue the joint venture through a newly established Japanese company which we, or we together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB (the "HB JV Company"). On October 3, 2018, we entered into a license agreement with the HB JV Company pursuant to the joint venture agreement pertaining to the licenses described therein.

Agreements with Cure Therapeutics

During 2018, we entered into a collaboration agreement with Cure Therapeutics in connection with the development of therapies based on NK cells and Liver cells. The NK cell-based technology offers enhancement of NK potency via proprietary platform of activation & expansion, concentrating of NK as well as NK homing technology that will improve the therapeutic effect of NK cell therapy on malignant disease. The agreement is governed by a joint steering committee and carried out in accordance with the projects' work plans. Effective July 1, 2019, we entered into a master service agreement for the provision of certain POC services to Cure Therapeutics in Korea and Japan.

As of December 31, 2019, the Company has incurred $1.1 million of expenses in relation to the project. As part of the agreement, Cure Therapeutics has subcontracted development and contract manufacturing activates to CureCell, for which service revenue of $323 thousand has been recognized.

Effective July 1, 2019, the Company entered into a master service agreement for the provision of certain POC services to Cure Therapeutics in Korea and Japan. A total of $982 thousand for these POC services was recognized as income during the year ended December 31, 2019.

Sponsored Research and Exclusive License Agreement with Columbia University

Effective April 2, 2019, we 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 we will provide financial support for studying the utility of serological tumor marker for tumor dynamics monitoring. Under the terms of the SRA, we 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, we and Columbia entered into an Exclusive License Agreement (the "Columbia License Agreement") whereby Columbia 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 (i) a royalty of 5% of net sales of any patented product sold and (ii) 2.5% of net sales of other products. Tech transfer from Columbia to us has been completed. We are now working on the completion of all the IND enabling requirements in order to get into Phase I study in a year's time under point-of-care centers.

Broaden Bioscience and Technology Corp

On November 10, 2019, the Maryland Subsidiary and Broaden Bioscience and Technology Corp, a Delaware corporation ("Broaden"), entered into a joint venture agreement (the "Broaden JVA") pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products and the setting up of POC processing facilities in China and the Middle East.

Caerus Therapeutics Corporation (a related party)

In October 2019, we concluded a license agreement with Caerus Therapeutics Corporation, 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.

ExcellaBio Ltd.

During 2018, we entered into an agreement (the "ExcellaBio Agreement") with ExcellaBio Ltd. ("ExcellaBio") for certain technologies developed by Sabina Glozman including an exosome-like membrane nanostructure (Bioxome™) and related processes for the production of exosomes/extracellular vesicles (EVs). These vesicles can be used for delivery of designed target cargo such as genes to specific cells. Under the ExcellaBio Agreement, we will have the exclusive, worldwide rights to certain commercial applications of the technology arising from the collaboration. Tech transfer and manufacturing process development for Bioxomes production was completed. Pre-clinical studies are ongoing.

Agreement with Regents of the University of California

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 intellectual property.

Joint Venture Agreement with SBH Sciences, Inc.

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.

During the third quarter of 2019, we transferred $50 thousand to SBH. Apart from the above, there was no material activity in the SBH Collaboration.

Competition in the Cell Therapy Field

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.

Trans-differentiation Technology

The current treatment for T1D, and some T2D, is constant monitoring of blood glucose and a highly controlled diet, coupled with multiple daily insulin injections. Despite the use of insulin and advances in its delivery, pharmaceutical insulin injections cannot replicate the level of feedback control afforded by naturally occurring intact beta cells. Even with the most diligent insulin use, the adverse short- and long-term effects of diabetes include life-threatening episodes of low blood sugar, nerve damage, blindness, kidney damage, erectile dysfunction, foot ulcers leading to amputations, and cardiovascular disease. Research has shown that, on average, the life expectancy of a person with T1D is reduced by approximately 12 years when compared to the general population.

T1D inflicts a significant economic cost on the U.S. healthcare system, estimated at $14.4 billion annually, and it is expected that a therapy that can modify the course of T1D could potentially achieve significant cost savings, and thus command high market penetration and premium pricing. In the near future, the market for T1D is expected to continue to be dominated by insulin replacement therapies.

Currently, there are no approved therapies for new onset T1D with potential curative effect but only regimens such as insulin or adjuvants to insulin that address the disease when the pancreas can no longer produce insulin. While not a direct competitor, in a more advanced population of T1D, sotagliflozin, an oral adjunctive therapy to insulin, is expected to receive FDA approval following positive results from a pivotal Phase 3 trial conducted by Lexicon Pharmaceuticals in collaboration with Sanofi SA and JDRF. There are multiple agents in development targeting the modification of the course of the disease. Current approaches in development can be broadly divided into immune modulatory agents that attempt to improve metabolic function by rescuing insulin producing beta cells, or regenerative agents that attempt to replace beta cells. From a broad review of these agents and approaches, no other autologous therapy for T1D is expected to be in advanced clinical trials or provide direct competition to our AIP cells in the near future. Another allogeneic approach being Viactye's PEC-01 technology entered clinical trial phase 1 in July 2017. Semma therapeutics, a US company developing patient specific induced pluripotent stem cells may enter clinical trial in the near future.

Insulin therapy is used for Insulin-Dependent Diabetes Mellitus (IDDM) patients who are not controlled with oral medications, although this therapy has well-known and well-characterized disadvantages. Weight gain is a common side effect of insulin therapy, which is a risk factor for cardiovascular disease. Injection of insulin causes pain and inconvenience for patients. Patient compliance and inconvenience of self-administering multiple daily insulin injections is also considered a disadvantage of this therapy. The most serious adverse effect of insulin therapy is hypoglycemia.

Specifically, we face significant competition from companies in the insulin therapy market. Insulin therapy is widely used for Insulin-Dependent Diabetes Mellitus (IDDM) patients who are not controlled with oral medications. The global diabetes market comprising the insulin, insulin analogues and other anti-diabetic drugs has been evolving rapidly. A look at the diabetes market reveals that it is dominated by a handful of participants such as Novo Nordisk A/S, Eli Lilly and Company, Sanofi-Aventis, Takeda Pharmaceutical Company Limited, Pfizer Inc., Merck KgaA, and Bayer AG.

POC

Currently, we know of no other companies pursuing a business model similar to what we are developing under our POC 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.

Grant Funding

Walloon Region, Belgium, Direction Générale Opérationnelle de l'Economie, de l'Emploi & de la Recherche ("DGO6")

On March 20, 2012, MaSTherCell was awarded an investment grant of Euro 1.2 million from the DGO6. This grant is related to the investment in the production facility with a coverage of 32% of the investment planned. As of November 30, 2018, the DGO6 transferred the entire amount to MaSTherCell. On February 10, 2020, we sold MaSTherCell.

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, we received final approval from the DGO6 for Euro 1.8 million costs invested in the project out of which Euro 1.2 million founded by the DGO6. As of December 31, 2019, we repaid to the DGO6 a total amount of $57 thousand (Euro 51 thousand) and amount of $124 thousand was recorded in other payables.

ln April 2016, the Company's 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 ($491 thousand). Up through December 31, 2019, an amount of Euro 358 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.

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 ($1.8 million). Up through December 31, 2019, an amount of Euro 1.5 million was recorded as deduction of research and development expenses and an amount of Euro 143 thousand was recorded as advance payments on account of grant.

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 will give a conditional grant of $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use of Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the "BIRD Project"). The BIRD Project started on March 1, 2015. Upon the conclusion of product development, the grant shall be repaid at the yearly 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, 2019, the Israeli Subsidiary received a total amount of $299 thousand under the grant and the project was completed.

Korea Israel Industrial R&D Foundation ("KORIL")

On March 14, 2016, the Israel Subsidiary entered into a collaboration agreement with CureCell, initially for the purpose of applying a grant from KORIL for pre-clinical and clinical activities related to the commercialization of the Israel Subsidiary AIP cell therapy product in Korea. The parties agreed to carry out at their own expenses and their respective commitments under the work plan approved by KORIL and any additional work plan to be agreed upon between the Israeli Subsidiary and CureCell. The Israeli Subsidiary will own sole rights to any intellectual property developed from the collaboration which is derived under the Israeli Subsidiary's AIP cell therapy product, information licensed from THM. Subject to obtaining the requisite approval needed to commence commercialization in Korea, the Israel subsidiary has agreed to grant to CureCell, or a fully owned subsidiary thereof, under a separate sub-license agreement an exclusive sub-license to the intellectual property underlying our API product solely for commercialization of the Israel Subsidiary's products in Korea. As part of any such license, CureCell has agreed to pay annual license fees, ongoing royalties based on net sales generated by CureCell and its sublicensees, milestone payments and sublicense fees. Under the agreement, CureCell is entitled to share in the net profits derived by the Israeli Subsidiary from world-wide sales (except for sales in Korea) of any product developed as a result of the collaboration. Additionally, CureCell was given the first right to obtain exclusive commercialization rights in Japan of the AIP product, subject to CureCell procuring all the regulatory approvals required for commercialization in Japan. As of December 31, 2019, none of the requisite regulatory approvals for conducting clinical trials had been obtained.

On May 26, 2016, the Israeli Subsidiary and CureCell entered into a pharma 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 "KORIL Project"). The KORIL 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 June 1, 2016. On July 26, 2018, KORIL approved an extension for the project period until May 31, 2019 and was further extended to May 2020. During 2019 the grant was assigned to Cure Therapeutics from CureCell. As of December 31, 2019, the Israeli Subsidiary and CureCell received $440 thousand under the grant.

Maryland Technology Development Corporation

On June 30, 2014, our 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. TEDCO is an independent organization that strives to be Maryland's lead source for entrepreneurial business assistance and seed funding for the development of startup companies in Maryland's innovation economy. TEDCO administers the Maryland Stem Cell Research Fund to promote State funded stem cell research and cures through financial assistance to public and private entities within the State. Under the agreement, TEDCO has agreed to give the U.S. Subsidiary an amount not to exceed approximately $406 thousand (the "Grant"). The Grant will be used solely to finance the costs to conduct the research project entitled "Autologous Insulin Producing (AIP) Cells for Diabetes" during a period of two years. On June 21, 2016, TEDCO approved an extension for the project period until June 30, 2017.

On July 22, 2014 and September 21, 2015, we received an advance payment of $406 thousand on account of the Grant.

CDMO Business

Companies developing cell therapies need to make a decision early on in their approach to the transition from the lab to the clinic regarding the process development and manufacturing of the cells necessary for their respective therapeutic treatments. Of the companies active in this market, only a small number have developed their own GMP manufacturing facilities due to the high costs and expertise required to develop these processes. In addition to the limitations imposed by a limited number of trained personnel and high infrastructure/operational costs, the industry faces a need for custom innovative process development and manufacturing solutions. Due to the complexity and diversity of the industry, such solutions are often customized to the particular needs of a company and, accordingly, a multidisciplinary team of engineers, cell therapy experts, cGMP and regulatory experts is required. Such a unique group of experts can exist only in an organization that both specializes in developing characterization assays and solutions and manufactures cell therapies.

Companies can establish their own process and GMP manufacturing facility or engage a contract manufacturing organization for each step. A CDMO is an entity that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from cell therapy development through cell therapy manufacturing for and end-to-end solution. Due to the complexity, global outreach needs, redundancy and operational costs of manufacturing biologics and cell therapies, the CDMO business is expanding. The complexity of manufacturing individual cell therapy treatments poses a fundamental challenge for cell therapy-based companies as they enter the field. This complexity potentially casts a spotlight on improved cGMP, large-scale manufacturing processes, such as the services provided by MaSTherCell. Manufacturing and delivery can be more complex in cell therapy products than for a typical drug. For example, in the U.S., only a few dozen specialized hospitals are currently qualified to provide CAR T treatments, which require retrieving, processing and then returning immune cells to the patient, all done under strict cGMP, as well as monitoring and treating side effects. These factors provide real incentives for cell therapy companies to seek third-party partners, or contract manufacturers, who possess technical, manufacturing, and regulatory expertise in cell therapy development and manufacturing such as cell therapy CDMOs like MaSTherCell. Additionally, establishing a manufacturing facility for cell therapy requires specific expertise and significant capital which can delay the clinical trials by at least two years. As companies are looking to expedite their market approval, utilization of a CDMO can result in faster time to market and overall lower expenditure.

Our decision to purchase MaSTherCell in 2015 was based on our having identified an industry trend and unmet demand for first-in-class cell and gene therapy CDMO services. Meanwhile, we believe the market opportunity and value proposition for our POC platform has continued to increase, as these solutions uniquely enable localized CGT development, processing and supply within the patient care setting. As such, our decision to sell Masthercell was not only based on the significant value we received as a result of the Masthercell Sale, but also the need for the CDMO business to be developed and scaled to its full potential by a much larger and financially capable enterprise, thereby enabling us financially and strategically to focus our efforts around our POC platform which we believe represents a major paradigm shift and will play a major role in the future of the CGT market due to the following factors:

- Utilizing closed systems and advanced technologies to provide cell processing and treatment within the patient care setting;
- Delivering unique cell and gene therapy capabilities in a cost effective, high quality and scalable manner;
- Establishing a global network of leading healthcare facilities to deliver autologous cell therapy products; and
- Growing therapeutic pipeline based on academic and hospital collaborations

Regarding the Masthercell sale, see Note 23 (d) to Item 8 of this Form 10K.

Current Development Facilities

Atvio Biotech Ltd.

Atvio Biotech Ltd. in Israel is a specialized process and technology development firm 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. Atvio 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 industries, process development capabilities and proficiency, custom-made engineering and a unique platform for creative design and process optimization. The company spreads over 1300 square meters of labs and offices resulting in an efficient and unique environment for cell therapy development. In connection with the sale of Masthercell, the Company has agreed that Atvio will sell to client only in the State of Israel, solely (x) for customers located within the State of Israel or (y) with respect to therapies intended for distribution solely within the State of Israel.

CureCell Co. Ltd.

CureCell Co. Ltd. in Korea 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, CureCell is accelerating the development of foreign technologies in Korea. In connection with the sale of Masthercell, the Company has agreed that CureCell will sell to client only in South Korea, solely (x) for customers located within South Korea or (y) with respect to therapies intended for distribution solely within South Korea.

Research and Development

We incurred $ 13,432 , $7,386 and $1,558 thousands in research and development expenditures in the fiscal years ended December 31, 2019 and November 30, 2018 and for the one month ended December 31, 2019, respectively, of which $ 974 , $922 and $127 thousand was covered by grant funding. The increase in research and development expenses was due to an increase in salaries and related expenses for the year ended December 31, 2019, as compared to 2018 and reflects management's plan to move our trans-differentiation technology to the next the stage towards clinical studies. In the fiscal years ended 2019 and 2018, we focused mainly on setting up infrastructure and regulatory approvals for sourcing of liver tissue and biopsies and combining the in-vitro research to increase insulin production and secretion with our pre-clinical studies' aim to evaluate the efficacy and safety of the product in animal models. In this respect, new trans-differentiation methods are being evaluated. Sourcing of the starting material (liver sampling and cell collection) and upscaling of virus production and cell propagation using advance technologies complement this effort with the target to establish start to end production capabilities. Our research and development scope was also expanded to the evaluation and development of new cell therapies related technologies in the field of immuno-oncology, liver pathologies and tissue regeneration.

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 it 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.

We own or have exclusive rights to ten (10) United States and eight (8) foreign issued patents, five (5) pending applications in the United States, thirty-three (33) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and one (1) international Patent Cooperation Treaty ("PCT") patent applications. These patents and applications relate, among others, to (1) 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, and (2) scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, trans-differentiation, and transplantation in the treatment of autoimmune diseases, including diabetes.

Granted U.S. patents, which are directed among others to compositions comprising sulfated polysaccharide bioconjugates, modified polysaccharides, and epithelial organoids having liver phenotype, will expire between 2025 and 2027, excluding any patent term extensions that might be available following the grant of marketing authorizations. Patents granted in Australia, France, Germany, Israel, Switzerland, and the United Kingdom, which are directed among others to compositions comprising sulfated polysaccharide bioconjugate, and to epithelial organoids having liver phenotype, will expire between 2025 and 2027, excluding any patent term extensions that might be available following the grant of marketing authorizations. Granted U.S. patents, which are directed, among others, to methods of inducing pancreatic hormone expression, methods of inducing a beta cell phenotype, methods for transdifferentiating cells, and methods of producing hydrogels, will expire between 2020 and 2035, excluding any patent term extensions that might be available following the grant of marketing authorizations. Patents granted in Australia, Canada, France, Germany, Israel, Italy, and the United Kingdom, which are directed, among others, to methods of inducing pancreatic hormone expression, methods of inducing a beta cell phenotype, and methods of producing hydrogels, will expire between 2020 and 2024, excluding any patent term extensions that might be available following the grant of marketing authorizations. A granted U.S. patent which is directed, among others, to components of a bioreactor will expire in 2024, excluding any patent term extensions that might be available following the grant of marketing authorizations. Patents granted in Austria, France, Germany, Israel, and the United Kingdom, which are directed, among others, to components of a bioreactor, will expire in 2024, excluding 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 compositions comprising clusters of transdifferentiated cells, modified polysaccharides, and dermatological compositions. If issued, these applications would expire between 2036 and 2038, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. We have pending patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Israel, Japan, the Republic of Korea, Mexico and Singapore directed, among others, to compositions comprising sulfated polysaccharide bioconjugates, modified polysaccharides, and multi-compartment hydrogel. If issued, these applications would expire between 2026 and 2036, excluding any patent term adjustment that might be available following the grant of the patent and 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 methods of isolating cells predisposed to trans-differentiation, methods of manufacturing insulin producing cells, and methods for treating autoimmune diseases. If issued, these applications would expire between 2035 and 2037, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. We have pending patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Israel, Japan, the Republic of Korea, Mexico and Singapore directed, among others, to methods of producing trans-differentiated cells having beta cell phenotype, methods for treating a liver disease, and methods for treating autoimmune disorders. If issued, these applications would expire between 2035 and 2038, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. We have PCT applications directed, among others, to compositions comprising clusters of transdifferentiated cells, compositions comprising vascular secretome components, methods of producing thereof, and methods for treating liver diseases with the compositions thereof. If issued, National Phase applications claiming benefit of those PCT applications would expire in 2038, excluding any patent term adjustment that might be available following the grant of the patent and 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 having 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 Our CDMO Business - Extensive industry regulation has had, and will continue to have, a significant impact on our CDMO business, and it may require us to substantially invest in our development, manufacturing and distribution capabilities and may negatively impact our ability to generate and meet future demand for our products and improve profitability" for additional discussion of the costs associated with complying with the various regulations.

CGT Business

We have not sought approval from the FDA for the AIP cells. Among all forms of cell therapy modalities, we believe that autologous cell replacement therapy is of the highest benefit. We believe that it is safer than other options as it does not alter the host genome but only alters the set of expressed epigenetic information that seems to be highly specific to the reprogramming protocol. It provides an abundant source of therapeutic tissue, which is not rejected by the patient and does not have to be treated by immune suppressants. It is highly ethical because no human organ donations or embryo-derived cells are needed. The proposed therapeutic approach does not require cell bio-banking at birth, which is both expensive and cannot be used for patients born prior to 2000.

Over the past decade, many studies published in leading scientific journals confirmed the capacity of reprogramming adult cells from many of our mature organs to either alternate organs or to "stem like cells". Most widely used autologous cell replacement protocols are used for autologous implantation of bone marrow stem cells. This protocol is widely used in patients undergoing a massive chemotherapy session that destroys their bone marrow cells. However, the stem cells used for cancer patients delineated above do not require extensive manipulation and is regarded by the FDA as "minimally manipulated."

An additional autologous cell therapy approach already used in man is autologous chondrocyte implantation ("ACI"). In the United States, Genzyme Corporation provides the only FDA approved ACI treatment called Carticel. The Carticel treatment is designated for young, healthy patients with medium to large sized damage to cartilage. During an initial procedure, the patient's own chondrocytes are removed arthroscopically from a non-load-bearing area from either the intercondylar notch or the superior ridge of the medial or lateral femoral condyles.

To aid us in our efforts to achieve the highest level of compliance with FDA requirements, we have looked to hire experts in the field of pharmaceutical compliance.

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 such as our AIP cells 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, 2019, we had an aggregate of 309 employees working at our Company and subsidiaries. Subsequent to the Masthercell Sale on February 10, 2020, we had an aggregate of 71 employees. 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.

Subsidiaries

Orgenesis Inc. is a Nevada corporation and, as of the date of this filing, our subsidiaries consist of Orgenesis Belgium SRL (formerly known as Orgenesis SPRL) , a Belgian-based entity (the "Belgian Subsidiary"), Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"), Orgenesis Maryland Inc., a Maryland corporation, Atvio Biotech Ltd. ("Atvio"), an Israeli-based CDMO, and CureCell Co. Ltd. ("CureCell"), a Korea-based CDMO (of which Orgenesis owns 94.12%). During and as of December 31, 2019, Masthercell Global's subsidiaries included MaSTherCell S.A. ("MaSTherCell") (of which Masthercell Global held 83.32%), a Belgian-based entity, and wholly-owned Cell Therapy Holdings S.A., a Belgian-based entity and Masthercell U.S., LLC, a U.S.-based entity.

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.

ITEM 1A. 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.

We expect to use the net proceeds from the sale of Masthercell 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.

We are not profitable as of December 31, 2019, 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, 2019 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, 2019 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 2020. There can be no assurances 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.

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, 2019, we had 309 employees. Following the sale of Masthercell, we had 71 employees. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

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

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

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

We depend 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.

Our success depends substantially on the efforts and abilities of our senior management and certain key personnel. The competition for qualified management and key personnel, especially engineers, is intense. The loss of services of one or more of our key employees, or the inability to hire, train, and retain key personnel, especially engineers and technical support personnel, could delay the development and sale of our products, disrupt our business, and interfere with our ability to execute our business plan.

Currency exchange fluctuations may impact the results of our operations.

The provision of services by our subsidiary, Masthercell Global, were usually transacted in U.S. dollars and European currencies during the year ended December 31, 2019. 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 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 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 independently develop, or develop with third parties, products that compete directly or indirectly with our products or 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. 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 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 an issued patent in the United States with a claim for a composition directed to a vector comprising a promoter linked to a pancreatic and duodenal homeobox 1 (PDX-1) polypeptide, and a carrier, a multicompartment hydrogels, epithelial organoids, tissue grafts, and compositions comprising sulfated polysaccharides, we cannot be certain that the claim 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 composition-of-matter of our transdifferentiated cell populations 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 populations of transdifferentiated cells issue as patents, the patents protect a specific transdifferentiated cell product 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. This type of patents may not be enforced against competitors making and marketing a product that has cells that may provide 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.

