

Orgenesis Inc.  
Form 10-K  
February 13, 2019

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended **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)



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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.

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**ORGENESIS INC.**

**2018 FORM 10-K ANNUAL REPORT**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
<b>PART I</b>	
ITEM 1. BUSINESS	4
ITEM 1A. RISK FACTORS	32
ITEM 1B. UNRESOLVED STAFF COMMENTS	53
ITEM 2. PROPERTIES	53
ITEM 3. LEGAL PROCEEDINGS	54
ITEM 4. MINE SAFETY DISCLOSURES	54
<b>PART II</b>	
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	54
ITEM 6. SELECTED FINANCIAL DATA	56
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	56
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	72
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	72
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	72
ITEM 9A. CONTROLS AND PROCEDURES	72
ITEM 9B. OTHER INFORMATION	73
<b>PART III</b>	

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	74
ITEM 11. EXECUTIVE COMPENSATION	79
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	85
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	88
ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES	89
 <b>PART IV</b>	
ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES	90
ITEM 16. FORM 10-K SUMMARY	93
SIGNATURES	94

## 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" "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"),

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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  $\beta$ -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.

-5-

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*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 an 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 disabled 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-based 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.

-6-

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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 health 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:

-10-

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- (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 sqm<sup>2</sup> 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., Apceh GmbH & Co. KG, Eufets GmbH, Fraunhofer Gesellschaft, Cellfor cure 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:

-16-

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*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  $\beta$ -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  $\beta$ -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  $\beta$ -cells that severely reduces  $\beta$ -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  $\beta$ -cell failure and a significant reduction in  $\beta$ -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  $\beta$ -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;
- An annual license fee of \$15,000, which commenced on January 1, 2012 and is due once every year thereafter (the 3)“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 funded 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  $\beta$ -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 through 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  $\beta$ -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 necessarily 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.**

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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:

<b><u>Entity</u></b>	<b><u>Property Description</u></b>
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These are the principal offices:

Orgenesis Inc./Orgenesis  
Maryland Inc.

- Located at 20271 Goldenrod Lane, Germantown, MD 20876.
- Occupy office space at the Germantown Innovation Center.
- Cost is \$200 per month on a month-to-month contract.

All activities located in Gosselies, Belgium, in the I-Tech Incubator 2. Property consists of:

MaSTherCell SA, Cell  
Therapy Holding SA and  
Orgenesis SPRL

- Operational production and Office area represent +/-2,400 m<sup>2</sup>.
- 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 480m<sup>2</sup> 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 m<sup>2</sup>.
  - Monthly costs are approximately 21,232 thousand KRW.
  - Lease agreement for the office and operational production area expires on July 14, 2020.
  - Located in 8 HaHaruv St. Bar Lev Industrial Park M.P. MISGAV, Israel.
- Atvio Biotech
- Operational production and Office area represent +/-1,264 m<sup>2</sup>.
  - 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 health 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 600m<sup>2</sup> 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 health 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 contained 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.

-62-

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*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:

	<b>Year Ended November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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**

	<b>Year Ended</b>	
	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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

	<b>Year Ended</b>	
	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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
	<b>\$10,824</b>	<b>\$ 6,807</b>

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

	<b>Year Ended</b>	
	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	<b>(in thousands)</b>	
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

	<b>Year Ended</b>	
	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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.

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

An increase of \$422 thousand in rent and related expenses mainly related to the occupation of additional space (iv) 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) An increase of \$1,033 thousand in other general and administrative expenses related to the increase in filing and other fees.

Financial Expenses, net

	<b>Year Ended</b>	
	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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)

	<b>Year Ended</b>	
	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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**

	<b>November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	<b>(in thousands)</b>	
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**

	<b>Year Ended</b>	
	<b>November 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(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.

-73-

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## 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.

<u>Name</u>	<u>Age</u>	<u>Position</u>
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 <sup>(1)</sup>	58	Director
Guy Yachin <sup>(1)</sup>	51	Director
Yaron Adler <sup>(1)</sup>	48	Director
Ashish Nanda <sup>(1)</sup>	53	Director

<sup>(1)</sup>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.

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

## **Director Independence**

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

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

## **Board Committees**

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

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

### Audit Committee

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

The Audit Committee held nine meetings in fiscal 2018. In addition, the Audit Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2018. The Board has determined that each member of the Audit Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations. In addition, the Board has determined that Dr. Sidransky is an

“audit committee financial expert” within the meaning of Item 407(d)(5) of Regulation S-K and has designated him to fill that role. See “Directors, Executive Officers and Corporate Governance – Directors” above for descriptions of the relevant education and experience of each member of the Audit Committee.

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

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

### Compensation Committee

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

The Compensation Committee acted by unanimous written consent or held one meeting in fiscal 2018. In addition, the Compensation Committee reviewed and approved various corporate items by way of written consent during the fiscal year 2018. The Board of Directors has determined that each member of the Compensation Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

### Nominating and Corporate Governance Committee

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

The Nominating and Corporate Governance Committee acted by unanimous written consent or held one meeting in fiscal 2018. The Board has determined that each member of the Nominating and Corporate Governance Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

## **SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

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

Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis, except that two reports, covering an aggregate of two transactions, were filed late by Vered Caplan, two reports, covering an aggregate of two transaction, were filed late by David Sidransky, one report, covering an aggregate of one transaction, was filed late by Guy Yachin, one report, covering an aggregate of one transaction, was filed late by Yaron Adler, one report, covering an aggregate of one transaction, was filed late by Sarah Ferber, one report, covering an aggregate of eight transactions, was filed late by Hugues Bultot, an initial report of ownership was filed late by David Sidransky and each of Ashish Nanda and Denis Bedoret did not timely file one report covering an aggregate of one transaction.

*Corporate Code of Conduct and Ethics*

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

## ITEM 11. EXECUTIVE COMPENSATION

The following table shows the total compensation paid or accrued during the fiscal year ended November 30, 2018, to our Chief Executive Officer, our Chief Financial Officer and our two next most highly compensated executive officers who earned more than \$100,000 during the fiscal year ended November 30, 2018 and were serving as executive officers as of such date (the “named executive officers”).

*Summary Compensation Table*

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) <sup>(1)</sup>	Non-Equity Non qualified Incentive Plan Compensa- tion (\$)	Deferred Compensation Earnings (\$)	All Other Compensation (\$) <sup>(2)</sup>	Total (\$)
						tion	Earnings		
Vered Caplan <i>CEO</i>	2018	226,122 <sup>(3)</sup>	350,000-	-	1,318,771-	-	-	80,697	1,975,590
Neil Reithinger <i>CFO, Treasurer &amp; Secretary</i>	2017	156,232 <sup>(3)</sup>	150,000-	-	685,318	-	-	63,262	1,054,812
	2018	266,452 <sup>(4)</sup>	-	-	139,590	-	-	-	406,042
Sarah Ferber <i>Chief Scientific Officer</i>	2017	112,652 <sup>(4)</sup>	-	-	136,148	-	-	-	248,800
	2018	225,523 <sup>(5)</sup>	-	-	464	-	-	42,796 <sup>(5)</sup>	268,783
Denis Bedoret, <i>Managing Director of MaSTherCell</i>	2017	128,907 <sup>(5)</sup>	-	-	-	-	-	43,328 <sup>(5)</sup>	172,235
	2018	211,847 <sup>(6)</sup>	56,539	-	20,214	-	-	-	288,600
	2017	208,542 <sup>(6)</sup>	31,281	-	-	-	-	-	239,823

In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this (1) column is a non-cash expense for the Company that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our Common Stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 15 to this Annual Report on Form 10-K for the year ended November 30, 2018.

(2) For 2018 and 2017, represents the compensation as described under the caption “All Other Compensation” below.

Due to cash flow considerations, part of the amounts earned have been deferred periodically and, as of November (3) 30, 2018, an aggregate of \$195,501 has been deferred by agreement and accrued by the Company. See below under “Employment/Consulting Agreements – Vered Caplan.”

(4) As of November 30, 2018, an aggregate of \$18,276 has been deferred and accrued by agreement and accrued the Company. See below under “Employment/Consulting Agreements – Neil Reithinger.”

Due to cash flow considerations, Prof. Ferber has been deferring part of her salary and social benefits due thereon (5) until such time as our cash position permits payment of salary and benefits in full without interfering with our ability to pursue our plan. As of November 30, 2018, such deferred amount totaled an aggregate of \$404,791 for the years 2013 to 2018.

On July 6, 2017, MaSTherCell’s Board of Directors appointed Denis Bedoret as General Manager and day-to-day (6) manager of MaSTherCell, effective as of July 11, 2017. On September 5, 2018, Mr. Bedoret was promoted to Managing Director of MaSTherCell. On January 22, 2019, Mr. Bedoret was appointed as President of Masthercell Global. Out of the 2018 amounts earned, \$241,835 was paid and \$26,552 was deferred by agreement with MaSTherCell.

*All Other Compensation*

The following table provides information regarding each component of compensation for 2018 and 2017 included in the All Other Compensation column in the Summary Compensation Table above. Represents amounts paid in New Israeli Shekels (NIS) and converted at average exchange rates for the year.

<u>Name</u>	<u>Year</u>	<b>Automobile and Communication Related Expenses</b>	<b>Israel- related Social Benefits</b>	<b>Total</b>
		\$ <u>(1)</u>	\$ <u>(2)</u>	\$ <u>(3)</u>
	2018	31,027	49,670	80,697
Vered Caplan	2017	21,921	41,371	63,262
	2018	5,379	37,418	42,797
Prof. Sarah Ferber	2017	5,144	38,183	43,328

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

These are comprised of contribution by the Company to savings, severance, pension, disability and insurance plans generally provided in Israel, including education funds and managerial insurance funds. For Ms. Caplan, this amount represents Israeli severance fund payments, managerial insurance funds, disability insurance, supplemental education fund contribution, and social securities. For Prof Ferber, this amount represents Israeli severance fund payments, managerial insurance funds, disability insurance, supplemental education fund contribution, and social securities. See discussion below under “Employment/Consulting Agreements – Vered Caplan and Sarah Ferber.”

*Outstanding Equity Awards at November 30, 2018*

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of November 30, 2018.



## Edgar Filing: Orgenesis Inc. - Form 10-K

Name	Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Vered Caplan	02-Feb-12 <sup>(1)</sup>	278,191	-	0.0012	02-Feb-22
	22-Aug-14 <sup>(1)</sup>	230,189	-	0.0012	22-Aug-24
	09-Dec-16 <sup>(2)</sup>	145,834	20,833	4.8	09-Dec-26
	06-Jun-17 <sup>(3)</sup>	83,334	-	7.2	06-Jun-27
	28-Jun-18 <sup>(4)</sup>	-	250,001	8.36	28-Jun-28
	22-Oct-18 <sup>(5)</sup>	-	85,000	5.99	22-Oct-28
Neil Reithinger	01-Aug-14 <sup>(6)</sup>	16,667		6	01-Aug-19
	09-Dec-16 <sup>(2)</sup>	72,918	10,416	4.8	09-Dec-26
Dr. Denis Bedoret	14-May-18 <sup>(7)</sup>	1,875	13,125	8.43	14-May-28
Prof. Sarah Ferber	02-Feb-12 <sup>(1)</sup>	231,826	-	0.0012	02-Feb-22
	22-Oct-18 <sup>(5)</sup>	-	3,750	5.99	22-Oct-28

- (1) The options were fully vested as of November 30, 2018.
- (2) The options vested on a quarterly basis over a period of two years from the date of grant.
- (3) The options vested in two equal installments on December 6, 2018 and on June 6, 2018.
- (4) The option vested in two annual installments of 125,001 and 125,000 on each of the 6th and 12th month anniversaries from the date of grant.
- (5) The options vest on a quarterly basis over a period of four years from the date of grant.
- (6) One quarter of the options vest at the end of each three months from the date of grant.
- (7) The options vested on a quarterly basis over a period of two years from the date of grant and were fully vested as of June 30, 2018.

### *Option Exercises in 2018*

There were no option exercises by our named executive officers during our fiscal year ended November 30, 2018.

### *Narrative Disclosure to Summary Compensation Table*

#### **Vered Caplan**

On August 14, 2014, our Board of Directors confirmed that Ms. Vered Caplan, who has served as our President and Chief Executive Officer on an interim basis since December 23, 2013, was appointed as our President and Chief Executive Officer. In connection with her appointment as our President and Chief Executive Officer, on August 22, 2014, our wholly-owned Israeli Subsidiary, Orgenesis Ltd., entered into a Personal Employment Agreement with Ms. Caplan (the “Caplan Employment Agreement”). The Caplan Employment Agreement replaced a previous employment agreement with Ms. Caplan dated April 1, 2012 pursuant to which she had served as Vice President.

