Orgenesis Inc.
Form 10-K
February 13, 2019

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 **November 30, 2018**

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:

Common stock, par value $0.0001 per share

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or

information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.[ ]

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 15,620,971 shares of common stock outstanding as of February 13, 2019. The aggregate market value of the common stock held by non-affiliates of the registrant as of May 31, 2018 was $92,456,008, as computed by reference to the closing price of such common stock on The Nasdaq Capital Market on such date.

ORGENESIS INC.

2018 FORM 10-K ANNUAL REPORT

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FORWARD-LOOKING STATEMENTS

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

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. Certain statements made in this discussion are “forward-looking statements” within the meaning of 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based upon beliefs of, and information currently available to, the Company’s management as well as estimates and assumptions made by the Company’s management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used herein, the words “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “future,” “intend,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” 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” o “Orgenesis” refer to Orgenesis Inc., a Nevada corporation, and its majority-owned subsidiary, Masthercell Global Inc., a Delaware corporation (“Masthercell Global”), and Orgenesis SPRL, 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. Masthercell Global's wholly-owned subsidiaries include 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, Masthercell U.S., LLC, a U.S.-based CDMO, Atvio Biotech Ltd. ("Atvio"), an Israeli-based CDMO, and CureCell Co. Ltd. ("CureCell"), a Korea-based CDMO.

Forward-looking statements made in this annual report on Form 10-K include statements about:

Corporate

- our ability to achieve profitability;
- our ability to increase revenues and raise sufficient capital or strategic business arrangements to expand our CDMO global network;
- our ability to grow the size and capabilities of our organization through further collaboration and strategic alliances;

- our ability to manage the growth of our CDMO business;
- 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 such as our cell trans-differentiation technology being developed by our Israeli Subsidiary and being able to compete favorably and profitably in the cell and gene therapy industry;

CDMO Business

- our ability to grow the business of Masthercell Global (including each of its subsidiaries, MaSTherCell, Atvio and CureCell, which we consolidated into Masthercell Global in 2018);
- our ability to attract and retain customers;
- our ability to expand and maintain our CDMO business through strategic alliances, joint ventures and internal growth;
- our ability to fund the operational and capital requirements of the global expansion of Masthercell Global and our CDMO business;
- our expectations regarding Masthercell Global's expenses and revenue, including our expectations that our research and development expenses and selling, general and administrative expenses may increase in absolute dollars;
- the successful integration of our clinical and CDMO strategy through Masthercell Global and its subsidiaries;
- our ability to contract (through Masthercell Global and its subsidiaries) with third-party suppliers and manufacturers and their ability to perform adequately;
- extensive industry regulation, and how that will continue to have a significant impact on our business, especially our product development, manufacturing and distribution capabilities;
- the ability of Masthercell Global to receive future payments pursuant to that certain Stock Purchase Agreement dated June 28, 2018 by and between the Company, Masthercell Global and GPP-II Masthercell, LLC ("GPP-II");
- our and our shareholders' ability to receive value on par with GPP-II upon its forced sale of Masthercell Global;
- our ability to control, direct the activities of or hold any shares in Masthercell Global if GPP-II were to assume control of the Board of Directors of Masthercell Global or if it were to purchase our shares in Masthercell Global;
- our ability to receive benefits or value from Masthercell Global in the event of a spin-off effectuated by GPP-II; and
- the significant potential dilution to our existing shareholders due to GPP-II's option to exchange its Masthercell Global Preferred Stock for shares of our common stock.

PT 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 ("POCare") cell therapy ("PT") 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; and
- expenditures not resulting in commercially successful products.

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 November 30, 2018, 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 technologies and services in the cell and gene therapy industry. We operate through two platforms: (i) a point-of-care ("POCare") cell therapy platform ("PT") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform conducted through our subsidiary, Masthercell Global. Through our PT business, our aim is to further the development of 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. 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. Through our CDMO platform, we are focused on providing contract manufacturing and development services for biopharmaceutical companies.

Activities in our PT business include a multitude of cell therapies, including autoimmune, oncologic, neurologic and metabolic diseases and other indications. We provide services for our joint venture ("JV") partners, pharmaceutical and biotech companies as well as research institutions and hospitals that have cell therapies in clinical development. Each of these customers and collaborations represents a revenue and growth opportunity upon regulatory approval. Furthermore, 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" Autologous Insulin Producing ("AIP") cells for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases. 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 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. With respect to this trans-differentiation technology, we own or have exclusive rights to ten (10) United States and nineteen (19) foreign issued patents, nine (9) pending applications in the United States, thirty-two (32) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and four (4) 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 -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, transdifferentiation, and transplantation in the treatment of autoimmune diseases, including diabetes.

Our CDMO platform operates through Masthercell Global, which currently consists of the following subsidiaries: MaSTherCell in Belgium, Atvio in Israel and CureCell in South Korea and Masthercell U.S., LLC in the United States, each having unique know-how and expertise for manufacturing in a multitude of cell types. As part of our United States ("U.S.") activity, we intend to also set up a CDMO facility in the United States. We believe that, in-order to provide the optimal service to our customers, we need to have a global presence. 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. Masthercell Global strives to provide services that are all compliant with Good Manufacturing Practice, or GMP, requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III and through commercialization.

We operate our CDMO and the PT 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 these categories.

Furthermore, we believe that autologous therapies will be a substantial segment of the ATMP market. Autologous therapies are produced from a patients' 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 POCare model may help overcome some of the development and supply challenges with bringing these therapies to patients.

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. With more than 861 companies in the field of cell therapy worldwide (versus 580 in 2015) and 959 clinical trials underway by the end of the first quarter of 2018 (versus 486 in first quarter of 2015), we believe that the industry shows a rapid growth rate accompanied by a lack of sufficient GMP manufacturing capacities (Source: *Informa*, 2015 and 2018). Over recent years, advances in the field of cell therapy, including the growth of autologous CAR T-cell therapies, led to a significant increase in investment in the industry. T-cells, the backbone of CAR T-cell therapy, are often called the workhorses of the immune system because of their critical role in orchestrating the immune response and killing cells infected by pathogens. The therapy requires drawing blood from patients and separating out the T-cells. Next, using a disarmed virus, the T-cells are genetically engineered to produce receptors on their surface called Chimeric Antigen Receptors, or CARs. The genetically modified T-cells that are re-injected into the patient are then much more effective at targeting and killing tumors.

Two landmark U.S. Food Drug Administration (the “FDA”) approvals in CAR T-cell therapy significantly impacted the cell therapy industry. In August 2017, Novartis’s CAR T-cell therapy, Kymriah, was approved for relapsed/refractory acute lymphoblastic leukemia for pediatric and young adult patients, making it the first cell-base immunotherapy to move across the finish line in the United States. Kymriah received a second FDA approval to treat appropriate relapsed/refractory patients with large B-cell lymphoma in May 2018. Europe has also followed this path as, in August 2018, the European Commission approved Kymriah based on the first global CAR-T registration trials, which included patients from eight European countries and demonstrated durable responses and a consistent safety profile in relapsed/refractory pediatric B-cell ALL and r/r DLBCL. Furthermore, after Gilead's acquisition of Kite Pharma, Inc. for $12 billion in 2017, Kite Pharma’s CAR T-cell therapy, Yescarta, was approved for adult patients with relapsed/refractory large B cell lymphoma after two or more lines of systemic therapy (Source: Alliance for Regenerative Medicine). We believe that these approvals are indicative of the future potential of many more cellular therapies that address a wide range of diseases. Celgene Corporation (“Celgene”) acquired Juno Therapeutics, Inc., another pioneer in the CAR-T space, in January 2018 for approximately $9 billion. Then, Bristol-Myers Squibb Company, in their pursuit of this new space of cancer treatments, acquired Celgene in January 2019 for approximately

$74 billion.

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 Global. Manufacturing and delivery can be more complex in cell therapy products than for a typical drug. 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 2 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.

Integration of development and manufacturing and logistics services through Masthercell Global (and its subsidiaries) provide the basis for generating a recurring revenue stream, as well as carefully managing our fixed cost structure to maximize optionality and drive down production cost. We believe that Masthercell Global is also beneficial for our own manufacturing needs and provides us, and our customers, with enhanced control of material supply for both clinical trials and the commercial market.

Consolidation of CDMO Entities and Strategic Funding

On June 28, 2018, the Company, 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 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 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"). Orgenesis holds 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 to be made in each of years 2018 and 2019 (the "Future Payments"), or an aggregate of $13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis' shareholders approve certain provisions of the Stockholders' Agreement referred to below on or before December 31, 2019. None of the future Consideration amounts, if any, will result in an increase in GPP-II's equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing. The proceeds of the investment will be used to fund the activities of Masthercell Global and its consolidated subsidiaries. Notwithstanding the foregoing, GPP-II may, in its sole discretion, elect to pay all or a portion of the future Consideration amounts even if the financial targets described above have not been achieved and the Orgenesis Stockholder Approval has not been obtained. In satisfaction of the two conditions described above, Masthercell Global achieved the specified EBITDA and revenues targets in 2018 as described in the SPA and obtained the approval from its requisite shareholders on October 23, 2018. As such, Masthercell Global received the First Future Payment of $6,600,000 on January 16, 2019.

In connection with the entry into the SPA, and pursuant to the terms hereof, 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 favorable, preferential rights to GPP-II (including, without limitation, a tag right, drag right and certain protective provisions), a right to exchange the Masthercell Global Preferred Stock for shares of Orgenesis common stock and certain other rights and obligations. In addition, 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 determined by one of the top ten independent accounting firms in the U.S. selected by GPP, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and the Masthercell Global Subsidiaries of at least $50 million. In addition, upon certain enumerated events as 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 of such equity holdings as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II, 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; 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. For the purposes of the foregoing, the following definitions shall apply: (A) "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; and (B) "Change of Control" shall mean any of: (a) the acquisition, directly or indirectly (in a single transaction or a series of related transactions) by a Person or group of Persons of either (I) a majority of the common stock of the Company (whether by merger, consolidation, stock purchase, tender offer, reorganization, recapitalization or otherwise), or (II) all or substantially all of the assets of the Company and its Subsidiaries (but only if such transaction includes the transfer of Securities held by the Company), (b) if any four (4) of the directors of the Company as of June 28, 2018 are removed or replaced or for any other reason cease to serve as directors of the Company, (c) the filing of a petition in bankruptcy or the commencement of any proceedings under bankruptcy laws by or against the Company, provided that such filing or commencement shall be deemed a Change of Control immediately if filed or commenced by the Company or after sixty (60) days if such filing is initiated by a creditor of the Company and is not dismissed; (d) insolvency of the Company that is not cured by the Company within thirty (30) days; (e) the appointment of a receiver for the Company, provided that such appointment shall constitute an Change of Control immediately if the appointment was consented to by the Company or after sixty (60) days if not consented to by the Company and such appointment is not terminated; or (f) or dissolution 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, as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II and the Company, divided by (ii) the average closing price per share of Orgenesis Common Stock during the thirty (30) 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 having an enterprise value of less than $250,000,000 and (B) the maximum number of shares of Orgenesis Common Stock to be issued shall not exceed 2,704,247 shares of outstanding Orgenesis Common Stock (representing approximately 19.99% of then outstanding Orgenesis Common Stock), unless Orgenesis obtains shareholder approval for the issuance of such greater amount of shares of Orgenesis Common Stock in accordance with the rules and regulations of the Nasdaq Stock Market. Such shareholder approval for a greater number was obtained on October 23, 2018.

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) $250,000 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 $2,000,000 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 $500,000. 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 months 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 Securities, LLC, a Delaware limited liability company and an affiliate of Great Point and Masthercell Global entered into a transaction services agreement pursuant to which GPP Securities, LLC is to provide certain brokerage services to Masthercell Global for which GPP Securities LLC 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% of the applicable transaction value.

Corporate Reorganization

Contemporaneous with the execution of the SPA and the Stockholders' Agreement, Orgenesis and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which Orgenesis contributed to Masthercell Global the Orgenesis' assets relating to the CDMO Business (as defined below), including the CDMO subsidiaries (the "Corporate Reorganization"). In furtherance thereof, Masthercell Global, as Orgenesis' assignee, acquired all of the issued and outstanding share capital of Atvio, the Company's Israel based CDMO partner since May 2016, and 94.12% of the share capital of CureCell, the Company's Korea based CDMO partner since March 2016. Orgenesis 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 Orgenesis common stock. In respect of the acquisition of Atvio, Orgenesis issued to the former Atvio shareholders an aggregate of 83,965 shares of Orgenesis common stock. In respect of the acquisition of CureCell, Orgenesis issued to the former CureCell shareholders an aggregate of 202,846 shares of Orgenesis common stock subject to a third-party valuation. Together with MaSTherCell S.A., Atvio and CureCell are directly held subsidiaries under Masthercell Global (collectively, the "Masthercell Global Subsidiaries").

Masthercell Global, through the Masthercell Global Subsidiaries, will be engaged in the business of providing manufacturing and development services to third parties related to cell and gene therapy products, processes and solutions and providing related manufacturing or development services, and the creation and development of technology, intellectual property, tools and optimizations in connection with such manufacturing and development services for third parties (the "CDMO Business"). Under the terms of the Stockholders' Agreement and SPA, Orgenesis has agreed that so long as it owns equity in Masthercell Global and for two years thereafter it will not engage in the CDMO Business, except through Masthercell Global. Notwithstanding the foregoing, nothing in the Stockholders' Agreement or the SPA prohibits or restricts the Company's ability to conduct any business outside the CDMO Business and the Company retained the right to research, manufacture, develop and conduct all other activities related to the development, discovery, manufacturing and commercialization of therapeutic products, and the process, methods and services thereof (including, without limitation, such therapeutic products for itself and in which the Company has an economic interest or any relationship with any Third Party in which the Company has an economic interest or that are created, developed, manufactured or sold by a joint venture, partnership or collaboration between the Company and a Third Party) with a Third Party. For purposes hereof, the term "Third Party" shall mean any entity (other than our Company or our subsidiaries) with whom we (or our subsidiaries) has a collaboration, joint venture, partnership or similar economic relationship for the development of a product with therapeutic use where the primary purpose of such collaboration, joint venture, partnership or relationship is not the manufacturing related to such product. We intend, through our direct subsidiaries, to continue engaging in such research, marketing, development, selling and commercialization of such therapeutic products either for our own internal purposes or with Third Parties.