We have exclusive rights to ten (10) United States (US) patents, one (1) of which is directed, among others, to a composition comprising a vector comprising a promoter linked to PDX-1 and having a term of 2021, three (3) having a term of 2023 and directed, among others, to methods of inducing endogenous PDX-1 expression in a human differentiated primary non-pancreatic cell, inducing or enhancing a pancreatic islet cell phenotype in non-pancreatic cells, and increasing PDX-1 induction in non-pancreatic primary cells; one (1) having a term of 2024 and directed, among others, to components of a bioreactor; two (2) having a term of 2026 and directed, among others, to a bioconjugate molecules comprising a sulfated polysaccharide; one (1) having a term of 2027 and directed, among others, to an epithelial organoid; one (1) having a term of 2033 and directed, among others, to methods for producing scaffolds; and one (1) having a term of 2034 and directed, among others, to methods for producing transdifferentiated cells. Further, we have exclusive rights to nineteen (19) foreign issued patents (six (6) patents granted in Australia, France, Germany, Israel, Switzerland, and the United Kingdom, having a term between 2025 and 2027, directed among others to compositions comprising sulfated polysaccharide bioconjugate, and to epithelial organoids having liver phenotype; eight (8) patents granted in Australia, Canada, France, Germany, Israel, Italy, and the United Kingdom, having a term between 2020 and 2024, and directed among others to methods of inducing pancreatic hormone expression, methods of inducing a beta cell phenotype, and methods of producing hydrogel; and five (5) patents granted in Austria, France, Germany, Israel, and the United Kingdom, having a term of 2024 and directed among others to components of a bioreactor. We also have nine (9) pending applications in the United States, which if granted would have a term of 2036-2038; thirty two (32) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, which if they were to be granted would have a term of 2026-2036; and four (4) International Patent Cooperation Treaty ("PCT") patent applications, which if filed and granted as national phase applications would have a term of 2028. These pending applications are directed, among others, to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell phenotype and function, and their use in the treatment of degenerative pancreatic disorders including diabetes, pancreatic cancer, and pancreatitis; and to scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, trans-differentiation, and transplantation in the treatment of autoimmune diseases, including diabetes..

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 our products have not reached clinical or commercial stage, we do not currently carry clinical trial or product liability insurance. In the future, our inability to obtain 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 in Israel and Belgium. 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.

Risks Related to the Sale of Masthercell

Our results of operations will differ materially from any expectations or guidance previously provided by us concerning future financial results, and our future financial results will be dependent on our ability to grow our POC business.

Masthercell and our CDMO business accounted for most of our revenues. Accordingly, following the consummation of the sale of Masthercell, our financial results will differ materially from our previous results and the guidance and expectations we had previously provided. In addition, our future financial results will be dependent primarily on our ability to grow our POC business. See "Item 1A. Risk Factors - Risks Related to Our Company and POC Business" in this report for a description of the risks related to our POC business.

The failure to effectively utilize the proceeds from the sale of Masthercell may adversely affect our business.

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. The remainder of the proceeds may be used, at the discretion of our Board of Directors, for working capital and other general corporate purposes, including, among other things, to grow our POC business and to further the development of Advanced Therapy Medicinal Products. We could also potentially identify and acquire, or partner on the development of, other product candidates. However, we do not have agreements or commitments for any such acquisitions or partnerships at this time. 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.

The announcement of the sale of Masthercell may adversely affect our POC business and other activities.

The announcement of the sale of Masthercell may adversely affect the trading price of our common stock, our business and our relationships with clients, customers, suppliers and employees. Additionally, employees working in our POC business may become concerned about the future of such business, and lose focus or seek other employment.

We are subject to a non-competition covenant under the Purchase Agreement, which will limit our ability to engage in the CDMO business except with respect to certain of our subsidiaries' operations in South Korea and Israel.

For a period of three (3) years in the European Union and five (5) years in the United States and the rest of the world (other than the European Union), and a period of three (3) years in the European Union, in each case from and after the sale of Masthercell February 10, 2020 closing date (the "Non-Competition Period"), we are subject to a non-competition covenant made in the Purchase Agreement that restricts our ability to engage in the CDMO business except with respect to certain of our subsidiaries' operations in South Korea and Israel. During the Non-Competition Period, we will be restricted from engaging in the business of providing on a contract basis to third-party customers cell or gene therapy development, analytical or manufacturing services or related products, including the development, analysis and manufacture of plasmids or genetically modified autologous or allogeneic cells; other cell characterization and engineering services; related analytical or bioanalytical services; or related fill and finish or other packaging services; provided, however, that we shall not be restricted from engaging in (i) our current or currently proposed POC business, (ii) research, manufacturing, development and other activities related to the research, development, manufacturing, discovery and commercialization of therapeutic products or technologies or (iii) our subsidiaries' CDMO operations in South Korea and Israel. This limitation may negatively impact the scope and/or volume of our business, which may adversely affect our financial condition and results of operations. In addition, certain third party acquirers of our current business would be subject to these limitations during the Non-Competition Period, which may limit our opportunities with respect to a future sale transaction of our current business during the Non-Competition Period that may otherwise be favorable to our stockholders.

We are obligated to indemnify Catalent for certain losses resulting from breaches of certain representation and warranties set forth in the Purchase Agreement relating to the sale of Masthercell.

Under the terms of the Purchase Agreement, we are obligated to indemnify Catalent for certain losses resulting from breaches of certain representations and warranties in the Purchase Agreement as well as certain litigation relating to the sale of Masthercell. Any and all such liability would reduce the net proceeds from the sale of Masthercell that are available for our use.

We may be exposed to litigation related to the sale of Masthercell from the holders of our stock.

Transactions such as the sale of Masthercell are sometimes subject to lawsuits by stockholders. Because the holders of our stock did not receive any consideration from the sale of Masthercell, it is possible that they may sue us or our Board of Directors. Such lawsuits could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Because we are expected to have significantly less revenue and significantly fewer assets following the sale of Masthercell, there is a possibility that such lack of revenues and diminished assets may affect our ability to satisfy the continued listing standards of the Nasdaq, which could result in the delisting of our common stock.

The continued listing standards of the Nasdaq Capital Market include, among other things, requirements that we maintain certain levels of stockholders' equity, market capitalization and/or minimum trading price. Even though we currently satisfy these requirements, following the sale of Masthercell, we will be smaller with limited revenue and significantly fewer assets, which may cause us to fail to satisfy the continued listing standards of the Nasdaq Capital Market. In the event that we are unable to satisfy such continued listing standards, our common stock may be delisted from the Nasdaq Capital Market. Any delisting of our common stock from such market could adversely affect our ability to attract new investors, decrease the liquidity of our outstanding shares of common stock, reduce our flexibility to raise additional capital, reduce the price at which our common stock trades and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholders. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our securities at all. For these reasons and others, delisting could adversely affect the price of our common stock, our business, our financial condition and results of operations.

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, 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. If THM cancels the THM License Agreement, our POC business may be materially adversely affected. 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. Any termination or cancellation of the THM License Agreement is likely to materially adversely affect our business and prospects.

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 collaboration with a partner, such as a large pharmaceutical organization, that is willing to further develop and commercialize a selected product candidate. To date, we have not entered into any such collaborative arrangement. By entering into any such strategic collaboration, 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 a collaboration 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.

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.

If we are unable to successfully acquire, develop or commercialize new products, our operating results will suffer. Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize our technology and businesses in a timely manner. There are numerous difficulties in developing and commercializing new technologies and products, including:

- successfully achieving major developmental steps required to bring the product to a clinical testing stage and clinical testing may not be positive;
- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;
- the failure to receive requisite regulatory approvals for such products in a timely manner or at all;
- developing and commercializing a new product is time consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development and commercialization of our product;
- incomplete, unconvincing or equivocal clinical trials data;
- experiencing delays or unanticipated costs;
- significant and unpredictable changes in the payer landscape, coverage and reimbursement for our future product;
- experiencing delays as a result of limited resources at the U.S. Food and Drug Administration ("FDA") or other regulatory agencies; and
- changing review and approval policies and standards at the FDA and other regulatory agencies.

As a result of these and other difficulties, products in development by us may not receive timely regulatory approvals, or approvals at all, necessary for marketing by us or other third-party partners. If any of our future products are not approved in a timely fashion or, when acquired or developed and approved, cannot be successfully manufactured, commercialized or reimbursed, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing product will be recouped, even if we are successful in commercializing these products.

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. 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.

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 never generated any revenue from therapeutic product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.

We have no therapeutic products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate. Our ability to generate revenue 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 one or more of the product candidates that we develop is 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 one or 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.

We have concentrated our research and development efforts on technology using cell-based therapy, and our future success is highly dependent on the successful development of that technology for diabetes.

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. Based on licensed know-how and patents, 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 (i.e., PDX-1, and additional pancreatic transcription factors in an adenovirus-vector) 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

When we commence our 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 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.

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.

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. The manufacture of our product candidates involves complex processes, including the biopsy of tissue from a patient's liver, propagation of the patient's liver cells from that liver tissue to obtain the desired dose, trans-differentiating those cells into insulin-producing cells ex vivo and ultimately infusing the cells back into a patient's body. 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.

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.

We currently have no sales, marketing, or commercial therapeutic product distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If we are unable to or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all products we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

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.

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.

Specifically, we face significant competition from companies in the insulin therapy market. Insulin therapy is widely used for Insulin-Dependent Diabetes Mellitus (IDDM) patients who are not controlled with oral medications. The global diabetes market comprising the insulin, insulin analogues and other anti-diabetic drugs has been evolving rapidly. A look at the diabetes market reveals that it is dominated by a handful of participants such as Novo Nordisk A/S, Eli Lilly and Company, Sanofi-Aventis, Takeda Pharmaceutical Company Limited, Pfizer Inc., Merck KgaA, and Bayer AG. Even if we obtain regulatory approval of our product candidates, we may not be the first to market and that may affect the price or demand for our product candidates. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our product candidates, that may prevent us from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances.

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 Scientific Officer, Prof. Sarah Ferber, and 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, 2019, our stock price has fluctuated from a low of $2.60 to a high of $5.60. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

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

Entity	**Property Description**
Orgenesis Inc./Orgenesis Maryland Inc.	These are the Company's principal offices: • 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 8 HaHaruv St. Bar Lev Industrial Park M.P. MISGAV, Israel. • The Company's offices are in the science park of Ness Ziona. Monthly costs are approximately $5 thousand.
CureCell	• Operational production and Office area represent +/-2,234 square meters. • Monthly costs are approximately 21,232 thousand KRW. • Lease agreement for the office and operational production area expires on July 14, 2020.
Atvio Biotech	• Located in 8 HaHaruv St. Bar Lev Industrial Park M.P. MISGAV, Israel. • Operational production and Office area represent +/-1,264 m². • Monthly costs are approximately $10.5 thousand. • Lease agreement for the office and operational production area expires on July 31, 2023.

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

As of March 6, 2020, there were 108 holders of record of our common stock, and the last reported sale price of our common stock on the Nasdaq CM on March 6, 2020 was $4.02. 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, 2019, our financing activities consisted of the following:

(1) During April 2019, we 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 our 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.

(2) During May 2019, we 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 our common stock at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of our common stock at a price of $7.00 per share.

(3) In May 2019, we agreed to enter into a 6% convertible loan agreement with a lender 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 our common stock at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of our 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

(4) In June 2019, we entered into private placement subscription agreements for convertible notes with lenders 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 our common stock at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of our common stock at a price of $7.00 per share.

(5) During October 2019, we 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 $250,000 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 $250,000 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 us, 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 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 our common stock at a conversion price per share equal to $7.00.

As at December 31, 2019, we had received $3.650 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.

(6) In December 2019, we 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 shares of our common stock at a conversion price per share equal to $7.00. In addition, the Company granted lender 183,481 warrants to purchase 183,481 additional shares of our common stock at a price of $7.00 per share.

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

We do not have a stock repurchase program for our common stock and have not otherwise purchased any shares of our common stock.

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, 2019 and November 30, 2018 and one month ended December 31, 2018 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, 2019, as compared to the fiscal year ended November 30, 2018 and the one month ended December 31, 2018. This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2019 and November 30, 2018 and one-month period ended December 31, 2018 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."

Corporate Overview

We are a biotechnology company specializing in the development, manufacturing and provision of cell and gene therapies ("CGTs") through point-of-care solutions. We have historically operated through two independent business platforms: (i) a point-of-care cell therapy ("POC") platform and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform, which provided contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). Through the POC platform, our aim is to further the development of CGTs, including Advanced Therapy Medicinal Products ("ATMPs"), through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. These therapies span a wide range of treatments including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration. We out-license these ATMPs, thus far primarily through joint venture ("JV') agreements, with regional partners including pharmaceutical and biotech companies as well as research institutions and hospitals. These regional partners have cell therapies in clinical development and are to whom we also provide manufacturing know-how, assay services, licensing, regulatory assistance, pre-clinical studies, intellectual property services, and co-development services (collectively "POC Development Services") to support their activity in order to reach patients in a point-of-care hospital setting. Currently, our POC Development Services constitute the entirety of our revenue from the POC platform. Through the CDMO platform, we had focused on providing contract manufacturing and development services for biopharmaceutical companies, and we continue to provide such CDMO, or development, services in Israel and South Korea.

On February 2, 2020, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with GPP-II Masthercell LLC ("GPP" and together with the Company, 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. Our audited financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations contains the consolidated results of Masthercell as of and through December 31, 2019.

Our therapeutic development efforts in our POC business are focused on advancing breakthrough scientific achievements in ATMPs, and namely autologous therapies, which have a curative potential. We base our development on therapeutic collaborations and in-licensing with other pre-clinical and clinical-stage biopharma companies as well as direct collaboration with research and healthcare institutes. We are engaging in therapeutic collaborations and in-licensing with other academic centers and research centers in order to pursue emerging technologies of other ATMPs in cell and gene therapy in such areas including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration Each of these customers and collaborations represents a growth opportunity and future revenue potential as we out-license these ATMPs through regional partners to whom we also provide regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting.

We carry out our POC business through three wholly-owned and separate subsidiaries. This corporate structure allows us to simplify the accounting treatment, minimize taxation and optimize local grant support. The subsidiaries related to this business are Orgenesis Maryland Inc., in the U.S., Orgenesis Belgium SRL (formerly Orgenesis SPRL), in the European Union and Orgenesis Ltd. in Israel.

During the periods covered by this report, we carried out our CDMO business through our subsidiaries Masthercell Global (of which we owned 62.2%), Atvio Biotech Ltd. ("Atvio"), an Israeli-based CDMO, and CureCell Co. Ltd. ("CureCell"), a Korea-based CDMO (of which we own 94.12%). Masthercell Global's subsidiaries, included MaSTherCell S.A., a Belgian-based entity ("MaSTherCell") (of which Masthercell Global owned 83.32%), wholly-owned Cell Therapy Holdings S.A., a Belgian-based entity, and Masthercell U.S., LLC, a U.S.-based entity.

Masthercell Global is a CDMO specialized in cell therapy development for advanced therapeutically products.

During the periods covered by this report, we operated our POC and CDMO businesses as two separate business segments.

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, patents and know-how related to 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 a wholly-owned subsidiary of Orgenesis. Through MaSTherCell, we became engaged in the CDMO business. As of December 31, 2019, most of our revenues were generated through MaSTherCell.

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, 2019. 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 Atvio, our Israel based CDMO partner since May 2016, and 94.12% of the share capital of CureCell, our Korea based CDMO partner since March 2016. We exercised the "call option" to which we were entitled under the joint venture agreements with each of these entities to purchase from the former shareholders their equity holding. The consideration for the outstanding share equity in each of Atvio and CureCell consisted solely of our common stock. In respect of the acquisition of Atvio, we issued to the former Atvio shareholders an aggregate of 83,965 shares of our common stock. In respect of the acquisition of CureCell, we issued to the former CureCell shareholders an aggregate of 202,846 shares of our common stock subject to a third-party valuation. Together with MaSTherCell S.A., Atvio and CureCell were directly held subsidiaries under Masthercell Global (collectively, the "Masthercell Global Subsidiaries").

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 Atvio and CureCell 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.

Material Developments During Fiscal 2019

Institutional Review Board Approval

On April 29, 2019, we announced that we had 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 Autologous Insulin Producing (AIP) cell production from their own liver biopsy. The secondary objective of the study is to evaluate patients' immune response to AIPs based on the patient's blood samples and followed by subcutaneous implantation into the patients' arm which would represent the first human trial. We have 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 enrollment for the study's 20 patients commenced in May 2019. 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 model in which the patient liver samples are processed, cryopreserved and potentially re-injected, all in the medical center under clinical grade/GMP level conditions.

Joint Venture Agreement with First Choice International Company, Inc.

On March 12, 2019, the Company and First Choice International Company, Inc. ("First Choice") entered into a Joint Venture Agreement (the "JVA") pursuant to which First Choice will collaborate with the Company to further the clinical development and commercialization of the Company's cell regeneration and gene therapeutic products in Panama and Latin America countries (the "Territory") and the Company will collaborate with First Choice to further the clinical development and commercialization of products to be introduced by First Choice, which will be offered for sale by the Company globally outside of the Territory. The parties intend to pursue the joint venture through a newly established company (hereinafter the "JV Company") which the Company by itself, or together with a designee, will hold a 50% participating interest therein, with the remaining 50% participating interest being held by First Choice by itself, or together with a designee.

Pursuant to the terms of the JVA, the JV Company will initially be owned 100% by First Choice and, until such JV Company is established, all activities in the Territory will be carried out through First Choice. Upon the Company's request, First Choice will transfer all activities, and results, data, information, material, IP, know-how, contracts, licenses, authorizations, permissions, grants, obligations and assets related to such activities to the JV Company. In addition, each party shall be required to exert best commercial efforts to carry out, in a timely and professional manner, its respective obligations according to a detailed work plan to be agreed upon by First Choice and Company within no later than sixty (60) days following the execution of the JVA.

Debt Financing Agreements

In April 2019, we 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 our 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.

In May 2019, we entered into a private placement subscription agreement with a non-U.S. 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 our common stock at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of our common stock at a price of $7.00 per share.

In June 2019, we 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 our common stock at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of our common stock at a price of $7.00 per share.

In October 2019, we 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 us access to us of 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, we are entitled to draw down an aggregate of $1 million (consisting of $250,000 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, we were entitled to draw down an additional aggregate of $1 million (consisting of $250,000 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 us 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 us, each of the Lenders is entitled to convert its respective drawdown amounts and all accrued interest, into shares of our 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 our common stock shall be amended to extend their exercise date to June 30, 2021 and we will issue to each of the Lenders warrants to purchase 50,000 shares of our 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 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 our common stock at a conversion price per share equal to $7.00.

As of December 31, 2019, we 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.

In December 2019, we 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 shares of our common stock at a conversion price per share equal to $7.00.

FDA Approval for Orphan Drug Designation for AIP Cells

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.

Other Developments and Agreements During Fiscal 2019

Joint Ventures, Collaborations and License Agreements During Fiscal 2019

On February 14, 2019, we entered into a joint venture agreement with Theracell Advanced Biotechnology, a corporation organized under the laws of Greece ("Theracell"), pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products in Greece, Turkey, Cyprus and Balkan countries and the clinical development and commercialization of Theracell's products worldwide. On February 14, 2019, we entered into a master service agreement with Theracell whereby, subject to mutually agreed timing and definition of the scope of services, we provide regulatory services, pre-clinical studies, intellectual property services, GMP process translation services and co-development services to Theracell during 2019. During the year ended December 31, 2019, we recognized POC development service revenue in the amount of $857 thousand.

On February 27, 2019, we entered into a collaboration agreement with Tarus Therapeutics Inc., a Delaware corporation ("Tarus"), in connection with 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. The parties plan to enter into pre-clinical studies as part of the preparations to clinical studies submission during 2020.

On March 12, 2019, we entered into a joint venture agreement with First Choice International Company, Inc., a corporation organized under the laws of Delaware ("First Choice"), pursuant to which the parties will collaborate in the clinical development and commercialization of our products in Panama and certain other Latin American countries as agreed by the parties (the "Territory") and the clinical development and commercialization of First Choice's products worldwide (other than in the Territory).

Effective April 2, 2019, we 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 we will provide financial support for studying the utility of serological tumor marker for tumor dynamics monitoring. Under the terms of the SRA, we 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, we and Columbia entered into an Exclusive License Agreement (the "Columbia License Agreement") whereby Columbia 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 (i) a royalty of 5% of net sales of any patented product sold and (ii) 2.5% of net sales of other products. Tech transfer from Columbia to us has been completed. We are now working on the completion of all the IND enabling requirements in order to get into Phase I study in a year's time under point-of-care centers.

On May 6, 2019, we entered into a joint venture agreement with KinerjaPay Corp., a Delaware corporation ("KinerjaPay"), pursuant to which the parties will collaborate in the clinical development and commercialization of our products in Singapore and the introduction of KinerjaPay products to be offered for sale by us globally outside Singapore.

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 November 10, 2019, the Maryland Subsidiary and Broaden Bioscience and Technology Corp, a Delaware corporation ("Broaden"), entered into a joint venture agreement (the "Broaden JVA") pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products and the setting up of POC processing facilities in China and the Middle East.

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.

Change of Fiscal Year

On October 22, 2018, the Board of Directors of the Company approved a change in the Company's fiscal year end from November 30 to December 31 of each year. This change to the calendar year reporting cycle began January 1, 2019. As a result of the change, the Company is reporting a December 2018 fiscal month transition period, which is separately reported in this Annual Report on Form 10-K for the calendar year ending December 31, 2019. Financial information for the year ended December 31, 2018 has not been included in this Form 10-K for the following reasons: (i) the year ended November 30, 2018 provides a meaningful comparison for the year ended December 31, 2019; (ii) there are no significant factors, seasonal or other, that would materially impact the comparability of information if the results for the year ended December 31, 2018 were presented in lieu of results for the year ended November 30, 2018; and (iii) it was not practicable or cost justified to prepare this information.

Results of Operations

Comparison of the Year Ended December 31, 2019 to the Year Ended November 30, 2018 and for the One Month Ended December 31, 2018.

Our financial results for the year ended December 31, 2019 are summarized as follows in comparison to the year ended November 30, 2018 and for the one month ended December 31,2018:

	Year Ended		One Month Ended
	December 31, 2019	**November 30, 2018**	**December 31, 2018**
	(in thousands)		
Revenues	$ 33,256	$ 18,655	$ 1,852
Cost of sales	18,232	10 ,824	1,221
Research and development expenses and Research and development service expenses, net	12,458	6 ,464	1,431
Amortization of intangible assets	2,061	1,913	179
Selling, general and administrative expenses	25,337	16,303	1,984
Other income	(228)	(2,930)	-
Share in losses of associated company	-	731	-
Financial expense, net	874	3,117	27
Loss before income taxes	$ 25,478	$ 17,767	$ 2,990

Revenues

The following table shows the Company's revenues by major revenue streams.

	Year Ended		**One Month Ended**
	December 31, 2019	**November 30, 2018**	**December 31, 2018**
	(in thousands)		
Revenue stream:			
CDMO	$ 30,147	$ 18,655	$ 1,852
POC Services	3,109	-	-
Total	$ 33,256	$ 18,655	$ 1,852

Our revenues for the year ended December 31, 2019 were $33,256 thousand, as compared to $18,655 thousand for the year ended November 30, 2018, representing an increase of 78%. Revenues for the one month ended December 31, 2018 were $1,852 thousand. The increase in revenues for the year ended December 31, 2019 compared to the corresponding period in 2018 is attributable to our POC services revenue which we recognized for the first time in 2019, as well as an increase in the revenues provided by MaSTherCell S.A., resulting primarily from the extension of existing customer service contracts with biotechnology clients and from revenues generated from existing manufacturing agreements. Management believes that revenue diversification by source in the CDMO segment, together with a leading position in immunotherapy and, in particular, CAR T-cell therapy development and manufacturing, strengthened MaSTherCell's resilience in the industry.

Backlog

We define our backlog as products that we are obligated to deliver or services to be rendered based on firm commitments relating to purchase orders received from customers. As of December 31, 2019, MaSTherCell S.A. had a backlog of approximately $19 million, consisting of services that we expect to deliver into fiscal year 2020. However, no assurance can be provided that such contracts will not be cancelled, in which case we will not be authorized to deliver and record the anticipated revenues.