On March 30, 2017, we and Ms. Caplan entered into an employment agreement replacing the Caplan Employment Agreement (the “Amended Caplan Employment Agreement”). Under the Amended Caplan Employment Agreement, which took effect April 1, 2017, Ms. Caplan's annual salary continued at \$160,000 per annum, subject to adjustment to \$250,000 per annum upon the listing of the Company's securities on an Exchange. Ms. Caplan is also entitled to an annual cash bonus with a target of 25% of base salary, provided that the actual amount of such bonus may be greater or less than the target amount. Ms. Caplan was entitled to a signing bonus of \$150,000 upon execution of the Amended Caplan Employment Agreement. Under the Amended Caplan Employment Agreement, Ms. Caplan is entitled to the following social benefits typically provided to Israeli employees, computed on the basis of her base salary: (i) Manager's Insurance under Israeli law pursuant to which the Company contributes between 6.5% and 7.5% (and Ms. Caplan contributes an additional 6%), (ii) severance pay under Israeli law pursuant to which the Company contributes 8 1/3% and (iii) Education fund pursuant to which the Company continues to contribute \$3,677 a year. In addition, Ms. Caplan is also entitled to paid annual vacation days, annual recreation allowance, sick leave and expenses reimbursement. In addition, we provide Ms. Caplan with a leased company car and a mobile phone.

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

On May 10, 2017, we and Ms. Caplan further amended the Amended Caplan Employment Agreement pursuant to which Ms. Caplan is entitled to a grant under the 2017 of options (the “Initial Option”) to purchase 83,334 shares of the Company’s common stock at a per share exercise price equal to the Fair Market Value (as defined in our 2017 Equity Incentive Plan (the “2017 Plan”)) of the Company’s common stock on the date of grant. The amendment further provides that beginning in fiscal 2018, subject to approval by the compensation committee, Ms. Caplan is entitled to an additional option (the “Additional Option”; together with the Initial Option, the “Options”) under the 2017 Plan for up to 250,000 shares of common stock of the Company to be awarded in such amounts per fiscal year as shall be consistent with the Plan, in each case at a per share exercise price equal to the Fair Market Value (as defined in the Plan) of the Company’s common stock on the date of grant.

In 2018, following the listing of the company’s securities on the NASDAQ market, Ms. Caplan’s annual salary was raised to \$250,000. On June 6, 2017 and June 28, 2018 the compensation committee approved a grant of 83,334 and 250,001 stock options, respectively. In October 2018, Ms. Caplan was awarded a further bonus of \$200,000 and 85,000 stock options. For additional information, see the Outstanding Equity Awards table above.

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

### **Neil Reithinger**

Mr. Reithinger was appointed Chief Financial Officer, Treasurer and Secretary on August 1, 2014. Mr. Reithinger’s employment agreement stipulates a monthly salary of \$1,500; payment of an annual bonus as determined by the Company in its sole discretion, participation in the Company’s pension plan; grant of stock options as determined by the Company; and reimbursement of expenses. In addition, on August 1, 2014, the Company entered into a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, of which Mr. Reithinger is the sole shareholder (“Eventus”), pursuant to which Eventus has agreed to provide financial consulting services to the Company. In consideration for Eventus’ services, the Company agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement was for a period of one year from August 1, 2014 and automatically renews for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Neil Reithinger. As of November 30, 2018, Eventus was owed \$18,276 for accrued and unpaid services under the financial consulting agreement.

### **Prof. Sarah Ferber**

Our wholly-owned Israeli Subsidiary, Orgenesis Ltd., entered into a Personal Employment Agreement with Prof. Ferber on February 2, 2012 to serve as Chief Scientific Officer (the “Ferber Employment Agreement”) on a part time basis. Under the Ferber Employment Agreement, Prof. Ferber earned an annual salary of the current New Israeli

Shekel equivalent of \$232,000 since September 2013. However, in order to reduce operating expenses and conserve cash, Prof. Ferber has been deferring a part of her salary and social benefits due thereon until such time as our cash position permits payment of salary in full without interfering with our ability to pursue our plan of operations, and, as of November 30, 2018, such deferred amount totaled an aggregate of \$404,791. Under the Ferber Employment Agreement, Prof. Ferber is entitled to the following social benefits out of her base salary typically provided to Israeli employees: (i) Manager's Insurance under Israeli law pursuant to which the Company contributes 2.5% (and Prof. Ferber contributes an additional 3.5%) and, in addition, the Company contributes 1.25% towards loss of working capacity disability insurance, (ii) pension plan to which the Company contributes 3.75% (and Prof. Ferber contributes an additional 3.5%), (iii) severance pay under Israeli law pursuant to which the Company contributes 8 1/3% and (iv) Education fund pursuant to which the Company contributes 7.5% (and Prof. Farber contributes an additional 2.5%). In addition, Prof. Ferber is also entitled to paid annual vacation days, annual recreation allowance, sick leave and expenses reimbursement. In addition, we provide Prof. Ferber with a mobile phone.

The Ferber Employment Agreement does not specify a stated term and either we or Ms. Ferber are entitled to terminate Prof. Ferber's employment upon four months' notice other than in the case of a termination for cause. The Ferber Employment Agreement contains customary provisions regarding confidentiality of information, non-competition and assignment of inventions.

In October 2018, Prof. Ferber was awarded 3,750 options. The options shall vest in equal quarterly installments over four years.

### **Denis Bedoret**

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

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

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

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

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

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

The following table sets forth the compensation that would have been received by each of the Company's executive officers had they been terminated as of November 30, 2018.

<u>Name</u>	<u>Salary</u>		<u>Accrued</u>	
	<u>Continuation</u>	<u>Bonus</u>	<u>Vacation Pay</u>	<u>Total Value</u>
Vered Caplan	\$ *	\$62,500	\$111,731	\$174,231
Prof. Sarah Ferber	\$ -	\$ -	\$183,534	\$183,534

(\*)

*Termination by Company without cause: \$250,000*

*Termination without cause following a change in control: \$375,000*

*Director Compensation*

The following table sets forth for each director certain information concerning his or her compensation for the year ended November 30, 2018:

<u>Name</u>	<b>Fees</b>		<b>Non-equity Incentive Plan Compensation</b>	<b>Nonqualified</b>		<b>Total</b>
	<b>Earned or Paid in Cash</b>	<b>Stock Awards</b>		<b>Option Awards</b>	<b>Deferred Compensation Earnings</b>	
	<b>(\$)</b>	<b>(\$)</b>	<b>(\$)</b>	<b>(\$)</b>	<b>(\$)</b>	<b>(\$)</b>
Guy Yachin	147,290-	83,480 -	-	-	-	230,770
Yaron Adler	6,680 -	83,480 -	-	-	-	90,160
Dr. David Sidransky	15,195 -	104,537 -	-	-	-	119,732
Hugues Bultot	1,480 -	- -	-	-	-	1,480
Ashish Nanda	4,375 -	12,900 -	-	-	-	17,275

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

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

On April 2, 2012, we entered into an agreement with Guy Yachin to serve as a member of our Board of Directors for a consideration of \$2,500 per month and an additional payment for every Board of Directors' meeting at the rate of \$300 for the first hour of attendance and \$200 for each additional hour or portion of an hour.



On April 17, 2012, we entered into an agreement with Yaron Adler to serve as a member of our Board of Directors. In consideration for Dr. Sidransky's services, we pay for his attendance at Board of Directors' meetings at the rate of \$300 for the first hour of attendance and \$200 for each additional hour or portion of an hour.

On July 17, 2013 we entered into an agreement with Dr. David Sidransky to serve as a member of our Board of Directors. In consideration for Dr. Sidransky's services, we pay for his attendance at Board of Directors' meetings at the rate of \$300 for the first hour of attendance and \$200 for each additional hour or portion of an hour.

*Compensation Policy for Non-Employee Directors.*

In October 2018, the Board of Directors adopted a compensation policy for non-employee directors which replaced the non-employee director compensation terms discussed above. By its terms, the policy became effective November 2018. Under the adopted policy, each director is to receive an annual cash compensation of \$30,000 and the Chairman and Vice Chairman is paid an additional \$15,000 per annum. Each committee member will be paid an additional \$7,500 per annum and each committee chairman is to receive \$15,000 per annum. Cash compensation will be made on a quarterly basis.

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

*Compensation Committee Interlocks and Insider Participation*

None of our executive officers has served as a member of the Board of Directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our Board of Directors or Compensation Committee during the fiscal year ended November 30, 2018.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of February 13, 2019 for (a) the named executive officers, (b) each of our directors, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of February 13, 2019 pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 15,620,971 shares of common stock outstanding on February 13, 2019

*Security Ownership of 5% or Greater Beneficial Owners*

<b>Name and Address of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership <sup>(1)</sup></b>		<b>Percent<sup>(1)</sup></b>
Oded Shvartz			
130 Biruintei Blvd.			
Pantelmon			
Ilfov, Romania			
Image Securities fzc.	1,830,658		11.72%
2310, 23rd floor, Tiffany			
Towers, JLT			
	2,336,390 <sup>(2)</sup>		13.39%

Dubai, UAE

SFPI - FPIM (Societe Federale de Participations et d'Investissement) SA

947,055<sup>(3)</sup>

5.72%

Avenue Louise 32, bte 4 at 1050 Bruxelles, Belgium, BCE n° 253.445.063

*Security Ownership of Directors and Executive Officers*

<b>Name and Address of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership <sup>(1)</sup></b>	<b>Percent<sup>(1)</sup></b>
Vered Caplan		
c/o Orgenesis Inc.	894,006 <sup>(4)</sup>	5.41%
20271 Goldenrod Lane		
Germantown, MD 20876		
Neil Reithinger		
14201 N. Hayden Road, Suite A-1	100,001 <sup>(5)</sup>	<1%
Scottsdale, AZ 85260		

Prof. Sarah Ferber		
c/o Orgenesis Inc.	232,295 <sup>(6)</sup>	1.47%
20271 Goldenrod Lane		
Germantown, MD 20876		
Dr. Denis Bedoret		
c/o Orgenesis Inc.	5,625 <sup>(7)</sup>	<1%
20271 Goldenrod Lane		
Germantown, MD 20876		
Guy Yachin		
c/o Orgenesis Inc.	80,934 <sup>(8)</sup>	<1%
20271 Goldenrod Lane		
Germantown, MD 20876		
Dr. David Sidransky		
c/o Orgenesis Inc.	62,501 <sup>(9)</sup>	<1%
20271 Goldenrod Lane		
Germantown, MD 20876		
Yaron Adler		
c/o Orgenesis Inc.	163,879 <sup>(10)</sup>	1.04%
20271 Goldenrod Lane		
Germantown, MD 20876		
Ashish Nanda		
c/o Orgenesis Inc.	- <sup>(11)</sup>	-
20271 Goldenrod Lane		
Germantown, MD 20876		
<b>Directors &amp; Executive Officers as a Group (8 persons)</b>	<b>1,539,241</b>	<b>9%</b>

**Notes:**

Percentage of ownership is based on 15,620,971 shares of our common stock outstanding as of February 13, 2019. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the (1) rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(2) Including 1,832,538 ordinary shares issuable upon exercise of outstanding warrants at a price of \$6.24 per share. The warrants are exercisable over a three year period from the date of issuance.

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

(4) Consists of (i) 508,380 ordinary shares issuable upon exercise of outstanding options at a price of \$0.0012 per share, (ii) 166,667 ordinary shares issuable upon exercise of outstanding options at a price of \$4.80 per share, (iii) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of \$7.20 per share, (iv) 125,000 ordinary shares issuable upon exercise of outstanding options at a price of \$8.36 per share and (v) 10,625 ordinary shares issuable upon exercise of outstanding options at a price of \$5.99 per share. Does not include options for (i) 125,001 shares of common stock with an exercise price of \$8.36 per share that are exercisable on June 28, 2019 and (ii) 74,375 shares of common stock with an exercise price of \$5.99 per share that are exercisable quarterly after December 22, 2018.

- (5) Consists of (i) 16,667 ordinary shares issuable upon exercise of outstanding options at a price of \$6.00 per share and (ii) 83,334 ordinary shares issuable upon exercise of outstanding options at a price of \$4.80 per share.

(6) Consists of (i) 231,826 ordinary shares issuable upon exercise of outstanding options at a price of \$0.0012 per share and (ii) 469 ordinary shares issuable upon exercise of outstanding options at a price of \$5.99 per share. Does not include options for 3,281 shares of common stock with an exercise price of \$5.99 per share that are exercisable quarterly after December 22, 2018.

(7) Consists of 5,625 ordinary shares issuable upon exercise of outstanding options at a price of \$8.43 per share. Does not include options for 9,375 shares of common stock with an exercise price of \$8.43 per share that are exercisable quarterly after December 30, 2018.

(8) Consists of (i) 39,267 ordinary shares issuable upon exercise of outstanding options at a price of \$10.2 per share and (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of \$4.80 per share. Does not include options for 28,750 shares of common stock with an exercise price of \$5.99 per share that are exercisable on October 22, 2019.