Masthercell Global's Business

Our subsidiary, Masthercell Global, is a CDMO specialized in cell therapy development for advanced therapeutically products. In the last decade, cell therapy medicinal products have gained significant importance, particularly in the fields of ex-vivo gene therapy and immunotherapy. While academic and industrial research has led scientific development in the sector, industrialization and manufacturing expertise remains insufficient. Masthercell Global plans to fill this gap by providing three types of services to its customers: (i) process and assay development services and (ii) current Good Manufacturing Practices (cGMP) contract manufacturing services and (iii) technology innovation and engineering services. These services offer a double advantage to Masthercell Global's customers. First, customers can continue allocating their financial and human resources on their product/therapy, while relying on a long-term reliable and trusted partner for their process development/production. Second, through its subsidiaries, it allows customers to benefit from Masthercell Global's expertise in cell therapy manufacturing and all related aspects.

Masthercell Global continues to invest in its manufacturing capabilities and services to offer a "one-stop-shop" service to its customers from pre-clinical up to commercial development. MaSTherCell S.A., Masthercell Global's Belgian subsidiary, has recently inaugurated a new production center in Gosselies, doubling its manufacturing capacity from 600 sqm GMP area to 1,200 sqm. This new facility can also accommodate commercial manufacturing. Masthercell Global's Israeli-based CDMO, Atvio, has relocated its process engineering activities into a new and larger facility located at Bar-Lev industrial park. These subsidiaries, including Masthercell Global's Korea-based CDMO, have started to offer viral vector CDMO services. Our target customers are primarily cell therapy companies that are in clinical trials with the aim of accompanying them as their manufacturing and logistic partner once their product candidates reach commercial stage.

We devote significant resources to process development and manufacturing in order to optimize the safety and efficacy of our future product candidates for our customers, as well as our cost of goods and time to market. This integration of development, manufacturing and logistics services through Masthercell Global aims to provide the basis for generating a recurring revenue stream, as well as carefully managing our fixed cost structure, maximize optionality, and drive long-term cost of goods as low as possible. We believe that operating our own manufacturing facility provides us with enhanced control of material supply for both clinical trials and the commercial market, will enable the more rapid implementation of process changes, and will allow for better long-term margins.

Masthercell Global continues to invest resources to maintain best practices in quality service, quality control, quality assurance and permanent staff training to uphold the highest standards to serve its customers. Masthercell Global (through itself and its subsidiaries) has built-up a team of more than 140 industry experts in Belgium, 30 experts in Korea, 19 experts in Israel and 3 people in the US. The entire team is dedicated to support process development and manufacturing efforts in a fast, safe and cost-effective way. Masthercell Global's strategy is to build long term relationships with its customers in order to help them bring highly potent cell therapy products faster to the market and in cost-effective ways. To provide these services, Masthercell Global relies on a team of dedicated experts both from academic and industry backgrounds. It operates through state-of-the-art facilities organized as a global network in Belgium, Israel, Korea and soon in the U.S. This network of facilities operates on a common Quality Management System backbone enabling for streamlined technology transfers among the different sites.

Our Growth Strategy

In light of the globalization of the industry in general and the therapeutics industry in particular, adding to that the high cost of reaching the market, developers of cell therapies see themselves as global organizations and build their models on global markets. As cell therapies are based on living cells, they are limited in their ability to be centrally manufactured. An additional challenge for globalization is the fact that the regulatory requirements for the therapies is not harmonized between jurisdictions, presenting additional operational challenges.

We have leveraged the recognized quality expertise and experience in cell process development and manufacturing of our Belgian subsidiary, MaSTherCell S.A., to first-class entities in Israel and Korea and to build a global CDMO in the cell therapy development and manufacturing area. We believe that cell therapy companies need to be global in order to truly succeed. We target the international manufacturing market as a key priority through joint-venture agreements that provide development capabilities, along with manufacturing facilities and experienced staff.

The main revenue drivers of our growth strategy on a global reach are the number of batches and the number of patients per manufacturing batch. These parameters vary along the development cycle of the new treatments (starting from as few as 20 patients in Phase I to thousands of patients when reaching commercialization). When a client reaches the commercial stage, their demand for manufacturing substantially increases, while barriers preventing the client from switching to another manufacturing organization remain extremely high. The difficulty in transferring

CDMOs is a function of the tech transfer of such complex manufacturing processes being extremely lengthy, requiring many months of training highly specialized employees, while also possibly requiring new regulatory approvals. Therefore, we believe we are well positioned to continue expanding our revenue for the following reasons:

(1) A higher number of companies in later phases of clinical trials and soon potentially in commercial phases;
(2) Therapy companies requiring higher manufacturing abilities concurrent with a global reach; and
(3) An increasing need for the manufacturing scalability provided by a CDMO.

Current CDMO Facilities

MaSTherCell S.A.

MaSTherCell S.A. in Belgium is in the European hub for the continental activities of the global CDMO network and the globally-recognized center of excellence of the GMP manufacturing activities of the group. At the heart of MaSTherCell is a team of more than 140 highly dedicated experts combining strong experience in cGMP cell therapy manufacturing with a technology-focused approach and a substantial knowledge of the industry. As a one-stop shop, they provide services from technology selection, business modeling to GMP manufacturing, process development, quality management and assay development. MaSTherCell's teams are fully committed to helping their clients fulfill their objective of providing sustainable and affordable therapies to their patients. The company operates in a validated and flexible facility located in Biowin, the strategic center of Europe within the Walloon healthcare cluster. The facility in Belgium has received the final cGMP manufacturing authorization from the Belgian Drug Agency (AFMPS) in September 2013 and a renewal in October 2017 for cell-based therapies manufacturing. It spreads over 2,000 sqm including 1,200 sqm of GMP area.

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 sqm2 of labs and offices resulting in an efficient and unique environment for cell therapy development.

CureCell Co. Ltd.

CureCell Co. Ltd. in Korea has a particular focus on developing innovative cell therapies for both the Korean and international markets. Together, with promising in-house research programs, the foreign technologies are currently under development for the rapidly growing Asian market well beyond the 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 and is well positioned to expand international markets for Korean technologies.

Planned CDMO Facilities

We are currently preparing to launch a new production center in Houston, Texas in the United States, which we expect will become operational during fiscal 2020. We will continue to engage in discussions with other strategic partners throughout the world to set up CDMO facilities in other geographic locations.

Our Competitive Advantages

We believe that we offer the following benefits to our CDMO clients:

We enable our clients to go faster to the market in a cost-effective way. We continue to invest in our manufacturing capabilities and expertise to offer a “one-stop-shop” service to our customers from pre-clinical up to commercial development. This can also include preferred access to critical raw materials supplies. This stems from the finding that these companies' processes have to be set up right from the start in order for them to obtain approved products that have the simplest possible process and with the lowest possible cost of goods sold (COGS).

Quality. We work alongside our customers to transform the promises of their cell-based therapies into a robust and scalable process, compliant with GMP requirements. Our stringent quality system is applied throughout the process and ensures identity, purity, stability, potency and robustness of cell therapy products from clinical phase I, II, III to commercialization. We continue to invest resources to maintain best practices in quality service, quality control, quality assurance and permanent staff training to uphold the highest standards.

Transforming academic technology to clinical and commercial manufacturing. One of the major issues with moving cell therapy products from "bench to manufacturing bedside" has been manufacturing bottlenecks. The heterogeneous nature of cell therapy products has introduced manufacturing complexity and regulatory concerns, as well as scale-up complexities that are not present within traditional pharmaceutical manufacturing. Over the years, MaSTherCell has developed experience and expertise necessary for transforming academic concepts into a clinical manufacturing program to support all phases of clinical trials. This includes assessing the clinical efficiency of the laboratory concept but also the development of efficient, robust and scalable manufacturing processes, including technology engineering service, when needed.

Access to a global network. Many companies developing autologous cell therapies envision using multiple manufacturing sites and processing centers to distribute the workload and minimize the shipping distances for such time- sensitive products. Many cell therapy products are fragile preparations that must be shipped and applied to a patient rapidly. This time pressure means that standard product-release testing procedures are not feasible. In particular, sterility testing often cannot be completed before patient treatment. This unique challenge in cell-therapy manufacturing requires tighter environmental and handling controls to greatly reduce any risk of sterility failure. Biotechnology companies have to anticipate their success and the logistics to cure at point of care. Therefore, the setup of a global CDMO meets this requirement and is the strategy behind our establishment of our CDMO facilities in Korea and Israel, and in the U.S. in the future. To comply with anticipated regulatory harmonization, we have also invested in our Quality and Management Systems (QMS) and to structure them in a way they could be shared with either affiliated companies or business partners, and even with customers or prospects. South Korea, Israeli and European requirements are essentially the same, allowing Masthercell Global to implement its QMS model in a quick and efficient way. This truly international footprint will give us a unique competitive advantage, thereby filling the gap of biotechnology companies' requirement of "quality comparability" between the respective regional sites.

Central continental locations to deal with key logistics challenges. With respect to this challenge, through our subsidiaries, Masthercell Global has built up the following:

- Team of dedicated experts both from academic and industry backgrounds with a strong experience in cGMP dealing with not yet harmonized regulatory requirements (European Medicines Agency (the "EMA"), FDA);
- State-of-the-art facilities located next to airports; and
- Multi-continental footprints to deal with therapies administration at or nearby point of care as many cell therapy products have a short shelf life.

Providing value-added manufacturing capacity. One of the biggest challenges is developing reliable (quality) and robust manufacturing processes for cell-based therapy products that ensure adequate product safety, potency, and consistency at an economically viable cost. Additionally, manufacturing quality and comparability is at the heart of biotechnology companies' challenges. MaSTherCell has built-up a strong expertise to customize the production and manufacturing process to suit the particular needs of a given client. This process facilitates a deep understanding of clients' needs and facilitates a long term revenue generating relationship.

Competition in the CDMO Field

We compete with a number of companies both directly and indirectly. Key competitors include the following CMOs and CDMOs: Lonza Group Ltd, Progenitor Cell Therapy (PCT) LLC (acquired by Hitachi), WuxiAppTec (WuXi PharmaTech (Cayman) Inc.), Cognate Bioservices Inc., Apceth GmbH & Co. KG, Eufets GmbH, Fraunhofer Gesellschaft, Cellforcure SASU, Cell Therapy Catapult Limited and Molmed S.p.A. Some of these companies are large, well-established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than those that we currently possess.

More generally, we face competition inherent in any third-party manufacturer's business - namely, that potential customers may instead elect to invest in their own facilities and infrastructure, affording them greater control over their products and the hope of long-term cost savings compared to a third party contract manufacturer. To be successful, we will need to convince potential customers that our current and expanding capabilities are more innovative, of higher-quality and more cost-effective than could be achieved through internal manufacturing and that our experience and quality manufacturing and process development expertise are unique in the industry. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in developing technologies that improve both the quality and profitability associated with cell therapy manufacturing. If we are unable to successfully compete against other manufacturers, we may not be able to develop our CDMO business plans which may harm our business, financial condition and results of operations.

We believe that Masthercell Global's services differ from our competition in two major aspects:

- Quality and expertise of its services: Clients identify the excellence of its facility, quality system, and people as a major differentiating point compared to competitors; and
- Agile and tailored approach: Our philosophy is to build a true partnership with our clients and adapt ourselves to clients' needs, which entails no "off-the-shelf process" nor in-house technology platform, but a dedicated person for each client, joint steering committees on each project and dedicated project managers.

* Diagram above signifies "one-stop-shop service offering" from process development through quality manufacturing and logistics to point of care.

We strengthen our position by our "one-stop-shop" service offering, from pre-clinical to commercial, with a clear focus on COGS of manufacturing processes. This differentiation results in a price premium compared to other CMO's as we operate with a lean organization focused solely on cell therapy. Quality is a critical aspect of our industry, and we believe we have developed unique expertise in this field. We devote significant resources to process development and manufacturing in order to optimize the safety and efficacy of our future product candidates for our customers, 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. We believe that operating our own manufacturing facility, which provides us with enhanced control of material supply for both clinical trials and the commercial market, will enable a more rapid implementation of process changes, and will allow for better long-term margins.

Finally, we have sought to establish manufacturing centers in regions which logistically offers an ideal location given the high concentration of companies active in cell therapy, including potential clients and companies with complementary know-how, products and services.

CDMO Government Regulation

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 by the FDA, as well as regulatory bodies of other jurisdictions, such as the EMA, Health Canada, and the Australian Department of Health, depending on the countries in which our customers market and sell the products we manufacture and/or package on their behalf. 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.

Manufacturing facilities that produce cellular therapies are subject to extensive regulation by the FDA. In particular, FDA regulations set forth requirements pertaining to establishments that manufacture human cells, tissues, and cellular and tissue-based products ("HCT/Ps"). Title 21, Code of Federal Regulations, Part 1271 provides for a unified registration and listing system, donor-eligibility, current Good Tissue Practice ("cGTP"), and other requirements that are intended to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. More specifically, key elements of Part 1271 include:

- Registration and listing requirements for establishments that manufacture HCT/Ps;
- Requirements for determining donor eligibility, including donor screening and testing;
- cGTP requirements, which include requirements pertaining to the manufacturer's quality program, personnel, procedures, manufacturing facilities, environmental controls, equipment, supplies and reagents, recovery, processing and process controls, labeling, storage, record-keeping, tracking, complaint files, receipt, pre-distribution shipment, distribution, and donor eligibility determinations, donor screening, and donor testing;
- Adverse reaction reporting;
- Labeling of HCT/Ps;
- Specific rules for importing HCT/Ps; and
- FDA inspection, retention, recall, destruction, and cessation of manufacturing operations.