Expenses

Cost of Revenues

	Year Ended		One Month Ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands)		
Salaries and related expenses	$ 7,333	$ 4,915	$ 457
Stock-based compensation	116	126	13
Professional fees and consulting services	223	145	32
Raw materials	9,024	4,614	558
Depreciation and amortization expenses, net	979	391	62
Other expenses	557	633	99
	$ 18,232	$ 10 ,824	$ 1,221

Cost of revenues for the year ended December 31, 2019 were $18,232 thousand, as compared to $10,824 thousand for the year ended November 30, 2018, representing an increase of 68%. Cost of revenues for the one month ended December 31, 2018 were $1,221 thousand. The increase for the year ended December 31, 2019 as compared to the corresponding period in 2018 is primarily attributed to the following:

(i) An increase in salaries and related expenses of $2,418 thousand, primarily attributable to an increase of activities and operational staff. This is in line with the increase in revenue of MaSTherCell S.A., as well as the inclusion of salaries and related expenses of CureCell which was consolidated from July 2018.

(ii) An increase in raw materials of $4,410 thousand, mainly attributed to the growth in the volume of services provided by MaSTherCell S.A., both from existing and new manufacturing agreements.

(iii) An increase in depreciation and amortization expenses, net of $588 thousand, primarily attributable to the increase in the property, plants and equipment.

Cost of Research and Development and Research and Development Services, net:

	Year Ended		One Month Ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands)		
Salaries and related expenses	$ 3,262	$ 2,077	$ 251
Stock-based compensation	762	659	56
Professional fees and consulting services	1,823	605	62
Lab expenses	3,231	3,370	1,118
First Choice JVA, see Note 12	2,741	-	-
Depreciation expenses, net	563	320	24
Other research and development expenses	1,050	355	47
Less - grant	(974)	(922)	(127)
Total	$ 12,458	$ 6,464	$ 1,431

The increase in research and development expenses reflects management's determination to move its trans-differentiation technology to the next stage towards clinical trials. In the fiscal year ended December 31, 2019, we continued to focus on combining the in vitro research to increase insulin production and secretion with pre-clinical studies aiming to evaluate the efficacy and safety of the product in rodents' model. In addition, we evaluated new transplantation methods during this period. Sourcing of the starting material (liver sampling and cell collection) and upscaling of virus production and cell propagation using advanced technologies complement this effort with the target to establish start-to-end production capabilities.

The scope of research and development expenses was also expanded to the evaluation and development of new cell therapies related technologies in the field of immuno-oncology, liver pathologies and others. In furtherance of these developments, salaries and related expenses increased for the year ended December 31, 2019 compared to year ended November 30, 2018, primarily due to the expansion of our development team in Israel and Belgium. Included in the research and development expenses are research and development services expenses.

Research and development expenses for the year ended December 31, 2019 were $12,458 thousand, as compared to $6,464 thousand for the year ended November 30, 2018, representing an increase of 93%. Research and development expenses (net) for the one month ended December 31, 2018 were $1,431 thousand. The increase in research and development, net expenses in the year ended December 31, 2019 is primarily attributable to the following:

(i) An increase in salaries and related expenses of $1,185 thousand, primarily attributable to an increase of activities and operational staff and the provision of research and development services.

(ii) The First Choice JVA (See Note 12 to Item 8 of this Annual Report on Form 10-K for further details).

(iii) An increase in other research and development expenses of $695 thousand, as a result of expenses related to new therapies and collaborations (See Note 12 to Item 8 of this Annual Report on Form 10-K for further details).

Selling, General and Administrative Expenses

	Year Ended		One Month Ended
	December 31, 2019	**November 30, 2018**	**December 31, 2018**
	(in thousands)		
Salaries and related expenses	$ 8,413	$ 4,581	$ 575
Stock-based compensation	2,179	3,399	665
Accounting and legal fees	2,849	2,528	325
Professional fees	3,992	2,000	129
Rent and related expenses	2,706	1,281	155
Business development	2,375	1,557	101
Expenses related to collaboration with Theracell (see note 12)	689	-	-
Depreciation expenses, net	203	7	-
Other general and administrative expenses	1,931	950	34
Total	$ 25,337	$ 16,303	$ 1,984

Selling, general and administrative expenses for the year ended December 31, 2019 were $25,337 thousand, as compared to $16,303 thousand for the year ended November 30, 2018, representing an increase of 55%. Selling, general and administrative expenses for the one month ended December 31, 2018 were $1,984 thousand. The increase for the year ended December 30, 2019 is primarily attributable to:

(i) An increase in salaries and related expenses of $3,832 thousand, as a result of additional managerial appointments especially in CureCell, Atvio and Masthercell Global not previously consolidated.

(ii) A decrease in stock-based compensation of $1,220 thousand, as a result of options granted to employees and consultants.

(iii) An increase in professional fees of $1,992 thousand, as a result of increased fees incurred at MaSTherCell as well as professional fees incurred at Masthercell Global, CureCell and Atvio not previously consolidated.

(iv) An increase in rent and related expenses of $1,425 thousand, mainly related to the occupation of additional space rented by MaSTherCell S.A. and Masthercell USA and rent and related expenses of CureCell (not previously consolidated).

(v) An increase in business development of $818 thousand, related to the increase in the related activities during the year especially at Masthercell Global.

(vi) An increase in other general and administrative expenses of $981 thousand, related mainly to Masthercell Global.

Financial Expenses, net

	Year Ended		One Month Ended
	December 31, 2019	**November 30, 2018**	**December 31, 2018**
	(in thousands)		
Decrease in fair value financial liabilities and assets measured at fair value	$ 63	$ 48	$ -
Stock-based compensation related to warrants granted debt holders	-	180	-
Interest expense on convertible loans and loans	657	2,753	40
Foreign exchange loss (income), net	350	129	(5)
Other expenses (income)	(196)	7	(8)
Total	$ 874	$ 3,117	$ 27

Financial expenses, net for the year ended December 31, 2019 were $874 thousand, as compared to $3,117 thousand for the year ended November 30, 2018, representing a decrease of 72%. Financial expenses, net for the one month ended December 31, 2018 were $27 thousand. The decrease in 2019 financial expenses is primarily attributable to:

(i) A decrease in Interest expense on convertible loans and loans of $2,096 thousand, most of which were converted in 2018.

(ii) A decrease in Other expenses (income) of $203 thousand,.

Tax expenses (income)

	Year Ended		One Month Ended
	December 31, 2019	**November 30, 2018**	**December 31, 2018**
	(in thousands)		
Tax expenses (income)	$ 563	$ 1,337	$ (83)
Total	$ 563	$ 1,337	$ (83)

Tax expenses, net for the year ended December 31, 2019 were $563 thousand, as compared to $1,337 thousand for the year ended November 30, 2018, representing a decrease of 58%. Tax income for the one month ended December 31, 2018 was $83 thousand. The decrease in 2019 is mainly due to higher tax expenses in 2018 mainly due to a decrease in deferred taxes related to carryforward losses in MaSTherCell S.A.

Working Capital

	As of	
	December 31, 2019	**December 31, 2018**
	(in thousands)	
Current assets	$ 25,979	$ 28,058
Current liabilities	$ 31,579	$ 17,161
Working capital (deficiency)	$ (5,600)	$ 10,897

Current assets decreased by $2,079 thousand between December 31, 2018 and December 31, 2019., which was primarily attributable to the following: (i) a decrease in cash and cash equivalents due the payment of operating expenses; (ii) an increase in inventory and accounts receivable at Masthercell as a result of increased sales, (iii) an increase in grants receivable, and (iv) GPP receivables due to us at December 31, 2018 received during 2019.

Current liabilities increased by $14,418 thousand between December 31, 2018 and December 31, 2019., which was primarily attributable to the following: (i) an increase in accounts payable and accrued expenses due to expanded operations, (ii) an increase in employees and related payables, (iii) increased advanced grant related payables, (iv) increased contract liabilities as a result of increased sales at Masthercell, and (v) the recording of current maturities of operating leases (See Note 10).

Liquidity and Capital Resources

	Year Ended		One Month Ended
	December 31, 2019	**November 30, 2018**	**December 31, 2018**
	(in thousands)		
Net loss	$ (26,041)	$ (19,104)	$ (2,907)
Net cash used in operating activities	(13,220)	(15,682)	(1,077)
Net cash used in investing activities	(13,778)	(6,268)	(592)
Net cash provided by financing activities	24,098	35,060	197
Net change in cash and cash equivalents and restricted cash	$ (2,900)	$ 13,110	$ (1,472)

As mentioned in Note 23(d) to Item 8 of this Annual Report on Form 10-K, 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.

During the year ended December 31, 2019, we funded our operations through various financing activities consisting of proceeds primarily from private placements of our equity securities, debt securities and equity-linked instruments in the net amount of approximately $ 11.4 million and $ 13.2 million from GPP. In addition, we generated cash flow through revenues from our POC services and the activities of MaSTherCell S.A, our Belgian Subsidiary.

Net cash used in operating activities for the year ended December 31, 2019 was approximately $13 million, as compared to net cash used in operating activities of approximately $16 million and 1 million for the year ended November 30, 2018 and for the one month ended December 31, 2018, respectively.

We expanded our pre-clinical studies in the U.S., Israel, Belgium and South Korea. The increase reflects management's focus on moving our trans-differentiation technology with first indication in Type 1 Diabetes to the next stage towards clinical trials as well as investments in new collaborations and therapies.

Net cash used in investing activities for the year ended December 31, 2019 was approximately $14 million, as compared to net cash used in investing activities of approximately $6 million and 1 million for the year ended November 30, 2018 and for the one month ended December 31, 2018, respectively. Net cash used in investing activities was primarily for POC related activities and additions to fixed assets at our subsidiaries, MaSTherCell, CureCell and Atvio.

Liquidity and Capital Resources Outlook

We believe that the proceeds from the Masthercell Sale, as well as our business plan, will provide sufficient liquidity to fund our operating needs for at least the next 12 months. However, there are factors that can impact our ability to continue to fund our operating needs, including:

- restrictions on our ability to expand sales volume from our POC business;
- the need for us to continue to invest in operating activities to remain competitive or acquire other businesses and technologies and to complement our products, expand the breadth of our business, enhance our technical capabilities or otherwise offer growth opportunities.

On February 10, 2020, we received approximately $126.7 million net proceeds from the sale of Masthercell, of which $7.2 million was used for the repayment of intercompany loans and payables. In addition, on January 20, 2020, we entered into a Securities Purchase Agreement with certain investors pursuant to which we issued an aggregate of 2,200,000 shares of our common stock and warrants to purchase up to an aggregate of 1,000,000 shares of our common stock, which resulted in our receipt of gross proceeds of approximately $9.24 million before deducting related offering expenses.

Based on our current cash resources and commitments, we believe that we will be able to maintain our current planned POC development activities and expected level of expenditures for at least 12 months from the date of the issuance of the financial statements. Also, if there are further increases in operating costs in general and administrative expenses for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, we may decide 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, 2019. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Fair Value Measurement

The fair value measurement guidance clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in the valuation of an asset or liability. It establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under the fair value measurement guidance are described below:

Level 1 - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2 - Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability; or

Level 3 - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

We did not have any Level 1, 2 or 3 assets and liabilities as of December 31, 2019 and November 30, 2018.

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 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. 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.

Redeemable Non-controlling Interest

Non-controlling interests with embedded redemption features, whose settlement is not at our 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 our consolidated balance sheets. Subsequent adjustment of the amount presented in temporary equity is required only if our 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.

Goodwill

Goodwill represents the excess of the purchase price of acquired business over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually (at December 31), at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired.

Commencing from the fourth quarter of 2019, we early adopted a new guidance which simplifies the test for goodwill impairment. Under the new guidance, the we perform our quantitative goodwill impairment test by comparing the fair value of its reporting unit with our carrying value. If the reporting unit's carrying value is determined to be greater than its fair value, an impairment charge is recognized for the amount by which the carrying value exceeds the reporting unit's fair value. If the fair value of the reporting unit is determined to be greater than its carrying amount, the applicable goodwill is not impaired and no further testing is required.

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.

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 and at least annually. 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.

Newly Issued and Recently Adopted Accounting Pronouncements

ASC 606 - Revenue from Contracts with Customers

On December 1, 2018, the Company adopted the new accounting standard ASC 606, *Revenue from Contracts with Customers* and the related amendments ("New Revenue Standard") to all contracts, using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was immaterial.

Revenue Recognition Prior to the Adoption of the New Revenue Standard

Refer to Note 2 of item 8 of this form 10-K.

Revenue Recognition Following the Adoption of the New Revenue Standard

Our agreements are primarily service contracts that range in duration from a few months to one year. 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, 2019	Transition Period, One-Month Ended December 31, 2018
Revenue stream:		
Cell process development services	$ 19,928	$ 1,488
Tech transfer services	5,396	364
POC development services	3,109	-
Cell manufacturing services	4,823	-
Total	$ 33,256	$ 1,852

Nature of Revenue Streams

During the period covered by this report, we operated through two platforms: (i) a point-of-care cell therapy platform ("POC") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform. As of the second quarter of 2019, we commenced our POC development services. Through our CDMO platform, we are focused on providing contract manufacturing and development services for biopharmaceutical companies.

We have three main revenue streams from our CDMO platform: cell process development services, tech transfer services, and upon success, cell manufacturing 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 independently or by using our competitors.

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 measure the revenue to be recognized over time on a contract by contract basis as services are provided.

Cell Process Development Services

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

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

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).

Significant Judgement and Estimates

The cost-based and output methods of revenue recognition require us to make estimates of costs to complete our projects and the percentage of completeness on an ongoing basis. Significant judgment is required to evaluate assumptions related to these estimates. The effect of revisions to estimates related to the transaction price (including variable consideration relating to reimbursement on a cost-plus basis on certain expenses) or costs to complete a project are recorded in the period in which the estimate is revised.

Practical Expedients

As part of ASC 606, we have adopted several practical expedients including our determination that we need 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 when we transfer a promised service to the customer and when the customer pays for that service will be one year or less.

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

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, 2019	Transition Period, One-month Ended December 31, 2018
Balance as of beginning of period	$ 3,226	$ 4,151
Additions	26,148	1,612
Collections	(20,803)	(2,561)
Exchange rate differences	(86)	24
Balance as of end of period	$ 8,485	$ 3,226

The activity for contract liabilities is comprised of:

	Year Ended December 31, 2019	Transition Period, One-month ended December 31, 2018
Balance as of beginning of period	$ 5,175	$ 5,317
Adoption of ASC 606:	-	(8)
Additions	9,850	28
Realizations	(6,307)	(251)
Exchange rate differences	(92)	89
Balance as of end of period	$ 8,626	$ 5,175

ASU 2018-07 Stock based Compensation

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." This guidance simplifies the accounting for non-employee share-based payment transactions. The amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods and services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606, "Revenue from Contracts with Customers." This standard, adopted as of January 1, 2019, had no material impact on our consolidated financial statements for the year ended December 31, 2019.

ASC 842 - Leases

In February 2016, the FASB issued ASU 2016-02 "Leases" (the "new lease standard"). The guidance establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The guidance became effective on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application.

The Company adopted the new lease standard and all the related amendments on January 1, 2019 and used the effective date as the Company's date of initial application. Consequently, financial information was not updated and the disclosures required under the new standard are not provided for dates and periods before January 1, 2019.

For more information, see Notes 2 (t) and 10 of Item 8 on this form 10K.

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. We are currently evaluating this guidance to determine the impact it may have on our consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18 "Collaborative Arrangements (Topic 808)-Clarifying the interaction between Topic 808 and Topic 606." The amendments provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606. It also specifically (i) addresses when the participant should be considered a customer in the context of a unit of account, (ii) adds unit-of-account guidance in ASC 808 to align with guidance in ASC 606 and (iii) precludes presenting revenue from a collaborative arrangement together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer. The guidance will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted and should be applied retrospectively. We are currently evaluating this guidance to determine the impact it may have on our consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12 "Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes" ("the Update"). The amendments in this Update simplify the accounting for income taxes by removing the following exceptions in ASC 740: (1) exception to the incremental approach for intra-period tax allocation when there is a loss from continuing operations and income or a gain from other items; (2) exception to the requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment; (3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary; and (4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year.

In addition, this Update also simplifies the accounting for income taxes in certain topics as follows: (1) requiring that an entity recognize a franchise tax (or similar tax) that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax; (2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction; (3) specifying that an entity can elect (rather than be required to) allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements; and (4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

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, 2019, or the Evaluation Date. Based on such evaluation, those officers 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.

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, 2019. 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, 2019 based on those criteria.

Attestation Report of Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited ("PwC"), an independent registered public accounting firm, as stated in their report which is included under "Item 8 - Financial Statements and Supplementary Data."

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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our each of our current Directors and Executive Officers as of March 9, 2020.

Name	Age	Position
Vered Caplan	51	Chief Executive Officer and Chairperson of the Board of Directors
Neil Reithinger	50	Chief Financial Officer, Secretary and Treasurer
Sarah Ferber	65	Chief Scientific Officer
David Sidransky (1)	59	Director
Guy Yachin (1)	52	Director
Yaron Adler (1)	49	Director
Ashish Nanda (1)	54	Director
Mario Philips	50	Director (appointed in January 2020)

(1) A member on each of the audit, compensation and nominating and corporate governance committees.

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 25 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.

Prof. Sarah Ferber - Chief Scientific Officer

Prof. Ferber has served as the Company's Chief Scientific Officer since her appointment on February 2, 2012. Since 2017, Prof. Ferber has been the Principal Investigator of cell therapy for TMU DiaCure. Prof. Ferber studied biochemistry at the Technion under the supervision of Professor Avram Hershko and Professor Aharon Ciechanover, winners of the Nobel Prize in Chemistry in 2004. Most of the research was conducted in Prof. Ferber's Endocrine Research Lab. Prof. Ferber received Teva, Lindner, Rubin and Wolfson awards for this research. Prof. Ferber's research work has been funded over the past 15 years by the JDRF, the Israel Academy of Science foundation (ISF), BIODISC and DCure. Prof. Ferber earned her B.Sc. from Technion-Haifa, a M.Sc. in Biochemistry from Technion-Haifa and a Ph.D. in Medical Sciences from Technion-Haifa. She also holds a Post Doctorate degree in Molecular Biology from Harvard Medical School and a degree in Cell Therapy Sciences from UTSW, Dallas.

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 460 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 serving, or has served on, the scientific advisory boards of MedImmune, LLC, Roche, Amgen Inc. and Veridex, LLC (a Johnson & Johnson diagnostic company), among others and is currently on the board of Directors of Galmed and Rosetta Genomics Ltd. and chairs the board of directors of Advaxis and Champions Oncology, Inc. 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 chairman of ExitValley Ltd., an equity-based crowdfunding platform, since April 2014 and 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 was appointed as a director in January 9, 2020. Since March 2019, Mr. Philips has been Chief Executive Officer of PolyNeuroS, 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. Mr. Philips also acts as strategic partner for the private equity fund, Archimed, and has been the Chairman of the Board for its portfolio company, Clean Biologics since July 2019.

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 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 each committee are Dr. Sidransky and Messrs. Adler and Yachin. On January 9, 2020, Mr. Mario Philips was appointed to the Company's Audit Committee.

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

Audit Committee

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

The Audit Committee held six meetings in fiscal 2019. In addition, the Audit Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2019. 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 the Company's 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 five meetings in fiscal 2019. 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 three meeting in fiscal 2019. 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.

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 one report, covering an aggregate of three transactions, were filed late by Vered Caplan, two reports, covering an aggregate of two transactions, were filed late by David Sidransky, two reports, covering an aggregate of seven transactions, were filed late by Yaron Adler, two reports, covering an aggregate of three transactions, were filed late by Guy Yachin, one report covering an aggregate of one transaction, was filed late by Denis Bedoret, two reports, covering an aggregate of two transactions, were filed late by Ashish Nanda, one report, covering an aggregate of two transactions, was filed late by Neil Reithinger and an initial report of ownership was filed late by each of Denis Bedoret, Ashish Nanda and Neil Reithinger.

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, 2019 and November 30, 2018 and the December 2018 transition period, to our Chief Executive Officer, our Chief Financial Officer and our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2019 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 *CEO (3)*	2019	250,000	200,000	-	871,036	-	-	77,020	1,398,056
	December 2018	25,000	-	-	149,048	-	-	5,554	179,602
	2018	226,122	350,000	-	1,318,771	-	-	80,697	1,975,590
Neil Reithinger *CFO, Treasurer & Secretary*	2019	213,653	-	-	22,970	-	-	-	236,623
	December 2018	21,650	-	-	3,442	-	-	-	25,092
	2018	266,452 (4)	-	-	139,590	-	-	-	406,042
Denis Bedoret, *President of MaSTherCell Global (5)(6)*	2019	221,954	33,249	-	66,157	-	-	-	321,360
	December 2018	13,314	6,047	-	5,004	-	-	-	24,365
	2018	211,847 (6)	56,539	-	20,214	-	-	-	288,600
Darren Head, *CEO of Masthercell Global (5)*	2019	250,000	112,500	-	9,241	-	-	120,000	491,741
	December 2018	-	-	-	348,916	-	-	-	348,916

(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 16 to this Annual Report on Form 10-K for the year ended December 31, 2019.

(2) For 2019 and 2018, represents the compensation as described under the caption "All Other Compensation" below.

(3) Due to cash flow considerations, part of the amounts earned have been deferred periodically and, as of November 30, 2018, an aggregate of $195,501 has been deferred by agreement and accrued by the Company. See below under "Narrative Disclosure to Summary Compensation Table - Vered Caplan."

(4) As of November 30, 2018, an aggregate of $18,276 has been deferred and accrued by agreement and accrued the Company. See below under "Narrative Disclosure to Summary Compensation Table - Neil Reithinger."

(5) As of February 10, 2020, the Company sold Masthercell Global and, accordingly, such officer is no longer an officer or employee of the Company. With respect to Dr. Bedoret, included is (i) the Company compensation option plan of $48,224 and $4,096 for the year ended December 31, 2019 and for the one month ended December 31, 2018 respectively, (ii) the MaSTherCell Global option plan of $17,933 and $908 for the year ended December 31, 2019 and for the one-month ended December 31, 2018, respectively. With respect to Mr. Head, included is MaSTherCell Global compensation option plan of $9,241 and $348,916 for the year ended December 31, 2019 and for the one-month ended December 31, 2018, respectively.

(6) On July 6, 2017, MaSTherCell's Board of Directors appointed Denis Bedoret as General Manager and day-to-day manager of MaSTherCell, effective as of July 11, 2017. On September 5, 2018, Dr. Bedoret was promoted to Managing Director of MaSTherCell. On January 22, 2019, Dr. Bedoret was appointed as President of Masthercell Global. Out of the 2019 amounts earned, $194,550 was paid and $71,123 was deferred by agreement with MaSTherCell.

All Other Compensation

The following table provides information regarding each component of compensation for fiscal years 2019 and 2018 and the December 2018 transition period included in the All Other Compensation column in the Summary Compensation Table above. Represents amounts paid in New Israeli Shekels (NIS) and converted at average exchange rates for the year.

Name	Year	Automobile and Communication Related Expenses $ (1)	Israel-related Social Benefits $ (2)	Total $
Vered Caplan	2019	18,876	58,144	77,020
	December 2018	1,143	4,411	5,554
	2018	31,027	49,670	80,697

(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, including education funds and managerial insurance funds. This amount represents Israeli 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, 2019

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of December 31, 2019.