(9) Consists of (i) 20,834 ordinary shares issuable upon exercise of outstanding options at a price of \$9 per share and (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of \$4.80 per share. Does not include options for 29,200 shares of common stock with an exercise price of \$5.99 per share that are exercisable in October 22, 2019.

(10) Includes (i) 58,908 ordinary shares issuable upon exercise of outstanding options at a price of \$9.48 per share and (ii) 41,667 ordinary shares issuable upon exercise of outstanding options at a price of \$4.80 per share. Does not include options for 28,750 shares of common stock with an exercise price of \$5.99 per share that are exercisable on October 22, 2019.

(11) Does not include options for 27,100 shares of common stock with an exercise price of \$5.99 per share that are exercisable on October 22, 2019.

*Securities Authorized for Issuance Under Existing Equity Compensation Plans*

The following table summarizes certain information regarding our equity compensation plans as of November 30, 2018:

Plan Category	Number of Securities	Weighted-Average	Number of Securities
	to be Issued Upon	Exercise Price of	Remaining Available for
	Exercise of	Outstanding	Future Issuance
	Outstanding	Options	Under
	Options		Equity Compensation
	(a)	(b)	Plans (Excluding
			Securities Reflected in
			Column (a))
			(c)
Equity compensation plans approved by security holders <sup>(1)</sup>	1,040,942	\$7.05	709,058
Equity compensation plans not approved by security holders <sup>(2)</sup>	1,805,465	\$3.37	300,009
<b>Total</b>	<b>2,846,407</b>	<b>\$4.72</b>	<b>1,009,067</b>

Consists of the 2017 Equity Incentive Plan and the Global Share Incentive Plan (2012). For a short description of <sup>(1)</sup>those plans see Note 15 to our 2018 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended November 30, 2018.

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

##### *Transactions with Related Persons*

Except as set out below, as of November 30, 2018, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of \$120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of the following persons had or will have a direct or indirect material interest:

- any director or executive officer of our company;
- any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our outstanding shares of common stock;
- any promoters and control persons; and

any member of the immediate family (including spouse, parents, children, siblings and in laws) of any of the foregoing persons.

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

In January 2017, the Company entered into definitive agreements with Image Securities fzc. ("Image") for the private placement of 2,564,115 units of the Company's securities for aggregate subscription proceeds to the Company of \$16 million at \$6.24 price per unit. Each unit is comprised of one share of the Company's Common Stock and a 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. The subscription proceeds were payable on a periodic basis. Each periodic payment of subscription proceeds was evidenced by the Company's standard securities subscription agreement. During the year ended November 30, 2017, Image remitted \$4.5 million to the Company, in consideration of which, the investor received 721,160 shares of the Company's Common Stock and three-year warrants to purchase up to an additional 721,160 shares of the Company's Common Stock at a per share exercise price of \$6.24.

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



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

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

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

#### *Named Executive Officers and Current Directors*

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

#### *Director Independence*

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

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Board of Directors of the Company has appointed Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited ("PwC") as our independent registered public accounting firm (the "Independent Auditor") for the fiscal year ending November 30, 2018. The following table sets forth the fees billed to the Company for professional services rendered by PwC for the years ended November 30, 2018 and 2017:

<u>Services</u>	<u>2018</u>	<u>2017</u>
-----------------	-------------	-------------

Audit Fees (1)	\$365,300	\$211,000
Audit-Related fees (2)	16,475	22,000
Tax fees (3)	31,822	-
<b>Total fees</b>	<b>\$413,597</b>	<b>\$233,000</b>

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

(2) Audit related fees consisted principally of audits of employee benefit plans and special procedures related to regulatory filings in 2018.

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

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

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

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

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

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

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

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

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

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

#### PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (a)  
(1) Financial Statements

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

- (2) Financial Statement Schedules

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

- (3) Exhibits required by Regulation S-K

**No. Description**

- 3.1 Articles of Incorporation (incorporated by reference to an exhibit to our registration statement on Form S-1, filed on April 2, 2009)  
3.2 Certificate of Change Pursuant to Nevada Revised Statutes Section 78.209 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 2, 2011)  
3.3 Articles of Merger (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 2, 2011)

<b>No.</b>	<b>Description</b>
<u>3.4</u>	<u>Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 21, 2011)</u>
<u>3.5</u>	<u>Amended and Restated Bylaws (incorporated by reference to an exhibit to our current report on Form 8-K, filed on September 21, 2011)</u>
<u>3.6</u>	<u>Certificate of Correction, dated February 27, 2012 (incorporated by reference to an exhibit to our current report on Form 8-K/A, filed on March 16, 2012)</u>
<u>3.7</u>	<u>Certificate of Change Pursuant to Nevada Revised Statutes Section 78.209, as filed by Orgenesis Inc. on November 13, 2017 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 16, 2017)</u>
<u>10.2</u>	<u>Convertible Loan Agreement, dated December 6, 2013, with Mediapark A.G. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 16, 2013)</u>
<u>10.3</u>	<u>Investment Agreement, dated December 13, 2013, with Kodiak Capital Group, LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 16, 2013)</u>
<u>10.4</u>	<u>Registration Rights Agreement, dated December 13, 2013, with Kodiak Capital Group, LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 16, 2013)</u>
<u>10.5</u>	<u>Form of subscription agreement (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 4, 2014)</u>
<u>10.6</u>	<u>Form of warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 4, 2014)</u>
<u>10.7</u>	<u>Consulting Agreement, dated April 3, 2014, with Aspen Agency Limited (incorporated by reference to an exhibit our current report on Form 8-K, filed on April 7, 2014)</u>
<u>10.8</u>	<u>Stock Option Agreement, dated April 3, 2014, with Aspen Agency Limited (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 7, 2014)</u>
<u>10.9</u>	<u>Form of subscription agreement with form of warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 28, 2014)</u>
<u>10.10</u>	<u>Convertible Loan Agreement, dated May 29, 2014, with Nine Investments Limited (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 30, 2014)</u>
<u>10.11</u>	<u>Service Agreement between Orgenesis SPRL and MaSTherCell S.A., dated July 3, 2014 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on July 7, 2014)</u>
<u>10.12</u>	<u>Financial Consulting Agreement, dated August 1, 2014, with Eventus Consulting, P.C. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 5, 2014)</u>
<u>10.13</u>	<u>Personal Employment Agreement, dated August 1, 2014, by and between Orgenesis Inc. and Neil Reithinger (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 5, 2014)</u>
<u>10.14</u>	<u>Personal Employment Agreement, dated July 23, 2014, by and between Orgenesis Maryland Inc. and Scott Carmer (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 7, 2014)</u>
<u>10.15</u>	<u>Release Agreement, dated November 18, 2016, by and between Orgenesis Maryland Inc. and Scott Carmer (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 23, 2016)</u>
<u>10.16</u>	<u>Strategic Advisory Agreement, dated November 18, 2016, by and between Orgenesis Inc. and Scott Carmer (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 23, 2016)</u>
<u>10.17</u>	<u>Executive Employment Agreement, dated March 30, 2017, between Orgenesis Inc. and Vered Caplan (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on July 24, 2017)</u>
<u>10.18</u>	<u>Amendment No. 1, dated May 10, 2017, to Executive Employment Agreement, dated as of March 30, 2017, between Orgenesis Inc. and Vered Caplan (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on July 24, 2017)</u>
<u>10.19</u>	<u>Share Exchange Agreement, dated November 3, 2014, by and between Orgenesis Inc. and MaSTherCell S.A. and Cell Therapy Holding SA (collectively "MaSTherCell") and each of the shareholders of MaSTherCell (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 10, 2014)</u>



No. Description

- 10.20 Addendum No. 1, dated March 2, 2015, to Share Exchange Agreement, dated November 3, 2014, by and between Orgenesis Inc., MaSTherCell, and each of the shareholders of MaSTherCell (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 5, 2015)
- 10.21 Escrow Agreement, dated February 27, 2015, by and between Orgenesis Inc., the shareholders of MaSTherCell S.A. and Cell Therapy Holding SA, the bondholders of MaSTherCell S.A. and Securities Transfer Corporation (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 5, 2015)
- 10.22 Orgenesis Inc. Board of Advisors Consulting Agreement, dated March 16, 2015 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on March 17, 2015)
- 10.23 Addendum No. 2, dated November 12, 2015, to Share Exchange Agreement, dated November 3, 2014, by and between Orgenesis Inc., MaSTherCell, and each of the shareholders of MaSTherCell (incorporated by reference to an exhibit our current report on Form 8-K, filed on November 13, 2015)
- 10.24 Joint Venture Agreement, dated March 14, 2016, by and between Orgenesis Inc. and CureCell Co., Ltd. (incorporated by reference to an exhibit to our annual report on Form 10-K, filed on February 28, 2017)
- 10.25 Joint Venture Agreement, dated May 10, 2016, by and between Orgenesis Inc. and Atvio Biotech Ltd. (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on April 19, 2017)
- 10.26 Private Placement Subscription Agreement, dated January 26, 2017, between Orgenesis Inc. and Image Securities FZC (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on April 19, 2017)
- 10.27 Amendment No. 1, dated February 9, 2017, to the Private Placement Subscription Agreement, dated January 26, 2017, between Orgenesis Inc. and Image Securities FZC (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on April 19, 2017)
- 10.28 2017 Equity Incentive Plan (incorporated by reference to an exhibit to our definitive proxy statement on Schedule 14A, filed on March 30, 2017)
- 10.29 Collaboration and License Agreement, dated as of June 8, 2018, between Orgenesis Inc. and Mircod Limited (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on October 12, 2018)
- 10.30 Private Placement Subscription Agreement, dated November 13, 2018, between Orgenesis Inc. and Avner Sonnino (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 20, 2018)
- 10.31 Private Placement Subscription Agreement, dated November 21, 2018, between Orgenesis Inc. and an accredited investor (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 28, 2018)
- 10.32 Private Placement Subscription Agreement, dated November 30, 2018, between Orgenesis Inc. and an accredited investor (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 6, 2018)
- 10.33 Private Placement Subscription Agreement, dated December 10, 2018, between Orgenesis Inc. and an accredited investor (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 14, 2018)
- 10.34 Controlled Equity Offering Sales Agreement, dated December 20, 2018, between Orgenesis Inc. and Cantor Fitzgerald & Co. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 20, 2018)
- 21.1\* List of Subsidiaries of Orgenesis Inc.
- 23.1\* Consent of independent registered public accounting firm
- 31.1\* Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
- 31.2\* Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002





**No. Description**

32.1\*\* Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002

32.2\*\* Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002

99.1 Global Share Incentive Plan (2012) (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 31, 2012)

99.2 Appendix – Israeli Taxpayers Global Share Incentive Plan (2012) (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 31, 2012)

\*Filed herewith

\*\*Furnished herewith

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ORGENESIS INC.**

By: /s/ Vered Caplan  
Vered Caplan  
Chief Executive Officer and Chairperson of the Board of Directors  
Date: February 13, 2019

By: /s/ Neil Reithinger  
Neil Reithinger  
Chief Financial Officer,  
Treasurer and Secretary  
Date: February 13, 2019

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

By: /s/ Vered Caplan  
Vered Caplan  
Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)  
Date: February 13, 2019

By: /s/ Neil Reithinger  
Neil Reithinger  
Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)  
Date: February 13, 2019

By: /s/ Guy Yachin  
Guy Yachin  
Director  
Date: February 13, 2019

By: /s/ David Sidransky  
David Sidransky  
Director  
Date: February 13, 2019

By: /s/ Yaron Adler  
Yaron Adler  
Director  
Date: February 13, 2019

By: /s/ Ashish Nanda  
Ashish Nanda  
Director  
Date: February 13, 2019

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**ORGENESIS INC.  
CONSOLIDATED FINANCIAL STATEMENTS AS OF NOVEMBER 30, 2018**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2
CONSOLIDATED FINANCIAL STATEMENTS:	
Consolidated Balance Sheets	F-4
Consolidated Statements of Comprehensive Loss	F-6
Consolidated Statements of Changes in Equity	F-7
Consolidated Statements of Cash Flows	F-9
Notes to Consolidated Financial Statements	F-10 to F-46

F-1

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheets of Orgenesis Inc. and its subsidiaries (the Company) as of November 30, 2018 and 2017, and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the two years in the period ended November 30, 2018, including the related notes (collectively referred to as the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of November 30, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of November 30, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended November 30, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of November 30, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

***Basis for Opinions***

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

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

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management's Report on Internal Control over Financial Reporting, management has excluded CureCell and Atvio from its assessment of internal control over financial reporting as of November 30, 2018 because they were acquired by the Company in purchase business combinations during 2018. We have also excluded CureCell and Atvio from our audit of internal control over financial reporting. CureCell and Atvio are wholly-owned

subsidiaries whose total assets and total revenues excluded from management's assessment and our audit of internal control over financial reporting represent 5% and 6% respectively, of the related consolidated financial statement amounts as of and for the year ended November 30, 2018.