Masthercell Global currently collects, processes, stores and manufactures HCT/Ps, including the manufacture of cellular therapy products. Therefore, Masthercell Global must comply with cGTP and with the current Good Manufacturing Practices ("cGMP") requirements that apply to biological products. Cell and tissue-based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products if they fail to meet all HCT/P criteria set forth in Title 21, Code of Federal Regulations, Section 1271.10.

The U.S. Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and FDA regulations govern the quality control, manufacture, packaging, and labeling procedures of products regulated as a drug or biological products, including cellular therapies comprising HCT/Ps. These laws and regulations include requirements for regulated entities to comply with cGTPs applicable to the specific product(s). The cGTPs are designed to ensure that a facility's processes - and products resulting from those processes - meet defined safety requirements. The FDA's objective in requiring compliance with cGTP standards is to protect the public health and safety by ensuring that regulated products (i) have the identity, strength, quality and purity that they purport or are represented to possess; (ii) meet their specifications; and (iii) are free of objectionable microorganisms and contamination. As a central focus of the cGTP requirements, regulated entities must design and build quality assurance safeguards into the manufacturing processes and the production facilities for regulated products and must ensure the consistency, product integrity, and reproducibility of results and product characteristics. This is done by implementing quality systems and processes including appropriate, controlled procedures, specifications and documentation. In addition, drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with applicable cGTPs. The FDA may also initiate for-cause investigations of manufacturing facilities if it learns of possible serious regulatory violations at such facilities. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGTPs. Failure to comply with applicable FDA requirements can result in regulatory inspections and associated observations, warning letters, other enforcement measures requiring remedial action, and, in the case of failures that are more serious, suspension of manufacturing operations, seizure of product, injunctions, product recalls, fines, and other penalties. We believe that our facilities are in material compliance with applicable, existing FDA requirements. Additionally, FDA, other regulatory agencies, or the U.S. Congress may be considering, and may enact laws or regulations regarding the use and marketing of stem cells, cell therapy products, or products derived from human cells or tissue. These laws and regulations may directly affect us or the business of some of Masthercell's Global's clients and, therefore, the amount of business Masthercell Global receives from these clients.

The Clinical Laboratory Improvement Amendments (“CLIA”) extends U.S. federal oversight to clinical laboratories that examine or conduct testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of disease or for the assessment of the health of human beings. CLIA requirements apply to those laboratories that handle biological matter. CLIA requires that these laboratories be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to biennial inspections and remit fees. The sanctions for failure to comply with CLIA include suspension, revocation, or limitation of a laboratory's CLIA certificate necessary to conduct business, fines, or criminal penalties. Additionally, CLIA certification may sometimes be needed when an entity, such as Masthercell Global, desires to obtain accreditation, certification, or license from non-government entities for cord blood collection, storage and processing.

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 FDA or other 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 FDA and comparable 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 CDMO operations involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal 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.

PT Business

Our therapeutic development efforts in our cell therapy business 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, 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.

PT Subsidiaries and Collaboration Agreements

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.

We carry out our PT 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 as follows:

- United States: Orgenesis Maryland Inc. – This is the center of activity for North America currently focused on technology licensing, therapeutic collaborations and preparation for U.S. clinical trials.

- European Union: Orgenesis SPRL – This is the center of activity for Europe, currently focused on process development and preparation of European clinical trials.

- Israel: Orgenesis Ltd. – 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 third parties around the world. We believe that these parties have the expertise, experience and strategic location to advance our PT therapy business. Activities in our PT platform include:

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" Autologous Insulin Producing ("AIP") cells for patients with Type 1 Diabetes ("T1D"), acute pancreatitis and other insulin deficient diseases. 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. 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. With respect to our trans-differentiation technology, we own or have exclusive rights to ten (10) United States and nineteen (19) foreign issued patents, nine (9) pending applications in the United States, thirty-two (32) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and four (4) 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 -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, transdifferentiation, and transplantation in the treatment of autoimmune diseases, including diabetes.

Collaboration Agreement with Hemogenyx Pharmaceuticals Plc - On October 18, 2018, we entered into a collaboration agreement and other ancillary agreements with Hemogenyx Pharmaceuticals Plc ("Hemogenyx") to collaborate on the development and commercialization of Hemogenyx's Human Postnatal Hemogenic Endothelial (Hu-PHEC) technology. Hu-PHEC is a cell replacement product candidate that is being designed to generate cancer-free, patient-matched blood stem cells after transplantation into the patient. Pursuant to the terms of the agreements, we shall exclusively manufacture and supply to Hemogenyx, its affiliates and licensees all Hu-PHEC related products both during and following completion of clinical trials. We shall also receive the worldwide -exclusive rights to market such products and shall serve as a global distributor of Hemogenyx's Hu-PHEC related products. In consideration for such rights, we agreed to advance to Hemogenyx a convertible loan in an amount of no less than $1.0 million for furthering the development of the Hu-PHEC technology. As of November 30, 2018, we have funded $0.5 million under this convertible loan. We also agreed to pay a royalty of 12% of our net revenues resulting from the sale or licensing of products covered by Hemogenyx's Hu-PHEC technology.

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. Immugenyx will collaborate with us to further the development and commercialization of its advanced hematopoietic chimeras ("AHC"). AHC, a new type of humanized mouse with a functional human immune system, is being developed by Immugenyx as an in vivo platform for disease modelling, drug and cell therapy development. Pursuant to the terms of the agreement, we shall receive non-exclusive worldwide rights to market the products and shall serve as a global distributor of Immugenyx's products. Immugenyx will retain exclusive rights to manufacture, make and supply us with all the Immugenyx technology and/or licensed products that are marketed, sold or otherwise commercialized by us. In consideration for the license, we agreed to advance to Immugenyx a convertible loan in an amount of no less than $1.0 million for furthering the development of humanized mice models and related antibody development. As of November 30, 2018, we have funded $0.5 million under this convertible loan. We also agreed to pay a royalty of 12% of our net revenues resulting from the sale or licensing of products covered by Immugenyx's AHC technology.

Collaboration and License Agreement with Mircod Limited - On June 18, 2018, we and Mircod Limited, a company formed under the laws of Cyprus ("Mircod") entered into a collaboration and license agreement for the research, development and commercialization of potential key technologies related to biological sensing for our clinical development and manufacturing projects. Within 45 days of the execution of the agreement, we agreed to approve a written project development plan outlining each party's responsibilities with respect to the project and said project development plan was duly approved. We also agreed to fund the projected development costs as outlined in the development plan. Under the terms of the agreement, we agreed to, and remitted, an advance payment of $50,000. Under the agreement, all project results of such collaboration shall be jointly owned by Mircod and the Company. We were also granted an exclusive, worldwide sublicensable license under Mircod's right in such project results to use and commercialize such project results in consideration for a royalty of 5% of Net Sales (as defined in the collaboration agreement) of products incorporating project results. We will be solely responsible for the commercialization of any resulting products. 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 incorporating the project results and, at our request, to provide support and maintenance service for such products. If for whatever reason Mircod and the Company 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, we are entitled to manufacture the products, in which event Mircod will be entitled to a payment of $80,000 and royalties on net sales are to increase to 8% of net sales.

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 "Agreements") with B.G. Negev Technologies and Applications Ltd. ("BGN") and/or The National Institute of Biotechnology in the Negev Ltd. (both herein, the "BG Entities"). Under the terms of the Agreements, we shall 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 and HekaBio K.K. ("HB"), a corporation organized under the laws of Japan, entered into a joint venture agreement pursuant to which we agreed to collaborate in the clinical development and commercialization of cell and gene therapeutic products in Japan (the "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 "JV Company"). 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 joint venture agreement, each party may invest up to $10 million, which may take the form of a loan, if required, as determined by the steering committee. 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. Additionally, HB was granted an option to affect an equity investment in us of up to $15 million within the next 12 months on mutually agreeable terms. If such investment is in fact consummated, we agreed to invest in the JV Company by way of a convertible loan an amount to HB's pro-rata participating interest in the JV Company, which initially will be at 51%. Such loan may then be converted by us into share capital of the JV Company at an agreed upon formula for determining the JV Company valuation which in no event shall be less than $10 million. Under the joint venture agreement, we can require HB to sell to us its participating (including equity) interest in the JV Company in consideration for the issuance of our common stock based on an agreed upon formula for determining the JV Company's valuation which in no event shall be less than $10 million. In addition, under the joint venture agreement, we shall grant the JV Company an exclusive license to certain intellectual property 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 us, in addition to other payments, royalties at the rate of 10% of the JV Company's net sales of the Products. On October 3, 2018, we entered into a license agreement with the JV Company pursuant to the joint venture agreement pertaining to the licenses described above.

- *Joint Venture Agreement with Image Securities Ltd.* - On July 11, 2018, we and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Cayman Islands ("India Partner") entered into a joint venture agreement 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. The joint venture agreement becomes effective upon the consummation of an equity investment by the India Partner in the Company of $5 million within 15 days of the execution of the joint venture agreement through the purchase of units of our securities at a per unit purchase price payable into the Company of $6.24, with each unit comprised of one share of our common stock and a three-year warrant for the acquisition of an additional common share at a per share exercise price of $6.24. Subject to the consummation of such equity investment in the Company, we are to advance to the joint venture company a convertible loan in the amount of $5 million. The loan is convertible into equity capital of the joint venture company at an agreed upon formula for determining joint venture company valuation. The investment in us by the India Partner was consummated by way of the previously disclosed private placement subscription agreement entered into in December 2016 between us and an affiliate of the India Partner. We advanced $1 million under our obligation under the convertible loan on October 18, 2018. Under the joint venture agreement, the India Partner agreed to invest in the joint venture company $10 million within 12 months of the incorporation of the joint venture company. If for whatever reason such investment is not made by the India Partner within such time, then we are authorized to convert our above-referenced loan into 50% of the equity capital of the joint venture company on a fully diluted basis, provided that if the pre- money valuation of the joint venture company is then independently determined to be less than $5 million, then such conversion to be effected in the basis of such valuation.

Background on Our Transdifferentiation Technology

Diabetes Mellitus ("DM"), or simply diabetes, is a metabolic disorder usually caused by a combination of hereditary and environmental factors, and results in abnormally high blood sugar levels (hyperglycemia). Diabetes occurs as a result of impaired insulin production by the pancreatic islet cells. The most common types of the disease are Type-1 Diabetes ("T1D") and Type-2 Diabetes ("T2D"). In T1D, the onset of the disease follows an autoimmune attack of -cells that severely reduces -cell mass. T1D usually has an early onset and is sometimes also called juvenile diabetes. In T2D, the pathogenesis involves insulin resistance, insulin deficiency and enhanced gluconeogenesis, while late progression stages eventually lead to -cell failure and a significant reduction in -cell function and mass. T2D often occurs later in life and is sometimes called adult onset diabetes. Both T1D and late-stage T2D result in marked hypoinsulinemia, reduction in -cell function and mass and lead to severe secondary complications, such as myocardial infarcts, limb amputations, neuropathies and nephropathies and even death. In both cases, patients become insulin-dependent, requiring either multiple insulin injections per day or reliance on an insulin pump.

Diabetes is one of the most challenging health problems in the 21st Century, resulting in staggering health, social, and economic impacts. Diabetes is currently the fourth or fifth leading cause of death in most developed countries and has been declared an epidemic in many developing and newly industrialized nations.

Within the field of cell therapy, research and development using stem cells to treat a host of diseases and conditions has greatly expanded. All living complex organisms start as a single cell that replicates, differentiates (matures) and perpetuates in an adult organism throughout its lifetime. Stem cells (in either embryonic or adult forms) are primitive and undifferentiated cells that have the unique ability to transform into or otherwise affect many different cells, such as white blood cells, nerve cells or heart muscle cells. Our technology employs a molecular and cellular approach directed at converting liver cells into functional insulin-producing cells as a treatment for diabetes. This new therapeutic approach does not use stem cells, but rather is focused on the use of autologous, fully mature, adult cells.

There are two general classes of cell therapies: allogeneic and autologous. In allogeneic procedures, cells collected from a person (the donor) are transplanted into or used to develop a treatment for another patient (the recipient) with or without modification. In cases where the donor and the recipient are the same individual, these procedures are referred to as “autologous”.

Our treatment for diabetes 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 transdifferentiated to become adult Autologous Insulin Producing (“AIP”) cells.

Through our Israeli and Belgian subsidiaries, our goal is to advance our AIP cell-based therapy into clinical development. AIP cells utilize the technology of 'cellular trans-differentiation' to transform an autologous adult liver cell into a fully functional and physiologically glucose-responsive insulin-producing cell. Treatment with AIP cells is expected to provide Type 1 Diabetes patients with long-term insulin independence. Because AIP cells are autologous, this benefit should be achieved and maintained without the need for concomitant immunosuppressive therapy.

Threats from Pancreas Islet Transplantation and Cell Therapies

To date, a significant portion of the amount invested in diabetes related research and development activities has been directed toward prevention and lifestyle management rather than toward the development of a cure. For some patients with severe and difficult to control diabetes (hypoglycemic unawareness), islet transplants are considered. Pancreatic islets are the cells in the pancreas that produce insulin. Scientists use enzymes to isolate the islets from the pancreas of a deceased donor. Because the islets are fragile, transplantation must occur soon after they are removed. Typically, a patient receives at least 10,000 islet "equivalents" per kilogram of body weight, extracted from pancreases obtained from different donors. Patients often require two separate transplants to achieve insulin independence.