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)]	21,250	63,750	5.99	22-Oct-28
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
Dr. Denis Bedoret	14-May-18[(2)]	11,250	3,750	8.43	14-May-28
Darren Head	12-Sep-18[(1)]	20,000	-	5.30	12-Sep-28

(1) The options were fully vested as of December 31, 2019.

(2) The options vested 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.

Masthercell Global Option Plan

The following table summarizes the outstanding equity awards held by each named executive officer of Masthercell Global as of December 31, 2019.

Name	Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Dr. Denis Bedoret	12-Dec-18[(1)]	2,222	14,445	13.52	12-Dec-28
Darren Head	10-Dec-18[(2)]	44,444	-	13.52	10-Dec-28

(1) The options were fully vested as of December 31, 2019.

(2) The options vested on a yearly basis over a period of five years from the date of grant.

Option Exercises in 2019

There were no option exercises by our named executive officers during our fiscal year ended December 31, 2019 or the December 2018 transition period.

Narrative Disclosure to Summary Compensation Table

Vered Caplan

On August 14, 2014, our Board of Directors confirmed that Ms. Vered Caplan, who has 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. In connection with her appointment as our President and Chief Executive Officer, on August 22, 2014, our wholly-owned Israeli Subsidiary, Orgenesis Ltd., entered into a Personal Employment Agreement with Ms. Caplan (the "Caplan Employment Agreement"). The Caplan Employment Agreement replaced a previous employment agreement with Ms. Caplan dated April 1, 2012 pursuant to which she had served as Vice President.

On March 30, 2017, we and Ms. Caplan entered into an employment agreement replacing the Caplan Employment Agreement (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. Ms. Caplan is also entitled to an annual cash bonus with a target of 25% of base salary, provided that the actual amount of such bonus may be greater or less than the target amount. Ms. Caplan was entitled to a signing bonus of $150,000 upon execution of the Amended Caplan Employment Agreement. Under the Amended Caplan Employment Agreement, Ms. Caplan is entitled to the following social benefits typically provided to Israeli employees, computed on the basis of her base salary: (i) Manager's Insurance under Israeli law pursuant to which the Company contributes between 6.5% and 7.5% (and Ms. Caplan contributes an additional 6%), (ii) severance pay under Israeli law pursuant to which the Company contributes 8 1/3% and (iii) Education fund pursuant to which the Company continues to contribute $3,677 a year. In addition, Ms. Caplan is also entitled to paid annual vacation days, annual recreation allowance, sick leave and expenses reimbursement. In addition, we provide Ms. Caplan with a leased company car and a mobile phone.

Either we or Ms. Caplan may terminate the employment under the Amended Caplan Employment Agreement upon six months prior written notice. Upon termination by us of Ms. Caplan's employment without cause (as defined therein) or by Ms. Caplan for any reason whatsoever, in addition to any accrued but unpaid base salary and expense reimbursement, she shall be entitled to receive an amount equal to 12 months of base salary at the highest annualized rate in effect at any time before the employment terminates payable in substantially equal installments. Upon termination by us of Ms. Caplan's employment without cause (as defined therein) or by Ms. Caplan for any reason following a Change of Control (as defined therein), in addition to any accrued but unpaid base salary and expense reimbursement, she shall be entitled to receive an amount equal to 18 months of one and a half times annual base salary at the highest annualized rate in effect at any time before the employment terminates payable in substantially equal installments.

On May 10, 2017, we and Ms. Caplan further amended the Amended Caplan Employment Agreement pursuant to which Ms. Caplan is 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 provides that beginning in fiscal 2018, subject to approval by the compensation committee, Ms. Caplan is 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. On June 6, 2017 and June 28, 2018 the compensation committee approved a grant of 83,334 and 250,000 stock options, respectively. In October 2018, Ms. Caplan was awarded a further bonus of $200,000 and 85,000 stock options. For additional information, see the Outstanding Equity Awards table above.

The employment agreement also contains restrictive covenants for customary protections of the Company's confidential information and intellectual property.

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. As of December 31, 2019, Eventus and Mr. Reithinger were owed $37,555 and $2,365 respectively for accrued and unpaid services under the financial consulting agreement.

Denis Bedoret

Effective October 24, 2017, our subsidiary, MaSTherCell, entered into a management agreement with BM&C SPRL/BVBA, a Belgian company owned by Denis Bedoret, for certain services to be performed by Dr. Bedoret on an exclusive and full-time basis (the "Bedoret Agreement"). The agreement appoints Dr. Bedoret as General Manager of MaSTherCell, requires him to work 220 days annually and stipulates compensation based on revenue with (i) a daily rate of Euro 800 until such time that MaSTherCell's annual revenue reaches Euro 10 million, (ii) a daily rate of Euro 850 until such time that MaSTherCell's annual revenue reaches Euro 15 million and (iii) a daily rate of Euro 900 until such time that MaSTherCell's annual revenue exceeds Euro 15 million. Dr. Bedoret is also entitled to expense reimbursement and a bonus equivalent to up 15% of the annual fees approved by MaSTherCell's Board of Directors, subject to goals and achievements to be agreed upon by the parties. Dr. Bedoret is also entitled to participation in Orgenesis' equity incentive plan after six months after the effective date. The Bedoret Agreement also contains customary termination clauses.

In May 2018, Dr. Bedoret was awarded 15,000 options. The options shall vest in equal quarterly installments over two years.

On September 5, 2018, Dr. Bedoret was promoted to Managing Director of MaSTherCell. On January 22, 2019, Dr. Bedoret was appointed to President of Masthercell Global.

Darren Head

Darren Head was appointed as President of Masthercell Global on June 28, 2018. He was promoted to the position of CEO of Masthercell Global on January 22, 2019. Mr. Head's employment contract granted him a base salary from 2019 (the "Base Salary") of $250,000 per annum provided, that (i) in the event that the U.S. Subsidiary of the Company has achieved revenue of at least $1,000,000 (but less than $3,000,000) for any trailing twelve (12) month period, then Employee's Base Salary shall thereafter be $325,000 per annum and (ii) in the event that the U.S. Subsidiary of the Company has achieved revenue of at least $3,000,000 for any trailing twelve (12) month period, then Employee's Base Salary shall thereafter be $400,000 per annum. In addition to the Base Salary, Mr. Head received an annual bonus of $150,000 for each calendar year and 44,444 options as per Masthercell Global's option plan.

In September 2018, Darren Head was awarded 20,000 options. The options vested upon grant.

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, 2019.

Name	Salary Continuation	Bonus	Accrued Vacation Pay	Total Value
Vered Caplan	$ *	$ 62,500	$ 144,298	$ 206,798

(*) 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, 2019 certain information concerning his or her compensation for the year ended December 31, 2019 and the December 2018 transition period:

Year Ended December 31, 2019

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	-	104,498(2)	-	-	-	156,998
Yaron Adler	52,500	-	104,498(3)	-	-	-	156,998
Dr. David Sidransky	75,000	-	106,118(4)	-	-	-	181,118
Ashish Nanda	52,500	-	98,556(5)	-	-	-	151,056

Month Ended December 2018 Transition Period

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	4,375	-	12,599	-	-	-	16,974
Yaron Adler	4,375	-	12,599	-	-	-	16,974
Dr. David Sidransky	6,250	-	12,770	-	-	-	19,020
Ashish Nanda	4,375	-	10,254	-	-	-	14,629

(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 16 (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, 2019 was 122,184 of which (i) 109,684 options are exercisable as of December 31,2019 and (ii) 12,500 options are exercisable on December 17, 2020. 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, 2019 was 141,825 of which (i) 129,325 options are exercisable as of December 31,2019 and (ii) 12,500 options are exercisable on December 17, 2020.

(4) Aggregate number of option awards outstanding as of December 31, 2019 was 104,201 of which (i) 91,701 options are exercisable as of December 31,2019 and (ii) 12,500 options are exercisable on December 17, 2020.

(5) Aggregate number of option awards outstanding as of December 31, 2019 was 39,600 of which (i) 27,100 options are exercisable as of December 31,2019 and (ii) 12,500 options are exercisable on December 17, 2020.

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 an 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, 2019.

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, 2020 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, 2020 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 18,361,050 shares of common stock outstanding on March 9, 2020.

Security Ownership of Greater than 5% Beneficial Owners

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership [1]	Percent[1]
Oded Shvartz 130 Biruintei Blvd. Pantelmon Ilfov, Romania	1,830,658	9.07%
Image Securities fzc. 2310, 23rd floor, Tiffany Towers, JLT Dubai, UAE	3,304,497 [2]	15.25%
Yehuda Nir c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	2,311,336 [3]	11.18%
Shutfut-Menayot Chul-Haphoenix Amitim 53 Derech Hashalom Street Givatayim Israel	1,253,132 [4]	6.39%
Sphera Global Healthcare Master Fund 21 Ha'Arba'Ah Street Tel-Aviv Israel	1,213,971 [5]	6.20%

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	1,040,256 [6]	5.36%
Neil Reithinger 14201 N. Hayden Road, Suite A-1 Scottsdale, AZ 85260	92,709 [7]	<1%
Dr. Denis Bedoret c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	13,125 [8]	<1%
Guy Yachin c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	109,684 [9]	<1%
Dr. David Sidransky c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	91,701 [10]	<1%
Yaron Adler c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	192,629 [11]	1.04%

Ashish Nanda c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	27,100 (12)	<1%
Mario Philips c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	- (13)	-
Darren Head c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	20,000 (14)	-
Directors & Executive Officers as a Group (9 persons)	1,587,204	8.64%

Notes:

(1) Percentage of ownership is based on 18,361,050 shares of our common stock outstanding as of March 9, 2020. 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) 1,832,538 ordinary shares and (ii) 1,471,959 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) 153,846 ordinary shares, (ii) 309,464 ordinary shares issuable upon exercise of outstanding warrants at a price of $6.24 per share, exercisable until June 21, 2021, (iii) 153,846 ordinary shares issuable upon exercise of outstanding warrants at a price of $6.24 per share, exercisable until June 9, 2021, (iv) 50,000 ordinary shares issuable upon exercise of outstanding warrants at a price of $7.00 per share. The warrants are exercisable until October 3, 2022, and (v) 1,644,180 ordinary shares issuable upon exercise of convertible debt at a price of $7.00 per share.

(4) Consists of (i) 861,528 ordinary shares and (ii) 391,604 ordinary shares issuable upon exercise of outstanding warrants at a price of $5.50 per share. The warrants are exercisable over a three-year period from the date of issuance.

(5) Consists of (i) 834,605 ordinary shares and (ii) 379,366 ordinary shares issuable upon exercise of outstanding warrants at a price of $5.50 per share. The warrants are exercisable over a three-year period from the date of issuance.

(6) 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) 31,875 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share.

Does not include options for 53,125 shares of common stock with an exercise price of $5.99 per share that are exercisable quarterly after July 22, 2020

(7) Consists of (i) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of $4.80 per share and (ii) 9,375 ordinary shares issuable upon exercise of outstanding options at a price of $5.07 per share. Does not include options for 15,625 shares of common stock with an exercise price of $5.07 per share that are exercisable quarterly after July 1, 2020.

(8) Consists of 13,125 ordinary shares issuable upon exercise of outstanding options at a price of $8.43 per share. Does not include options for 1,875 shares of common stock with an exercise price of $8.43 per share that are exercisable quarterly after June 30, 2010.

(9) 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. Does not include options for 12,500 shares of common stock with an exercise price of $2.99 per share that are exercisable on December 17, 2020 or 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.

(10) 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. Does not include options for 12,500 shares of common stock with an exercise price of $2.99 per share that are exercisable in December 17, 2020.

(11) 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. Does not include options for 12,500 shares of common stock with an exercise price of $2.99 per share that are exercisable on December 17, 2020.

(12) Including 27,100 ordinary shares issuable upon exercise of outstanding options at a price of $5.99 per share. Does not include options for 12,500 shares of common stock with an exercise price of $2.99 per share that are exercisable on December 17, 2020.

(13) Does not include options for 6,250 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, 2021.

(14) Including 20,000 ordinary shares issuable upon exercise of outstanding options at a price of $5.30 per share.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2019:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders [1]	1,275,034	$6.58	1,724,966
Equity compensation plans not approved by security holders	1,788,798	$3.35	316,676
Total	3,063,832	$4.69	2,041,642

[1] Consists of the 2017 Equity Incentive Plan and the Global Share Incentive Plan (2012). For a short description of those plans, see Note 16 to our 2019 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended December 31, 2019.

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

Transactions with Related Persons

Except as set out below, as of December 31, 2019, 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.

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, 2019. The following table sets forth the fees billed to the Company for professional services rendered by PwC for the years ended December 31, 2019 and November 30, 2018, and for the one month transition period ended December 2018:

Services		**2019**	**December 2018**	**2018**
Audit Fees (1)	$	426,040	43,882	365,300
Audit-Related fees (2)		26,900	-	16,475
Tax fees (3)		18,300	-	31,822
Other		49,500	-	-
Total fees	**$**	**520,740**	**43,882**	**413,597**

(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 2019.

(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. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

(1) 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.

(2) 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.

(3) Exhibits required by Regulation S-K

No.	Description
3.1*	Articles of Incorporation (incorporated by reference to an exhibit to our registration statements on Form S-1, filed on April 2, 2009)
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)
3.3	Articles of Merger (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 2, 2011)
3.4	Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 21, 2011)
3.5	Amended and Restated Bylaws (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 21, 2011)
3.6	Certificate of Correction, dated February 27, 2012 (incorporated by reference to an exhibit to our current report on Form 8-K/A, filed on March 16, 2012)
3.7	Certificate of Change Pursuant to Nevada Revised Statutes Section 78.209, as filed by Orgenesis Inc. on November 13, 2017 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 16, 2017)
4.1*	Description of Securities
4.2	Form of Convertible Note convertible into Units, by and between the Company and Investors(incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
4.3	Form of Warrant included in Units, by and between the Company and Investors (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)

No.	Description
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 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)
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)

No.	Description
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)
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 the Company's Current Report on Form 8-K, filed on August 13, 2019)
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

No.	Description
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, 2020

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)
Date: March 9, 2020

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, 2020

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
Date: March 9, 2020

By: */s/ Guy Yachin*
Guy Yachin
Director
Date: March 9, 2020

By: */s/ David Sidransky*
David Sidransky
Director
Date: March 9, 2020

By: */s/ Yaron Adler*
Yaron Adler
Director
Date: March 9, 2020

By: */s/ Ashish Nanda*
Ashish Nanda
Director
Date: March 9, 2020

By: */s/ Mario Philips*
Mario Philips
Director
Date: March 9, 2020

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Orgenesis Inc. and its subsidiaries (the "Company") as of December 31, 2019 and December 31, 2018and the related consolidated statements of comprehensive loss, changes in equity and cash flows for the years ended December 31, 2019 and November 30, 2018 and the one month period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and December 31, 2018, and the results of its operations and its cash flows for the years ended December 31, 2019 and November 30, 2018 and the one month period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

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

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in *Management's Report on Internal Control Over Financial Reporting* appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting 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 the 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 the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

Tel-Aviv, Israel
March 9, 2020

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

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

	December 31,	
	2019	**2018**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 11,388	$ 14,612
Restricted cash	653	387
Accounts receivable, net	8,485	3,226
Prepaid expenses and other receivables	1,227	1,132
GPP receivable, see Note 3	-	6,600
Grants receivable	2,183	441
Inventory	2,043	1,660
Total current assets	25,979	28,058
NON CURRENT ASSETS:		
Deposits	$ 625	$ 143
Loan to related party, see Note 12(e)	2,623	1,012
Property, plants and equipment, net	24,454	12,458
Intangible assets, net	14,206	16,642
Operating lease right-of-use assets	9,585	-
Goodwill	14,941	15,266
Other assets	82	297
Total non-current assets	66,516	45,818
TOTAL ASSETS	$ 92,495	$ 73,876

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

	December 31,	
	2019	**2018**
Liabilities and equity		
CURRENT LIABILITIES:		
Accounts payable	$ 11,305	$ 4,583
Accrued expenses and other payables	1,987	1,499
Employees and related payables	3,719	3,052
Advance payments on account of grant	2,750	1,603
Short-term loans and current maturities of long term loans	763	641
Contract liabilities	8,626	5,175
Current maturities of finance leases	291	226
Current maturities of operating leases	1,722	-
Current maturities of convertible loans	416	382
TOTAL CURRENT LIABILITIES	31,579	17,161
LONG-TERM LIABILITIES:		
Non-current operating leases	$ 7,524	$ -
Loans payable	1,230	1,633
Convertible loans	12,143	1,214
Retirement benefits obligation	41	280
Deferred taxes	1,926	1,656
Long-term finance leases	688	661
Other long term liabilities	331	297
TOTAL LONG-TERM LIABILITIES	23,883	5,741
TOTAL LIABILITIES	55,462	22,902
COMMITMENTS		
REDEEMABLE NON CONTROLLING INTEREST	30,955	24,224
EQUITY:		
Common stock of $0.0001 par value, 145,833,334 shares authorized, 16,140,962 and 15,540,333 shares issued as of December 31, 2019 and December 31, 2018, respectively	2	2
Additional paid-in capital	94,691	90,597
Accumulated other comprehensive income	213	669
Accumulated deficit	(89,429)	(65,163)
Equity attributable to Orgenesis Inc.	5,477	26,105
Non-controlling interests	601	645
TOTAL EQUITY	6,078	26,750
TOTAL LIABILITIES AND EQUITY	$ 92,495	$ 73,876

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

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

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
REVENUES	$ 33,256	$ 18,655	$ 1,852
COST OF REVENUES	18,232	10,824	1,221
COST OF RESEARCH AND DEVELOPMENT AND RESEARCH AND DEVELOPMENT SERVICES, net	12,458	6,464	1,431
AMORTIZATION OF INTANGIBLE ASSETS	2,061	1,913	179
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	25,337	16,303	1,984
OTHER INCOME, net	(228)	(2,930)	-
OPERATING LOSS	24,604	13,919	2,963
FINANCIAL EXPENSES, net	874	3,117	27
SHARE IN LOSSES OF ASSOCIATED COMPANY	-	731	-
LOSS BEFORE INCOME TAXES	25,478	17,767	2,990
TAX EXPENSES (INCOME)	563	1,337	(83)
NET LOSS	$ 26,041	$ 19,104	$ 2,907
NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS (INCLUDING REDEEMABLE)	(1,920)	(813)	(163)
NET LOSS ATTRIBUTABLE TO THE COMPANY	$ 24,121	$ 18 ,291	$ 2,744
LOSS PER SHARE:			
Basic	$ 1.77	$ 1.43	$ 0.19
Diluted	$ 1.77	$ 1.43	$ 0.19
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE:			
Basic	15,907,995	13,374,103	15,423,040
Diluted	15,907,995	13,374,103	15,423,040
COMPREHENSIVE LOSS			
Net loss	$ 26,041	$ 19,104	$ 2,907
Other Comprehensive (income) loss - Translation adjustment	456	1,000	(244)
Comprehensive loss	$ 26,497	$ 20,104	$ 2,663
Comprehensive income attributed to non-controlling interests (including redeemable)	(1,920)	(813)	(163)
COMPREHENSIVE LOSS ATTRIBUTED TO THE COMPANY	$ 24,577	$ 19 ,291	$ 2,500

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)

	Number	Par Value	Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Total
BALANCE AT DECEMBER 1, 2017	9,872,659	$ 1	$ 55,334	$ 1,483	$ 1,425	$ (44,120)	$ 14,123	$ -	$ 14,123
Changes during the Year ended November 30, 2018:									
Stock-based compensation to employees and directors			2,42 6				2,426		2,426
Stock-based compensation to service providers	315,19 8	*	1,938				1,938		1,938
Issuance of shares and warrants due to conversion of convertible loans and shares in escrow account	1,486,722	*	7,511				7,511		7,511
Issuance of shares related to acquisition of Atvio and CureCell	286,811	*	2,452				2,452	299	2,751
Issuance of warrants and Beneficial conversion feature of convertible loans			438				438		438
Issuance of shares and warrants and receipts on account of shares to be allotted	2,853,747	*	18,021	770			18,791		18,791
Issuance of shares due to exercise of warrants	136,646		846				846		846
Adjustment to redemption value of redeemable non-controlling interest			(884)				(884)		(884)
Comprehensive loss for the year					(1,000)	(18,291)	(19,291)		(19,291)
BALANCE AT NOVEMBER 30, 2018	14,951,783	$ 1	$ 88,082	$ 2,253	$ 425	$ (62 ,4 11)	$ 28,350	$ 299	$ 28,649

*Represents an amount lower than $ 1 thousand

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)

	Number	Par Value	Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Total
BALANCE AT DECEMBER 1, 2018	14,951,783	$ 1	$ 88,082	$ 2,253	$ 425	$ (62,411)	$ 28,350	$ 299	$ 28,649
ASC 606 implementation						(8)	(8)		(8)
Balance at December 1, 2018, adjusted	14,951,783	$ 1	$ 88,082	$ 2,253	$ 425	$ (62,419)	$ 28,342	$ 299	$ 28,641
Changes during the one month ended December 31, 2018:									
Stock-based compensation to employees and directors			274				274	355	629
Stock-based compensation to service providers	38,069	*	105				105		105
Beneficial conversion feature of convertible loans and warrants issued			63				63		63
Issuance of shares and warrants and receipts on account of shares to be allotted	550,481	1	2,253	(2,253)			1		1
Adjustment to redemption value of redeemable non-controlling interest			(180)				(180)		(180)
Comprehensive loss for the period					244	(2,744)	(2,500)	(9)	(2,509)
BALANCE AT DECEMBER 31, 2018	15,540,333	$ 2	$ 90,597	$ -	$ 669	$ (65,163)	$ 26,105	$ 645	$ 26,750

*Represents an amount lower than $ 1 thousand

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)

	Number	Par Value	Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Total
BALANCE AT DECEMBER 31, 2018	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, (see note 12)	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 statements.