F-2

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*Definition and Limitations of Internal Control over Financial Reporting*

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Kesselman & Kesselman

Certified Public Accountants (Isr.)

A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel

February 13, 2019

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

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

	November 30,	
Assets	2018	2017
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 16,064	\$ 3,519
Restricted Cash	392	-
Accounts receivable, net	4,151	1,336
Prepaid expenses and other receivables	913	841
GPP receivable, see Note 3	6,600	-
Receivables from related party	-	691
Grants receivable	441	183
Inventory	1,736	725
Total current assets	30,297	7,295
<b>NON CURRENT ASSETS:</b>		
Bank deposits	85	-
Loan to related party, see Note 11(e)	1,007	-
Call option derivative	-	339
Investments in associates, net	-	1,321
Property and equipment, net	11,901	5,104
Intangible assets, net	16,700	15,051
Goodwill	15,165	10,684
Other assets	292	78
Total non-current assets	45,150	32,577
<b>TOTAL ASSETS</b>	<b>\$ 75,447</b>	<b>\$ 39,872</b>

F-4



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

	November 30,	
	2018	2017
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 3,804	\$ 3,914
Accrued expenses and other payables	2,269	1,435
Employees and related payables	3,006	2,961
Related parties	-	116
Advance payments on account of grant	1,724	1,719
Short-term loans and current maturities of long term loans	647	378
Deferred income	5,317	3,611
Current maturities of convertible loans	378	2,780
<b>TOTAL CURRENT LIABILITIES</b>	<b>17,145</b>	<b>16,914</b>
<b>LONG-TERM LIABILITIES:</b>		
Loans payable	\$ 1,662	\$ 2,118
Convertible loans	1,038	2,415
Retirement benefits obligation	265	6
Deferred taxes	1,702	690
Other long term liabilities	833	-
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>5,500</b>	<b>5,229</b>
<b>TOTAL LIABILITIES</b>	<b>22,645</b>	<b>22,143</b>
<b>COMMITMENTS</b>		
<b>REDEEMABLE NON CONTROLLING INTEREST EQUITY:</b>	<b>24,153</b>	<b>3,606</b>
Common stock of \$0.0001 par value, 145,833,334 shares authorized, 14,951,783 and 9,872,659 shares issued as of November 30, 2018 and November 30, 2017, respectively	1	1
Additional paid-in capital	88,082	55,334
Receipts on account of shares to be allotted	2,253	1,483
Accumulated other comprehensive income	425	1,425
Accumulated deficit	(62,411)	(44,120)
Equity attributable to Orgenesis Inc.	28,350	14,123
Non-controlling interests	299	-
<b>TOTAL EQUITY</b>	<b>28,649</b>	<b>14,123</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 75,447</b>	<b>\$ 39,872</b>

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

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

	Year ended November 30,	
	2018	2017
<b>REVENUES</b>	\$ 18,655	\$ 10,089
<b>COST OF REVENUES</b>	10,824	6,807
<b>GROSS PROFIT</b>	7,831	3,282
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	6,464	2,478
<b>AMORTIZATION OF INTANGIBLE ASSETS</b>	1,913	1,631
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b>	16,303	9,189
<b>OTHER INCOME, net</b>	(2,930)	-
<b>SHARE IN LOSSES OF ASSOCIATED COMPANY</b>	731	1,214
<b>OPERATING LOSS</b>	14,650	11,230
<b>FINANCIAL EXPENSES, net</b>	3,117	2,447
<b>LOSS BEFORE INCOME TAXES</b>	17,767	13,677
<b>TAX EXPENSES (INCOME)</b>	1,337	(1,310)
<b>NET LOSS</b>	\$ 19,104	\$ 12,367
<b>NET INCOME ATTRIBUTABLE TO NON- CONTROLLING INTERESTS (INCLUDING REDEEMABLE)</b>	(813)	-
<b>NET LOSS ATTRIBUTABLE TO THE COMPANY LOSS PER SHARE:</b>	\$ 18,291	\$ 12,367
Basic	\$ 1.43	\$ 1.28
Diluted	\$ 1.43	\$ 1.31
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE:</b>		
Basic	13,374,103	9,679,964
Diluted	13,374,103	9,714,252
<b>COMPREHENSIVE LOSS -</b>		
Net loss	\$ 19,104	\$ 12,367
Other Comprehensive (income) loss Translation adjustment	1,000	(2,630)
<b>Comprehensive loss</b>	\$ 20,104	\$ 9,737
<b>Comprehensive income attributed to non-controlling interests (including redeemable)</b>	(813)	-
<b>COMPREHENSIVE LOSS ATTRIBUTED TO ORGENESIS INC.</b>	\$ 19,291	\$ 9,737

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

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

	Common Stock		Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non- Controlling Interest
	Number	Par Value						
<b>BALANCE AT DECEMBER 1, 2016</b>	9,508,068	\$ 1	\$ 45,454	\$ -	(1,205)\$	(31,753)\$	12,497	\$
<b>Changes during the Year ended November 30, 2017:</b>								
Stock-based compensation to employees and directors			1,536				1,536	
Stock-based compensation to service providers	79,167	*	1,828				1,828	
Beneficial conversion feature of convertible loans and warrants issued			2,814				2,814	
Issuances of shares and warrants from equity investments and Issuance, cancellation of contingent shares, and receipts on account of shares and warrants to be allotted	285,424	*	3,702	1,483			5,185	

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Comprehensive income (loss) for the year					2,630	(12,367)	(9,737)
--	--	--	--	--	-------	----------	---------

**BALANCE  
AT  
NOVEMBER**

<b>30, 2017</b>	9,872,659 \$	1 \$	55,334 \$	1,483 \$	1,425 \$	(44,120)\$	14,123 \$
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F-7

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

	Number	Par Value	Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interests
<b>BALANCE AT DECEMBER 1, 2017</b>	9,872,659	\$ 1	\$ 55,334	\$ 1,483	\$ 1,425	\$(44,120)	\$ 14,123	
<b>Changes during the Year ended November 30, 2018:</b>								
Stock-based compensation to employees and directors			2,426				2,426	
Stock-based compensation to service providers	315,198	*	1,938				1,938	
Issuance of shares and warrants due to conversion of convertible loans and shares in escrow account	1,486,722	*	7,511				7,511	
Issuance of shares related to acquisition of Atvio and CureCell	286,811	*	2,452				2,452	
Issuance of warrants and Beneficial conversion feature of convertible loans			438				438	
Issuance of shares and warrants and	2,853,747	*	18,021	770			18,791	

receipts on  
account of  
shares to be  
allotted

Issuance of  
shares due to  
exercise of  
warrants

136,646

846

846

Adjustment to  
redemption  
value of  
redeemable  
non-controlling  
interest

(884)

(884)

Comprehensive  
loss for the year

(1,000)

(18,291)

(19,291)

**BALANCE AT  
NOVEMBER**

**30, 2018**

14,951,783 \$

1 \$

88,082 \$

2,253 \$

425 \$

(62,411)\$

28,350 \$

\*Represents an amount lower than \$ 1 thousand

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

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

	Year ended November 30,	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (19,104)	\$ (12,367)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,364	3,364
Share in losses of associated company	731	1,214
Depreciation and amortization expenses	2,624	2,598
Net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date at fair value	(4,509)	-
Change in fair value of warrants and embedded derivatives	26	(826)
Change in fair value of convertible bonds		(192)
Interest expense accrued on loans and convertible loans (including amortization of beneficial conversion feature)	2,564	1,110
Increase (decrease) in deferred taxes	1,982	(1,310)
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable, net	(2,901)	33
Increase in inventory	(931)	(265)
Increase in other assets	(19)	(3)
Decrease (increase) in prepaid expenses, other accounts receivable and GPP receivable	380	(107)
Decrease in related parties, net	(532)	(583)
Decrease in accounts payable	(796)	(933)
Increase in accrued expenses	428	92
Increase (decrease) in employee and related payables	(105)	1,142
Increase in deferred income	1,309	1,044
Increase (decrease) in advance payments and receivables on account of grant	(193)	2,156
Net cash used in operating activities	(15,682)	(3,833)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(5,556)	(975)
Investments in associates	-	(2,429)
Long-term bank deposits	(15)	-
Increase in loan to JV with a related party	(1,000)	-
Acquisition of CureCell, net of cash acquired (see Note 4)	58	-
Acquisition of Atvio, net of cash acquired (see Note 4)	245	-
Net cash used in investing activities	(6,268)	(3,404)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Short-term line of credit	-	(21)
Proceeds from issuance of shares and warrants (net of transaction costs)	17,392	5,297
Redeemable non-controlling interest	14,058	2,349
Proceeds from receipts on account of shares to be allotted	2,252	-
Repayment of short and long-term debt	(377)	(1,108)
Repayment of convertible loans and convertible bonds	(177)	(4,051)

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Proceeds from issuance of convertible loans (net of transaction costs)	1,912		5,899
Net cash provided by financing activities	35,060		8,365
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	13,110		1,128
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	(173)		1,497
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	3,519		891
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR</b>	\$ 16,456	\$	3,519
<b>SUPPLEMENTAL NON-CASH FINANCING ACTIVITY</b>			
Conversion of principal amount and accrued interest of convertible loans and bonds to common stock and warrants	\$ 7,511	\$	1,277
Classification of loan receivable into services to be received from CureCell	\$ 836		-
Leases of Fixed assets	\$ 955		-
Receivable from GPP	\$ 6,600		-
<b>SUPPLEMENTAL INFORMATION ON INTEREST PAID IN CASH</b>	-	\$	903

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



**ORGENESIS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE FISCAL YEARS ENDED NOVEMBER 30, 2018 AND 2017**

**NOTE 1 DESCRIPTION OF BUSINESS**

*a. General*

Orgenesis Inc., a Nevada corporation (the Company), is a biotechnology company specializing in the development, manufacturing and provision of services in the cell and gene therapy industry. The Company operates through two platforms: (i) a point-of-care (POCare) cell therapy (PT) platform and (ii) a Contract Development and Manufacturing Organization (CDMO) platform conducted through its subsidiary, Masthercell Global Inc., a Delaware corporation. Through the PT business, the Company's 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. The Company out-licenses these ATMPs through regional partners to whom the Company also provides regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting. Through the CDMO platform, the Company is focused on providing contract manufacturing and development services for biopharmaceutical companies.

Activities in the PT business include a multitude of cell therapies, including autoimmune, oncologic, neurologic and metabolic diseases and other indications. The Company provides services for its 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, the Company's 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 the Orgenesis Ltd (the Israeli Subsidiary) and is based on the work of Prof. Sarah Ferber, the Company's Chief Science Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. (THM) in Israel. The development plan calls for conducting additional pre-clinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating human clinical trials.

The CDMO platform operates through Masthercell Global Inc. (Masthercell Global), which currently consists of the following subsidiaries: MaSTherCell S.A (MaSTherCell) in Belgium, Atvio Biotech Ltd. (Atvio) in Israel, CureCell Co., Ltd. (CureCell) in South Korea and Masthercell U.S. LLC in the United States (collectively, the Masthercell Global Subsidiaries), having unique know-how and expertise for manufacturing in a multitude of cell types. Masthercell Global strives to provide services that are all compliant with GMP requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III and through commercialization. (Masthercell U.S. LLC was incorporated in June 2018 and had no activity as of November 30, 2018).

MaSTherCell Global, through the Masthercell Global Subsidiaries, is 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).

The Company operates its CDMO and PT business as two separate business segments.

These consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries, including those of the Masthercell Global Subsidiaries; Orgenesis SPRL (the Belgian Subsidiary), a Belgian-based subsidiary which is engaged in development and manufacturing activities together with clinical development studies in Europe; Orgenesis Maryland Inc. (the U.S. Subsidiary), a Maryland corporation; and Orgenesis Ltd., an Israeli corporation, (the Israeli Subsidiary).

F-10

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

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

*b. Change in Fiscal Year End*

On October 22, 2018, the Board of Directors of the *Company* approved a change in the *Company*'s fiscal year end from November 30 to December 31 of each year. This change to the calendar year reporting cycle 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 quarter ending March 31, 2019, June 30, 2019, September 30, 2019 and in the *Company*'s Annual Report on Form 10-K for the calendar year ending December 31, 2019.

*c. Liquidity*

As of November 30, 2018, the *Company* has accumulated losses of approximately \$62.4 million. Although the *Company* is showing positive revenues and gross profit trends in the CDMO platform, the *Company* expects to incur further losses in the PT business.

To date, the *Company* has been funding operations primarily from the proceeds from private placements of the *Company*'s equity securities and convertible debt and from revenues generated by Masthercell Global, mainly revenues generated from MaSTherCell S.A. in Belgium. From December 1, 2017 through November 30, 2018, the *Company* received, through MaSTherCell, proceeds of approximately \$17.3 million in revenues and accounts receivable from customers, \$12.6 million from SFPI and GPP (See also Note 3) and \$21.5 million from the private placement to accredited investors of the *Company*'s equity and convertible loans net of finders' fees, convertible loans and exercise of warrants. In addition, from December 1, 2018 through February 13, 2019, the *Company* raised \$0.25 million from the private placement referred to above of unsubscribed units under such investor's subscription agreement, \$6.6 million from GPP (See Note 3(b)) and proceeds of approximately \$4.7 million in accounts receivable from customers of MaSTherCell.