Transplants are often performed by an interventional radiologist, who uses x-rays and ultrasound to guide placement of a catheter - a small plastic tube - through the upper abdomen and into the portal vein of the liver. The islets are then infused slowly through the catheter into the liver. The patient receives a local anesthetic and a sedative. In some cases, a surgeon may perform the transplant through a small incision, using general anesthesia. Because the islets are obtained from cadavers that are unrelated to the patient, the patient needs to be treated with drugs that inhibit the immune response so that the patient doesn't reject the transplant. In the early days of islet transplantation, the drugs were so powerful that they actually were toxic to the islets; improvements in the procedure are widely used and are now referred to as the Edmonton Protocol.

Pancreatic islet transplantation (cadaver donors) is an allogeneic transplant, and, as in all allogeneic transplantations, there is a risk for graft rejection and patients must receive lifelong immune suppressants. Though this technology has shown good results clinically, there are several setbacks, such as patients being sensitive to recurrent T1D autoimmune attacks and a shortage in tissues available for islet cells transplantation.

Pancreatic islet auto transplantation is a means of reducing the risk of brittle diabetes following total pancreatectomy. In 1977, researchers at the University of Minnesota School of Medicine pioneered the first Total Pancreatectomy with Islet Autologous Transplant ("TP-IAT") for the treatment for induced diabetes post-surgery. At that time, islet cell isolation techniques, which had been pursued to treat insulin-dependent diabetes via allotransplant, yielded variable results and raised uncertainty regarding the future efficacy of TP-IAT. Since then, advances in isolation and purification have improved islet transplant outcomes, and the practice of TP-IAT has expanded. In the United States, there are currently approximately 12 centers performing TP-IAT, with 1 to 2 centers annually establishing programs; there is no available information on the worldwide use of this procedure.

TP-IAT has the distinct advantage of allowing patients the ability to avoid the significant postoperative complication of surgically induced brittle diabetes. The severity of brittle diabetes, a condition in which a patient experiences both severe hyper and hypoglycemic episodes, should not be underestimated; in one early series, 50% of late deaths after TP were secondary to iatrogenic hypoglycemic episodes. Although total pancreatectomy in the era of modern endocrine and exocrine replacement therapy has witnessed improvements in long-term morbidity and mortality, it remains one of the most morbid abdominal operations performed today.

Our Solution

We are developing and bringing to clinical stage a technology that is based on the published work of Prof. Sarah Ferber, our Chief Scientific Officer and a researcher at THM, that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver into “pancreatic beta cell-like” insulin-producing cells. Furthermore, those cells were found resistant to the autoimmune attack and able to produce insulin in a glucose-sensitive manner. Our cell therapy business 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 an 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”).

Toward this goal, we are working to advance a unique product into clinical development. AIP cells utilize the technology of ‘cellular trans-differentiation’ to transform an autologous adult liver cell into an adult, fully functional and physiologically glucose-responsive pancreatic-like insulin producing cell. Treatment with AIP cells is expected to provide diabetes patients with long-term insulin independence. Our aim is to develop our AIP cell therapy in the treatment of diabetes by essentially correcting malfunctioning organs with new functional tissues created from the patient’s own existing organs.

Because the AIP cells are autologous, this benefit should be achieved and maintained without the need for concomitant immunosuppressive therapy. The procedure to generate AIP cells begins with liver tissue accessed via needle biopsy from a patient. The liver tissue is then sent to a CDMO, such as MaSTherCell, where biopsied liver cells are isolated, expanded and trans-differentiated into AIP cells. The final product is a solution of AIP cells, which are packaged in an infusion bag and sent back to the patient’s treating physician where the cells are transplanted back into the patient’s liver via portal vein infusion. The entire process, from biopsy to transplantation, is expected to take 5-6 weeks.

Unique Benefits of AIP Cells

We believe that our singular focus on the acquisition, development, and commercialization of AIP cells may have many and meaningful benefits over other technologies, including:

- Physiologically glucose-responsive insulin production within one week of AIP cell transplantation;
- Insulin-independence within one month;
- Single course of therapy (~10-year insulin-independence);
- No need for concomitant immunosuppressive therapy;
- Return to (near) normal quality of life for patients;
- Single liver biopsy supplies unlimited source of therapeutic tissue (bio-banking for future use if needed);
- Highly controlled and tightly closed GMP systems; and
- Quality control of final product upon release and distribution.

We are aware of no other company focused on development of AIP cells based on trans-differentiation. The pharmaceutical industry is fragmented, and it is a competitive market. We compete with many pharmaceutical companies, both large and small and there may be technologies in development of which we are not aware.

We believe our ability to further develop our AIP cells is augmented by the following:

IP Strength - Orgenesis has broad patent claims on its process and has 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, the company’s 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, the company has both freedom to operate and ability to obstruct competitors in developing autologous cells for treatment of diabetes.

Simplicity - There is no need for anti-rejection treatment or encapsulation. Using liver as pancreatic progenitor tissue allows the diabetic patient to be the donor of his own insulin-producing tissue, thus allowing autologous implantations with no need for anti-rejection therapy, which restricts the target population only to adult, severe diabetic patients. Moreover, drugs used for preventing the allo-transplanted tissue rejection are deleterious to insulin producing cell function and to the patient.

Safety - the generated cells do not regress to pluripotency, and no adverse effects of uncontrolled cells proliferation occur. The cells are already mature and can be inserted in to the patient following extensive quality assurance testing. Moreover, our cells transplanted in rodents do not cause any adverse effects even following many weeks in the animals.

Availability - Sufficient liver cells to treat a patient as well to store cells for additional future treatments may be generated. The cells can be frozen and thawed, without losing the trans-differentiation capacity for up to 20 passages in culture. It is anticipated that a biopsy from the diabetic patient's own liver is sufficient to generate enough insulin-producing cells to replace the entire cell function and control blood glucose level. As opposed to islets that are non-dividing (i.e., post-mitotic), it is necessary to use stem cells to generate sufficient numbers of cells that are then differentiated.

Future Product Candidates **-** Currently, liver cells are best suited for generating AIP cells. Future products may involve the use of cell types other than liver that are more easily accessible from the diabetic patient or from unrelated donors. Additionally, other adult cells (i.e. fibroblasts) may be studied for trans-differentiation into functional cells in diseases other than insulin-dependent disorders (i.e. neurodegenerative).

The THM License Agreement

Our cell therapy business 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 November 30, 2018, 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.

Competition in the Cell Therapy Field

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. Other allogeneic approaches, such as Viactye’s PEC-01 technology, may enter clinical trials 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.

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.

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.

PT Revenue Model

Through analysis of the cell therapy landscape, we are introducing a novel POCare therapy business model with our goal of bringing autologous therapies in a cost-effective, high-quality and scalable manner to patients. We are establishing and positioning our PT business in order to bring POCare 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., Korea and Japan.

Our unique understanding of industry needs allows us to offer our clients a range of technologies and processes that potentially generate revenues. This may include:

- Development Services – Industrial manufacturing know-how to the cell and gene therapy 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

- POCare 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.

PT Business Strategy

Our aim is to provide a pathway to bring ATMPs in the cell and gene therapy industry from research to patients worldwide through our POCare network. We define POCare cell and gene therapy 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 POCare 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.

While our PT business strategy is currently limited to early stage development to overcome certain industry challenges, we intend to continue developing a global POCare 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 PT 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 POCare systems in major hospitals and key geographies, including Europe, Asia, North America, and South America.

Grant Funding

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

i. 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 to MaSTherCell the entire amount.

ii. 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 a 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 partially refundable subject to certain conditions and are also subject to conditions and restrictions with respect to the Belgian Subsidiary's work in the Walloon Region and ownership of results of the research program. 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 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 November 30, 2018, the Company repaid $34 thousand (Euro 30 thousand) to the DGO6 and $152 thousand was recorded in other payables in the financial statements.

iii. In April 2016, the Belgian Subsidiary received 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. On December 19, 2016, the Belgian Subsidiary received advance payment of Euro 359 thousand ($374 thousand). Up through November 30, 2018, Euro 303 thousand was recorded as a deduction of research and development expenses and $64 thousand was recorded as advance payments on account of the grant. The grants are partially refundable subject to certain conditions and are also subject to conditions and restrictions with respect to the Belgian Subsidiary's work in the Walloon Region and ownership of results of the research program.

iv. On October 8, 2016, the Belgian Subsidiary received 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 held during a period of three years that commenced on January 1, 2017. The financial support is awarded to the Belgium Subsidiary at 55% of budgeted costs, or for 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 November 30, 2018, $1.1 million was recorded as a deduction of research and development expenses and $847 thousand was recorded as advance

payments on account of the grant. The grants are partially refundable subject to certain conditions and are also subject to conditions and restrictions with respect to the Belgian Subsidiary's work in the Walloon Region and ownership of results of the research program.

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. To date, the Israeli Subsidiary received $200 thousand under the grant. Up through November 30, 2018, $359 thousand was recorded as a deduction of research and development expenses and $159 thousand was recorded as a receivable on account of the grant.

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 the Company's 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 with CureCell. 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 November 30, 2018, 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. As of November 30, 2018, the Israeli Subsidiary and CureCell received $440 thousand under the grant.

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. 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, the U.S. Subsidiary received an advance payment of $406 thousand on account of the Grant. Through November 30, 2018, the Company utilized $356 thousand from the grant and recorded it as a deduction of research and development expenses in the statement of comprehensive loss.

Research and Development

We incurred $7,386 and $3,326 thousand in research and development expenditures in the fiscal years ended November 30, 2018 and 2017, respectively, of which $922 thousand and $848 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 November 30, 2018, as compared to 2017 and reflects management's plan to move our transdifferentiation technology to the next the stage towards clinical studies. In the fiscal year ended 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 transdifferentiation 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 immunoncology, 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 nineteen (19) foreign issued patents, nine (9) pending applications in the United States, thirty-two (32) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and four (4) 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 -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, transdifferentiation, 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 transdifferentiation, 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 transdifferentiated 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

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 product is 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 product, 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.

Employees

As of November 30, 2018, we had an aggregate of 231 employees working at our Company and subsidiaries. In addition, we retain the services of outside consultants for various functions including clinical work, finance, accounting and business development services. Most of our senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees are covered by collective bargaining agreements. We believe that we have good relations with our employees.

Subsidiaries

Orgenesis Inc. is a Nevada corporation, and our subsidiaries currently consist of Masthercell Global Inc., a Delaware corporation ("Masthercell Global"), Orgenesis SPRL, a Belgian-based entity (the "Belgian Subsidiary "), Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"), and Orgenesis Maryland Inc., a Maryland corporation. Masthercell Global's wholly-owned subsidiaries include MaSTherCell S.A. ("MaSTherCell"), a Belgian-based entity, Cell Therapy Holdings S.A., a Belgian-based entity, Masthercell U.S., LLC, a U.S.-based entity, Atvio Biotech Ltd. ("Atvio"), an Israeli-based CDMO, and CureCell Co. Ltd. ("CureCell"), a Korea-based CDMO (Orgenesis owned 94.12% of CureCell which was consolidated into Masthercell Global).

The corporate organization diagram below shows how we classify each subsidiary and each joint venture partner between its two business units:

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 Business

We will need to raise capital in order to realize our business plan, the failure of which could adversely impact our operations.

Although we currently have sufficient capital resources for the next 12 months, without adequate funding or a significant increase in revenues, we may not be able to expand our global CDMO network, establish additional CDMO facilities in the United States or other parts of the world, implement our POCare therapy business, seek out strategic CDMO acquisitions, commence clinical trials for our diabetes solution or respond to competitive pressures. As of November 30, 2018, we had available cash resources of $16.1 million.

Overall, we have funded our cash needs from inception through the date hereof with a series of debt and equity transactions, grants from governmental agencies and, more recently, through cash flow from our revenue generating operations from Masthercell Global.

We expect to continue to finance our operations, acquisitions and develop strategic relationships, primarily by issuing equity or convertible debt securities, which could significantly reduce the percentage ownership of our existing stockholders. Furthermore, any newly issued securities could have rights, preferences and privileges senior to those of our existing common stock. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. We may also issue securities in one or more of our subsidiaries, and these securities may have rights or privileges senior to those of our common stock.

We may have difficulty obtaining additional funds as and when needed, and we may have to accept terms that would adversely affect our stockholders. In addition, any adverse conditions in the credit and equity markets may adversely affect our ability to raise funds when needed. Any failure to achieve adequate funding will delay our development programs and product launches and could lead to abandonment of one or more of our development initiatives, as well

as prevent us from responding to competitive pressures or take advantage of unanticipated acquisition opportunities. Any additional equity financing will likely be dilutive to stockholders, and certain types of equity financing, if available, may involve restrictive covenants or other provisions that would limit how we conduct our business or finance our operations.

We are not profitable as of November 30, 2018, have limited cash flow and, unless we increase revenues and cash flow or raise additional capital, we may be unable to take advantage of any commercial opportunities that arise or expand CDMO operations, all of which could adversely impact us.

For the fiscal year ended November 30, 2018 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. Our auditor's report for the year ended November 30, 2018 does not include a going concern opinion on the matter. However, management is still required to assess our ability to continue as a going concern. We had a net loss of $19.1 million for the year ended November 30, 2018. During the same period, cash used in operations was $15.7 million, the working capital surplus and accumulated deficit as of November 30, 2018 were $13.2 million and $62.4 million, respectively. Management is unable to predict if and when we will be able to generate significant positive cash flow or achieve profitability. Our plan regarding these matters is to strengthen our revenues and continue improving the net results in the CDMO segment and to raise additional equity financing to allow us the ability to cover our cash flow requirements into fiscal year 2019. There can be no assurances that we will be successful in increasing revenues, improving CDMO segment results or that financing will be available or, if available, that such financing will be available under favorable terms. In the event that we are unable to generate adequate revenues to cover expenses and cannot obtain additional financing into fiscal year 2019, we may need to cut back or curtail our expansion plans.