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

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (26,041)	$ (19 ,104)	$ (2,907)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	3,057	4,364	734
Stock-based compensation for strategic collaborations	2,641	-	-
Gain from sale of property, plants and equipment	(29)	-	-
Share in losses of associated company	-	731	-
Depreciation and amortization expenses	3,806	2,62 4	265
Net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date at fair value	-	(4,509)	-
Change in fair value of warrants and embedded derivatives	-	26	-
Net changes in operating leases	(339)	-	-
Interest expense accrued on loans and convertible loans (including amortization of beneficial conversion feature)	387	2,56 4	12
Changes in operating assets and liabilities:			
Decrease (increase) in accounts receivable, net	(5,308)	(2,901)	951
Decrease (increase) in inventory	(414)	(931)	89
Increase in other assets	(46)	(19)	(3)
Effect of exchange differences on inter-company balances	214	-	-
Decrease (increase) in prepaid expenses, other accounts receivable	(112)	380	(213)
Change in related parties, net	-	(532)	-
Increase (Decrease) in accounts payable	4,626	(796)	743
Increase (decrease) in accrued expenses and other payable	271	428	(421)
Increase (decrease) in employee and related payables	474	(105)	45
Increase (decrease) in contract liabilities	3,536	1,30 9	(181)
Change in advance payments and receivables on account of grant, net	(247)	(193)	(133)
Increase (decrease) in deferred taxes	304	982	(58)
Net cash used in operating activities	$ (13,220)	$ (15,682)	$ (1,077)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Sale of property, plants and equipment	79	-	-
Purchase of property, plants and equipment	(12,129)	(5,556)	(535)
Long-term deposits	(228)	(15)	(57)
Increase in loan to JV with a related party (see Note 12 e)	(1,500)	(1,000)	-
Acquisition of CureCell, net of cash acquired (see Note 4)	-	58	-
Acquisition of Atvio, net of cash acquired (see Note 4)	-	245	-
Net cash used in investing activities	$ (13,778)	$ (6,268)	$ (592)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payment received from redeemable non-controlling interest related to GPP transaction see note 3	13,200	-	-
Proceeds from issuance of shares and warrants (net of transaction costs)	-	17,392	-
Redeemable non-controlling interest	-	14,058	-
Proceeds from receipts on account of shares to be allotted	-	2,252	-
Repayment of short and long-term debt and Finance Leases	(772)	(377)	(53)
Repayment of convertible loans and convertible bonds	-	(177)	-

Proceeds from issuance of convertible loans (net of transaction costs)	11,400	1,912	250
Proceeds from issuance of loans payable	270	-	-
Net cash provided by financing activities	$ 24,098	$ 35,060	$ 197
NET CHANGE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	$ (2,900)	$ 13,110	$ (1,472)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(58)	$ (173)	$ 15
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	$ 14,999	3,519	16,456
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 12,041	$ 16,456	$ 14,999
SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:			
Interest paid in cash during the year	$ 157	$ 134	$ 15
Income taxes, net of refunds paid in cash during the year	$ 156	$ -	$ -
SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES			
Conversion of principal amount and accrued interest of convertible loans and bonds to common stock and warrants	$ -	$ 7,511	$ -
Classification of loan receivable into services to be received from CureCell	$ -	$ 836	$ -
Transaction costs of issuance of convertible loans	$ 546	$ -	$ -
Receivable from GPP	$ -	$ 6,600	$ -
Right-of-use assets obtained in exchange for new operation lease liabilities, net	$ 8,229	$ -	$ -
Purchase of property, plant and equipment included in accounts payable	$ 1,584	$ -	$ -
Finance Leases of property, plant and equipment	$ 355	$ 955	$ -

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

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc., a Nevada corporation (the "Company"), is a biotechnology company specializing in the development, manufacturing and provision of cell and gene therapies ("CGTs") through point-of-care solutions. The Company has historically operated through two independent business platforms: (i) a point-of-care cell therapy ("POC") platform and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform, which provided contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). Through the POC platform, the Company's aim is to further the development of CGTs, including Advanced Therapy Medicinal Products ("ATMPs"), through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. These therapies span a wide range of treatments including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration. The Company out-licenses these ATMPs, thus far primarily through joint venture ("JV") agreements, with regional partners including pharmaceutical and biotech companies as well as research institutions and hospitals. These regional partners have cell therapies in clinical development and are to whom we also provide manufacturing know-how, assay services, licensing, regulatory assistance, pre-clinical studies, intellectual property services, and co-development services (collectively "POC Development Services") to support their activity in order to reach patients in a point-of-care hospital setting. Currently, the Company's POC Development Services constitute the entirety of our revenue from the POC platform. Through the CDMO platform, the Company had focused on providing contract manufacturing and development services for biopharmaceutical companies, and it continues to provide such CDMO, or development, services in Israel and South Korea.

The Company's therapeutic development efforts in its POC business are focused on advancing breakthrough scientific achievements in ATMPs, and namely autologous therapies, which have a curative potential. It bases its development on therapeutic collaborations and in-licensing with other pre-clinical and clinical-stage biopharma companies as well as direct collaboration with research and healthcare institutes. It is engaging in therapeutic collaborations and in-licensing with other academic centers and research centers in order to pursue emerging technologies of other ATMPs in cell and gene therapy in such areas including, but not limited to, cell-based immunotherapies, therapeutics for metabolic diseases, neurodegenerative diseases and tissue regeneration Each of these customers and collaborations represents a growth opportunity and future revenue potential as it out-licenses these ATMPs through regional partners to whom it also provides regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting.

The Company conducted the POC platform through its wholly-owned 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 technology licensing, therapeutic collaborations and preparation for U.S. clinical trials.
- European Union: Orgenesis Belgium SRL (which changed its name and statutory designation in August 2019 from Orgenesis SPRL) (the "Belgian Subsidiary") is the center of activity in Europe currently focused on process development and preparation of European clinical trials.
- Israel: Orgenesis Ltd. (the "Israeli Subsidiary") is a research and technology center, as well as a provider of regulatory, clinical and pre-clinical services.

The CDMO platform operates through (i) majority-owned Masthercell Global (which currently consists 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")), (ii) wholly-owned Atvio Biotech Ltd. in Israel ("Atvio"), and 94.12% owned CureCell Co., Ltd. in South Korea ("CureCell"). Each of these subsidiaries had unique know-how and expertise for manufacturing in a multitude of cell types.

Masthercell Global is a CDMO specialized in cell therapy development for advanced therapeutically products.

During the periods covered by this report, we operated our POC and CDMO businesses as two separate business segments.

These consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries, including the U.S. Subsidiary, the Belgian Subsidiary, the Israeli Subsidiary, Masthercell Global and its subsidiaries, Atvio and CureCell.

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

Until March 13, 2018, the Company's common shares were traded on OTC Market Group's OTCQB, at which point the Company's common stock began to be listed and traded on the Nasdaq Capital Market under the symbol "ORGS."

On February 2, 2020, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with GPP-II Masthercell LLC ("GPP" and together with the Company, 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. These financial statements contain the consolidated results of Masthercell as of and through December 31, 2019.

The Stock Purchase Agreement contains customary representations, warranties, and covenants of the Sellers and the Buyer. From the date of the Stock Purchase Agreement until the closing of the Sale, the Sellers are required to operate Masthercell's business in the ordinary course and to comply with certain covenants regarding the operation of the business. Subject to certain limitations, the Company is required to indemnify the Buyer for losses resulting from breaches of certain representations and warranties made by the Company in the Stock Purchase Agreement.

The Company determined that the Masthercell business met the criteria to be classified as a discontinued operation as of the first quarter of 2020.

b. Change in Fiscal Year End

On October 22, 2018, the Board of Directors of the Company approved a change in the Company's fiscal year end from November 30 to December 31 of each year. This change to the calendar year reporting cycle became effective on January 1, 2019. As a result of the change, the Company is reporting a December 2018 fiscal month transition period, which is separately reported in this Annual Report on Form 10-K for the calendar year ended December 31, 2019.

As permitted under SEC rules, prior-period financial statements have not been recast as management believes the year ended December 31, 2019 provides a meaningful comparison for year ended November 30, 2018 and recasting prior-period results is not practicable or cost justified.

c. Liquidity

As of December 31, 2019, the Company has accumulated losses of approximately $89 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. 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 $9.240 million before deducting related offering expenses. (See note 23).

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 the financial statements. Also, if there are further increases in operating costs in general and administrative expenses 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

a. Use of Estimates in the Preparation of Financial Statements

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the financial statement date and the reported expenses during the reporting periods. Actual results could differ from those 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, 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. Cash Equivalents

The Company considers all short term, highly liquid investments, which include 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, to be cash equivalents.

d. Research and Development, net

Research and development expenses 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 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.

e. 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.

f. 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.

g. 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 CureCell 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 CureCell 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.

h. 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.

i. 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	5-20
Laboratory equipment	5
Office equipment and computers	3-5

j. Intangible assets

Intangible assets and their useful lives are as follows:

	Useful Life (Years)	Amortization Recorded at Comprehensive Loss Line Item
Customer Relationships	3-10	Amortization of intangible assets
Brand	10	Amortization of intangible assets
Know-How	12	Amortization of intangible assets
Backlog	2	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.

k. Goodwill

Goodwill represents the excess of the purchase price of acquired business over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually (at December 31), at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired.

Commencing from January 1, 2019, the Company has early adopted a new guidance which simplifies the test for goodwill impairment. Under the new guidance, the Company may first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company performs a qualitative assessment and concludes that it is more likely than not that the fair value of a reporting unit exceeds its carrying value, goodwill is not considered impaired and the impairment test is not required. However, if the Company concludes otherwise, it is then required to perform a quantitative assessment for goodwill impairment. Under the new guidance, the Company performs its quantitative goodwill impairment test by comparing the fair value of its reporting unit with its carrying value. If the reporting unit's carrying value is determined to be greater than its fair value, an impairment charge is recognized for the amount by which the carrying value exceeds the reporting unit's fair value. If the fair value of the reporting unit is determined to be greater than its carrying amount, the applicable goodwill is not impaired and no further testing is required. The goodwill impairment valuation is considered as significant estimate.

There were no impairment charges in 2019 and 2018 and the month ended December 31, 2018, See note 7 for the Company's goodwill impairment analysis.

l. 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 2019 and 2018 and the month ended December 31, 2018.

m. 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.

n. Stock-based Compensation

The Company accounts for employee stock-based compensation in accordance with the guidance of ASC Topic 718, *Compensation - Stock Compensation*, which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their grant date fair values.

The fair value of the equity instrument is charged to compensation expense and credited to additional paid in capital over the period during which services are rendered. The Company recorded stock based compensation expenses using the straight line method. Forfeitures are recognized as they occur.

The Company adopted the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees.

The Company adopted this guidance effective January 1, 2019, with no material impact on its consolidated financial statements.

o. 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.

p. Loss per Share of Common Stock

Basic net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding for each period. Diluted net loss 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 15).

q. 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, 2019 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.

r. 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 8).

s. Other Comprehensive Loss

Other comprehensive loss represents adjustments of foreign currency translation.

t. Newly issued and recently adopted Accounting Pronouncements

ASC 606 - Revenue from Contracts with Customers

On December 1, 2018, the Company adopted the new accounting standard ASC 606,*Revenue from Contracts with Customers* and the related amendments ("New Revenue Standard") to all contracts, using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was immaterial.

Revenue Recognition Prior to the Adoption of the New Revenue Standard

The Company recognized revenue for services linked to cell process development and cell manufacturing services based on individual contracts in accordance with Accounting Standards Codification ("ASC") 605, Revenue Recognition, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery of the processed cells had occurred or the services that are milestones based had been provided; the price is fixed or determinable and collectability is reasonably assured. The Company determined that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. In addition, the Company determined that services had been delivered in accordance with the arrangement. The Company assessed whether the fee was fixed or determinable based on the payment terms associated with the transaction and whether the sales price was subject to refund or adjustment. Service revenues were recognized as the services were provided. In addition, as part of the services, the Company recognized revenue based on use of consumables, which it received as reimbursement on a cost-plus basis on certain expenses.

Revenue Recognition Following the Adoption of the New Revenue Standard

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.

For the majority of its contracts, the Company receives non-refundable upfront payments. 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 ninety days.

The Company does not disclose the value of unsatisfied performance obligations for contracts with original expected duration of one year or less.

Nature of Revenue Streams

The Company operated through two platforms: (i) a point-of-care cell therapy platform ("POC") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform. Through its CDMO platform, the Company is focused on providing contract manufacturing and development services for biopharmaceutical companies. As of the second quarter of 2019, the Company commenced its POC development services.

The Company has three main revenue streams from its CDMO platform: cell process development services, tech transfer services, and upon success, cell manufacturing services.

Cell Process Development Services

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

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

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).

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 independently or by using competitors of the Company.

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 measures the revenue to be recognized over time on a contract by contract basis as services are provided.

Significant Judgement and Estimates

The cost-based and output methods of revenue recognition require the Company to make estimates of costs to complete its projects and the percentage of completeness on an ongoing basis. Significant judgment is required to evaluate assumptions related to these estimates. The effect of revisions to estimates related to the transaction price (including variable consideration relating to reimbursement on a cost-plus basis on certain expenses) or costs to complete a project are recorded in the period in which the estimate is revised.

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.

Reimbursed Expenses

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

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.

ASU 2018-07 Stock based Compensation

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." This guidance simplifies the accounting for non-employee share-based payment transactions. The amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods and services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606, "Revenue from Contracts with Customers." This standard, adopted as of January 1, 2019, had no material impact on the Company's consolidated financial statements for the year ended December 31, 2019.

ASC 842 - Leases

In February 2016, the FASB issued ASU 2016-02 "Leases" (the "new lease standard"). The guidance establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The guidance became effective on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application.

The Company adopted the new lease standard and all the related amendments on January 1, 2019 and used the effective date as the Company's date of initial application. Consequently, financial information was not updated and the disclosures required under the new standard are not provided for dates and periods before January 1, 2019.

For more information, see Note 10.

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 November 2018, the FASB issued ASU 2018-18 "Collaborative Arrangements (Topic 808)-Clarifying the interaction between Topic 808 and Topic 606." The amendments provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606. It also specifically (i) addresses when the participant should be considered a customer in the context of a unit of account, (ii) adds unit-of-account guidance in ASC 808 to align with guidance in ASC 606 and (iii) precludes presenting revenue from a collaborative arrangement together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer. The guidance will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted and should be applied retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12 "Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes" ("the Update"). The amendments in this Update simplify the accounting for income taxes by removing the following exceptions in ASC 740: (1) exception to the incremental approach for intra-period tax allocation when there is a loss from continuing operations and income or a gain from other items; (2) exception to the requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment; (3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary; and (4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year.

In addition, this Update also simplifies the accounting for income taxes in certain topics as follows: (1) requiring that an entity recognize a franchise tax (or similar tax) that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax; (2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction; (3) specifying that an entity can elect (rather than be required to) allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements; and (4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

NOTE 3 - REDEEMABLE NON CONTROLLING INTEREST

See note 1 regarding the Masthercell sale

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 in the aggregate amount of Euro 5 million (approximately $5.9 million), for approximately 16.7% of MaSTherCell (SFPI received B-shares of MaSTherCell which have the same voting, dividend and other rights as the existing shares of MaSTherCell). The equity investment commitment included the conversion of the outstanding loan and accrued interest of Euro 1.07 million (approximately $1.18 million), previously made by SFPI to MaSTherCell. In November 2017, the initial subscription amount of Euro 2 million ($2.3 million) was paid by SFPI to MaSTherCell. The proceeds from the investment are to be used in accordance with the long-

term business plan that was appended to the SFPI Agreement which includes, without limitation, expanding MaSTherCell's facilities in Belgium with the addition of five new cGMP manufacturing cleanrooms. The agreement contains customary representations, warranties and covenants by MaSTherCell and the Company, in respect of which the Company has undertaken to indemnify SFPI for the consequences of any breach thereof by MaSTherCell or the Company.

Under the Agreement, SFPI has the right to appoint one member to the board of directors of MaSTherCell's five-person board. In addition, the holders of the B-Shares have a right to, along with the Company, appoint an independent director who will serve as the chairman of the board of MaSTherCell for a renewable three-year term. The agreement provides that, under certain specified circumstances, SFPI is entitled to transfer its equity interest in MaSTherCell to the Company at a price equal to the total investment amount, plus a specified annual premium ranging from 10% to 25%, depending on the year following the subscription in which the put is exercised.

Under the terms of the agreement since the Company listed to Nasdaq, SFPI is entitled to convert its MaSTherCell equity interest (using an exchange rate of approximately $0.85), into shares of Common Stock of the Company based upon a conversion price of $6.24, the exercise period of the option is 3 years from the closing date of the SFPI Agreement. The $6.24 conversion price represents the price after the previous stock split of the Company.

Furthermore, under the agreement, the Company had the right to spin-off the CDMO business into a Subsidiary provided that the Subsidiary adhered to the terms of the agreement. In June 2018, the Company effectuated such a spin-off and consolidated the CDMO business into Masthercell Global and Masthercell Global adhered to the terms of this agreement. Also, the Company possesses a drag along right under the Agreement whereby if the Company transfers all or the majority of its shares in MaSTherCell, it can force SFPI to do the same. (See also Note 3(b)).

On June 13, 2018, SFPI paid MaSTherCell the remaining amount of Euro 1.9 million (approximately $2.3 million) to complete its subscription obligations under the agreement.

Due to the embedded redemption feature whose settlement is not at the Company discretion, the Company accounted for the investment made by SFPI as a redeemable non-controlling interest. As of December 31, 2019 and November 30, 2018, the SFPI investment was presented as redeemable non-controlling interest in the balance sheet, in the amount of $6.0 million and $5.8, respectively.

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. In connection therewith, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company ("GPP-II") and an affiliate of GPP entered into 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 a cash consideration to be paid into Masthercell Global of up to $25 million, of which $13.2 million was subject to certain contingencies described below (the "Consideration"). An initial cash payment of $11.8 million of the Consideration was remitted at closing by GPP-II. $1.5 Million of the initial capital contributed to Masthercell Global was used to reimburse the investors for their fees and expenses incurred in conjunction with this transaction (net payment of $10.3 million). Under the terms of the SPA the follow up payments were to be in the amount of $6.6 million to be made in each of years 2018 and 2019 (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 SPA entered into by these parties. Such shareholder approval was obtained on October 23, 2018. Masthercell Global achieved the specified EBITDA and revenue targets in both 2018 and 2019, and the Company received an aggregate of $13.2 million from GPP in 2019.

In connection with the entry into the SPA as described above, each of the Company, Masthercell Global and GPP-II entered into the Masthercell Global Inc. Stockholders' Agreement (the "Stockholders' Agreement") providing for certain restrictions on the disposition of Masthercell Global securities, the provisions of certain options and rights with respect to the management and operations of Masthercell Global, certain rights to GPP-II (including, without limitation, a tag along right, drag along right and certain protective provisions). After the earlier of the second anniversary of the closing or certain enumerated circumstances, GPP-II is entitled to effectuate a spinoff of Masthercell Global and the Masthercell Global Subsidiaries (the "Spinoff").

The Spinoff is required to reflect a market value, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and its Subsidiaries of at least $50 million. In addition, upon certain enumerated events described below, GPP-II is entitled, at its option, to put to the Company (or, at Company's discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global or, alternatively, purchase from the Company its share capital in Masthercell Global at a purchase price equal to the fair market value provided that the purchase price shall not be greater than three times the price per share of Masthercell Global Preferred Stock paid by GPP-II and shall not be less than the price per share of Masthercell Global Preferred Stock paid by GPP-II. GPP-II may exercise its put or call option upon the occurrence of any of the following: (i) there is an Activist Shareholder of the Company; (ii) the Chief Executive Officer and/or Chairman of the board of directors of the Company resigns or is replaced, removed, or terminated for any reason prior to June 28, 2023; (iii) there is a change of control event of the Company as defined in the Stockholders' Agreement; or (iv) the industry expert director appointed to the board of directors of Masthercell Global is removed or replaced (or a new such director is appointed) without the prior written consent of GPP-II. Activist Shareholder shall mean any Person who acquires shares of capital stock of the Company who either: (x) acquires more than a majority of the voting power of the Company, (y) actively takes over and controls a majority of the board of directors of the Company, or (z) is required to file a Schedule 13D with respect to such Person's ownership of the Company and has described a plan, proposal or intent to take action with respect to exerting significant pressure on the management of or directors of, the Company.

The Stockholders' Agreement further provides that GPP-II is entitled, at any time, to convert its share capital in Masthercell Global for the Company's common stock in an amount equal to the lesser of (a)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged, divided by (ii) the average closing price per share of the Company's Common Stock during the thirty day period ending on the date that GPP-II provides the exchange notice (the "Exchange Price") and (b)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged assuming a value of Masthercell Global equal to three and a half (3.5) times the revenue of Masthercell Global during the last twelve (12) complete calendar months immediately prior to the exchange divided by (ii) the Exchange Price; provided, that in no event will (A) the Exchange Price be less than a price per share that would result in Orgenesis Inc. having an enterprise value of less than $250 million and (B) the maximum number of shares of the Company's Common Stock to be issued shall not exceed 2,704,247 shares, unless the Company obtains shareholder approval for the issuance of such greater amount of shares of the Company in accordance with the rules and regulations of the Nasdaq Stock Market.

Great Point and Masthercell Global entered into an advisory services agreement pursuant to which Great Point is to provide management services to Masthercell Global for which Great Point will be compensated at an annual base compensation equal to the greater of (i) $250 thousand per each 12 month period or (ii) 5% of the EBITDA for such 12 month period, payable in arrears in quarterly installments; provided, that these payments will (A) begin to accrue immediately, but shall not be paid in cash to Great Point until such time as Masthercell Global generates EBITDA of at least $2 million for any 12 month period or the sale of or change in control of Masthercell Global, and (B) shall not exceed an aggregate annual amount of $0.5 million. Such compensation accrues but is not owed to Great Point until the earlier of (i) Masthercell Global generating EBITDA of at least $2 million for any 12-month period following the date of the agreement or (ii) a Sale of the Company or Change of Control of the Company (as both terms are defined therein).

GPP and Masthercell Global entered into a transaction services agreement pursuant to which GPP is to provide certain brokerage services to Masthercell Global for which GPP will be entitled to a certain exit fee and transaction fee (as both terms are defined in the agreement), such fees not to be less than 2 percent of the applicable transaction value.

Each of the agreements described above terminated upon the sale of Masthercell Global on February 10, 2020.

Due to the embedded redemption feature whose settlement is not at the Company discretion, the Company accounted for the investment made by GPP as a redeemable non-controlling interest. As of December 31, 2019, the GPP redeemable non-controlling interest was $25 Million.

NOTE 4 - CORPORATE REORGANIZATION OF CURECELL AND ATVIO

Description of the Transactions

Contemporaneous with the execution of the SPA and the Stockholders' Agreement (see Notes 3 and 13), the Company and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which the Company contributed to Masthercell Global assets relating to the CDMO platform including: (i) all of the Company's holdings in Masthercell Global Subsidiaries; (ii) the debt in the total amount of $2.3 million owed to the Company by Atvio and CureCell; (iii) the license agreement between the Company and MaSTherCell dated December 30, 2016; (v) the Joint Venture Agreement with Atvio dated May 10, 2016 (as amended on May 30, 2016); (vi) the SFPI Agreement and (vii) the Joint Venture Agreement between Orgenesis and CureCell dated March 14, 2016 (the "Corporate Reorganization"). See Note 13(b).

In furtherance thereof, Masthercell Global, as the Company assignee, acquired all of the issued and outstanding share capital of Atvio and 94.12% of the share capital of CureCell. The Company exercised the "call option" to which it was entitled under the joint venture agreements with each of these entities to purchase from the former shareholders their equity holding. The consideration for the outstanding share equity in each of Atvio and CureCell consisted solely of the Company Common Stock.

In respect of the acquisition of Atvio, the Company issued to the former Atvio shareholders an aggregate of 83,965 shares of Company's Common Stock. In respect of the acquisition of CureCell, the Company issued the former CureCell shareholders an aggregate of 202,846 shares of the Company Common Stock. The exercise of the call options of CureCell and Atvio, pursuant to which the Company obtained effective control over such entities, was accounted for as a business combination. The results of operations of CureCell and Atvio have been included in the Company's condensed consolidated statements of operations starting from June 28, 2018, the date on which the Company obtained effective control of CureCell and Atvio. Before the closing date Atvio and CureCell were associated companies, see Note 13. The net gain on remeasurement of the previously held equity interest in Atvio and CureCell to acquisition date fair value was $4.5 million.