Based on its current cash resources and commitments, the *Company* believes it will be able to maintain its current planned development activity and corresponding level of expenditures for at least 12 months from the date of the issuance of the financial statements, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, or decreases in MaSTherCell's income, the *Company* will need to seek additional financing.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES**

The accounting policies adopted are generally consistent with those of the previous financial year.

*a. Use of Estimates in the Preparation of Financial Statements*

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

*b. Business Combination*

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

F-11

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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.

*c. Cash Equivalents*

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

*d. Bank Deposits*

Bank deposits with maturity of more than one year are considered long-term. The fair value of bank deposits approximates the carrying value since they bear interest at rates close to the prevailing market rates.

*e. Research and Development, net*

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, stock-based compensation expenses, payroll taxes and other employees' benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred. Participation from government departments and from research foundations for development of approved projects is recognized as a reduction of expense as the related costs are incurred.

*f. Principles of Consolidation*

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

*g. Non-Marketable Equity Investments*

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

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

*h. Functional Currency*

The currency of the primary economic environment in which the operations of the Company and part of its Subsidiaries are conducted is the U.S. dollar ( \$ or dollar ). The functional currency of the Belgian Subsidiaries is the Euro ( € or Euro ). The functional currency of CureCell is the Won ( KRW ). Most of the Company's expenses incurred in dollars, and the source of the Company's financing has been provided in dollars. Thus, the functional currency of the Company and its other subsidiaries is the dollar. Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for nonmonetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions exchange rates at transaction dates or average rates and (2) for other items (derived from nonmonetary balance sheet

items such as depreciation) historical exchange rates. The resulting transaction gains or losses are recorded as financial income or expenses. The financial statements of the Belgian Subsidiaries and CureCell are included in the consolidated financial statements, translated into U.S. dollars. Assets and liabilities are translated at year-end exchange rates, while revenues and expenses are translated at yearly average exchange rates during the year. Differences resulting from translation of assets and liabilities are presented as other comprehensive income.

F-12

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*i. Inventory*

The Company's inventory consists of raw material for use for the services provided. The Company periodically evaluates the quantities on year end. Cost of the raw materials is determined using the weighted average cost method.

*j. Property and Equipment*

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

Annual rates of depreciation are presented in the table below:

	<b>Weighted Average Useful Life (Years)</b>
Production facility	5-20
Laboratory equipment	5
Office equipment and computers	3-5

Intangible assets and their useful lives are as follows:

	<b>Weighted Average Useful Life (Years)</b>	<b>Amortization Recorded at Comprehensive Loss Line Item</b>
Customer Relationships	2.5-10	Amortization of intangible assets
Brand	9.75	Amortization of intangible assets
Know-How	11.75-12	Amortization of intangible assets
Backlog	1.5	Amortization of intangible assets

Intangible assets are recorded at acquisition cost less accumulated amortization and impairment. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the asset are expected to be generated.

*k. Goodwill*

Goodwill represents the excess of the purchase price of acquired business over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually (at 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. There were no impairment charges in 2018 and 2017.

#### *l. Impairment of Long-lived Assets*

The Company reviews its property and equipment, intangible assets subject to amortization and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset class may not be recoverable. Indicators of potential impairment include: an adverse change in legal factors or in the business climate that could affect the value of the asset; an adverse change in the extent or manner in which the asset is used or is expected to be used, or in its physical condition; and current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of the asset. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted cash flows. There were no impairment charges in 2018 and 2017.

#### *m. 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.

#### *n. Financial Liabilities Measured at Fair Value*

##### 1) Fair Value Option

Topic 815 provides entities with an option to report certain financial assets and liabilities at fair value with subsequent changes in fair value reported in earnings. The election can be applied on an instrument by instrument basis. The Company elected the fair value option to its convertible bonds. The liability is measured both initially and in subsequent periods at fair value, with changes in fair value charged to finance expenses, net (See Note 17).

##### 2) Derivatives

Embedded derivatives are separated from the host contract and carried at fair value when (1) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract and (2) a separate, standalone instrument with the same terms would qualify as a derivative instrument. The derivative is measured both initially and in subsequent periods at fair value, with changes in fair value



charged to finance expenses, net. As to embedded derivatives arising from the issuance of convertible debentures (See Note 17).

*o. Income Taxes*

1) With respect to deferred taxes, income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

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

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

*p. Stock-based Compensation*

The Company accounts for employee stock-based compensation in accordance with the guidance of ASC Topic 718, *Compensation - Stock Compensation*, which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their grant date fair values. The fair value of the equity instrument is charged to compensation expense and credited to additional paid in capital over the period during which services are rendered. The Company recorded stock based compensation expenses using the straight line method.

The Company follows ASC Topic 505-50, *Equity-Based Payments to Non-Employees*, for stock options issued to consultants and other non-employees. In accordance with ASC Topic 505-50, these stock options issued as compensation for services provided to the Company are accounted for based upon the fair value of the options. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

*q. Redeemable Non-controlling Interest*

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

*r. Loss per Share of Common Stock*

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

*s. Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentration of credit risk consist of principally cash and cash equivalents, bank deposits and certain receivables. The Company held these instruments with highly rated financial institutions and the Company has not experienced any significant credit losses in these accounts and does not believe the Company is exposed to any significant credit risk on these instruments apart of accounts receivable. The Company performs ongoing credit evaluations of its customers for the purpose of determining the appropriate allowance for doubtful accounts. An appropriate allowance for doubtful accounts is included in the accounts and netted against accounts receivable. In the year ended November 30, 2018 the Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on

these instruments. In the year ended November 30, 2017, the Company has recorded an allowance of \$897 thousand.

F-15

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

*t. Beneficial Conversion Feature ( BCF )*

When the Company issues convertible debt, if the stock price is greater than the effective conversion price (after allocation of the total proceeds) on the measurement date, the conversion feature is considered "beneficial" to the holder. If there is no contingency, this difference is treated as issued equity and reduces the carrying value of the host debt; the discount is accreted as deemed interest on the debt (See Note 8).

*u. Other Comprehensive Loss*

Other comprehensive loss represents adjustments of foreign currency translation.

*v. Newly issued and recently adopted Accounting Pronouncements*

1) In January 2016, the 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. The Company does not expect to have a material impact on its consolidated financial statements.

2) 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 completion 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.

3) 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.

4) 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 after, the date of initial application, with an option to elect to use certain transition relief. The Company expects 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. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

5) 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. The Company does not expect to have a material impact on its consolidated financial statements.



6) 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. The Company does not expect the implementation of this new pronouncement to have a material impact on its consolidated financial statements.

7) 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. The Company does not expect to have a material impact on its consolidated financial statements.

8) 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.

### **NOTE 3 REDEEMABLE NON CONTROLLING INTEREST**

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

On November 15, 2017, the Company, MaSTherCell and SFPI entered into a Subscription and Shareholders Agreement (SFPI Agreement) pursuant to which SFPI made an equity investment in MaSTherCell in the aggregate amount of Euro 5 million (approximately \$5.9 million), for approximately 16.7% of MaSTherCell (SFPI received B-shares of MaSTherCell which have the same voting, dividend and other rights as the existing shares of MaSTherCell). The equity investment commitment included the conversion of the outstanding loan and accrued interest of Euro 1.07 million (approximately \$1.18 million), previously made by SFPI to MaSTherCell. In November 2017, the initial subscription amount of Euro 2 million (\$2.3 million) was paid by SFPI to MaSTherCell. The proceeds from the investment are to be used in accordance with the long-term business plan that was appended to the SFPI Agreement which includes, without limitation, expanding MaSTherCell's facilities in Belgium with the addition of five new cGMP manufacturing cleanrooms. The agreement contains customary representations, warranties and covenants by MaSTherCell and the Company, in respect of which the Company has undertaken to indemnify SFPI for the consequences of any breach thereof by MaSTherCell or the Company.

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

Under the terms of the agreement since the Company listed to Nasdaq, SFPI is entitled to convert its MaSTherCell's equity interest (using an exchange rate of approximately \$0.85), into shares of Common Stock of the Company



based upon a conversion price of \$6.24, the exercise period of the option is 3 years from the closing date of the SFPI Agreement. The \$6.24 conversion price represents the price after the previous stock split of the Company.

F-18

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

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

Due to the embedded redemption feature whose settlement is not at the Company discretion, the Company accounted for the investment made by SFPI as a redeemable non-controlling interest. As of November 30, 2018, and 2017 SFPI investment was presented as redeemable non-controlling interest in the balance sheet, in the amount of \$5.8 million and \$3.6, respectively.

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

On June 28, 2018, the Company, Masthercell Global GPP, and certain of GPP's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business. In connection therewith, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company ( GPP-II ) and an affiliate of GPP entered into Stock Purchase Agreement (the SPA ) pursuant to which GPP-II purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the Masthercell Global Preferred Stock ), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for a cash consideration to be paid into Masthercell Global of up to \$25 million, of which \$13.2 million was subject to certain contingencies described below (the Consideration ). 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. \$1.5 Million of the initial capital contributed to Masthercell Global was used to reimburse the investors for their fees and expenses incurred in conjunction with this transaction (net payment of \$10.3 million). Under the terms of the SPA the follow up payments will be in the amount of \$6.6 million to be made in each of years 2018 and 2019 (the Future Payments ), if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis shareholders approve certain provisions of the SPA entered into by these parties. Such shareholder approval was obtained on October 23, 2018. None of the future Consideration amounts, if any, will result in an increase in GPP-II's equity holdings in MaSTherCell.

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

The Spinoff is required to reflect a market value, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and its Subsidiaries of at least \$50 million. In addition, upon certain enumerated events described below, GPP-II is entitled, at its option, to put to the Company (or, at Company's discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global or, alternatively, purchase from the Company its share capital in Masthercell Global at a purchase price equal to the fair market value provided that the purchase price shall not be greater than three times the price per share of Masthercell Global Preferred Stock paid by GPP-II and shall not be less than the price per share of Masthercell Global Preferred Stock paid by GPP-II. GPP-II may exercise its put or call option upon the occurrence of any of the following: (i) there is an Activist Shareholder of the Company; (ii) the Chief

Executive Officer and/or Chairman of the board of directors of the Company resigns or is replaced, removed, or terminated for any reason prior to June 28, 2023; (iii) there is a change of control event of the Company as defined in the Stockholders Agreement; or (iv) the industry expert director appointed to the board of directors of Masthercell Global is removed or replaced (or a new such director is appointed) without the prior written consent of GPP-II.

Activist Shareholder shall mean any Person who acquires shares of capital stock of the Company who either: (x) acquires more than a majority of the voting power of the Company, (y) actively takes over and controls a majority of the board of directors of the Company, or (z) is required to file a Schedule 13D with respect to such Person's ownership of the Company and has described a plan, proposal or intent to take action with respect to exerting significant pressure on the management of or directors of, the Company.

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

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

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

Due to the embedded redemption feature whose settlement is not at the Company's discretion, the Company accounted for the investment made by GPP as a redeemable non-controlling interest in the amount of \$18.4.

On November 30, 2018 Masthercell Global achieved the specified EBITDA and revenues targets for 2018 as described in the SPA. The Company reflected the \$6.6 million in the balance sheet as GPP receivable. On January 16, 2019, GPP-II remitted to Masthercell Global the \$6.6 million.

#### **NOTE 4- CORPORATE REORGANIZATION AND EXERCISE OF CALL OPTIONS OF CURECELL AND ATVIO**

##### *Description of the Transaction*

Contemporaneous with the execution of the SPA and the Stockholders' Agreement (see Note 3), the Company and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which the Company contributed to Masthercell Global assets relating to the CDMO platform including: (i) all of the Company's holdings in Masthercell Global Subsidiaries (ii) the debt in the total amount of \$2.3 million owed to the Company by

Atvio and CureCell (iii) the license agreement between the Company and MaSTherCell dated December 30, 2016; (v) the Joint Venture Agreement with Atvio dated May 10, 2016 (as amended on May 30, 2016); (vi) the SFPI Agreement (vii) the Joint Venture Agreement between Orgenesis and CureCell dated March 14, 2016 (the Corporate Reorganization ). See Note 12(b).

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

In respect of the acquisition of Atvio, the Company issued to the former Atvio shareholders an aggregate of 83,965 shares of Company's Common Stock. In respect of the acquisition of CureCell, the Company issued the former CureCell shareholders an aggregate of 202,846 shares of the Company Common Stock. The exercise of the call options of CureCell and Atvio, pursuant to which the Company obtained effective control over such entities, was accounted for as a business combination. The results of operations of CureCell and Atvio have been included in the Company's condensed consolidated statements of operations starting from June 28, 2018, the date on which the Company obtained effective control of CureCell and Atvio. Before the closing date Atvio and CureCell were associated companies, see Note 12. The net gain on remeasurement of the previously held equity interest in Atvio and CureCell to acquisition date fair value was \$4.5 million.