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

As of November 30, 2018, we had 231 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, are usually transacted in U.S. dollars and European currencies. Our results of operations are affected by fluctuations in currency exchange rates in both sourcing and selling locations. Although we enter into foreign currency exchange forward contracts from time to time to reduce our risk related to currency exchange fluctuation, 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, 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 -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, transdifferentiation, 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.

Risks Related to Our CDMO Business

While there is an increasing number of product candidates in clinical trials with a smaller number that have reached commercial production, cell therapy is a developing industry and a significant global market for manufacturing services may never emerge.

Cell therapy is in its early stages and is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace, making it difficult for their own funding to enable them to continue their business. In addition to providing in-house process development and manufacturing expertise for our own product candidates in development, Masthercell Global provides development and manufacturing of cell and tissue-based therapeutic products in clinical and pre-clinical trials. The number of people who may use cell or tissue-based therapies, and the demand for cell processing services, is difficult to forecast. If cell therapies under development by us or by others to treat disease are not proven safe and effective, demonstrate unacceptable risks or side effects or, where required, fail to receive regulatory approval, our manufacturing business will be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved cell therapy products in the U.S. Ultimately, our success in deriving revenue from manufacturing depends on the development and growth of a broad and profitable global market for cell-, gene- and tissue-based therapies and services and our ability to capture a share of this market through our global CDMO network.

Masthercell Global's revenues may vary dramatically change from period to period making it difficult to forecast future results.

Masthercell Global (which includes our CDMO subsidiaries) (“Masthercell” or “Masthercell Global”) recorded revenues of approximately $22 million for the year ended November 30, 2018, representing an increase of 92% over the same period last year. The nature and duration of Masthercell’s contracts with customers often involve regular renegotiation of the scope, level and price of the services we are providing. If our customers reduce the level of their spending on research and development or are unsuccessful in attaining or retaining product sales due to market conditions, reimbursement issues or other factors, our results of operations may be materially impacted. In addition, other factors, including the rate of enrollment for clinical studies, will directly impact the level and timing of the products and services we deliver. As such, the levels of our revenues and profitability can fluctuate significantly from one period to another and it can be difficult to forecast the level of future revenues with any certainty. Furthermore, a dramatic change in our future revenue may result an impairment of our goodwill.

The loss of one or more of MaSTherCell’s major clients or a decline in demand from one or more of these clients could harm MaSTherCell’s business.

MaSTherCell has a limited number of major clients that together account for a large percentage of the total revenues earned. Over the past year, MaSTherCell has increased its client portfolio and diversified source of revenues, but there can be no assurance that such clients will continue to use MaSTherCell's services at the same level or at all. A reduction or delay in the use of MaSTherCell's services, including reductions or delays due to market, economic or competitive conditions, could have a material adverse effect on MaSTherCell's business, operating results and financial condition.

MaSTherCell's business is subject to risks associated with a single manufacturing facility.

The majority of Masthercell Global's contract manufacturing services are from MaSTherCell S.A., our Belgian subsidiary and are dependent upon its single fully operational facility located in Gosselies (Belgium). A catastrophic loss of the use of all or a portion of the manufacturing facility due to accident, fire, explosion, labor issues, weather conditions, other natural disaster or otherwise, whether short or long-term, could have a material adverse effect on MaSTherCell's customer relationships and financial results. While its global network partners offer alternative manufacturing sites as part of a disaster recovery plan, this may require it to invest significant time and effort in tech transfer.

If MaSTherCell loses electrical power at its manufacturing facility, its business operations may be adversely affected.

If MaSTherCell loses electrical power at its manufacturing facility for more than a few hours, MaSTherCell would be unable to continue its manufacturing operations for an extended period of time. Additionally, MaSTherCell does not have an alternative manufacturing location located nearby. While MaSTherCell implemented remediation measures to address this risk by setting up a back-up generator allowing it to provide for its manufacturing power consumption needs for a few hours and by being granted a priority access to power in case of global power outage, in the industrial park in Belgium where its premises are located, these measures may not prevent a significant disruption in MaSTherCell's manufacturing operations which could materially and adversely affect its business operations during an extended period of power outage.

The logistics associated with the distribution of materials produced by MaSTherCell for third parties and for us are significant, complex and expensive and may negatively impact our ability to generate and meet future demand for our products and improve profitability.

Current cell therapy products and product candidates have a limited shelf life, in certain instances limited to less than 12 hours. Thus, it is necessary to minimize the amount of time between when the cell product is extracted from a patient, arrives at our facility for processing, and is returned for infusion in the patient. To do so, we need our cell therapy facilities to be located in major population centers in which patients are likely to be located and within close

proximity of major airports. In the future, it may be necessary to build new facilities or invest into new technologies enabling final formulation at point of care, which would require a significant commitment of capital and may not then be available to us. Even if we are able to establish such new facilities or technologies, we may experience challenges in ensuring that they are compliant with cGMP standards, EMEA requirements, and/or applicable state or local regulations. We cannot be certain that we would be able to recoup the costs of establishing a facility in a given market. Given these risks, we could choose not to expand our cell processing and manufacturing services into new geographic markets which will limit our future growth prospects.

Product liability and uninsured risks may adversely affect MaSTherCell's continuing operations and damage its reputation.

MaSTherCell operates in an industry susceptible to significant product liability claims. MaSTherCell may be liable if it manufactures any product that causes injury, illness, or death for intentional or gross fault on its part. In addition, product liability claims may be brought against MaSTherCell's clients, in which case MaSTherCell's clients or others may seek contribution from MaSTherCell if they incur any loss or expenses related to such claims. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. While MaSTherCell's liability may be limited to instances where it was grossly negligent, nonetheless, the defense of such claims may be costly and time-consuming and could divert the attention of MaSTherCell's management and technical personnel.

A breakdown or breach of MaSTherCell's information technology systems could subject MaSTherCell to liability.

MaSTherCell relies upon its information technology systems and infrastructure for its business. The size and complexity of MaSTherCell's computer systems make it potentially vulnerable to breakdown and unauthorized intrusion. MaSTherCell could also experience a business interruption, theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise MaSTherCell's system infrastructure or lead to data leakage, either internally or at MaSTherCell's third-party providers.

Similarly, data privacy breaches by those who access MaSTherCell's systems may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to MaSTherCell or its employees, clients or other business partners, may be exposed to unauthorized persons or to the public. Even if MaSTherCell runs regular IT security audits by third-parties, there can be no assurance that MaSTherCell's efforts to protect its data and information technology systems will prevent breakdowns or breaches in MaSTherCell's systems that could adversely affect its business and result in financial and reputational harm to MaSTherCell.

We face competition from other third party contact manufacturers, as well as more general competition from companies and academic and research institutions that may choose to self-manufacture rather than utilize a contract manufacturer.

We face competition from companies that are large, well-established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than those that we currently possess. In addition, certain of our leading competitors, such as Lonza Group, WuXi AppTec and PCT have international capabilities that we do not currently possess though we are pursuing.

More generally, we face competition inherent in any third-party manufacturer's business - namely, that potential customers may instead elect to invest in their own facilities and infrastructure, affording them greater control over their products and the hope of long-term cost savings compared to a third party contract manufacturer. To be successful, we will need to convince potential customers that our current and expanding capabilities are more innovative, of higher-quality and more cost-effective than could be achieved through internal manufacturing and that our experience and quality manufacturing and process development expertise are unique in the industry. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in developing technologies that improve both the quality and profitability associated with cell therapy manufacturing. If we are unable to successfully compete against other manufacturers, we may not be able to develop our CDMO business plans which may harm our business, financial condition and results of operations.

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.

Although we seek to conduct our business in compliance with applicable governmental healthcare laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The cell therapy industry is the topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and/or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations could result in significant enforcement actions, civil or criminal penalties, which along with the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

Joint-venture partnerships integration into our global CDMO network would be subject to various risks and uncertainties and may involve significant time and attention, all of which could disrupt or adversely affect our business and harm our reputation.

We need our cell therapy facilities to be located in major population centers in which patients are likely to be located and within close proximity of major airports. To do so, we intend to build up a global CDMO network partnership offering alternative manufacturing sites for our third-party clients currently operating out of Belgium, Korea and Israel. The failure to provide harmonized manufacturing quality standards between the current and any future sites to our clients and compliance with local regulatory agencies requirements could have a material adverse effect on our reputation, business, operating results and financial condition.

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 management and on our trained staff turnover. If the staff turnover increases, it could result in additional hiring and training expenses, potentially delays in product development and manufacturing and harm our business and our growth. 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, some of 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.

Masthercell Global may not receive the future payments pursuant to the Stock Purchase Agreement with GPP-II.

The purchase price for the Masthercell Global Preferred Stock was up to $25 million, subject to certain adjustments, of which $11.8 million was paid in cash at closing. The Stock Purchase Agreement also requires GPP-II to make up to two additional payments to Masthercell Global if certain specified EBITDA (as defined in the Stock Purchase Agreement) and revenue targets are satisfied by Masthercell Global during each of years 2018 and 2019. For each of those fiscal years in which such specified EBITDA and revenue targets are satisfied by Masthercell Global, GPP-II

will be obligated to pay an additional $6.6 million, subject to adjustment, to Masthercell Global shortly after the end of that fiscal year.

To earn such contingent payment for the 2018 fiscal year, Masthercell Global must have (i) during any twelve month period ending on or prior to December 31, 2018, generated Net Revenue equal to or greater than €14,100,000 and EBITDA equal to or greater than €1,800,000, and (ii) by December 31, 2018, obtained stockholder approval of the Stockholders' Agreement Terms in accordance with law the and in a manner that will ensure that GPP-II is able to exercise its rights under the Stockholders' Agreement without any further action or approval by GPP-II, us, our stockholders, or any other person, which includes the stockholder approval sought in our proxy statement for our annual meeting of stockholders ("Proper Approval"). In satisfaction of these conditions, Masthercell Global achieved the specified EBITDA and revenues targets in 2018 as described in the SPA and received $6,600,000 of the Future Payments on January 16, 2019 and received approval from the requisite shareholders on October 23, 2018.

To earn such contingent payment for the 2019 fiscal year, Masthercell Global must (i) during any twelve-month period ending on or prior to December 31, 2019, generate Net Revenue equal to or greater than €19,100,000 and EBITDA equal to or greater than €3,900,000, and (ii) by December 31, 2019, obtain Proper Approval, if not already obtained. Accordingly, if our stockholders do not approve the Stockholders' Agreement Terms and do not meet the applicable Net Revenue and EBITDA targets, Masthercell Global will not be eligible to receive the future payments. In addition, in such event, GPP-II will obtain the right to put to us (or, at our discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global.

GPP-II may force the sale of Masthercell Global which may result in GPP-II receiving a greater value than the Company and its shareholders.

At any time following the earlier to occur of (i) after June 28, 2020 or (ii) Masthercell Global's failure to generate positive EBITDA for any twelve (12) month period as determined on a quarterly basis prior to June 28, 2020 or its failure to generate at least $1,000,000 of EBITDA during any such twelve (12) month period after June 28, 2020 (collectively, a "Material Underperformance Event"), GPP-II has the right, in its sole discretion, to approve and force the sale of Masthercell Global. While we have the right of first refusal with respect to acquiring Masthercell Global in its entirety, if GPP-II elects to exercise such a right and if we are not in the position to acquire Masthercell Global, GPP-II may cause the sale of Masthercell Global to any third party on terms GPP-II approves on an arm's length basis and subject to the receipt of a fairness opinion. If this occurs, we are contractually obligated to approve such a sale and execute any documents as required by GPP-II. We must also share in any costs and expenses relating to such a sale on a pro rata basis. Based on this, there may be a situation where GPP-II approves a sale that is more valuable or beneficial to GPP-II than to our Company and our shareholders, and we will not be able to prevent such a transaction. A sale of Masthercell Global could have impacts to the CDMO activities of Orgenesis as conducted through Masthercell Global and to Orgenesis' overall value as a whole.

GPP-II may, under certain circumstances, assume control of the Board of Directors of our subsidiary, Masthercell Global, which would result in our inability to control and direct the activities of such subsidiary.

Currently, the Board of Directors of Masthercell Global is comprised of seven (7) directors, four (4) of whom are appointed by us (one of whom must be an industry expert (the "Industry Expert Director")) and three (3) of whom are appointed by GPP-II. In the event the Industry Expert Director is removed or replaced without the prior written approval of GPP-II, or a Material Underperformance Event has occurred after June 28, 2020, GPP-II has the right to increase the size of the Board of Directors of Masthercell Global and appoint additional directors to fill such vacancies so that GPP-II appointments represent a majority of the directors. If this were to occur, GPP-II would control the Board of Directors of Masthercell Global and will be entitled to direct its activities and approve any transactions of Masthercell Global, even if such transactions provide greater value to GPP-II than they do to Orgenesis and its stockholders. This lack of control could diminish the value of Masthercell Global as it relates to Orgenesis' overall activity and significantly impact CDMO activities of Orgenesis as conducted through Masthercell Global.

GPP-II has the right to buy our shares in Masthercell Global upon the occurrence of certain events resulting in Orgenesis not holding any shares in Masthercell Global.