CureCell

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:

Total assets acquired:		
Cash and cash equivalents	$	58
Property, plants and equipment, net		1,104
Inventory		148
Other assets		300
Other Intangible assets (a)		3,933
Goodwill (b)		3,950
Total assets		9,493
Total liabilities assumed:		
Deferred income from the Company and others		1,945
Deferred taxes		80
Fair value of convertible loan from the Company		892
Non-controlling interests*		299
Other liabilities		1,487
Total liabilities		4,703
Total consideration transferred	$	4,790
Fair value of 36.4% of shared issued *		1,853
Acquisition date fair value of previously held equity interest		2,937
Total consideration transferred	$	4,790

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

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: Customer Relationships of $859 and "Know How" of $3,074. These other intangible assets have a useful life of 10 and 12 years, respectively. The useful life of the other 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.

The fair value of the Know How was estimated using a relief of royalties' approach. Under this method, the fair value of the Know How is equal to the royalty fee that the owner of the Know How could profit from if he was to license the Know How out.

Customer Relationships 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.

Atvio

The total consideration of Atvio of $890 thousand was attributed mainly to goodwill.

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 Atvio and CureCell to Orgenesis Inc in exchange for one dollar ($1.00). The Transfer Agreement also contains agreements made with respect to certain intercompany loans. The Company accounted for the Transfer Agreement as a transaction with non-controlling interest.

NOTE 5 - SEGMENT INFORMATION

The Chief Executive Officer ("CEO") is the Company's chief operating decision-maker ("CODM"). Management has determined that there are two operating segments, based on the Company's organizational structure, its business activities and information reviewed by the CODM for the purposes of allocating resources and assessing performance.

POC Platform

Through the POC platform, the Company is focused on (i) the development of proprietary cell and gene therapies, including its autologous trans-differentiation technology, (ii) therapeutic collaborations and licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes and (iii) regulatory services, pre-clinical studies, intellectual property services, and co-development services ("POC development services"). Currently, the Company's POC development services constitute the entirety of the Company's revenue in the POC platform.

CDMO Platform

The CDMO platform was comprised of a specialization in cell manufacturing and development and includes two types of services to its customers: (i) manufacturing and development services and (ii) current good manufacturing practice ("cGMP") contract manufacturing services. The CDMO platform operated (i) through Masthercell Global, which currently consists of MaSTherCell in Belgium and Masthercell U.S. in the United States, and (ii) through subsidiaries Atvio in Israel and CureCell in South Korea, each having unique know-how and expertise for manufacturing in a multitude of cell types. See Note 23 (d) regarding the Masthercell sale.

The Company does not review assets by segment, therefore the measure of assets has not been disclosed for each segment.

Segment data for the year ended December 31, 2019 is as follows:

	CDMO	POC Business	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 33,312	$ 3,109	$ (3,165)	$ 33,256
Cost of revenues	(19,213)	-	2,076	(17,137)
Cost of research and development and research and development services, net	(470)	(9,145)	1,123	(8,492)
Operating expenses	(15,063)	(7,858)	(34)	(22,955)
Other income	228	-	-	228
Segment operating profit (loss)	$ (1,206)	$ (13,894)	$ -	$ (15,100)
Adjustments to presentation of segment Adjusted EBIT				
Depreciation and amortization	(3,783)	(23)		(3,806)
Segment performance	$ (4,989)	$ (13,917)		$ (18,906)

Reconciliation of segment performance to loss for the year:

	Year ended December 31, 2019
	in thousands
Segment subtotal performance	$ (18,906)
Stock-based compensation	(3,057)
Stock-based compensation to First Choice	(2,641)
Financial expenses, net	(874)
Loss before income tax	$ (25,478)

Segment data for the year ended November 30, 2018 is as follows:

	CDMO	POC Business	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 22,582	$ -	$ (3,927)	$ 18,655
Cost of revenues	(11,541)		1,235	(10,306)
Segment gross profit (loss)	11,041	-	(2,692)	8,349
Research and development expenses, net	(39)	(7 ,931)	2,485	(5,485)
Operating expenses	(6,889)	(6,224)	207	(12,906)
Other expenses	(77)	-		(77)
Segment operating profit (loss)	$ 4,036	$ (14,155)	$ -	$ (10,119)
Adjustments to presentation of segment Adjusted EBIT				
Depreciation and amortization	(2,613)	(11)		(2,624)
Segment performance	$ 1,423	$ (14,166)		$ (12,743)

Reconciliation of segment performance to loss for the year:

	Year ended November 30, 2018
	in thousands
Segment subtotal performance	$ (12,743)
Stock-based compensation	(4,364)
Financial expenses, net	(2,938)
Net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date fair value	4,509
Transaction expenses related to GPP agreement	(1,500)
Share in losses of associated companies	(731)
Loss before income tax	$ (17,767)

Segment data for the one-month transition period ended December 31, 2018 is as follows:

	CDMO	POC Business	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 2,377	$ -	$ (525)	$ 1,852
Cost of revenues	(1,314)	-	167	(1,147)
Segment gross profit (loss)	1,063	-	(358)	705
Research and development expenses, net	(78)	(1,573)	301	(1,350)
Operating expenses	(776)	(600)	57	(1,319)
Other income	-	-		-
Segment operating profit (loss)	$ 209	$ (2,173)	$ -	$ (1,964)
Adjustments to presentation of segment Adjusted EBIT:				
Depreciation and amortization	(264)	(1)		(265)
Segment performance	$ (55)	$ (2,174)		$ (2,229)

Reconciliation of segment performance to loss for the transition period, one-month ended December 31, 2018:

	Transition Period, one-month ended December 31, 2018 (in Thousands)
Segment performance	$ (2,229)
Stock-based compensation	(734)
Financial expenses, net	(27)
Loss before income tax	$ (2,990)

Geographic, Product and Customer Information

Most of the Company's revenues are located in Belgium through its subsidiary, MaSTherCell. Net revenues from single customers from the CDMO segment that exceed 10% of total net revenues are:

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
		(in thousands)	
Customer A	$ -	$ 2,338	$ -
Customer B	$ 8,789	$ 5,236	$ 593
Customer C	$ 3,218	$ 3,002	$ 267
Customer D	$ 3,824	$ 2,242	$ 266
Customer E	$ 3,458	$ -	$ 266
Customer F	$ 3,755	$ 1,372	$ -

The CDMO business has diversified revenues by source signing contracts with biotech companies in their respective cell-based therapy field.

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

	December 31,	
	2019	2018
	(in thousands)	
United States	$ 16,708	$ -
Belgium	$ 14,303	$ 10,313
Korea	$ 1,127	$ 1,062

Israel	$ 1,901	$ 1,083
Total	$ 34,039	$ 12,458

NOTE 6 - PROPERTY, PLANTS AND EQUIPMENT

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

	December 31,	
	2019	2018
	(in thousands)	
Cost:		
Production facility	$ 23,111	$ 12,150
Office furniture and computers	2,296	1,211
Lab equipment	5,661	3,909
Subtotal	31,068	17,270
Less - accumulated depreciation	(6,614)	(4,812)
Total	$ 24,454	$ 12,458

Depreciation expense for the years ended December 31, 2019 and November 30, 2018 were $ 1,745 thousand and $1,096 thousand, respectively. Depreciation expense for the one month ended December 31, 2018 was $86 thousand.

NOTE 7 - INTANGIBLE ASSETS AND GOODWILL

Changes in the carrying amount of the Company's goodwill in our CDMO platform for the years ended December 31, 2019 and 2018 are as follows:

	(in thousands)
Goodwill as of November 30, 2017	$ 10,684
Goodwill acquired	4,918
Translation differences	(437)
Goodwill as of November 30, 2018	15,165
Translation differences	101
Goodwill as of December 31, 2018	$ 15,266
Translation differences	(325)
Goodwill as of December 31, 2019	$ 14,941

Goodwill Impairment

The Company reviews goodwill for impairment annually and whenever events or changes in circumstances indicate the carrying amount of goodwill may not be recoverable. The Company performed a quantitative or qualitative assessment for goodwill impairment for each reporting unit.

Reporting Unit of MaSTherCell' s Goodwill

The Company performed a qualitative assessment based on actual results and future growth as well as Masthercell's position in the market. As a result of this assessment the Company concluded that no impairment charge was required.

Reporting Unit of Atvio's and CureCell's Goodwill

As part of the impairment test, the Company compared the fair value of the reporting unit to its carrying value and determined that the carrying amount of the unit do not exceed its fair value. The Company estimated the fair value of the unit by using an income approach based on discounted cash flows. The assumptions used to estimate the fair value of the Company's reporting unit were based on expected future cash flows and an estimated terminal value using a terminal year growth rate based on the growth prospects for each reporting unit. The Company used an applicable discount rate which reflected the associated specific risks for the reporting unit future cash flows.

CureCell's Goodwill

Key assumptions used to determine the estimated fair value of CureCell include: (a) expected cash flow for the four-year period following the testing date (including market share, sales volumes and prices, costs to produce and estimated capital needs); (b) an estimated terminal value using a terminal year growth rate of 3% determined based on the growth prospects; and (c) a discount rate of 18.9%. Based on the Company's assessment, as of November 30, 2018, December 31, 2018 and December 31, 2019, the carrying amount of its reporting unit does not exceed its fair value and therefore no impairment charge was required.

A decrease in the terminal year growth rate of 1% or an increase of 1% to the discount rate would reduce the fair value of the reporting unit by approximately $336 thousand and $607 thousand, respectively. These changes would result an impairment of approximately $187 thousand and $458 thousand, respectively. A decrease in the terminal year growth rate and an increase in the discount rate of 1% would reduce the fair value of the reporting unit by approximately $894 thousand.

Atvio's Goodwill

Key assumptions used to determine the estimated fair value of Atvio include: (a) expected cash flow for the four-year period following the testing date (including market share, sales volumes and prices, costs to produce and estimated capital needs); (b) an estimated terminal value using a terminal year growth rate of 3% determined based on the growth prospects; and (c) a discount rate of 17.8%. Based on the Company's assessment, as of November 30, 2018, December 31, 2018 and December 31, 2019, the carrying amount of its reporting unit does not exceed its fair value and therefore no impairment charge was required.

A decrease in the terminal year growth rate of 1% or an increase of 1% to the discount rate would reduce the fair value of the reporting unit by approximately $149 thousand and $245 thousand, respectively. These changes would result an impairment of approximately $85 thousand and $181 thousand, respectively. A decrease in the terminal year growth rate and an increase in the discount rate of 1% would reduce the fair value of the reporting unit by approximately $371 thousand.

Other Intangible Assets

Other intangible assets consisted of the following:

	December 31,	December 31,

	2019	2018
	(In thousands)	
Gross Carrying Amount:		
Know How	$ 20,068	$ 20,498
Backlog	-	372
Customer relationships	1,245	1,280
Brand name	1,344	1,370
	22,657	23,520
Accumulated amortization	(8,451)	(6,878)
Net carrying amount of other intangible assets	$ 14,206	$ 16,642

Intangible assets amortization expenses were approximately $2.1 million and $1.9 million for the years ended December 31, 2019 and November 30, 2018, respectively. Amortization expense for the one month ended December 31, 2018 was $179 thousand.

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

	2020	2021 to 2024
	(in thousands)	
Amortization expenses	$ 1,993	$ 7,741

NOTE 8- CONVERTIBLE LOANS

a. Long term convertible loans outstanding as of December 31, 2019 and December 31, 2018 are as follows:

Principal Amount (in thousands)	Issuance Year	Interest Rate	Maturity Period (Years)	Exercise Price	BCF
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 Outstanding as of December 31, 2018					
$ 1,500	2018	2%	3	7.00 (1)	124

Convertible Loans converted during the year ended November 30, 2018

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF	Accumulated Interest Up to Conversion Date (in thousands)	Shares and Warrants Issued Upon Conversion: Shares	Shares and Warrants Issued Upon Conversion: Warrants (6)
220	2018	6%	2	$ 6.24	$ 87	$ 2	35,543	35,543
500 (3)	2018	6%	0.5	6.24	106	4	80,756	80,756
5,050	2017	6%	2	6.24	2,311	235	846,961	846,961
798 (4)	2017	6%	0.5-1.7	6.24	81	40	134,372	34,269
1,388	2016	6%	2	6.24	251	132	243,443	243,443
100	2014	6%/24% (5)	0.5	4.80	85	81	37,662	-
8,056						494	1,378,737	1,240,972

There were no repayments of convertible loans during the fiscal years ended November 30, 2018 and December 31, 2019 and month ended December 31, 2018. In addition, there were no conversions during the fiscal year ended December 31, 2019 and the month one ended December 31, 2018.

(1) The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 219,018 shares and 219,018 three-year warrants to purchase up to an additional 219,018 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, 2019, the loans are presented in long term convertible notes in the balance sheet. See Note 12(f) and 12(g).

(2) The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 1,673,913 shares and 1,110,736 three-year warrants to purchase up to an additional 1,110,736 shares of the Company's common stock at a per share exercise price of $7. See also Notes 14a(2), 14a(3), 14a(5), 14a(6) and 14a(7).

(3) On the issuance date of the note the Company issued to certain investors 40,064 three-year warrants to purchase up to an additional one share of the Company's common stock at a per share exercise price of $6.24.

(4) On the issuance date of the note the Company issued to certain investors 145,509 three-year warrants to purchase up to an additional one share of the Company's common stock at a per share exercise price of $6.24.

(5) The Company failed to reimburse the loan by the maturity date, therefore the interest expenses increase to loan had a default interest of 24% under the terms of the agreement.

(6) The warrant, exercisable for a period of three years from the date of conversion, for an additional share of Common Stock, at a per share exercise price of $6.24.

b. On February 27, 2017, the Company and Admiral Ventures Inc. ("Admiral") entered into an agreement resolving the payment of convertible loan received in prior years and owed to Admiral. Under the terms of the settlement agreement, Admiral extended the maturity date to June 30, 2018. The Company agreed to pay to Admiral, on or before March 1, 2017, between $0.3 million and $1.5 million. Further, beginning April 2017, the Company agreed to make a monthly payment of $125 thousand on account of remaining unpaid balance, and also agreed to remit additional payments under the term of the agreement. The Company accounted for the above changes as a modification of the old debt.

During the year ended November 30, 2017, the Company repaid $1,875 thousand on account of the principal amount and accrued interest. In January 2018, the Company repaid the remaining of accrued interest in total amount of $179 thousand. In 2018 and 2017 the Company was in arrears in its payment obligations under such agreement therefore, the Company issued to Admiral 120,193 units as forbearance fees according to the terms of the agreement. Each unit consisting of one share of the Company's common Stock and one three-year warrant exercisable into an additional share of common stock at a per share exercise price of $6.24. The fair value of the units was recorded as financial expenses during the year ended November 30, 2018 and 2017 in the total amount of $179 and 983 thousand, respectively, out of which $434 thousand reflect the fair value of the warrants using the Black-Scholes valuation model.

c. 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, 2019.

NOTE 9 - LOANS

a. *Terms of Long-term Loans*

		Principal Amount	Grant Year	Interest Rate	Year of Maturity	December 31, 2019	December 31, 2018
		(in thousands)				(in thousands)	
Long-term loan (*)	€	1,400	2012	4.05%	2022	$ 512	$ 692
Long-term loan		1,000	2013	6%-7.5%	2023	776	858
Long-term loan		790	2012-2015	5.5%-6%	2021-2024	314	454
						$ 1,602	$ 2,004
Current portion of loans payable						(372)	(371)
						$ 1,230	$ 1,633

(*) The loan has a business pledge on the Company's assets at the same value.

b. *Terms of Short-term Loans and Current Portion of Long-Term Loans*

	Currency	Interest Rate	December 31, 2019	December 31, 2018
			(in thousands)	
Current portion of loans payable	Euro	4.05%	$ 174	$ 168
Current portion of loans payable	Euro	6%-7.5%	66	70
Current portion of loans payable	Euro	5.5%-6%	132	133
Short term loans	KRW	3.61%	260	270
Short term loans	KRW	6.00%	131	-
			$ 763	$ 641

NOTE 10 - LEASES

As of January 1, 2019, the Company adopted ASU No. 2016-02, "Leases (Topic 842)," which requires leases with durations greater than twelve months to be recognized on the balance sheet. The Company adopted the standard using the modified retrospective approach with an effective date as of the beginning of our fiscal year, January 1, 2019. The total impact of the adoption of this standard at January 1, 2019 is an increase of assets and liabilities in the amount of 2,909 thousand. The weighted average discount rate used in the adoption date was 5.6%. Prior year financial statements were not recast under the new standard and, therefore, those amounts are not presented below. The Company elected the package of transition provisions available for expired or existing contracts, which allowed us to carryforward our historical assessments of (1) whether contracts are or contain leases, (2) lease classification and (3) initial direct costs.

The Company leases research and development facilities, equipment, offices and cars 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 CDMO facilities in Belgium, Israel and the United States under operating lease agreements. The leasing contracts are for a period of 1 - 16 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 years .

Equipment

The Company leases laboratory equipment in Belgium under several finance lease agreements. The equipment is the basic material for our new production center (such as incubator, laminar flow and bio-reactor). Each leasing contract is valid for a term of 5 years .

Offices

The Company leases space for offices in Belgium and Israel under operating leases. The leasing contracts are valid for terms of 1 - 5 years These contracts are considered as operational leasing and under operating lease right-of-use assets.

Cars

The Company leases cars. Each leasing contract is valid for a term of 2 - 4 years . These contracts are considered as operational leasing and 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, 2019
Assets		
Operating Leases		
Operating lease right-of-use assets	$	9,585
Finance Leases		
Property, plants and equipment, gross		1,348
Accumulated depreciation		(247)
Property, plants and equipment, net	$	1,101
Liabilities		
Current liabilities		
Current maturities of operating leases	$	1,722
Current maturities of long-term finance leases	$	291
Long-term liabilities		
Non-current operating leases	$	7,524
Long-term finance leases	$	688
Weighted Average Remaining Lease Term		
Operating leases		10 years
Finance leases		3.5 years
Weighted Average Discount Rate		
Operating leases		5.6%
Finance leases		6.0%

Lease Costs

The table below presents certain information related to lease costs and finance and operating leases during the year ended December 31, 2019.

		Year ended December 31, 2019
Operating lease cost:	$	1,994
Finance lease cost:		
Amortization of leased assets	$	214
Interest on lease liabilities	$	20
Total finance lease cost	$	234

The table below presents supplemental cash flow information related to leases during the year ended December 31, 2019:

	Year ended December 30, 2019
	(in Thousands)
Cash paid for amounts included in the measurement of leases liabilities:	
Operating leases	$ 2,320
Finance leases	$ 267
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases, net	$ 8,229
Finance leases	$ 355

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,		
2020	$ 1,532	$ 314
2021	1,145	252
2022	1,032	233
2023	925	174
2024	773	56
Thereafter	8,310	-
Total minimum lease payments	13,717	1,029
Less: amount of lease payments representing interest	(4,471)	(50)
Present value of future minimum lease payments	9,246	979
Less: Current leases obligations	(1,722)	(291)
Long-term leases obligations	$ 7,524	$ 688

Future minimum lease payments as of November 30, 2018

Future minimum lease commitments under non-cancelable operating lease agreements are as follows:

2019	$ 783
2020	626
2021 and thereafter	3,504
Total	$ 4,913

Future minimum lease payments as of December 31, 2018

No material change in the month ended December 31, 2018.

Lease facilities in the United States

During January 2019, Masthercell U.S. executed a lease agreement for production facilities in the United States. Under the terms of the agreement, Masthercell U.S. leased approximately 32,011 square feet for 180 months. Masthercell U.S. advanced $1.6 million on account of a security deposit, tenant improvement allowance and prepaid base rent.

Lease facilities in Belgium

In March 2019, Masthercell announced plans to establish a new, state-of-the-art production site in the Gosselies Biopark in Belgium, designed to manufacture late-stage and commercially approved cell and gene therapy products. In connection with this announcement, the Company signed a lease agreement for a 61,354 square foot building.

NOTE 11 - COMMITMENTS

See note 12 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 March 20, 2012, MaSTherCell was awarded an investment grant from the DGO6 of Euro 1.2 million. This grant is related to the investment in the production facility with a coverage of 32% of the investment planned. In 2018, the DGO6 transferred the entire amount to MaSTherCell.

(2) 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 founded by the

DGO6. As of December 31, 2019, the Company repaid to the DGO6 a total amount of $57 thousand (Euro 51 thousand) and amount of $124 thousand was recorded in other payables.

(3) ln April 2016, the Company's 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 ($491 thousand). Up through December 31, 2019, an amount of Euro 358 thousand ($402 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.

(4) 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 ($1.8 million). Up through December 31, 2019, an amount of Euro 1.5 million was recorded as deduction of research and development expenses and an amount of Euro 143 thousand was recorded as advance payments on account of grant.

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, 2019, 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 CureCell 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 CureTherapeutics from CureCell. As of December 31, 2019, the Israeli Subsidiary and CureCell received $440 thousand under the grant.

e. *BIRD Secant*

On July 30, 2018, Orgenesis Inc and Atvio 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 Atvio 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, Atvio 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, 2019, Atvio received a total amount of $305 thousand under the grant. Up through December 31, 2019, an amount of $164 thousand was recorded as deduction of research and development expenses and $35 thousand as a receivable on account of grant.

NOTE 12 - 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 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 through any of their respective contract development and manufacturing organization (CDMO) service centers during such term. 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, 2019, 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. *Mircod Limited*

On June 19, 2018, the Company and Mircod Limited, a company formed under the laws of Cyprus ("Mircod") entered into a Collaboration and License Agreement (the "Mircod Collaboration Agreement") for the adaptation of Mircod's background technologies related to biological sensing for use for the Company's clinical development and manufacturing projects (the "Development Project"). The Development Project is to be carried out in accordance with an agreed development plan. Under the Mircod Collaboration Agreement, subject to fulfillment of Mircod's obligations, Company is required to pay Mircod certain amounts in accordance with the agreed upon budget. Under the Mircod Collaboration Agreement, all results of such Development Project ("Project Results") shall be jointly owned by Mircod and the Company. The Company was granted an exclusive, worldwide sub licensable license under Mircod's right in such Project Results to use and commercialize Project Results and a non-exclusive license under Mircod's background technology to the extent required to use and commercialize the Project Results in consideration for a royalty of 5% of net sales (as defined in the Collaboration Agreement) of biological systems of devices incorporating Project Results ("Products"). Upon and subject to completion of the Development Project, Mircod and the Company are to negotiate and enter into a manufacturing and supply agreement under which Mircod is to manufacture and supply Products only to Company and/or its affiliates and, at the Company's request, to provide support and maintenance service for such Products. If, for whatever reason, the parties fail to enter into such manufacturing and supply agreement within 90 days of the completion of the Development Project or if Mircod is unable to perform such services, then: (i) the Company shall be required to pay Mircod a one-time payment of $80,000; (ii) the Company and its affiliates shall have the exclusive right to manufacture the Products; and (iii) and royalties on Net Sales of Products shall be increased to 8% of Net Sales.