### *CureCell*

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

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

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

a. The allocation of the purchase price to the net assets acquired and liabilities assumed resulted in the recognition of other intangible assets which comprised of: Customer Relationships of \$859 and Know How of \$3,074. These other intangible assets have a useful life of 10 and 12 years, respectively. The useful life of the other intangible assets for amortization purposes was determined considering the period of expected cash flows generated by the assets used to measure the fair value of the intangible assets adjusted as appropriate for the entity-specific factors, including legal, regulatory, contractual, competitive, economic or other factors that may limit the useful life of intangible assets.



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

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

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

#### *Atvio*

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

#### *Pro forma Impact of Business Combination*

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

The acquired business contributed revenues of \$1.1 million for the period of June 28, 2018 to November 30, 2018. The following unaudited pro forma summary presents consolidation information of the Company as if the business combination had occurred on December 1, 2017:

	<b>Year Ended November 30,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(in thousands)</b>	
Revenue	\$ 18,794	\$ 10,216
Net loss	\$ 20,919	\$ 14,520

#### **NOTE 5 - SEGMENT INFORMATION**

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

#### *CDMO*

The CDMO platform is comprised of a specialization in cell therapy development and comprised of two types of services to its customers: (i) manufacturing and development services and (ii) cGMP contract manufacturing services. The CDMO platform operates through Masthercell Global, which currently consists of MaSTherCell in Belgium, Atvio in Israel and CureCell in South Korea, having unique know-how and expertise for manufacturing in a multitude of cell types. The CDMO activities include the operations of Masthercell Global, Atvio and CureCell from the date of the Corporate Reorganization.



*PT Business*

F-22

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Through the PT business, the Company is focused on the development of proprietary cell and gene therapies, including the autologous trans-differentiation technology, and therapeutic collaborations and licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes.

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

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

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

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

Segment data for the year ended November 30, 2017 is as follows:

	<u>CDMO</u>	<u>CT Business</u>	<u>Corporate and Eliminations</u>	<u>Consolidated</u>
	(in thousands)			
	\$ 11,484	\$ -	\$ (1,395)	\$ 10,089

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Revenues from external customers				
Cost of revenues	(6,356)		638	(5,718)
<b>Gross profit</b>	5,128	-	(757)	4,371
Research and development expenses, net		(2,517)	757	(1,760)
Operating expenses	(4,699)	(3,335)		(8,034)
<b>Operating profit</b>	429	(5,852)	-	(5,423)
Adjustments to presentation of segment Adjusted EBIT				

F-23

Depreciation and amortization	(2,720)	(6)
<b>Segment performance</b>	<b>(2,291)</b>	<b>(5,858)</b>

Reconciliation of segment performance to loss for the year: **Year ended  
November  
30,  
2017**

	<b>in thousands</b>
<b>Segment performance</b>	(8,149)
Stock-based compensation	(3,364)
Financial income (expenses), net	(950)
Share in losses of associated company	(1,214)
Loss before income tax	\$ (13,677)

*Geographic, Product and Customer Information*

Substantially all the Company's revenues and long-lived assets are located in Belgium through its subsidiary, MaSTherCell. Net revenues from single customers from the CDMO segment that exceed 10% of total net revenues are:

	<b>Year Ended November 30, 2018</b>	<b>Year Ended November 30, 2017</b>
	(in thousands)	
Customer A	\$ 2,338	\$ 4,115
Customer B	\$ 4,374	\$ 2,837
Customer C	\$ -	\$ 2,055
Customer D	\$ 5,236	\$ -
Customer E	\$ 2,242	\$ -

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

**NOTE 6 PROPERTY AND EQUIPMENT**

The following table represents the components of property and equipment:

	<b>2018</b>	<b>November 30, 2017</b>
	(in thousands)	
Cost:		
Production facility	\$ 11,413	\$ 6,246
Office furniture and computers	1,875	353
Lab equipment	3,292	2,039
	16,580	8,638
Less accumulated depreciation	(4,679)	(3,534)
Total	\$ 11,901	\$ 5,104

Depreciation expense for the years ended November 30, 2018 and 2017 was \$711 thousand and \$1,096 thousand, respectively.

**NOTE 7 INTANGIBLE ASSETS AND GOODWILL**

F-24

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Changes in the carrying amount of the Company's goodwill in our CDMO platform for the years ended November 30, 2018 and 2017 are as follows:

	(in thousands)
Goodwill as of November 30, 2016	\$ 9,584
Translation differences	1,100
Goodwill as of November 30, 2017	10,684
Goodwill as acquired	4,918
Translation differences	(437)
Goodwill as of November 30, 2018	\$ 15,165

#### *Goodwill Impairment*

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

#### *Reporting Unit of MaSTherCell's Goodwill*

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

Key assumptions used to determine the estimated fair value include: (a) expected cash flow for the five-year period following the testing date (including market share, sales volumes and prices, costs to produce and estimated capital needs); (b) an estimated terminal value using a terminal year growth rate of 2% determined based on the growth prospects; and (c) a discount rate of 15%. Based on the Company's assessment as of November 30, 2018 and 2017, respectively, the carrying amount of its reporting unit does not exceed its fair value.

A decrease in the terminal year growth rate of 1% or an increase of 1% to the discount rate would reduce the fair value of the reporting unit by approximately \$1,126 thousand and \$1,961 thousand, respectively. These changes would not result in an impairment. A decrease in the terminal year growth rate and an increase in the discount rate of 1% would reduce the fair value of the reporting unit by approximately \$2,899 thousand. These changes would not result in an impairment.

#### *Reporting Unit of Atvio's Goodwill and Reporting Unit of CureCell's Goodwill*

As of the year ended November 30, 2018 the Company elected to preform qualitative assessment. Due to the fair value measurement that was performed on June 28, 2018 as part of the business combination. Based on the Company's assessment as of November 30, 2018, the carrying amount of its reporting unit does not exceeds its fair value.

#### *Other Intangible Assets*

Other intangible assets consisted of the following:

November 30,	November 30,
-----------------	-----------------

	2018		2017
	(In thousands)		
<b>Gross Carrying Amount:</b>			
Know How	\$ 20,344	\$	17,998
Backlog	117		-

F-25

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Customer relationships	1,274	369
Brand name	1,359	1,418
	23,094	19,785
Accumulated amortization	6,394	4,734
Net carrying amount of other intangible assets	\$ 16,700	\$ 15,051

Intangible asset amortization expenses were approximately \$1.9 and \$1.8 million for the years ended November 30, 2018 and 2017, respectively.

Estimated aggregate amortization expenses for the five succeeding years ending November 30<sup>th</sup> are as follows:

	<b>2019</b>	<b>2020</b>
		<b>to</b>
		<b>2023</b>
	<b>(in thousands)</b>	
Amortization expenses	\$ 2,086	\$ 7,929

## NOTE 8 CONVERTIBLE LOANS

a. Long term convertible loans outstanding as of November 30, 2018 and 2017 are as follows:

<u>Principal Amount</u>	<u>Issuance Year</u>	<u>Interest Rate</u>	<u>Maturity Period</u>	<u>Exercise Price</u>	<u>BCF</u>	<u>Accumulated Interest Up to Conversion Date</u>	<u>Shares and Warrants Issued Upon Conversion</u>	
							<u>Shares</u>	<u>Warrants</u>
(in thousands)			(Years)			(in thousands)		(5)
<b>Convertible Loans Outstanding as of November 30, 2018</b>								
\$ 1,250	2018	2%	3	\$ 7(1)	114	\$ -	-	-

### Convertible Loans converted during the year ended November 30, 2018

220	2018	6%	2	\$ 6.24	87	\$ 2	35,543	35,543
500 (2)	2018	6%	0.5	\$ 6.24	106	4	80,756	80,756
5,050	2017	6%	2	\$ 6.24	2,311	235	846,961	846,961
798 (3)	2017	6%	0.5-1.7	\$ 6.24	81	40	134,372	34,269
1,388	2016	6%	2	\$ 6.24	251	132	243,443	243,443
100	2014	6%/24%(4)	0.5	\$ 4.8	85	81	37,662	-
8,056						\$ 494	1,378,737	1,240,972

### Convertible Loans repaid during the year ended November 30, 2017

\$ 400 (6)	2017	6%	0.25	\$ 6.24		-	-	-
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(1) The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 178,570 shares and 178,570 three-year warrants to purchase up to an additional 178,570 shares of the Company's common stock at a per share exercise price of \$7. In the initial two years, the holders have the right to convert the outstanding principal amount and accrued interest into shares of capital stock of Hemogenyx-Cell or Immugenyx, LLC according under the relevant note agreement, subsidiaries of Hemogenyx Pharmaceuticals Plc, at a price per share based on a pre-money valuation of Hemogenyx-Cell or Immugenyx, LLC of \$12 million and \$8 million, respectively, pursuant to the collaboration agreement with Hemogenyx Pharmaceuticals Plc and Immugenyx, LLC. As of November 30, 2018, the loans are presented in long term convertible notes in the balance sheet. See Note 11(f) and 11(g).

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

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

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

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

(6) The principal amount and accrued interest were repaid by the Company on March 7, 2017. The fair value of the shares as of March 7, 2017, was \$494 thousand and was recorded as financial expenses.

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

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

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

In March 2018, the investor submitted a notice of its intention to convert into shares of the Company's common stock the principal amount and accrued interest of approximately \$383 thousand outstanding. A related party of such investor at the same time, exercised warrants issued in November 2016 to purchase shares of the Company's Common Stock. The exercise price of the warrants and conversion price were fixed at \$0.52 per share (pre-reverse stock split implemented by the Company in November 2017). There is a significant disagreement between the Company and these two entities as to the number of shares of Common Stock issuable to these entities, and they contend that the number of shares of Common Stock issuable to them should not consider the reverse stock split. The Company rejects these contentions in their entirety and, based on the advice of specially retained counsel, believes that these claims are without legal merit and not made in good faith. The Company intends to vigorously defend its interests and pursue other avenues of legal address. Through its counsel, the Company has advised these entities that unless they withdraw their request within a specified period, the Company will cancel the above referenced agreements and these parties right to receive any shares of the Company's Common Stock. In April 2018, the Company withdrew the agreements and deposited the shares in total amount of 107,985 issued under those agreements and the principal amount and accrued interest of the loan in escrow account. The deposit of the principal amount and accrued interest presented as restricted cash in the balance sheet as of November 30, 2018.

d. In January 2017, MaSTherCell repaid all but one of its bondholders (originally issued on September 14, 2014), and the aggregate payment amounted to \$1.7 million (€1.5 million). On January 17, 2017, the remaining bondholder agreed to extend the duration of his Convertible bond until March 21, 2017. In consideration for the extension, the Company issued to the bondholder warrants to purchase 8,569 shares of the Company's Common Stock, exercisable over a three-year period at a per share exercise price of \$6.24. The fair value of those warrants as of the date of grant was \$20 thousand using the Black-Scholes valuation model.

On March 20, 2017, the remaining bondholder converted his convertible bonds into 40,682 shares of the Company's Common Stock (See also note 13(c)).

## NOTE 9 LOANS

### a. Terms of Long-term Loans

	<b>Principal</b>			<b>Year of</b>		<b>November</b>
	<b>Amount</b>	<b>Grant</b>	<b>Interest</b>	<b>Maturity</b>	<b>2018</b>	<b>30,</b>
		<b>Year</b>	<b>Rate</b>			<b>2017</b>
	(in thousands)				(in thousands)	
Long-term loan (*)	€ 1,400	2012	4.05%	2022	\$ 700	\$ 899
Long-term loan	€ 1,000	2013	6%-7.5%	2023	869	977
Long-term loan	€ 790	2012-2016	5.5%-6%	2021-2024	461	620
					\$ 2,030	\$ 2,496
Current portion of loans payable					(368)	(378)
					\$ 1,662	\$ 2,118

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

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

	<b>Currency</b>	<b>Interest</b>	<b>2018</b>	<b>November 30,</b>
		<b>Rate</b>		<b>2017</b>
				(in thousands)
Current portion of loans payable	Euro	4.05%	\$ 168	\$ 169

Current portion of loans payable	Euro	6%-7.5%	67	70
Current portion of loans payable	Euro	5.5%-6%	133	139
Short term loans	KRW	3.02%, 4.15%	279	-
			\$ 647	\$ 378

**NOTE 10 - COMMITMENTS***a. Maryland Technology Development Corporation*

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

*b. Department De La Gestion Financiere Direction De L analyse Financiere ( DGO6 )*

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

(2) On November 17, 2014, the Belgian Subsidiary, received the formal approval from the DGO6 for a Euro 2 million (\$2.4 million) support program for the research and development of a potential cure for Type 1 Diabetes. The financial support was composed of Euro 1,085 thousand (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of Euro 930 thousand (60% of budgeted costs) of the experimental development part of the research program. In December 2014, the Belgian Subsidiary received advance payment of Euro 1,209 thousand under the grant. The grants are subject to certain conditions with respect to the Belgian Subsidiary s work in the Walloon Region. In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. In 2017 the Company received by the DGO6 final approval for Euro 1.8 million costs invested in the project out of which Euro 1.2 million founded by the DGO6. As of November 30, 2018, the Company repaid to the DGO6 a total amount of \$34 thousand (Euro 30 thousand) and amount of \$152 thousand was recorded in other payables.