GPP-II has the right to purchase all of the shares of stock we hold in Masthercell Global if any of the following occurs: (i) there is an Activist Shareholder (as defined in the Stockholders' Agreement) of the Company; (ii) the Chief Executive Officer and/or Chairman of the Board of Directors of the Company is replaced prior to June 28, 2023; (iii) there is a Change of Control (as defined in the Stockholders' Agreement) of the Company; or (iv) the Industry Expert Director is removed or replaced without the prior written consent of GPP-II. If any of these events occur, GPP-II,

upon notice to the Company, can force the Company to sell all of the securities it holds in Masthercell Global to GPP-II based upon a valuation of Masthercell Global to be determined by one of the top ten (10) independent third-party accounting firms in the United States with experience in performing valuations as selected by GPP-II. This right of GPP-II expires if GPP-II fails to exercise this right within three (3) years from the first occurrence of any of the events listed above. In the event GPP-II does exercise its right following the occurrence of any such event, Orgenesis shall cease to be a stockholder of Masthercell Global and will no longer derive any benefits from this subsidiary or its activities. This would also affect the CDMO activities being conducted by Orgenesis through Masthercell Global.

GPP-II has the right to effectuate a spin-off of our subsidiary, Masthercell Global

In addition to the other rights GPP-II has obtained under the Stockholders' Agreement, GPP-II also has the right to effectuate a spin-off of Masthercell Global upon the earlier to occur of: (i) any of the four events listed in the section above or (ii) ninety (90) days after GPP-II provides the Company of its intent to exercise this right provided that such notice cannot be delivered by GPP-II before June 28, 2020. Such a spin-off would be based on a valuation of Masthercell Global as determined in accordance with the terms of the Stockholders' Agreement. If such a spin-off was completed, there is a chance that Masthercell Global would no longer be a subsidiary of Orgenesis, which would result in a significant loss of value to Orgenesis. In addition, without control or ownership of Masthercell Global, Orgenesis' ability to conduct CDMO activities independently would also be greatly affected in the event such a spin-off is completed.

If GPP-II opts to exchange its Masthercell Global Preferred Stock for shares of our common stock, we could potentially issue a substantial number of shares of our common stock to GPP-II, which may result in significant dilution to our existing stockholders.

The Stockholders' Agreement provides that GPP-II is entitled, at any time, to convert its share capital in Masthercell Global for our common stock (such exchange option being the "Stock Exchange Option"). Under the Stock Exchange Option, GPP-II is entitled to exchange the Masthercell Global Preferred Stock for our common stock based on an exchange price (as defined in the Stockholders' Agreement) that is not currently known. If GPP-II opts to exchange its Masthercell Global Preferred Stock for shares of our common stock, we could potentially issue a substantial number of shares of our common stock to GPP-II. The common stock issuable to GPP-II upon exchange of the Masthercell Global Preferred Stock for our common stock could have a depressive effect on the market price of our common stock by increasing the number of shares of common stock outstanding. Such downward pressure could encourage short sales by certain investors, which could place further downward pressure on the price of the common stock. Accordingly, the number of shares of outstanding common stock may increase significantly and the ownership interests and proportionate voting power of the existing stockholders may be significantly diluted.

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 PT 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 2019. 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.

We expect that continued development of our manufacturing facility via MaSTherCell and our global CDMO network will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

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 CDMO 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, including further impairment to unproved oil and gas properties;
- 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 oil and natural gas 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 November 30, 2018, our stock price has fluctuated from a low of $4.50 to a high of $14.68 (adjusted to account for the 1:12 reverse split implemented in November 2017). 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 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.
MaSTherCell SA, Cell Therapy Holding SA and Orgenesis SPRL	All activities located in Gosselies, Belgium, in the I-Tech Incubator 2. Property consists of: · Operational production and Office area represent +/-2,400 m². · Monthly costs are approximately €25 thousand. · Lease agreement for the office and operational production area expires on March 31, 2030. · Additional offices are leased in a separate building to temporarily locate MaSTherCell corporate service and meeting rooms; it represents 480m² for a monthly cost of €7 thousand and termination lease agreement on February 29, 2020. · The new production area designed during 2016 was built in 2017-2018 and was operational at the end of 2018.

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.
Masthercell Korea	· Operational production and Office area represent +/-2,234 m². · 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. From March 13, 2018 the Company's common stock began trading on the Nasdaq Capital Market (Nasdaq CM) under the symbol "ORGS."

As of February 11, 2019, there were 156 holders of record of our common stock, and the last reported sale price of our common stock on the Nasdaq CM on February 12, 2019 was $4.88. 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 November 30, 2018, our financing activities consisted of the following:

(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 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 have been 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 had 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 and 2017, the investor and the assignees remitted to the Company $11.5 and $4.5 million, respectively, and the Company issued 1,813,687 and 721,160 Units, respectively.

(2) During the fiscal year ended November 30, 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of 1,237,642 units. Each unit is comprised of (i) one share of the Company's common stock and (ii) 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, for aggregate proceeds to the Company of approximately $7.7 million.

(3) During the year ended November 30, 2018, investors exercised 136,646 warrants into 136,646 shares of the Company's Common Stock, for aggregate proceeds of $853 thousand.

(4) In November 2018, we entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of $625 thousand. The loans bear an annual interest rate of 2% and mature in three years unless converted earlier. The holders, at their option, may convert the outstanding principal amount and accrued interest under those notes into 89,285 shares of our common stock and 89,285 three-year warrants to purchase up to an additional 89,285 shares of our 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, a subsidiary of Hemogenyx Pharmaceuticals Plc, at a price per share based on a pre-money valuation of Hemogenyx-Cell of $12 million (the "Hemogenyx Securities"), pursuant to the collaboration agreement with Hemogenyx Pharmaceuticals Plc.

(5) In November 2018, we entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of $625 thousand. The loan bears an annual interest rate of 2% and matures in three years unless converted earlier. The holders, at their option, may convert the outstanding principal amount and accrued interest under those notes into 89,285 shares of our common stock and 89,285 three-year warrants to purchase up to an additional 89,285 shares of our 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 Immugenyx, LLC, a subsidiary of Hemogenyx Pharmaceuticals Plc, at a price per share based on a pre-money valuation of Immugenyx of $8 million (the "Immugenyx Securities"), pursuant to the collaboration agreement with Immugenyx, LLC.

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 two-year period

ended November 30, 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 fiscal year ended November 30, 2018, as compared to the fiscal year ended November 30, 2017. This discussion should be read in conjunction with our consolidated financial statements for the two-year period ended November 30, 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 technologies and services in the cell and gene therapy industry. We operate through two platforms: (i) a point-of-care ("POCare") cell therapy platform ("PT") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform conducted through our subsidiary, Masthercell Global. Through our PT business, our aim is to further the development of 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. 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. Through our CDMO platform, we are focused on providing contract manufacturing and development services for biopharmaceutical companies.

Our therapeutic development efforts in our PT 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 as cell-based immunotherapies, 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 PT 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 SPRL, in the European Union and Orgenesis Ltd. in Israel.

Our subsidiary, Masthercell Global, is a CDMO specialized in cell therapy development for advanced therapeutically products. In the last decade, cell therapy medicinal products have gained significant importance, particularly in the fields of ex-vivo gene therapy and immunotherapy. While academic and industrial research has led scientific development in the sector, industrialization and manufacturing expertise remains insufficient. Masthercell Global plans to fill this gap by providing three types of services to its customers: (i) process and assay development services and (ii) current Good Manufacturing Practices (cGMP) contract manufacturing services and (iii) technology innovation and engineering services. These services offer a double advantage to Masthercell Global’s customers. First, customers can continue allocating their financial and human resources on their product/therapy, while relying on a long-term reliable and trusted partner for their process development/production. Second, through its subsidiaries, it allows customers to benefit from Masthercell Global’s expertise in cell therapy manufacturing and all related aspects.

Masthercell Global’s wholly-owned subsidiaries include MaSTherCell S.A., a Belgian-based subsidiary and a Contract Development and Manufacturing Organization (“CDMO”) specialized in cell therapy development and manufacturing for advanced medicinal products, Atvio Biotech Ltd. (“Atvio”), an Israeli-based CDMO, and CureCell Co. Ltd. (“CureCell”), a Korea-based CDMO.

We operate our CDMO and the PT 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, the Company changed its 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. Currently, most of the Company’s revenues are generated through MaSTherCell.

On June 28, 2018, the Company, 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 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 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”). Orgenesis holds 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 to be made in each of years 2018 and 2019 (the “Future Payments”), or an aggregate of $13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis’ shareholders approve certain provisions of the Stockholders’ Agreement referred to below on or before December 31, 2019. None of the future Consideration amounts, if any, will result in an increase in GPP-II’s equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing.

Contemporaneous with the execution of the SPA, Orgenesis and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which Orgenesis contributed to Masthercell Global the Orgenesis’ assets relating to the CDMO Business (as defined below), including the CDMO subsidiaries (the “Corporate Reorganization”). In furtherance thereof, Masthercell Global, as Orgenesis’ assignee, acquired all of the issued and outstanding share capital of Atvio, the Company’s Israel based CDMO partner since May 2016, and 94.12% of the share capital of CureCell, the Company’s Korea based CDMO partner since March 2016. Orgenesis 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 Orgenesis common stock. In respect of the acquisition of Atvio, Orgenesis issued to the former Atvio shareholders an aggregate of 83,965 shares of Orgenesis common stock. In respect of the acquisition of CureCell, Orgenesis Inc. issued to the former CureCell shareholders an aggregate of 202,846 shares of Orgenesis Common Stock subject to a third-party valuation. Together with MaSTherCell S.A., Atvio and CureCell are directly held subsidiaries under Masthercell Global (collectively, the “Masthercell Global Subsidiaries”).

Material Developments During Fiscal 2018

Funding from SFPI

On November 15, 2017, we, MaSTherCell and the Belgian Sovereign Funds Société Fédérale de Participations et d'Investissement (“SFPI”) entered into a Subscription and Shareholders Agreement (the “ SFPI Agreement”) pursuant to which SFPI completed an equity investment in MaSTherCell in the aggregate amount of €5 million (approximately $5.9 million), for approximately 16.7% 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.

Following the SFPI investment in MaSTherCell, in November 2017, MaSTherCell announced the expansion by 600m² of its facility in Belgium with a dedicated, late-stage clinical and commercial cGMP unit, which was opened in the first quarter of 2019. This new expansion enables MaSTherCell to augment its commercial capabilities in Europe with five state-of-the-art advanced manufacturing units and extended GMP-accredited quality control (QC) laboratories. On June 13, 2018, SPFI has paid the balance of Euro 1.9 million (approximately $2.3 million) to MaSTherCell.

Consolidation of CDMO Entities and Strategic Funding

On June 28, 2018, the Company, Masthercell Global Inc., a Delaware company and a newly formed subsidiary of the Company that holds our business relating to the third party contract manufacturing for cell therapy companies (CDMO) ("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 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 Great Point 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 cash consideration to be paid into Masthercell Global of up to $25 million, subject to certain adjustments (the "Consideration"). Orgenesis holds 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, with a follow up payment of $6,600,000 to be made in each of years 2018 and 2019 (the "Future Payments"), or an aggregate of $13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis' shareholders approve certain provisions of the Stockholders' Agreement referred to below on or before December 31, 2019. None of the future Consideration amounts, if any, will result in an increase in GPP-II's equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing. The proceeds of the investment will be used to fund the activities of Masthercell Global and its consolidated subsidiaries. Notwithstanding the foregoing, GPP-II may, in its sole discretion, elect to pay all or a portion of the future Consideration amounts even if the financial targets described above have not been achieved and the Orgenesis Stockholder Approval has not been obtained. In satisfaction of the first of the two conditions described above, Masthercell Global achieved the specified EBITDA and revenues targets in 2018 as described in the SPA and received $6,600,000 of the Future Payments on January 16, 2019.

In connection with the entry into the SPA 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 favorable, preferential rights to GPP-II (including, without limitation, a tag right, drag right and certain protective provisions), a right to exchange the Masthercell Global Preferred Stock for shares of Orgenesis common stock and certain other rights and obligations. In addition, 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 determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and the Masthercell Global Subsidiaries of at least $50 million. In addition, upon certain enumerated events as 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 of such equity holdings as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II, 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; 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. For the purposes of the foregoing, the following definitions shall apply: (A) "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; and (B) "Change of Control" shall mean any of: (a) the acquisition, directly or indirectly (in a single transaction or a series of related transactions) by a Person or group of Persons of either (I) a majority of the common stock of the Company (whether by merger, consolidation, stock purchase, tender offer, reorganization, recapitalization or otherwise), or (II) all or substantially all of the assets of the Company and its Subsidiaries (but only if such transaction includes the transfer of Securities held by the Company), (b) if any four (4) of the directors of the Company as of June 28, 2018 are removed or replaced or for any other reason cease to serve as directors of the Company, (c) the filing of a petition in bankruptcy or the commencement of any proceedings under bankruptcy laws by or against the Company, provided that such filing or commencement shall be deemed a Change of Control immediately if filed or commenced by the Company or after sixty (60) days if such filing is initiated by a creditor of the Company and is not dismissed; (d) insolvency of the Company that is not cured by the Company within thirty (30) days; (e) the appointment of a receiver for the Company, provided that such appointment shall constitute an Change of Control immediately if the appointment was consented to by the Company or after sixty (60) days if not consented to by the Company and such appointment is not terminated; or (f) or dissolution 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, as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II and the Company, divided by (ii) the average closing price per share of Orgenesis Common Stock during the thirty (30) 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 having an enterprise value of less than $250,000,000 and (B) the maximum number of shares of Orgenesis Common Stock to be issued shall not exceed 2,704,247 shares of outstanding Orgenesis Common Stock (representing approximately 19.99% of then outstanding Orgenesis Common Stock), unless Orgenesis obtains shareholder approval for the issuance of such greater amount of shares of Orgenesis Common Stock in accordance with the rules and regulations of the Nasdaq Stock Market. Such shareholder approval for a greater number was obtained on October 23, 2018.