In addition, Mircod shall form a wholly owned US subsidiary named Mircod Biotech ("Mircod subsidiary"), and that the Mircod Subsidiary shall perform the duties of Mircod under the Collaboration Agreement, provided that Mircod shall remain responsible for the performance of the Mircod Subsidiary. At any time, the Company shall have the option, at its sole discretion, to transfer and require Mircod or the Mircod Subsidiary to transfer the Project and/or the rights and licenses granted by Mircod to a joint venture company ("JV Entity") which shall be established by the Parties for the purposes of carrying out the Development Project and commercializing the Product, and in which the the Company and Mircod will each hold 50%. The Company shall also have the option to, at its sole discretion and subject to all rules and regulations to which it is then subject, require Mircod to transfer to the the Company the entirety of Mircod's equity interest in the JV Entity for a consideration of shares of common stock of the Company according to an agreed formula. The Parties agreed to amend the development plan to reflect the fact that the Parties shall collaborate with each other on: (i) Point of Care processing, regulatory and therapy development; (ii) setting up one or more point of care processing facilities in institutions or hospitals the territory of Russia; (iii) supply of the Company's products and services within Russia and (iv) clinical, regulatory, development and commercialization in Russia. The Company may, at its sole discretion agree to provide Mircod with a convertible loan (which may be converted into shares of Mircod then outstanding or into the JV Entity, upon a valuation to be agreed between the Parties and validated by a third party subject to terms to be agreed upon by the parties in a separate convertible loan agreement. The convertible loan will be used to finance the modification of the processing facility or facilities including, planning, designing, testing, training and supervising, as required for obtaining cGMP status approval(s) and/or relevant certification for any processing facility and other activities. As at December 31, 2019, the loan agreement was not executed and the JV Entity was not incorporated.

d. *HekaBio K.K*

On July 10, 2018, the Company and HekaBio K.K. ("HB"), a corporation organized under the laws of Japan entered into a Joint Venture Agreement (the "HB JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products (hereinafter the "Products") in Japan (the "Project"). The parties intend to pursue the joint venture through a newly established Japanese company (hereinafter the "JV Company") which the Company by itself, or together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB. HB will fund, at its sole expense, all costs associated with obtaining the requisite regulatory approvals for conducting clinical trials, as well as performing all clinical and other testing required for market authorization of the Products in Japan.

Under the JVA, each party may invest up to $10 million, which may take the form of a loan, if (i) such additional sum is deemed required, as determined by the steering committee or (ii) for a party to maintain its pro-rata interest in the JV Company. The terms of such investment, if any, will be on terms mutually agreeable to the parties, provided that the minimum pre-money valuation for any such investment shall not be less than $10 million. As at December 31, 2019 no investments were made. Additionally, HB was granted an option to affect an equity investment in the Company of up to $15 million within the next 12 months on mutually agreeable terms. If such investment is in fact consummated, the Company agreed to invest in the JV Company by way of a convertible loan an amount equal to HB's pro-rata participating interest in the JV Company, which initially will be at 51%. Such loan may then be converted by the Company into share capital of the JV company at an agreed upon formula for determining JV Company valuation which in no event shall be less than $10 million. Under the JVA, the Company can require HB to sell to the Company its equity) interest in the JV Company in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining JV Company valuation which in no event shall be less than $10 million.

In addition, under the JVA, the Company shall grant the JV Company an exclusive license to certain intellectual property of the Company as may be required for the JV Company to develop and commercialize the Products in Japan. In consideration of such license, the JV Company shall pay the Company, in addition to other payments, royalties at the minimum rate of 10% of the JV Company's net sales of Products.

It was further agreed that the JV Company shall grant the Company (and its affiliates) a non-exclusive, worldwide (other than Japan), royalty-free and fully paid-up license to use and practice, for any purpose, new inventions, discoveries and intellectual property rights that are generated by and/or on behalf of HB and/or the JV Company in connection with the Project.

On October 3, 2018, the Company entered into a License Agreement with the JV Company pursuant to the JVA pertaining to the licenses described above.

Apart from the above, as of December 31, 2019, no activity had begun in the said JV and no investments were made therein.

e. *Image Securities Ltd. (a related party)*

On July 11, 2018, the Company and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Cayman Islands ("India Partner") entered into a Joint Venture Agreement (the "India JVA") pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products in India (the "Cell Therapy Products"). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the Cell Therapy Products.

The India JVA became effective upon the consummation of an equity investment by the India Partner in the Company of $5 million through the purchase of units of the Company securities at a per unit purchase price payable into the Company of $6.24, with each unit comprised of one share of the Company and three-year warrant for the acquisition of an additional common share at a per share exercise price of $6.24. Following the consummation of such equity investment in the Company, on October 18, 2018, the Company entered into a convertible loan agreement with the India Joint Venture company ("India JV") pursuant to which the Company agreed to invest $5 million into the India JV. The loan is convertible into equity capital of the India JV at an agreed upon formula for determining India JV valuation. The investment in the Company by the India Partner was the consummation of the previously disclosed private placement subscription agreement entered into in December 2016 between the Company and an affiliate of the India Partner pursuant to which the closing of such subscription agreement was by the terms thereof delayed until terms comprising the India JV were mutually agreed to. As of December 31, 2019, the Company has advanced $2.5 million to the JV Company under the convertible loan agreement (held under escrow), the loan will bear interest of 6% per annum and the outstanding amount (principal and interest) will be payable after two years. The loan was presented in the balance sheet as loan to related party.

Under the India JVA, the India Partner agreed to invest in the JV $10 million within 12 months of the incorporation of the India JV. If for whatever reason such investment is not made by the India Partner within such time, then the Company is authorized to convert its above-referenced loan into 50% of the equity capital of the India JV on a fully diluted basis, provided that if the pre-money valuation of the India JV is then independently determined to be less than $5 million, then such conversion to be effected on the basis of such valuation. Under the India JVA, the Company can require the India Partner to sell to the Company its entire equity interest in the JV Company in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining JV Company valuation.

Effective January 1, 2019, the Company entered into a master service agreement for the provision of certain POC services. Payments of $1.5 million for these POC services were received during 2019. Total amount of $1,270 thousand was recognized as income during the year ended December 31, 2019. Prior to the establishment of the JV Entity, all activities are being carried out by the India Partner.

Apart from the above, there was no material activity with respect to the Indian JV Entity during the year ended December 31, 2019. See also note 23.

f. *Hemogenyx Pharmaceuticals PLC.*

On October 18, 2018, the Company and Hemogenyx Pharmaceuticals PLC., a corporation with its registered office in the United Kingdom and Hemogenyx-Cell ("H-Cell"), a corporation with its registered office in Belgium (together "Hemo"), who are engaged in the development of cell replacement bone marrow therapy technology, entered into a Collaboration Agreement (the "Hemo Agreement") pursuant to which the parties will collaborate in the funding, continued development, and commercialization of the Hemo technology via Hemo. Pursuant to the Hemo agreement the Company and Hemogenyx LLC ("Hemo-LLC") (a wholly owned US subsidiary of Hemo) entered into a loan agreement on November 7, 2018 according to which the Company agreed to loan Hemo-LLC not less than $1 million by way of a convertible loan. On November 25, 2018 the Company and Hemo entered into a License and Distribution agreement according to which Company received the worldwide rights to market the products under the agreement in consideration for the payment of a 12% royalty all subject to the terms of the agreement. 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 the Company advanced $0.75 million 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.

During 2019, no further transfers were made to Hemo.

See Note 8.

g. *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 the Company advanced $0.75 million 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.

During 2019, no further transfers were made to Immu. See Note 8.

h. *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.

During 2019, the Company was charged $352 for development work by BGN.

i. *Cure Therapeutics*

During 2018, the Company and Cure Therapeutics entered into a collaboration agreement for the development of therapies based on liver and NK cells. The agreement will be governed by a joint steering committee and carried out in accordance with the projects' work plans. Under the plan, each party will generally bear its own share of expenses. For the year ended December 31, 2019, the Company incurred $1.1 million of expenses (2018: $1.5 million) in relation to the project. As part of the agreement, Cure Therapeutics had subcontracted development and contract manufacturing activates to CureCell, for which service revenue of $323 for the year ended December 31, 2019 thousand has been recognized (2018: $1 million).

Effective July 1, 2019, the Company entered into a master service agreement for the provision of certain POC services to Cure Therapeutics in Korea and Japan. $982 Thousand for these POC services were recognized as income during the year ended December 31, 2019.

j. *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, 2019, 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.

k. *Theracell Advanced Biotechnology*

On February 14, 2019, the Company and Theracell Advanced Biotechnology ("Theracell"), a corporation organized under the laws of Greece, entered into a Joint Venture Agreement (the "Greek JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products (hereinafter, the "Company Products") in Greece, Turkey, Cyprus and Balkan countries (the "Territory") and the clinical development and commercialization of Theracell's products (hereinafter, the "Theracell Products") worldwide (the "Project"). The parties intend to pursue the Project through a joint venture ("JV") by forming a JV entity (the "Greek JV Entity"). Until the Greek JV Entity is formed, all JV activities are being carried out by Theracell. The Company by itself, or together with a designee, will hold a 50% participating interest in the Greek JV Entity, with the remaining 50% participating interest being held by Theracell or its affiliate following the parties' contributions to the Greek JV Entity as set forth under the Greek JVA. The Greek JV Entity will have a steering committee that will act as the board of directors of the Greek JV Entity and shall be composed of a total of five members, with two members appointed by each party and one industry expert.

Under the Greek JVA, each party shall be responsible for providing up to $10 million in funding, of which $5 million shall be provided in the form of in-kind contributions. Each party shall also have the right to invest up to an additional $10 million, if such financing is determined to be necessary by the steering committee of the Greek JV Entity or if a party wishes to maintain its pro rata participating interest upon a future financing round in the Greek JV Entity ("Additional Investment"). The terms of such Additional Investment, if any, will be on terms mutually agreeable to the parties, provided that the minimum pre-money valuation for any such Additional Investment shall be at least $20 million. Any Additional Investment by a Party may lead to dilution of the other Party's participating interest unless such other party provides the requisite investment to maintain its participating percentage within two (2) years of such Additional Investment.

Under the Greek JVA, the Company can require Theracell to sell to the Company its entire participating interest in the Greek JV Entity in consideration for the issuance of the Company's Common Stock based on an agreed upon formula for determining the Greek JV Entity's valuation, which shall be the higher of (i) $20 million, (ii) two times the revenues of the Greek JV Entity, (iii) four times the EBITDA of the Greek JV Entity or (iv) the valuation of the Greek JV Entity in its last Additional Investment round. If the parties decide to sell the Greek JV Entity, they will mutually agree upon the terms of such sale.

Under the Greek JVA, the Company shall, subject to fulfilment of Theracell's obligations under the Greek JVA, grant the Greek JV Entity an exclusive license to certain intellectual property of the Company as may be required for the Greek JV Entity to develop and commercialize the Company Products in the Territory. In consideration for such license, the Greek JV Entity shall pay the Company, royalties at the rate of 15% of the Greek JV Entity's net sales of Company Products in the Territory.

In addition, under the Greek JVA, Theracell shall, subject to fulfillment of the Company's obligations under the Greek JVA, grant the Greek JV Entity an exclusive license to certain intellectual property of Theracell as may be required for the Greek JV Entity to develop and commercialize the Theracell Products globally. In consideration of such license, the Greek JV Entity shall pay Theracell, in addition to other payments, royalties at the rate of 15% of the Greek JV Entity's worldwide net sales of Theracell Products.

Any new intellectual property discovered in connection with the development undertaken by the Greek JV Entity shall belong to the Greek JV Entity and such intellectual property will be licensed to the Company on a non-exclusive, worldwide (other than the Territory, as defined in the Greek JVA), royalty free basis.

On February 14, 2019, the Company entered into a master service agreement with Theracell whereby the Company, subject to mutually agreed timing and definition of the scope of services provided regulatory services, pre-clinical studies, intellectual property services, GMP process translation services and co-development services to Theracell during 2019. During the year ended December 31, 2019, the Company recognized POC development service revenue in the amount of $857 thousand.

During 2019 the Company recorded expenses related to activities in the territory in the amount of $698 thousand. Prior to the establishment of the JV Entity, all

activities were being carried out by Theracell.

Apart from the above, there was no material activity under the Greek JVA and the Greek JV had not yet been incorporated.

l. First Choice International Company, Inc.

On March 12, 2019, the Company and First Choice International Company, Inc. ("First Choice"), a corporation organized under the laws of Delaware, entered into a Joint Venture Agreement (the "Panama JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products (hereinafter the "Company Products") in Panama and certain other Latin American countries as agreed by the parties (the "Territory") and the clinical development and commercialization of First Choice's products (hereinafter the "First Choice Products") worldwide (other than in the Territory) (the "Project"). The parties intend to pursue the Project through a joint venture ("Panama JV") by forming a JV entity ("Panama JV Entity"). Until the Panama JV Entity is formed, all Panama JV activities will be carried out by First Choice within the Territory. Upon formation of the Panama JV Entity, the Company by itself, or together with a designee, will hold a 50% participating interest in the Panama JV Entity, with the remaining 50% participating interest being held by First Choice or its affiliate or partner. The Panama JV Entity will have a steering committee that will act as the board of directors of the Panama JV Entity and shall be composed of five members, with two members appointed by each party and one industry expert.

Under the Panama JVA, each party shall endeavor to provide up to $5 million in funding for development, either through investment instruments or in-kind contributions within the first three (3) years of the Panama JV. Each party shall also have the right to invest additional funds in the Panama JV Entity (which such investment(s) may also be in the form of a convertible loan), if such financing is determined to be necessary by the steering committee of the Panama JV Entity or to maintain such Party's pro-rata share of the Panama JV Entity ("Additional Investment").

In order to compensate First Choice for the Panama JV activities that First Choice has already completed prior to the Panama JVA, the Company paid First Choice $100,000. In addition, it issued to First Choice 525,000 shares of Common Stock. These payments and 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 under ASC 730-10-50 and ASC 20-50.

Each of the Company and First Choice shall provide strategic guidance to the Panama JV Entity and the Company shall provide hospital (management) services to the Panama JV Entity, among other POC development services as shall be set forth in a master service agreement to be negotiated in good faith and entered into by the parties.

Under the Panama JVA, the Company can require First Choice to sell to the Company its participating interest in the JV Entity in consideration for the issuance of the Company's Common Stock by dividing an agreed upon Panama JV Entity valuation by the weighted average price of the Company's Common Stock during the three (3) trading day preceding the closing of such sale. The Panama JV Entity valuation will be the higher of (i) two times the revenues of the Panama JV Entity, (ii) four times the EBITDA of the Panama JV Entity or (iii) the valuation of the Panama JV Entity in its last Additional Investment round. If the parties decide to sell the Panama JV Entity, they will mutually agree on the terms of such sale.

Under the Panama JVA, the Company shall, subject to fulfilment of First Choice's obligations under the Panama JVA, grant the Panama JV Entity an exclusive license to certain intellectual property of the Company as may be required for the Panama JV Entity to develop and commercialize the Company Products in the Territory, subject to minimum sales obligations. In consideration of such license, the Panama JV Entity shall pay the Company royalties at the rate of 15% of the Panama JV Entity net sales of Company Products sold in the Territory.

In addition, under the Panama JVA, First Choice shall, subject to fulfilment of the Company's obligations under the Panama JVA, grant the Panama JV Entity an exclusive license to certain intellectual property of First Choice as may be required for the Panama JV Entity to develop and commercialize the First Choice Products globally. In consideration of such license, the Panama JV Entity shall pay First Choice, royalties at the rate of 15% of the Panama JV Entity's worldwide net sales of First Choice Products. Additionally, and for separate consideration to the Company, First Choice shall be granted a limited, non-exclusive license to certain Company owned rights relating to the Human Papilloma Virus.

Any new inventions discovered during the development with respect to the Panama JV shall belong to the Panama JV Entity and will be licensed to the Company on a non-exclusive, worldwide (other than the Territory), royalty free basis.

At the request of either party, the parties shall discuss between them in good faith the terms upon which a party may convert its participating interests in the Panama JV Entity into streaming royalties based on Panama JV Entity's revenues.

Apart from the above, there was no activity in the Panama JVA and the Panama JV had not been incorporated.

m. KinerjaPay Corp.

On May 6, 2019 (the "Effective Date"), the Company and KinerjaPay Corp., a Delaware corporation, entered into a Joint Venture Agreement (the "Singapore JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products in Singapore and the introduction of KinerjaPay products to be offered for sale by the Company globally outside Singapore. The parties intend to pursue the joint venture through a newly established company (hereinafter the "Singapore JV Entity"), which the Company by itself, or together with a designee, will hold a 51% participating interest therein, with the remaining 49% participating interest being held by KinerjaPay Corp.

Under the Singapore JVA, each party shall endeavor to provide the Singapore JV Entity up to $5 million within three (3) years of the Singapore JVA. Funding may be provided in part in the form of convertible loans, in-kind contributions, including intellectual property, and services related to advancement of the Singapore JV Entity. The Company's in-kind contribution may be in the form of 250,000 shares of the Company's restricted stock, issuable to KinerjaPay or KinerjaPay designated third party (instead of to the Singapore JV Entity) on the Effective Date and to be held in escrow by the Company to be released to KinerjaPay in return for services to be provided by KinerjaPay or KinerjaPay designated third party as will be mutually agreed between the parties.

Under the Singapore JVA, the Company can require KinerjaPay to sell to the Company its participating interest in the Singapore JV Entity in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining Singapore JV Entity valuation.

Apart from the above, there was no activity in the Singapore JV Entity and the Singapore JV had not been incorporated.

n. 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.

o. 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.

p. Joint Venture Agreement with SBH Sciences, Inc.

On May 15, 2019, the Company entered into a Joint Venture Agreement with SBH Sciences, Inc., a Massachusetts corporation, ("SBH") for the establishment of a joint venture with SBH to 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 JV Agreement"). Under the terms of the SBH JV Agreement, a joint venture entity shall be formed as an LLC in the State of Delaware, with participating interests equally held by the Company and SBH (the "SBH JV Entity"). The SBH JV Agreement requires that SBH and the Company shall each contribute $250,000 to the SBH JV Entity for the purpose of carrying out the initial development activities relating to (i) a development hub for in vitro assays design, development and optimization of standard operating procedures in order to demonstrate product safety, identity, purity, content and potency for cell-based product quality control, as required by regulatory agencies and (ii) novel therapies/assays in the gene and cell therapy field. In addition to the Company's and SBH's cash contributions to the SBH JV Entity, SBH and the Company shall make an in-kind contribution toward the development activities valued at least $250 thousand (i) SBH to create and manage a certified facility, know-how related to assay development, contribution of a human cell-line bank, the provision of a fully equipped in vitro cell culture lab, and the establishment and training and performance of developed assays and for (ii) the Company to identify potential business development and revenue opportunities, regulation and intellectual property consulting, assay development as required for GMP manufacturing, budget and work planning and control testing. The board of directors of the SBH JV Entity 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.

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, 2019.

q. 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.

r. Broaden Bioscience and Technology Corp

On November 10, 2019, the Maryland Subsidiary and Broaden Bioscience and Technology Corp, a Delaware corporation ("Broaden") entered into a Joint Venture Agreement (the "Broaden JVA") pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products and the setting up of POC processing facilities in China and the Middle East (the "Project").

Under the Broaden JVA, Broaden undertook to set up a Joint Venture company ("Broaden JV Entity") to carry out the Project and until otherwise requested by the Maryland Subsidiary, will hold 100% of its equity. The Maryland Subsidiary has the right, at any time, to request that its shareholding be raised to 49% of the Broaden JV Entity and Broaden will accede to such request. Broaden shall be responsible for providing to the Broaden JV Entity the funding required to complete clinical and regulatory activities, including, pre-clinical and clinical trials as required for obtaining required regulatory approvals and/or reimbursement approval for commercialization of the Company's products and commercialization of Broaden products globally and for any and additional activities as may be defined in any work plans agreed upon, including without limitation, regulatory and management expenses. Orgenesis shall be responsible for providing to the Broaden JV Entity the funding required to complete the modification of the relevant POC facilities including, planning, designing, remodeling, testing, training and supervising, as required for obtaining cGMP status approval(s) and/or relevant certification.

Prior to and as a condition to the financing of the Broaden JV Entity by the Maryland Subsidiary and/or Broaden, the evaluation of the Broaden JV Entity will be agreed upon by the parties. The financing may be in the form of an equity financing, convertible debt or and other form agreed by the Parties

If required in order to maintain the activity of the Broaden JV Entity (as determined by the steering committee) or to maintain a Party's participating inserts in the Broaden JV Entity, each Party shall have the right, to invest additional sums in the JV Entity in an aggregate amount of up to ten million US Dollars each, of which five million may be provided in the form of in-kind contributions, and such investments may also be in the form of a convertible loan. See note 24.

At any time the Maryland Subsidiary shall have the option to require that Broaden transfer to the Maryland Subsidiary the entirety of Broaden's equity interest in the JV Entity inconsideration of such number of shares of common stock of the Company to be calculated by dividing: (A) (i) the number of Broaden JV Entity's outstanding and issued shares being purchased from the Broaden expressed as a percentage of the then total outstanding equity interest of Broaden JV Entity that Broaden holds, multiplied by (ii) the Call Valuation (where "Call Valuation" is defined as the JV Entity Valuation in addition to any other financing invested by the Parties, immediately prior to the closing of the Sale Transaction), by (B) the weighted average price of the Company's common stock during the three (3) trading day preceding the closing of the Sale Transaction. The "Broaden JV Entity Valuation" will be defined as the higher of the following: (i) the latest Additional Investment round valuation as defined in Section 3.1 above; or (ii) an amount equal to two (2) times the revenues of the Broaden JV Entity (if applicable); or (iii) an amount equal to four (4) times the EBIDA of the Broaden JV Entity.

The Broaden JV Entity shall be governed by a steering committee which shall also serve as its Board of Directors of the JV Entity. The Steering Committee shall be composed of a total of five members with each Party having the right to appoint and replace two members and one member shall be an independent industry expert whose appointment requires the joint consent of both Parties.

Under the Broaden JVA, and subject to the entering into a separate license agreement between the Maryland Subsidiary and the JV Entity ("ORGS License"), the Maryland Subsidiary shall grant the JV Entity a non-exclusive license to certain intellectual property of the Maryland Subsidiary as may be required for the JV Entity to develop and commercialize the Maryland Subsidiary's products solely within the China, Middle East and other POC processing facilities which may be agreed upon by the Parties ("Facility"). In consideration for such license, the JV Entity shall pay the Maryland Subsidiary royalties at the rate of 10% net sales generated by the JV Entity's and/or its sublicensees with respect to providing treatment to patients within treatment facilities where such treatment utilizes the Maryland Subsidiary's Products. Broaden shall grant the JV Entity an exclusive license to certain intellectual property of Broaden ("Broaden Background IP") as may be required for the JV Entity to develop and commercialize the Broaden products globally (not including China). In consideration for such license, the JV Entity shall pay Broaden royalties at the rate of 10% of the JV Entity's or its sublicensees' net sales with respect to providing treatment to patients within treatment facilities where such treatment utilizes' Broaden products.

It was further agreed that as part of and as a condition to the ORGS Licenses, the JV Entity will grant the Maryland Subsidiary and its affiliates an: (i) exclusive, perpetual, irrevocable, worldwide, sublicensable license to make use of new intellectual property generated, conceived, developed and/or reduced to practice by and/or on behalf of Broaden and/or the Broaden JV Entity (as applicable), alone or together with others, resulting from the performance of the Project ("Project IP") for any and all lawful purposes (outside of the Facility), including without limitation, for their respective worldwide operations; and (ii) an exclusive, worldwide (not including China), sublicensable, sublicense under its rights in the Broaden Background IP, to develop and commercialize the Broaden products globally (not including China) during the term of the Broaden JVA, in consideration for the payment by the Maryland Subsidiary to the Broaden JV Entity of royalties in a minimum amount equal to fifteen percent (15%) of the net sales generated by the Maryland Subsidiary and/or its sublicensees with respect to providing treatment to patients within treatment facilities where such treatment utilizes Project IP and/or Broaden Products.

The Broaden JV Entity reserves the non-exclusive right to use the Project IP to the extent required in order to develop and commercialize ORGS Products within the Facility.