(3) In April 2016, the Company's Belgian Subsidiary received the formal approval from DGO6 for a Euro 1.3 million (\$1.5 million) support program for the development of a potential cure for Type 1 Diabetes. The financial support was awarded to the Belgium Subsidiary as a recoverable advance payment at 55% of budgeted costs, or for a total of Euro 717 thousand (\$800 thousand). The grant will be paid over the project period. On December 19, 2016, the Belgian Subsidiary received advance payment of Euro 359 thousand (\$374 thousand). Up through November 30, 2018, an amount of Euro 303 thousand was recorded as deduction of research and development expenses and an amount of \$64 thousand was recorded as advance payments on account of grant.

b. On October 8, 2016, the Belgian Subsidiary received the formal approval from the DGO6 for a Euro 12.3 million (\$12.8 million) support program for the GMP production of AIP cells for two clinical trials that will be performed in Germany and Belgium. The project will be held during a period of three years commencing January 1, 2017. The financial support is awarded to the Belgium subsidiary at 55% of budgeted costs, a total of Euro 6.8 million (\$7 million). The grant will be paid over the project period. On December 19, 2016, the Belgian Subsidiary received a first payment of Euro 1.7 million (\$1.8 million). Up through November 30, 2018, an amount of \$1.1 million was recorded as deduction of research and development expenses and an amount of \$847 thousand was recorded as advance payments on account of grant.

*c. Israel-U.S Binational Industrial Research and Development Foundation ( BIRD )*

On September 9, 2015, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with BIRD and Pall Corporation, a U.S. company. BIRD 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 Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project ). The Project started on March 1, 2015. Upon the conclusion of product development, the grant shall be repaid at the rate of 5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting on March 1, 2015. To date the Israeli Subsidiary received \$200 thousand under the grant. On July 28, 2016 BIRD approved an extension till May 31, 2017 and final report was submitted to BIRD.

Up through November 30, 2018, an amount of \$359 thousand was recorded as deduction of research and development expenses and \$159 thousand as a receivable on account of grant.

*d. Korea-Israel Industrial Research and Development 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 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 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 Cooperation and Project Funding Agreement (CPFA) with KORIL. KORIL will give a conditional grant of up to \$400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use of AIP Cells for the Treatment of Diabetes (the “Project”). The Project started on June 1, 2016. Upon the conclusion of product development, the grant shall be repaid at the yearly rate of 2.5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting. On July 26, 2018 KORIL approved extension for the project period till May 31, 2019. As of November 30, 2018, The Israeli Subsidiary and CureCell received total amount of \$440 thousand under the grant. Up through November 30, 2018, The Israeli Subsidiary recorded an amount of \$279 thousand as a deduction of research and development expenses and \$119 thousand as a receivable on account of grant, and CureCell recorded \$134 thousand as advance payments on account of grant.

*e. BIRD Secant*

On July 30, 2018, Orgenesis Inc and Atvio entered into a collaboration agreement with Secant Group LLC (“Secant”). Under the agreement, Secant will engineer and prototype 3D scaffolds based on novel biomaterials and technologies involving bioresorbable polymer microparticles, while Atvio will provide expertise in cell coatings, cell production, process development and support services. Under the agreement, Orgenesis is authorized to utilize the jointly developed technology for its autologous cell therapy platform, including its Autologous Insulin Producing (“AIP”) cell technology for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases. In the beginning of 2018, Atvio entered into a Cooperation and Project Funding Agreement (CPFA) with BIRD and Secant. BIRD will give a conditional grant up to \$450 thousand each to support the joint project (according to terms defined in the agreement).

As of November 30, 2018, Atvio received a total amount of \$125 thousand under the grant. Up through November 30, 2018, an amount of \$275 thousand was recorded as deduction of research and development expenses and \$163 thousand as a receivable on account of grant.

*f. Lease Agreement*

The Company leases office space for its CDMO facilities and research and development facilities in Belgium, Korea, Israel and the United States of America under several lease agreements. The expiration dates of the lease agreements for the facilities in each country are as follow:

Country	Expire Date
Belgium	February 29, 2020 and March 31, 2030
Israel	July 31, 2023
Korea	July 14, 2020
United States	*

\*The company signed a new lease agreement during January 2019, see Note 21(f)

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

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

F-30

**NOTE 11 COLLABORATION AND LICENSE AGREEMENTS***a. Adva Biotechnology Ltd.*

On January 28, 2018, the Company and Adva Biotechnology Ltd. ( Adva ), entered into a Master Services Agreement ( MSA ), under which the Company and/or its affiliates are to provide certain services relating to development of products to Adva, as may be agreed between the parties from time to time. Under the MSA, the Company undertook to provide Adva with in kind funding in the form of materials and services having an aggregate value of \$750 thousand at the Company s own cost in accordance with a project schedule and related mutually acceptable project budget. The Company entered into agreement with Atvio, to fulfill its obligations pursuant this MSA. As of November 30, 2018, the Company incurred a total expense of \$361 thousand.

In consideration for and subject to the fulfillment by the Company of such in-kind funding commitment, Adva agreed that upon completion of the development of the products, the Company and/or its affiliates and Adva shall enter into a supply agreement pursuant to which for a period of eight (8) years following execution of such supply agreement, the Company and/or its affiliates (as applicable) is entitled (on a non-exclusive basis) to purchase the products from Adva at a specified discount pricing from their then standard pricing. The Company and/or its affiliates were also granted a non-exclusive worldwide right to distribute such products, directly or through any of their respective contract development and manufacturing organization (CDMO) service centers during such term. The MSA shall remain in effect for 10 years unless earlier terminated in accordance with its terms.

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

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

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

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

As of November 30, 2018, the Israeli Subsidiary had not reached any of these milestones.



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

*c. Mircod Limited*

On June 18, 2018, the Company and Mircod Limited, a company formed under the laws of Cyprus ( Mircod ) entered into a Collaboration and License Agreement (the Mircod Collaboration Agreement ) for the research, development and commercialization of potential key technologies related to biological sensing for the Company's clinical development and manufacturing projects (the Development Project ).

Under the Mircod Collaboration Agreement, all results of such collaboration ( Project Results ) shall be jointly owned by Mircod and the Company. The Company was granted an exclusive, worldwide sub licensable license under Mircod s right in such Project Results to use and commercialize Project Results in consideration for a royalty of 5% of net sales (as defined in the Collaboration Agreement) of products incorporating Project Results.

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 the Company s request, to provide support and maintenance service for such products. If for whatever reason the parties fail to enter into such manufacturing and supply agreement within 90 days of the completion of the Development Project or if Mircod is unable to perform such services, the Company is 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. As of November 30, 2018, the Developments Project has not completed.

*d. HekaBio K.K*

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

Under the JVA, each party may invest up to \$10 million, which may take the form of a loan, if 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 the Company of up to \$15 million within the next 12 months on mutually agreeable terms. If such investment is in fact consummated, the Company agreed to invest in the JV Company by way of a convertible loan an amount equal to HB s pro-rata participating interest in the JV Company, which initially will be at 51%. Such loan may then be converted by the Company into share capital of the JV company at an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million. Under the JVA, the Company can require HB to sell to the Company its participating (including equity) interest in the JV Company in consideration for the issuance of the Company s common stock based on an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million.

In addition, under the JVA, the Company shall grant the JV Company an exclusive license to certain intellectual property of the Company as may be required for the JV Company to develop and commercialize the Products in

Japan. In consideration of such license, the JV Company shall pay the Company, in addition to other payments, royalties at the rate of 10% of the JV Company's net sales of Products.

F-32

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

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

Apart from the above, as of November 30, 2018, no activity had begun in the said JV and no investments were made therein.

*e. Image Securities Ltd.*

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

The India JVA 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 India JVA through the purchase of units of the Company securities at a per unit purchase price payable into the Company of \$6.24, with each unit comprised of one share of the Company and three-year warrant for the acquisition of an additional common share at a per share exercise price of \$6.24. Following the consummation of such equity investment in the Company, on October 18, 2018, the Company entered into a convertible loan agreement with the India Joint Venture company ( India JV ) pursuant to which the Company agreed to invest \$5 million into the India JV. The loan is convertible into equity capital of the India JV at an agreed upon formula for determining India JV valuation. The investment in the Company by the India Partner was the consummation of the previously disclosed private placement subscription agreement entered into in December 2016 between the Company and an affiliate of the India Partner pursuant to which the closing of such subscription agreement was by the terms thereof delayed until terms comprising the India JV were mutually agreed to. As of November 30, 2018, the Company has advanced \$1 million to the JV Company under the convertible loan agreement, the loan will bear interest of 6% per annum and the outstanding amount (principal and interest) will be payable after two years. The loan was presented in the balance sheet as loan to related party.

Under the India JVA, the India Partner agreed to invest in the JV \$10 million within 12 months of the incorporation of the India JV. If for whatever reason such investment is not made by the India Partner within such time, then the Company is authorized to convert its above-referenced loan into 50% of the equity capital of the India JV on a fully diluted basis, provided that if the pre-money valuation of the India JV is then independently determined to be less than \$5 million, then such conversion to be effected in the basis of such valuation. Apart from the above, as of November 30, 2018, no activity had begun.

As part of the agreement, the Indian joint venture will procure consulting services from the Company in the amount of \$1 million per month See also Note 21(c).

*f. Hemogenyx Pharmaceuticals PLC.*

On October 18, 2018, the Company and Hemogenyx Pharmaceuticals PLC., a corporation with its registered office in the United Kingdom and Hemogenyx-Cell ( H-Cell"), a corporation with its registered office in Belgium (together Hemo ) which are engaged in the development of cell replacement bone marrow therapy technology entered into a Collaboration Agreement (the Hemo agreement ) pursuant to which the parties will collaborate in the funding of the

continued development of, and commercialization of the Hemo technology via the Hemo group companies. Pursuant to the Hemo agreement the Company and Hemogenyx LLC ( Hemo-LLC ) (a wholly owned USA subsidiary of Hemo) entered into a loan agreement on November 7, 2018 according to which the Company agreed to loan Hemo-LLC not less than \$1 million by way of a convertible loan. On November 25, 2018 the Company and Hemo entered into a License and Distribution agreement according to which Company received the worldwide rights to market the products under the agreement in consideration for the payment of a 12% royalty all subject to the terms of the agreement. On November 25, 2018, the Company and H-Cell signed an Exclusive Manufacturing agreement according to which the Company will receive the right to manufacture certain of H-Cell products.

F-33

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As of November 30, 2018, the Company advanced \$0.5 million as a convertible loan and an additional \$0.25 million was advanced in December 2018 (see Note 21(b)). The entire loan as of November 30, 2018, in the amount of \$0.5 million, was charged to expense under ASC 730-10-50 and 20-50 and presented as research and development costs. See Note 8 (a).

*g. Immugenyx LLC.*

On October 16, 2018, the Company and Immugenyx LLC., a corporation with its registered office in the USA (“Immu”) which is engaged in the development of technology related to the production and use of humanized mice entered into a Collaboration Agreement (the “Immu agreement”) pursuant to which the parties will collaborate in the funding of the continued development of, and commercialization of the Immu technology. Pursuant to the agreement, the Company received the worldwide rights to market the products under the agreement in consideration for the payment of a 12% royalty all subject to the terms of the agreement. Pursuant to the Immu agreement the Company and Immu entered into a loan agreement on November 7, 2018 according to which the Company agreed to loan Immu not less than US\$1 Million by way of a convertible loan. As of November 30, 2018, the Company advanced \$0.5 million as convertible loan, and an additional \$0.25 million was advanced in December 2018 (see Note 21(b)). The entire loan as of November 30, 2018, in the amount of \$0.5 million, was charged to expense under ASC 730-10-50 and 20-50 and presented as research and development costs. See also Note 8 (a).

*h. BG Negev Technologies and Applications ( BGN ).*

On August 2, 2018, the Company’s USA Subsidiary entered into a licensing agreement with BGN. According to the agreement, the USA Subsidiary was granted a worldwide, royalty bearing, exclusive license to develop and commercialize a novel alginate scaffold technology for cell transplantation focused on autoimmune diseases.