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) $250,000 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 $2,000,000 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 $500,000. 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 months 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 Securities, LLC, a Delaware limited liability company and an affiliate of Great Point and Masthercell Global entered into a transaction services agreement pursuant to which GPP Securities, LLC is to provide certain brokerage services to Masthercell Global for which GPP Securities LLC 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.

Corporate Reorganization

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

Orgenesis 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 Orgenesis common stock. In respect of the acquisition of Atvio, Orgenesis issued to the former Atvio shareholders an aggregate of 83,965 shares of Orgenesis common stock. In respect of the acquisition of CureCell, Orgenesis Inc. issued to the former CureCell shareholders an aggregate of 202,846 shares of Orgenesis Common Stock subject to a third-party valuation. Together with MaSTherCell S.A., Atvio and CureCell are directly held subsidiaries under Masthercell Global (collectively, the "Masthercell Global Subsidiaries").

Masthercell Global, through the Masthercell Global Subsidiaries, will be engaged in the business of providing manufacturing and development services to third parties related to cell therapy products, and the creation and development of technology, and optimizations in connection with such manufacturing and development services for third parties (the "CDMO Business"). Under the terms of the Stockholders' Agreement, Orgenesis has agreed that so long as it owns equity in Masthercell Global and for two years thereafter it will not engage in the CDMO Business, except through Masthercell Global (but may continue to engage in its other areas of business). In addition, except for certain limited circumstances, each of Orgenesis and GPP-II agreed in the Stockholders' Agreement to not recruit or solicit or hire any officer or employee of Masthercell Global that was or is involved in the CDMO Business.

We intend, through our direct subsidiaries, to continue to engage in the manufacturing, researching, marketing, developing, selling and commercializing (either alone or jointly with third parties) products that are not directly related to the CDMO business, including, joint ventures, collaboration, partnership or similar arrangement with a third party.

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 will have a December 2018 fiscal month transition period, the results of which will be separately reported in the Company's Quarterly Report on Form 10-Q for the calendar quarters ending March 31, 2019, June 30, 2019 and September 30, 2019, and in the Company's Annual Report on Form 10-K for the calendar year ending December 31, 2019.

Collaboration Agreements with Immugenyx and Hemogenyx

On October 16, 2018, we entered into a collaboration agreement with Immugenyx, LLC ("Immugenyx"), a wholly owned subsidiary of Hemogenyx Pharmaceuticals Plc ("Hemogenyx"). Immugenyx will collaborate with the Company to further the development and commercialization of its advanced hematopoietic chimeras ("AHC"). AHC, a new type of humanized mouse with a functional human immune system, is being developed by Immugenyx as an in vivo platform for disease modelling, drug and cell therapy development. Pursuant to the terms of the agreement, we shall receive the worldwide rights to market the products and shall serve as a global distributor of Immugenyx's products. Immugenyx will retain exclusive rights to manufacture, make and supply to the Company or our affiliates all the Immugenyx technology and/or licensed products that are marketed, sold or otherwise commercialized by the Company. In consideration for the license, we and/or our affiliates will advance to Immugenyx a convertible loan in an amount of no less than $1.0 million for advancing the development of humanized mice models and related antibody development. We also agreed to pay a royalty of 12% of our net revenues resulting from the sale or licensing of products involving the use of Immugenyx's AHC technology. As of November 30, 2018, we have funded $0.5 million.

On October 18, 2018, we entered into a collaboration agreement with Hemogenyx Pharmaceuticals Plc to collaborate on the development and commercialization of Hemogenyx's Human Postnatal Hemogenic Endothelial ("Hu-PHEC") technology. Hu-PHEC is a cell replacement product candidate that is being designed to generate cancer-free, patient-matched blood stem cells after transplantation into the patient. Pursuant to the terms of the agreement, we shall manufacture and supply all Hu-PHEC related products both during and following completion of clinical trials. We shall also receive the worldwide rights to market the products and shall serve as a global distributor of Hemogenyx's Hu-PHEC related products. In consideration for the license, we and/or our affiliates will advance to Hemogenyx a convertible loan in an amount of no less than $1.0 million for advancing the development of the Hu-PHEC technology. We also agreed to pay a royalty of 12% of our net revenues resulting from the sale or licensing of products involving the use of Hemogenyx's Hu-PHEC technology. As of November 30, 2018, we have funded $0.5 million.

Convertible Note Agreements

During November 2018, we entered into private placement subscription agreements (the "Hemogenyx-Cell Subscription Agreement") with certain accredited investors (the "Investors"), pursuant to which we agreed to sell an aggregate principal amount of $625,000 in a 2% Unsecured Convertible Note (the "Hemogenyx Convertible Note"), which is convertible, at the discretion of the Investor, into either (i) units, each unit consisting of one share of common stock of the Company, par value $0.0001 per share ("Common Stock") and one three-year warrant to purchase one share of Common Stock at an exercise price of $7.00 per share, at a conversion price of $7.00 per unit (the "Units") or (ii) shares of capital stock of Hemogenyx-Cell, a subsidiary of Hemogenyx, at a price per share based on a pre-money valuation of Hemogenyx-Cell of $12,000,000 (the "Hemogenyx Securities") pursuant to the previously disclosed collaboration agreement with Hemogenyx.

In addition, on such same month, we entered into a private placement subscription agreement (the "Immugenyx Subscription Agreement") with the Investors, pursuant to which we agreed to sell an aggregate principal amount of $625,000 in a 2% Unsecured Convertible Note (the "Immugenyx Convertible Note "). The Investors may convert all or any portion of the outstanding principal amount of the Immugenyx Convertible Note, plus accrued interest thereon, into the, at the discretion of the Investors, either (i) units, each unit consisting of one share of common stock of the Company, par value $0.0001 per share ("Common Stock") and one three-year warrant to purchase one share of Common Stock at an exercise price of $7.00 per share, at a conversion price of $7.00 per unit (the "Units") or (ii) shares of capital stock of Immugenyx , at a price per share based on a pre-money valuation of Immugenyx of $8,000,000 (the "Immugenyx Securities") pursuant to the previously disclosed collaboration agreement with Immugenyx.

The entire principal amount, plus accrued interest thereon, shall automatically convert into Units if at any time from and after the date hereof, the closing price of the Company's Common Stock on the Nasdaq Capital Market (or other national stock exchange or market on which the Common Stock is then listed or quoted) equals or exceeds $20.00 per share (which amount may be adjusted for certain capital events, such as stock splits) for thirty (30) consecutive trading days.

The Convertible Notes contain standard and customary events of default including, but not limited to, failure to make payments when due, failure to observe or perform covenants or agreements contained in the Convertible Notes, the breach of any material representation or warranty contain therein or the bankruptcy or insolvency of the Company. If any event of default occurs, subject to any cure period, the full principal amount, together with interest (including default interest of 12% per annum) and other amounts owing in respect thereof to the date of acceleration shall become, at the Investor's election, immediately due and payable in cash.

The Warrants included in the Units expire three years from the date of issuance and have an exercise price of $7.00 per share. If at any time from and after the date of issuance, the closing price of our Common Stock on the Nasdaq Capital Market (or other national stock exchange or market on which the Common Stock is then listed or quoted) equals or exceeds $20.00 per share (which amount may be adjusted for certain capital events, such as stock splits, as

described herein) for thirty (30) consecutive trading days, then the Company shall have the right to require the holder to exercise all or any portion of the Warrant still unexercised for a cash exercise into shares of Common Stock in accordance with the terms of the Warrant.

Results of Operations

Comparison of the year ended November 30, 2018 to the year ended November 30, 2017

Our financial results for the year ended November 30, 2018 are summarized as follows in comparison to the year ended November 30, 2017:

	Year Ended November 30,	
	2018	**2017**
	(in thousands)	
Revenues	$18,655	$10,089
Cost of sales	10,824	6,807
Research and development expenses, net	6,464	2,478
Amortization of intangible assets	1,913	1,631
Selling, general and administrative expenses	16,303	9,189
Other income	(2,930)	-
Share in losses of associated company	731	1,214
Financial expense, net	3,117	2,447
Loss before income taxes	$17,767	$13,677

Revenues

	Year Ended November 30,	
	2018	**2017**
	(in thousands)	
Services	$14,065	$8,024
Goods	4,590	2,065
Total	$18,655	$10,089

All our revenues were derived from the CDMO segment, most of which were generated from our Belgian Subsidiary, MaSTherCell S.A. We believe 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.

Our revenues for the year ended November 30, 2018 were $18,655 thousand, as compared to $10,089 thousand for the corresponding period in 2017, representing an increase of 85%. The increase in revenues for the year ended November 30, 2018 compared to the corresponding period in 2017 is attributable to an increase in the projects provided by MaSTherCell S.A, resulting primarily from the extension of existing customer service contracts with biotechnology clients, as well as from revenues generated from existing manufacturing agreements.

In addition, we acquired all the issued and outstanding share capital of Atvio, our Israel-based CDMO partner since August 2016, and 94.12% of the share capital of CureCell, our Korea-based CDMO partner since March 2016, which are both reflected in the increase in our revenues from services provided of $1,174 thousand during the year ended November 30, 2018.

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 November 30, 2018, MaSTherCell S.A. had a backlog of approximately $12.6 million, consisting of services that we expect to deliver into fiscal year 2019. 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 November 30,	
	2018	**2017**
	(in thousands)	
Salaries and related expenses	$4,915	$ 2,642
Stock-based compensation	126	-
Professional fees and consulting services	145	-
Raw materials	4,614	2,692
Depreciation and amortization expenses, net	391	986
Other expenses	633	487
	$10,824	$ 6,807

Cost of revenues for the year ended November 30, 2018 were $10,824 thousand, as compared to $6,807 thousand during the same period in 2017, representing an increase of 59%. The increase for the year ended November 30, 2018 as compared to the corresponding period in 2017 is primarily attributed to the following:

(i) An increase in salaries and related expenses of $2,273 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 Atvio and CureCell for the five months ended in November 30, 2018 (not included in the prior year).

(ii) An increase of stock-based compensation for the year ended November 30, 2018 generated from options granted to employees.

(iii) An increase of $1,922 thousand in raw materials, mainly attributed to the growth in the volume of services provided by MaSTherCell S.A., both from existing and new manufacturing agreements.

(iv) A decrease of $595 thousand in depreciation and amortization expenses. This was primarily attributable to the increase in the production facility and laboratory equipment useful life from 10 to 20 years and from 5 to 3 years, respectively. This change occurred in the last quarter of 2017.

Research and Development Expenses

	Year Ended November 30,	
	2018	2017
	(in thousands)	
Salaries and related expenses	$2,077	$1,181
Stock-based compensation	659	711
Professional fees and consulting services	605	854
Lab expenses	3,370	287
Depreciation expenses, net	320	110
Other research and development expenses	355	183
Less – grant	(922)	(848)
Total	$6,464	$2,478

The increase in research and development expenses reflects management’s determination to move transdifferentiating technology to the next the stage towards clinical studies. In the fiscal year ended 2018, we focused primarily 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 immunoncology, liver pathologies and others. In furtherance of these developments, salaries and related expenses increased for the year ended November 30, 2018 compared to 2017, primarily due to the expansion of our development team in Israel and Belgium.

Research and development expenses (net) for the fiscal year ended November 30, 2018 were $6,464 thousand, as compared to $2,478 thousand for the same period in 2017, representing an increase of 160%. The increase in research and development, net expenses in the year ended November 30, 2018 is primarily attributable to the following:

(i) An increase of $896 thousand in salaries and related expenses primarily attributable to an increase of activities and operational staff.

(ii) A decrease of $249 thousand in the expenses of professional fees and consulting services, mostly related to the conclusion of the BIRD and KORIL projects in Orgenesis Ltd. and decrease in consultant service in Orgenesis Maryland Inc

(iii) An increase of $3,083 thousand of lab expenses, mostly attributed to new therapeutics projects and to the DGO6 project.

Selling, General and Administrative Expenses

	Year Ended November 30,	
	2018	2017
	(in thousands)	
Salaries and related expenses	$4,581	$2,862
Stock-based compensation	3,399	1,155
Accounting and legal fees	2,528	1,773
Professional fees	2,000	2,017
Rent and related expenses	1,281	859
Business development	1,557	599
Other general and administrative expenses	957	(76)
Total	$16,303	$9,189

Selling, general and administrative expenses for the fiscal year ended November 30, 2018 were $16,303 thousand, as compared to $9,189 thousand for the same period in 2017, representing an increase of 77%. The increase is primarily attributable to:

(i) An increase of $1,719 thousand in salaries and related expenses as a result of additional managerial appointments, and salaries and related expenses of CureCell, Atvio and Masthercell Global not previously consolidated.

(ii)

An increase of $2,244 thousand in stock-based compensation as a result of options granted to employees and consultants.

(iii) An increase of $755 thousand in accounting and legal fees mainly attributed to expenses related to the Company's Nasdaq listing, and legal and accounting services related to the strategic agreements with GPP-II and the CureCell and Atvio consolidation.

(iv) An increase of $422 thousand in rent and related expenses mainly related to the occupation of additional space rented by MaSTherCell S.A. and to rent and related expenses in 2018 of CureCell and Atvio (not previously consolidated).

(v) An increase of $958 thousand in business development expenses related to the increase in the related activities during the year.

(vi) (vi) An increase of $1,033 thousand in other general and administrative expenses related to the increase in filing and other fees.

Financial Expenses, net

	Year Ended November 30,	
	2018	2017
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	$50	$ (902)
Stock-based compensation related to warrants granted debt holders	180	1,497
Interest expense on convertible loans and loans	2,753	1,233
Foreign exchange loss, net	129	562
Other expenses	7	57
Total	$3,117	$ 2,447

Financial expenses, net for the fiscal year ended November 30, 2018, increased by $670 thousand, compared to the same period in 2017. The increase in financial expenses is primarily attributable to:

(i) An increase of $952 thousand in fair value of the put options of Atvio.