Apart from the above, as of December 31, 2019, no activity had begun in the said JV and no investments were made therein and the JV had not been incorporated.

s. 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.

t. 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.

NOTE 13 - INVESTMENTS IN ASSOCIATES, NET

a. On May 10, 2016, the Company and Atvio entered into joint venture agreement, pursuant to which the parties agreed to collaborate in the field of the CDMO in Israel (the "Atvio JVA"). The parties pursued the joint venture through Atvio, the Company had 50% participating interest therein in any and all rights and obligations and in any and all profits and losses. Atvio's operations commenced in September 2016. On June 28, 2018, the Company exercised its call options in Atvio. See also Note 4.

b. On March 14, 2016, Orgenesis Inc. and CureCell entered into a joint venture agreement (the "CureCell JVA"), pursuant to which the parties are collaborating in the field of the CDMO in Korea.

Under the CureCell JVA, CureCell had procured, at its sole expense, a GMP facility and appropriate staff in Korea for the manufacture of the cell therapy products. The Company had to share with CureCell the Company's know-how in the field of cell therapy manufacturing All obligations were fulfilled by the parties and each party had 50% from the participating interest and in any and all profits and losses of the joint venture. The Company remitted to CureCell $2.1 million under the terms of the CureCell JVA. On June 28, 2018, the Company exercised its call options in CureCell. See also Note 4.

c. The table below sets forth a summary of the changes in the investments for the year ended November 30, 2018:

	November 30, 2018

	(In thousands)
Opening balance	$ 1,321
Reclass with short-term receivables	(795)
Investments during the period	-
Share in losses	(731)
Reductions due to the acquisition of CureCell and Atvio - see also Note 4	205
	$ -

NOTE 14 - EQUITY

a. *Financings*

(1) In January 2017, the Company entered into definitive agreements with an institutional investor 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. Each unit is comprised of one share of the Company's Common Stock and a one warrant, exercisable over a three-years period from the date of issuance, to purchase one additional share of Common Stock at a per share exercise price of $6.24 ("Unit"). The subscription proceeds were paid to the Company on a periodic basis through October 2018.

In July 2018, the Company entered into definitive agreements with assignees of the aforementioned institutional investor whereby these assignees remitted $4.6 million in respect of the units available under the original subscription agreement that were 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 the year ended November 30, 2018 the investor remitted to the Company $6.9 million and the Company issued 1,111,380 units.

In connection therewith, during the year ended November 30, 2018 and 2017, the Company had transaction costs of approximately $328 and $225 thousand, respectively, out of which $121 and $253 thousand are stock-based compensation expenses due to issuance of warrants and shares.

(2) 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. See also note 23.

(3) 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.

(4) 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.

(5) 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.

(6) 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 $3.650 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, See also Note 23.

(7) 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. As of December 31, 2019, $36 thousands were offset against the convertible loan amount. No costs were recognized during the year ended December 31, 2019

(8) 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.

b. *Warrants*

A summary of the Company's warrants granted to investors and as finder's fees as of December 31, 2019, November 30, 2018 and December 31, 2018 and changes for the periods then ended is presented below:

	December 31, 2019		November 30, 2018		December 31, 2018 ***	
	Number of Warrants	Weighted Average Exercise Price $	Number of Warrants	Weighted Average Exercise Price $	Number of Warrants	Weighted Average Exercise Price $
Warrants outstanding at the beginning of the period	6,286,351	6.29	2,609,864	6.26	6,512,991	6.27
Changes during the period:						
Issued	471,980	6.95	4,488,854	6.27	2,858	7.00
Exercised	-	-	(136,646)	6.24	-	-
Expired	(748,244)	6.24	(382,414)	6.10	(229,498)	6.24
Cancelled**	-	-	(66,667)	6.24	-	-
Warrants outstanding and exercisable at end of the period*	6,010,087	6.35	6,512,991	6.27	6,286,351	6.29

* As of December 31, 2018, and November 30, 2018, 542,465 and 769,411 warrants respectively, are subject to exercise price adjustments. As of December 31, 2019, there are no warrants that are subject to exercise price adjustments.

** see also Note 16(d).

*** For the month ended December 31, 2018

NOTE 15 - LOSS PER SHARE

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

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands, except per share data)		
Basic:			
Net loss attributable to Orgenesis Inc.	24,121	18,291	2,744
Adjustment of redeemable non-controlling interest to redemption amount	4,095	884	180
Net loss attributable to Orgenesis Inc. for loss per share	28,216	19,175	2,924
Weighted average number of common shares outstanding	15,907,995	13,374,103	15,423,040
Basic loss per common share	1.77	1.43	0.19
Diluted:			
Net loss attributable to Orgenesis Inc. for loss per share	28,216	19,175	2,924
Loss for the year	28,216	19,175	2,924
Weighted average number of shares used in the computation of basic loss per share	15,907,995	13,374,103	15,423,040
Weighted average number of common shares outstanding	15,907,995	13,374,103	15,423,040
Diluted loss per common share	1.77	1.43	0.19

For the year ended December 31, 2019, November 30, 2018 and for the one month ended December 31, 2018, 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 8,531,547 shares underlying outstanding options and warrants and 970,104 shares upon conversion of convertible loans for the year ended December 31, 2019, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 16- 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, 2019, 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, 2019, 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, 2019, and November 30, 2018 and for the one month ended December 31, 2018:

	Year Ended	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Employees	December 2019	94,500	$3.14-$5.07	Quarterly over a period of two years	$322	10 years
Directors	December 2019	50,000	$2.99	One-year anniversary	$103	10 years
Employees	November 2018	762,400	$4.42-$8.91	Immediately-4 years	$4,233	10 years
Directors	November 2018	113,800	$5.99	One-year anniversary	$507	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		One month ended
	December 31, 2019	November 30, 2018	December 2018
Value of one common share	$2.99-$5.07	$4.42-$8.7	-
Dividend yield	0%	0%	-
Expected stock price volatility	83%-88%	88%-98%	-
Risk free interest rate	1.45%-2.47%	2.33%-3.2%	-
Expected term (years)	5.38-5.56	5-6.06	-

A summary of the Company's stock options granted to employees and directors as of December 31, 2019 and November 30, 2018 and changes for the years then ended and the one-month ended December 31, 2018 is presented below:

	Year Ended December 2019		Year Ended November 2018		One month ended December 31, 2018	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the period	2,376,427	4.51	1,605,055	3.11	2,376,427	4.51
Changes during the period:						
Granted	144,500	4.15	876,200	7.13	-	-
Expired	(16,750)	6.01	(61,463)	5.26	-	-
Forfeited	(38,655)	7.11	(43,365)	4.68	-	-
Options outstanding at end of the period	2,465,522	4.44	2,376,427	4.51	2,376,427	4.51
Options exercisable at end of the period	2,112,567	4.21	1,504,542	2.91	1,716,042	3.56

The following table presents summary information concerning the options granted and exercisable to employees and directors outstanding as of December 31, 2019:

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	4.65	1,072	230,189	-
0.012	510,017	2.09	2,371	510,017	6
2.99	50,000	9.97	84	-	-
3.14	5,000	9.91	8	-	-
4.42	50,000	7.94	12	50,000	221
4.5	34,000	9.47	5	6,938	31
4.8	525,004	6.41	-	510,420	2,450
5.07	54,188	9.16	-	13,524	69
5.99	363,426	8.32	-	224,319	1,344
6	16,667	4.59	-	16,667	100
7.2	83,334	7.44	-	83,334	600
8.36	250,001	8.50	-	250,001	2,090
8.43	151,937	8.25	-	83,025	700
8.91	22,750	5.79	-	15,125	135
9	20,834	3.54	-	20,834	187
9.48	58,908	2.52	-	58,908	558
10.2	39,267	2.43	-	39,267	401
	2,465,522	6.01	3,552	2,112,567	8,892

Costs incurred with respect to stock-based compensation for employees and directors for the years ended December 31, 2019 and November 30, 2018 were $ 2,107 thousand and $2,426 thousand respectively. Costs incurred with respect to options granted to employees for the one month ended December 31, 2018 was $274 thousand. As of December 31, 2019, there was $ 1,415 thousands of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 2.81 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, 2019 and November 30, 2018 and for the one-month period ended December 31, 2018:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employees	2019	128,336	$3.14-$7	Vest immediately-5 years	$394	10 years
Non-employees	2018	102,763	$4.42-$8.34	vest immediately-4 years	$444	10 years

The fair value of options granted during 2019 and 2018 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		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
Value of one common share	$3.14-$5.07	$4.42-$8.34	-
Dividend yield	0%	0%	-
Expected stock price volatility	89%-92%	91%-95%	-
Risk free interest rate	1.52%-2.62%	2.33%-3.20%	-
Expected term (years)	10	9.79-10	-

A summary of the Company's stock options granted to consultants and service providers as of December 31, 2019, and November 30, 2018 and changes for the years then ended and the one-month ended December 31, 2018 is presented below:

	2019		2018		One month ended December 31, 2018	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	469,974	5.75	399,380	7.47	469,974	5.75
Changes during the year:						
Granted	128,336	5.65	102,763	4.92	-	-
Forfeited	-	-	(15,500)	-	-	-
Cancelled	-	-	(16,669)	7.02	-	-
Options outstanding at end of the year	598,310	5.76	469,974	5.75	469,974	5.75
Options exercisable at end of the year	539,515	5.88	436,640	5.75	438,514	5.75

The following table presents summary information concerning the options granted and exercisable to consultants and service providers outstanding as of December 31, 2019 (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)
3.14	15,000	9.91	23	-	-
3.36	136,775	6.33	179	136,775	460
3.6	83,334	6.17	88	83,334	300
4.09	25,000	9.76	14	12,500	51
4.42	10,325	7.94	2	10,325	46
4.5	13,335	9.53	2	-	-
4.8	16,668	6.95	-	16,668	80
5.07	5,000	9.19	-	1,000	5
5.3	35,000	8.71	-	29,375	156
5.99	25,005	8.82	-	21,671	130
6	90,000	4.59	-	90,000	540
7	70,000	9.83	-	70,000	490
7.32	8,334	2.89	-	8,334	61
8.34	8,600	8.52	-	8,600	72
8.43	8,333	8.05	-	3,332	28
11.52	8,334	3.26	-	8,334	96
16.8	39,267	2.29	-	39,267	660
	598,310	6.77	308	539,515	3,175

Costs incurred with respect to options granted to consultants and service providers for the years ended December 31, 2019 and November 30, 2018 were $ 330 thousand and $331 thousand respectively.

Offsetting costs incurred with respect to options granted to consultants and service providers for the one month ended December 31, 2018 were $2 thousand. As of December 31, 2019, there was $ 137 thousands of unrecognized compensation costs related to non-vested consultants and service providers, to be recorded over the next 5.59 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) 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.

2) 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 $165 thousand using the fair value of the shares on the grant date. $82 thousand was recognized during the year ended December 31, 2019.

3) 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. (See note 12 to Item 8 of this Form 10K for further details).

4) 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 31, 2019.

5) 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.

6) 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.

7) 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.

8) 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.

NOTE 17 - 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, 2019, the Company has an accumulated tax loss carryforward of approximately $37 million (as of December 31, 2018, approximately $19 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 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.

b. *Corporate taxation in Israel*

The Israeli Subsidiaries are taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2019 and 2018 are 23%.

As of December 31, 2019, the Israeli Subsidiaries has an accumulated tax loss carryforward of approximately $10 million (as of December 31, 2018, approximately $7 million). Under the Israeli tax laws, carryforward tax losses have no expiration date.

c. *Corporate taxation in Belgium*

The majority of the Company’s tax expense are as a result of Masthercell SA’s operations. The Belgian Subsidiaries are taxed according to Belgian tax laws. The corporate tax rate applicable to 2020, 2019-2018 are 25% and 29.58%.

As of December 31, 2019, the Belgian Subsidiaries has an accumulated tax loss carryforward of approximately $7 million (€6 million), (as of December 31, 2018 $9 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, 2019, CureCell has an accumulated tax loss carryforward of approximately $3 million (KRW 3,486 million), (as of December 31, 2018, approximately $3 million).

e. *Deferred Taxes*

The following table presents summary of information concerning the Company's deferred taxes as of the periods ending December 31, 2019 and December 31, 2018 (in thousands):

	December 31, 2019	December 31, 2018
	(U.S. dollars in thousands)	
Net operating loss carry forwards	$ 14,807	$ 9,765
Research and development expenses	2,172	3,065
Employee benefits	314	181
Property, plants and equipment	(36)	(51)
Loans	-	(117)
Contract liabilities	(104)	(118)
Intangible assets	(3,452)	(4,115)
Other	11	-
Less: Valuation allowance	(15,638)	(10,266)
Net deferred tax liabilities	$ (1,926)	$ (1,656)

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 MaSTherCell and CureCell have recorded full valuation allowance.

The changes in valuation allowance are comprised as follows:

	Year Ended December 31, 2019	Year Ended November 30, 2018	Transition Period, One-month Ended December 31, 2018
	(U.S dollars in thousands)		
Balance at the beginning of year	$ (10,266)	$ (8,358)	$ (9,235)
Additions during the year	(5,372)	(877)	(1,031)
Balance at end of year	$ (15,638)	$ (9,235)	$ (10,266)

f. *Reconciliation of the Theoretical Tax Expense to Actual Tax Expense*

The main reconciling items 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 and changes in cooperate tax rate in the U.S and Belgium.

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, 2019, the Company has not accrued a provision for uncertain tax positions.

NOTE 18 - REVENUES

Disaggregation of Revenue

The following table disaggregates the Company's revenues by major revenue streams.

	Year Ended December 31, 2019	Transition Period, One-Month Ended December 31, 2018
Revenue stream:		
Cell process development services	$ 19,928	$ 1,488
Tech transfer services	5,396	364
POC development services	3,109	-
Cell manufacturing services	4,823	-
Total	$ 33,256	$ 1,852

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, 2019	Transition Period, One-month Ended December 31, 2018
Balance as of beginning of period	$ 3,226	$ 4,151
Additions	26,148	1,612
Collections	(20,803)	(2,561)
Exchange rate differences	(86)	24
Balance as of end of period	$ 8,485	$ 3,226

The activity for contract liabilities is comprised of:

	Year Ended December 31, 2019	Transition Period, One-month ended December 31, 2018
Balance as of beginning of period	$ 5,175	$ 5,317
Adoption of ASC 606:	-	(8)
Additions	9,850	28
Realizations*	(6,307)	(251)
Exchange rate differences	(92)	89
Balance as of end of period	$ 8,626	$ 5,175

* Out of which $4,897 thousand and $251 thousand were realized from the beginning of the period for the year ended December 31, 2019 and for the one-month ended December 31, 2018 respectively.

NOTE 19 - COST OF RESEARCH AND DEVELOPMENT AND RESEARCH AND DEVELOPMENT SERVICES, NET

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands)		
Total expenses	$ 13,432	$ 7 ,386	$ 1,558
Less grants	(974)	(922)	(127)
Total	$ 12,458	$ 6 ,464	$ 1,431

NOTE 20- FINANCIAL EXPENSES, NET

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands)		
Increase in fair value of warrants and financial liabilities measured at fair value	$ 63	$ 48	$ -

Stock-based compensation related to warrants granted due to issuance of credit facility	-	180	-
Interest expense on convertible loans	657	2,753	40
Foreign exchange loss (income), net	350	129	(5)
Other expenses (income)	(196)	7	(8)
Total	$ 874	$ 3,117	$ 27

NOTE 21- RELATED PARTIES TRANSACTIONS

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

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands)		
Stock-based compensation expenses to executive officers	$ 974	$ 1,479	$ 506
Stock-based compensation expenses to Board Members*	$ 414	$ 304	$ 48
Compensation of executive officers	$ 1,497	$ 1,119	$ 527
Management and consulting fees to Board Members	$ 233	$ 52	$ 19
Interest expenses on convertible loan from director	$ -	$ 13	$ -

* Does not include $192 thousand 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.

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

	Year ended		One month ended
	December 31, 2019	November 30, 2018	December 31, 2018
	(in thousands)		
Executive officers' payables	$ 1,329	$ 1,164	$ 984
Non-executive directors payable	$ 202	$ 41	$ 46
Loan to Related Party. See Note 12(e)*	$ 2,623	$ 1,007	$ 1,012

*This includes finance income in the amount of $123 thousand for the year ended December 31, 2019.

NOTE 22 - TRANSITION PERIOD

Comparable Financial Information

In conjunction with the Company's change in fiscal year end, the Company had a Transition Period of one month that began on December 1, 2018 and ended on December 31, 2018. The most comparable prior-year period, is the one month ended December 31, 2017.

The following table presents certain financial information during the periods presented:

	Transition Period December 1 to December 31, 2018	Comparable Period December 1 to December 31, 2017 (Unaudited)
Total revenue	1,852	802
Operating loss	(2,963)	(1,349)
Income tax benefit	(83)	(132)
Net loss	(2,907)	(2,056)
Net loss per weighted-average share, basic	(0.19)	(0.20)
Net loss per weighted-average share, diluted	(0.19)	(0.20)
Weighted-average shares, basic	15,423,040	10,367,472
Weighted-average shares, diluted	15,423,040	10,367,472

NOTE 23 - SUBSEQUENT EVENTS

a. On January 2, 2020, the Company entered into private placement subscription agreements with investors for an aggregate amount of $250 thousand. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of 1 share of common stock of the Company at a conversion price per share equal to $7.00. In addition, the Company granted lender 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.

b. On January 9, 2020, the Company granted 6,250 options to a director to purchase an equal number of additional shares of the Company's common stock at a price of $4.70 per share.

c. On January 20, 2020, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors pursuant to which the Company issued and sold, in a private placement (the "Offering"), 2,200,000 shares of the Company's 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 $9.240 million before deducting related offering expenses. The Company has agreed to register the resale of the Shares and the shares of common stock underlying the Warrants.

d. See note 1 regarding the Masthercell sale.

e. During January 2020, the Maryland Subsidiary and Broaden Bioscience and Technology Corp entered into a convertible loan agreement according to which Company agreed to lend Broaden Bioscience and Technology Corp an amount of up to $5 million as convertible loan as part of Company's investment in the Broaden JVA (see Note 12).

f. During January 2020 the Company transferred $500 thousand to Image Securities Ltd (a related party) as an additional payment under the convertible loan agreement (held under escrow).

g. During February 2020 the company repaid the convertible loan referred to in note 14 (a) 2 in the amount of $500 thousand.

h. During March 2020 the company repaid a convertible loan referred to in note 14 (a) 6 in the amount of $1.15 million.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 9, 2020, Orgenesis Inc. ("Orgenesis," "we," "us" or the "Company") had one class of securities registered under Section 12(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): Common Stock, $0.0001 par value per share ("Common Stock"). Each of the Company's securities registered under Section 12(b) of the Exchange Act are listed on The Nasdaq Capital Market.

General

As of the date of this Annual Report on Form 10-K, our authorized capital stock consists of 145,833,334 shares of common stock, $0.0001 par value per share. As of March 9, 2020, there were 18,361,050 shares of our common stock outstanding.

In addition, as of the date of this Annual Report on Form 10-K, we had issued and outstanding:

- options to purchase 2,200,000 shares of our common stock, at a weighted average exercise price of $4.20 per share; and
- warrants to purchase 1,327,428 shares of our common stock, at a weighted average exercise price of $5.65 per share.

The following summary description of our capital stock is based on the provisions of our certificate of incorporation and bylaws, the applicable provisions of the Nevada Revised Business Corporations Act, and the agreements described below. This information may not be complete in all respects and is qualified entirely by reference to the provisions of our certificate of incorporation and bylaws, Nevada law and such agreements.

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the stockholders including the election of directors. Except as otherwise required by law the holders of our common stock possess all voting power. According to our bylaws, when a quorum is present or represented at any meeting, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy shall be sufficient to elect members of the Board of Directors or to decide any question brought before such meeting, unless the question is one upon which by express provision of the statutes or of the Articles of Incorporation, a different vote is required in which case such express provision shall govern and control the decision of such question.. Our bylaws provide that stockholders holding at least 33.3% of the shares entitled to vote, represented in person or by proxy, constitute a quorum at the meeting of our stockholders. Our bylaws also provide that any action which may be taken by the vote of the stockholders at a meeting may be taken without a meeting if authorized by the written consent of stockholders holding at least a majority of the voting power, unless the provisions of the statutes or of the Articles of Incorporation require a greater proportion of voting power to authorize such action in which case such greater proportion of written consents shall be required.

Our articles of incorporation and bylaws do not provide for cumulative voting in the election of directors. Because the holders of our common stock do not have cumulative voting rights and directors are generally to be elected by a majority of the votes casts with respect to the directors at any meeting of our stockholders for the election of directors, holders of more than fifty percent, and in some cases less than 50%, of the issued and outstanding shares of our common stock can elect all of our directors.

Dividend Rights

The holders of our common stock are entitled to receive such dividends as may be declared by our board of directors out of funds legally available for dividends. Our board of directors is not obligated to declare a dividend. Any future dividends will be subject to the discretion of our board of directors and will depend upon, among other things, future earnings, the operating and financial condition of our company, its capital requirements, general business conditions and other pertinent factors. We do not anticipate that dividends will be paid in the foreseeable future.

Miscellaneous Rights and Provisions

In the event of our liquidation or dissolution, whether voluntary or involuntary, each share of our common stock is entitled to share ratably in any assets available for distribution to holders of our common stock after satisfaction of all liabilities.

Our common stock is not convertible or redeemable and has no preemptive, subscription or conversion rights. There are no conversions, redemption, sinking fund or similar provisions regarding our common stock.

Our common stock, after the fixed consideration thereof has been paid or performed, are not subject to assessment, and the holders of our common stock are not individually liable for the debts and liabilities of our company.

Our bylaws provide that our board of directors may amend our bylaws by a majority vote of our board of directors including any bylaws adopted by our stockholders, but our stockholders may from time to time specify particular provisions of these bylaws, which must not be amended by our board of directors. Our current bylaws were adopted by our board of directors. Therefore, our board of directors can amend our bylaws to make changes to the provisions relating to the quorum requirement and votes requirements to the extent permitted by the Nevada Revised Statutes.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Securities Transfer Corporation located at 2591 Dallas Parkway, Suite 102, Frisco, TX 75034.

Exhibit 21.1

ORGENESIS INC.

List of Subsidiaries

- Orgenesis Belgiuim SRL
- Orgenesis Ltd.
- Orgenesis Maryland Inc.
- Masthercell Global Inc.
- Cell Therapy Holdings S.A
- Atvio Biotech Ltd.
- CureCell Co. Ltd.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on FormS-3 (No. 333-223777) of Orgenesis Inc of our report dated March 9, 2020 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

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

Tel-Aviv, Israel
March 9, 2020

Exhibit 31.1

ORGENESIS INC.
CEO CERTIFICATE
PURSUANT TO SECTION 302

I, Vered Caplan, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of Orgenesis Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 9, 2020

By: /s/ Vered Caplan
Name: Vered Caplan
Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

ORGENESIS INC.
CFO CERTIFICATE
PURSUANT TO SECTION 302

I, Neil Reithinger, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of Orgenesis Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 9, 2020

By: /s/ Neil Reithinger
Name: Neil Reithinger
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

ORGENESIS INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of Orgenesis Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

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

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

Date: March 9, 2020

By: /s/ Vered Caplan
Name: Vered Caplan
Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

ORGENESIS INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of Orgenesis Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: March 9, 2020

By: */s/ Neil Reithinger*
Name: Neil Reithinger
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer and Principal Accounting Officer)