(ii) A decrease of $1,317 thousand in stock-based compensation related to warrants granted to bondholders.

(iii) An increase of $1,520 thousand in interest expenses on convertible loans and loans.

Tax expenses (income)

	Year Ended November 30,	
	2018	2017
	(in thousands)	
Tax expenses (income)	$1,337	$ (1,310)
Total	$1,337	$ (1,310)

Tax expenses for the fiscal year ended November 30, 2018, increased by $2,647 thousand, compared to the same period in 2017. The increase in tax expenses is mainly due to a decrease in deferred taxes related to carryforward losses in MaSTherCell S.A.

Working Capital

	November 30,	
	2018	2017
	(in thousands)	
Current assets	$30,297	$7,295
Current liabilities	17,145	16,914
Working capital (deficiency)	$13,152	$(9,619)

Current assets increased by $23,002 thousand, which was primarily attributable to the following: (i) an increase in cash and cash equivalents due to proceeds from private placements of debt and equity securities and a cash payment and receivable of $16.9 million from GPP-II to our subsidiary, Masthercell Global; (ii) an increase in inventory and accounts receivable due to the acquisition of CureCell and (iii) higher sales of MaSTherCell.

Liquidity and Capital Resources

	Year Ended November 31,	
	2018	**2017**
	(in thousands)	
Net loss	$(19,104)	$(12,367)
Net cash used in operating activities	(15,682)	(3,833)
Net cash used in investing activities	(6,268)	(3,404)
Net cash provided by financing activities	35,060	8,365
Increase in cash and cash equivalents	$13,110	$1,128

Since inception, we have funded our operations primarily through private placements and debt instruments and through revenues generated from the activities of MaSTherCell S.A., our Belgian Subsidiary. As of November 30, 2018, we had positive working capital of $13.2 million, including cash and cash equivalents and restricted cash of $16.5 million.

Net cash used in operating activities was approximately $15.7 million for the fiscal year ended November 30, 2018, as compared with net cash used in operating activities of approximately $3.8 million for the same period in 2017. 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. We also expanded our global activity of the CDMO business with Masthercell Global, while maintaining the same level of cash used in operating activities as a result of the increased revenues at our subsidiaries MaSTherCell, Cure Cell and Atvio, thereby increasing gross profit and generating cash to pay our ongoing operating expenses. Additionally, we improved payment terms to our service providers.

Net cash used in investing activities for the fiscal year ended November 30, 2018 was approximately $6.3 million, as compared with approximately $3.4 million for the same period in 2017. Net cash used in investing activities was primarily for additions to fixed assets at our subsidiaries, MaSTherCell, CureCell and Atvio.

During the year ended November 30, 2018, our financing activities consisted of proceeds from private placements of our equity securities, warrants exercise and equity-linked instruments in the net amount of approximately $21.5 million and $12.6 million from SFPI and GPP.

Liquidity and Capital Resources Outlook

We believe that our business plan will provide sufficient liquidity to fund our operating needs for the next 12 months. However, there are factors that can impact our ability continue to fund our operating needs, including:

- our ability to expand sales volume, which is highly dependent on implementing our growth strategy in Masthercell Global;
- restrictions on our ability to continue receiving government funding for our PT business;
- additional CDMO expansion into other regions that we may decide to undertake; and
- 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.

If we cannot effectively manage these factors, we may need to raise additional capital before such date to fund our operating needs.

From December 1, 2017 to the date of this Annual Report on Form 10-K, we funded our operations primarily from the proceeds from private placements of our equity securities and convertible debt and from revenues generated by Masthercell Global, mainly revenues generated from MaSTherCell. From December 1, 2017 through November 30, 2018, we received, through MaSTherCell, proceeds of approximately $17.3 million in revenues and accounts receivable from customers, $12.6 million from SFPI and GPP-II and $21.5 million from private placements to accredited investors of our equity and convertible debt, net of finders' fees, and exercise of warrants. In addition, from December 1, 2018 through February 13, 2019, we raised $0.25 million from the private placement of our equity-linked securities, $6.6 million from GPP and proceeds of approximately $4.7 million in accounts receivable from customers of MaSTherCell.

We believe that the investment consummated in June 2018 by an affiliate of GPP in our newly formed subsidiary, Masthercell Global, which has included to the date of this report a total net amount of $16.9 million and, subject to meeting certain specified financial targets and other conditions over the course of 2019, an additional $6.6 million, should cover the costs associated with the current business plan of Masthercell Global.

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 November 30, 2018. 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 or Level 2 assets and liabilities as of November 30, 2018 and 2017.

The derivative liabilities are Level 3 fair value measurements; we did not have any Level 3 assets and liabilities as of November 30, 2018.

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 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 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.

Revenue Recognition

The Company recognizes 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 has occurred or the services that are milestones based have been provided; the price is fixed or determinable and collectability is reasonably assured. The Company determines that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. In addition, the Company determines that services have been delivered in accordance with the arrangement. The Company assesses whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Service revenues are recognized as the services are provided. In addition, as part of the services, the Company recognizes revenue based on use of consumables, which it received as reimbursement on a cost-plus basis on certain expenses.

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 November 30), at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired. The goodwill impairment test is applied by performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is considered not more likely than not that the fair value of the reporting unit is less than the carrying amount, further testing of goodwill for impairment would not be required. Otherwise, goodwill impairment is tested using a two-step approach.

The first step involves comparing the fair value of the reporting unit to its carrying amount. If the fair value of the reporting unit is determined to be greater than its carrying amount, there is no impairment. If the reporting unit's carrying amount is determined to be greater than the fair value, the second step must be completed to measure the amount of impairment, if any. The second step involves calculating the implied fair value of goodwill by deducting the fair value of all tangible and intangible assets, excluding goodwill, of the reporting unit from the fair value of the reporting unit as determined in step one. The implied fair value of the goodwill in this step is compared to the carrying value of goodwill. If the implied fair value of the goodwill is less than the carrying value of the goodwill, an impairment loss equivalent to the difference is recorded.

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.

On December 22, 2017, the President of the United States signed and enacted into law H.R. 1 (the “Tax Reform Law”). The Tax Reform Law, effective for tax years beginning on or after January 1, 2018, except for certain provisions, resulted in significant changes to existing United States tax law, including various provisions that are expected to impact us. The Tax Reform Law reduces the federal corporate tax rate from 35% to 21% effective January 1, 2018. We have analyzed the provisions of the Tax Reform Law to assess the impact on our consolidated financial statements.

Impairment of LongLived Assets

We will periodically evaluate the carrying value of longlived assets to be held and used when events and circumstances warrant such a review and at least annually. The carrying value of a longlived 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 longlived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Losses on longlived assets to be disposed of are determined in a similar manner, except that fair values are reduced for the cost to dispose.

Recently Issued Accounting Standards

In January 2016, the Financial Accounting Standards Board (“FASB”) issued guidance on recognition and measurement of financial assets and financial liabilities (ASU No. 2016-01) that will supersede most current guidance. Changes to the U.S. GAAP model primarily affect the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities, is largely unchanged. The classification and measurement guidance became effective as of December 1, 2018. We do not expect the implementation of this new pronouncement to have a material impact on our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-09 “Revenue from Contracts with Customers (Topic 606)” (“Topic 606”) that will supersede most current revenue recognition guidance, including industry

specific guidance. Under the new standard, a good or service is transferred to the customer when (or as) the customer obtains control of the good or service, which differs from the risk and rewards approach under current guidance. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance is effective in annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company will implement the guidance for our annual period ending on December 31, 2019 and interim periods within such annual periods, using the modified retrospective method and will adjust the accumulated deficit and deferred revenue as of the adoption date.

Under current GAAP, the Company recognizes revenue for services linked to cell process development based on both the input and output methods of measurement. The Company has evaluated the application of the requirements of ASC 606 to 'recognize revenue when or as the entity satisfies a performance obligation to its business. The Company has several types of revenue contracts:

a) Cell process development services

The Company has concluded that under the revised standard, contracts for cell process development services are in some cases a single performance obligation (where promises offered to customers are not distinct within the context of the contract), and in other cases have multiple performance obligations (where promises to the customers are distinct). In all cases the performance obligations are satisfied over time. Under the new standard, the Company will recognize revenue over time using either a cost-based input method or output method, whichever fairly depicts the transfer of control over the life of the performance obligation, as appropriate.

b) Cell manufacturing services

Regarding revenues from cell manufacturing services, the Company concluded that these comprised a single performance obligation. 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).

c) Tech transfer

The Company has concluded that under the revised standard, contracts for Tech Transfer services are considered a single performance obligation and will be measured 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.

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. The adoption of the new standard is not expected to result in a material effect on the total stockholders' equity as of December 1, 2018.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a Consensus of the FASB Emerging Issues Task Force) ("ASU 2016-18"), which requires entities to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for annual reporting periods (including interim periods within those annual reporting periods) beginning after December 15, 2017. The Company adopted this standard during the year ended November 30, 2018.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)” (“ASU 2016-02”), which supersedes the existing guidance for lease accounting, “Leases (Topic 840)”. ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in ASU 2016-02 are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. We expect to apply the ASU without adjusting the comparative periods and, if applicable, recognizing a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. We are currently evaluating the impact of this new standard on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments-Credit Losses (Topic 326)” (“ASU 2016-13”). ASU 2016-13 requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis. The income statement reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We do not expect the implementation of this new pronouncement to have a material impact on our consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting” (“ASU 2017-09”), which gives direction on which changes to the terms or conditions of share-based payment awards require an entity to apply modification accounting in Accounting Standard Codification (“ASC”) Topic 718. In general, entities will apply the modification accounting guidance if the value, vesting conditions or classification of the award changes. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. We do not expect the implementation of this new pronouncement to have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, “Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting” that expands the scope of ASC Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of ASC Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. We do not expect the implementation of this new pronouncement to have a material impact on our consolidated financial statements.

In January 2017, FASB issued Accounting Standards Update (ASU) 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which eliminated the calculation of implied goodwill fair value. Instead, companies will record an impairment charge based on the excess of a reporting unit’s carrying amount of goodwill over its fair value. This guidance simplifies the accounting as compared to prior GAAP. The guidance is effective for fiscal years beginning after December 15, 2019. The Company does not expect the implementation of this new pronouncement to have a material impact 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 November 30, 2018, 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.

The CureCell and Atvio acquisitions which were completed in the second half of 2018 were excluded from management's evaluation of internal control over financial reporting as of November 30, 2018. Curecell and Atvio, collectively, represent 5% of our total consolidated assets and 6% of our total consolidated revenues as of and for the year ended November 30, 2018.

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 November 30, 2018. 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 November 30, 2018 based on those criteria.

Attestation Report of Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of November 30, 2018 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".

Changes in Internal Control Over Financial Reporting

Prior to listing our common stock on the Nasdaq Capital Market, we identified a material weakness in our internal control over financial reporting as of November 30, 2017. As defined in Regulation 12b-2 under the Securities Exchange Act of 1934, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our company's annual or interim financial statements will not be prevented or detected on a timely basis. The deficiency in our internal control over financial reporting was due to the applied risk-based approach which is indicative of many small companies with limited number of staff in corporate functions which have insufficient segregation of duties and insufficient controls over period end financial disclosure and reporting processes. Subsequently, the following had occurred in order to remediate the material weakness: (a) during the fiscal year ended November 30, 2018, we hired additional qualified personnel to the corporate finance team, as well as to our subsidiaries; (b) in the beginning of the third quarter of 2018, we engaged an internal control Sarbanes and Oxley (SOX) expert to assist us in improving our internal processes and in reviewing the design and implementation of our internal control over financial reporting; (c) during the year ended November 30, 2018, our procedures of internal control over financial reporting and made changes to our processes to improve controls and increase efficiency, by implementing new, more efficient consolidating activities, and migrating processes. Management believes that due to the foregoing, as of November 30, 2018, it has remediated the material weakness previously identified.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our Directors and Executive Officers. The age of each Director and Executive Officer listed below is given as of November 30, 2018.

Name	Age	Position
Vered Caplan	50	Chief Executive Officer and Chairperson of the Board of Directors
Neil Reithinger	48	Chief Financial Officer, Secretary and Treasurer
Sarah Ferber	64	Chief Scientific Officer
Denis Bedoret	38	Managing Director of MaSTherCell S.A
David Sidransky [(1)]	58	Director
Guy Yachin [(1)]	51	Director
Yaron Adler [(1)]	48	Director
Ashish Nanda [(1)]	53	Director

(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, director of the following companies: Opticul Ltd., Inmotion Ltd., Nehora Photonics Ltd., Ocure Ltd., Eve Medical Ltd., Menopause and PMS 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.

Dr. Denis Bedoret – General Manager of MaSTherCell, S.A.

Dr. Bedoret has served as the General Manager of MaSTherCell since his appointment on July 6, 2017. Dr. Bedoret joined MaSTherCell in October 2016 as Chief Business and Administration Officer. Prior to joining MaSTherCell, from January 2014 to September 2016, he held the position of Chief Operations Officer at Quality Assistance, a leading European analytical CRO where he was also member of the board of directors. Between September 2011 and January 2014, Dr. Bedoret served as Engagement Manager at McKinsey & Company, focusing on bio-pharmaceutical projects. Through those experiences, he gained a strong expertise in biologicals, FDA and EMA regulations, as well as team management. He holds a degree in Veterinary Medicine, a Ph.D. in Life Sciences from ULg and a post-doctorate degree in Immunology from Harvard Medical School.

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.

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.

Board of Directors

Our Board of Directors currently consists of five 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.