On November 25, 2018, the Company’s USA Subsidiary entered into a further licensing agreement with BGN. According to the agreement, the USA Subsidiary was granted a worldwide, royalty bearing, exclusive license to develop and commercialize technology directed to RAFT modification of polysaccharides and use of a bioreactor for supporting cell constructs.

As consideration for the licenses, the USA Subsidiary will pay royalties of between 2% and 4% of net sales of the licensed product, sub-license fees of between 15% and 20% of sub-license income received, license fees of \$10,000 per year per license, and milestone and budget payments according to agree upon work plans to BGN.

*i. Collaboration agreement*

During 2018, the Company and Cure Therapeutics entered into a collaboration agreement for the development of therapies based on liver and NK cells. The agreement will be governed by a joint steering committee and carried out in accordance with the projects' work plans. Under the plan, each party will generally bear its own share of expenses. As of November 30, 2018, the Company has incurred \$1.2 million of research and development expenses in relation to the project. As part of the agreement, Cure Therapeutics has subcontracted development and contract manufacturing activities to CureCell, for which service revenue of \$1 million has been recognized.

**NOTE 12 INVESTMENTS IN ASSOCIATES, NET**

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



The Company remitted to Atvio \$1 million under the terms of the Atvio JVA to defray the costs associated with the setting up and the maintenance of the GMP facility. The Company's funding was made by way of a convertible loan to Atvio, which could have been convertible at the Company's option at any time. The Company concluded that, based on the terms of the agreement, it had the ability to exercise significant influence in Atvio, but had no control. Therefore, the investment was accounted for under the equity method. In addition, at any time following the first anniversary year of the Effective Date the Company had the option to require the Atvio's shareholders to transfer to the Company the entirety of their interest in Atvio for the consideration specified in the agreement. Within three years from the Effective Date, the Atvio's shareholders had the option to require the Company to purchase from Atvio's shareholders their entire interest in Atvio for the consideration based on Atvio's valuation mechanism as specified in the agreement. The above-mentioned options were accounted as derivatives and measured at fair value and was presented in the balance sheet in " put option derivative " line item (See Note 17). On June 28, 2018 the Company exercised its call options in Atvio, see also Note 4.

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

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

c. The table below sets forth a summary of the changes in the investments for the years ended November 30, 2018 and 2017:

	2018	November 30, (In thousands)	2017
Opening balance	\$ 1,321	\$	(12)
Reclass with short-term receivables	(795)		118
Investments during the period	-		2,429
Share in losses	(731)		(1,214)
Reductions due to the acquisition of CureCell and Atvio see also Note 4	205		-
	\$ -	\$	1,321

### NOTE 13 EQUITY

#### a. Share Capital

The Company's common shares were traded on the OTCQB Venture Market under OTC Market Group's OTCQB tier under the symbol ORGS . On March 13, 2018, the Company's common stock began to be listed and traded on the Nasdaq Capital Market under the symbol ORGS.

#### b. Financings

(1) In January 2017, the Company entered into definitive agreements with an institutional investor for the private placement of 2,564,115 units of the Company's securities for aggregate subscription proceeds to the Company of \$16 million at \$6.24 price per unit. Each unit is comprised of one share of the Company's Common Stock and a one warrant, exercisable over a three-years period from the date of issuance, to purchase one additional share of Common

Stock at a per share exercise price of \$6.24 ( Unit ). The subscription proceeds have been paid to the Company on a periodic basis through October 2018.

F-35

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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 have not been subscribed for, entitling such investors to 702,307 units, with each unit being comprised of (i) one share of the Company's common stock and (ii) one three-year warrant to purchase up to an additional one share of the Company's common stock at a per share exercise price of \$6.24.

During the year ended November 30, 2018 and 2017 the investor and the assignees remitted to the Company \$11.5 and \$4.5 million, and the Company issued 1,813,687 and 721,160 Units, respectively.

As of November 30, 2018, 550,481 shares have not been issued and therefore the Company has recorded \$2.3 million in receipts on account of shares to be allotted in the statement of equity.

In connection therewith, during the year ended November 30, 2018 and 2017, the Company had transaction costs of approximately \$328 and \$225 thousand, respectively, out of which \$121 and \$253 thousand are stock-based compensation expenses due to issuance of warrants and shares. See also Note 15(d).

(2) During the 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.

The transaction costs were approximately \$349 thousand, out of which \$125 thousand are stock-based compensation due to issuance of warrants. See also 15(d).

(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.

*c. Contingent Shares*

According to the share exchange agreement signed during 2015, the former shareholders of MaSTherCell received a consideration of shares of Orgenesis Inc. in exchange of their shares in MaSTherCell. At the time of MaSTherCell's acquisition by the Company, there was outstanding convertible bonds issued by MaSTherCell in an amount of \$1.8 million (Euro 1.6 million). Under the share exchange agreement in case MaSTherCell is repaying the principal amount and the accrued interest of the convertible bonds, the former shareholders will give back to the Company a portion of the consideration shares. To that effect, the number of consideration shares to be released back to the Company, shall be determined by dividing the subscription amount of the outstanding convertible bonds plus interest owed thereunder (converted into USD according to the currency exchange rate applicable on the day of conversion) by the consideration and by applying the resulting quotient to actual total number of consideration shares received by former shareholder of MaSTherCell.

During January 2017 MaSTherCell repaid all but one of its bondholders and the aggregate payment amounted to \$1.7 million (Euro 1.5 million). According to the terms of the release back pursuant the share exchange agreement, the Company returned to treasury a total of 263,148 shares. These shares have been retired and cancelled. See also Note 8(d).

*d. Warrants*

A summary of the Company's warrants granted to investors and as finders fees as of November 30, 2018 and 2017 and changes for the years then ended is presented below:

	2018	Weighted Average Exercise Price \$	2017	Weighted Average Exercise Price \$
	Number of Warrants		Number of Warrants	
<b>Warrants</b> outstanding at the beginning of the year	2,609,864	6.26	1,620,993	6.25
Changes during the year:				
Issued	4,488,854	6.27	1,144,647	6.32
Exercised	(136,646)	6.24	-	
Expired	(382,414)	6.10	(155,776)	6.24
Cancelled**	(66,667)	6.24	-	
<b>Warrants</b> outstanding and exercisable at end of the year*	6,512,991	6.27	2,609,864	6.26

\* As of November 30, 2018, and 2017, 769,411 and 1,066,691 warrants respectively, are subject to exercise price adjustments

\*\* see also Note 15(d).

	<b>Year Ended November 30,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands, except per share data)	
<b>Basic:</b>		
Net loss attributable to Orgenesis Inc	\$ 18,291	\$ 12,367
Adjustment of redeemable non-controlling interest to redemption amount	884	-
Net loss attributable to Orgenesis Inc. for loss per share	\$ 19,637	\$ 12,367
Weighted average number of common shares outstanding	13,374,103	9,679,964
Basic loss per common share	\$ 1.43	\$ 1.28
<b>Diluted:</b>		
Net loss attributable to Orgenesis Inc. for loss per share	\$ 19,175	12,367
Changes in fair value of embedded derivative and interest expenses on convertible note	-	392
Loss for the year	\$ 19,175	\$ 12,759
Weighted average number of shares used in the computation of basic loss per share	13,374,103	9,679,964
Number of dilutive shares related to convertible note	-	34,288
Weighted average number of common shares outstanding	13,374,103	9,714,252
Diluted loss per common share	\$ 1.43	\$ 1.31

**NOTE 14 LOSS PER SHARE**

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

For the year ended November 30, 2018, all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

For the year ended November 30, 2017, all outstanding options and warrants and 1,057,785 shares upon conversion of convertible notes have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

**NOTE 15 STOCK-BASED COMPENSATION***a. Global Share Incentive Plan*

On May 11, 2017, the annual meeting of the Company's stockholders approved the 2017 Equity Incentive Plan (the 2017 Plan) under which, the Company had reserved a pool of 1,750,000 shares of the Company's common stock, which may be issued at the discretion of the Company's board of directors from time to time. Under this Plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years. As of November 30, 2018, total options granted under this plan are 1,040,942, and the total options that are available for grants under this plan are 709,058.

On May 23, 2012, the Company's board of directors adopted the Global Share Incentive Plan 2012 (the "2012 Plan") under which, the Company had reserved a pool of 1,000,000 shares of the Company's common stock, which may be issued at the discretion of the Company's board of directors from time to time. Under this plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years. As of November 30, 2018, total options granted under this plan are 699,991, and the total options that are available for grants under this plan are 300,009.

*b. Options Granted to Employees and Directors*

Below is a table summarizing all of the options grants to employees and made during the years ended November 30, 2018, and 2017:

	<b>Year of grant</b>	<b>No. of options granted</b>	<b>Exercise price</b>	<b>Vesting period</b>	<b>Fair value at grant (in thousands)</b>	<b>Expiration period</b>
Employees	2018	762,400	\$4.42-\$8.91	vest immediately-4 years	\$4,233	10 years
Directors	2018	113,800	\$5.99	1 year	\$507	10 years
Directors	2017	166,668	\$4.80	2 years	\$558	10 years
Employees	2017	525,005	\$4.8,\$7.2	vest immediately-4 years	\$1,915	10 years

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for past periods based on expected term. The expected option term is calculated using the simplified method, as the Company concludes that its historical share option exercise experience does not provide a reasonable basis to estimate its expected option term. The fair value of each option grant is based on the following assumptions:

	<b>Year Ended November 30,</b>	
	<b>2018</b>	<b>2017</b>
Value of one common share	\$4.42-\$8.7	\$4.68,\$7.2
Dividend yield	0%	0%
Expected stock price volatility	88%-98%	93.8%-95.4%
Risk free interest rate	2.33%-3.2%	1.89%-1.76%
Expected term (years)	4.13-10	5

A summary of the Company's stock options granted to employees and directors as of November 30, 2018 and 2017 and changes for the years then ended is presented below:

	<b>2018</b>		<b>2017</b>	
	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
		<b>\$</b>		<b>\$</b>
Options outstanding at the beginning of the year	1,605,055	3.11	978,853	1.92
Changes during the year:				

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Granted	876,200	7.13	691,673	5.28
Expired	(61,463)	5.26	(38,106)	7.58
Forfeited	(43,365)	4.68	(27,365)	4.8
Options outstanding at end of the year	2,376,427	4.51	1,605,055	3.11
Options exercisable at end of the year	1,504,542	2.91	1,135,107	2.57

F-38

The following table presents summary information concerning the options granted and exercisable to employees and directors outstanding as of November 30, 2018:

Exercise Price \$	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value \$ (in thousands)	Number of Exercisable Options	Aggregate Exercisable Options Value \$ (in thousands)
0.0012	462,015	4.78	2,776	462,015	1
0.012	278,191	3.18	1,669	278,191	3
4.42	50,000	9.02	79	37,500	166
4.8	524,999	8.03	635	440,104	2,112
5.99	384,050	9.35	8	32,750	196
6	33,334	5.67	-	33,334	200
7.2	83,334	8.51	-	83,334	600
8.36	250,000	9.58	-	-	-
8.43	160,994	9.46	-	14,492	156
8.91	30,500	9.55	-	3,813	34
9	20,834	4.63	-	20,834	188
9.48	58,908	3.61	-	58,908	558
10.2	39,268	3.51	-	39,267	401
	2,376,427	7.15	5,167	1,504,542	4,598

Costs incurred with respect to stock-based compensation for employees and directors for the years ended November 30, 2018 and 2017 were \$2,426 thousand and \$1,536 thousand, respectively. As of November 30, 2018, there was \$3,783 thousand of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 3.89 years.

*c. Options Granted to Consultants and service providers*

Below is a table summarizing all the compensation granted to consultants and service providers during the years ended November 30, 2018 and 2017:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employees	2018	102,763	\$4.42-\$8.34	vest immediately-4 years	\$444	10 years
Non-employees	2017	16,668	\$4.8	Quarterly over a period of one year	\$68	10 years

The fair value of options granted during 2018 and 2017 to consultants and service providers, was computed using the Black-Scholes model. The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for past periods based on the expected term period, the expected term is the contractual term of each grant. The expenses are subsequently adjusted to fair value at the end of each reporting period until such options vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period. The underlying data used for computing the fair value of the options are as follows:



	<b>Year Ended November 30,</b>	
	<b>2018</b>	<b>2017</b>
Value of one common share	\$4.42-\$8.34	\$3.6-\$7.44
Dividend yield	0%	0%
Expected stock price volatility	91%-95%	87%-95%
Risk free interest rate	2.33%-3.20%	1.19%-1.89%
Expected term (years)	9.79-10	4-5

A summary of the status of the stock options granted to consultants and service providers as of November 30, 2018, and 2017 and changes for the years then ended is presented below:

	<b>2018</b>		<b>2017</b>	
	<b>Number of Options</b>	<b>Weighted Average Exercise Price \$</b>	<b>Number of Options</b>	<b>Weighted Average Exercise Price \$</b>
Options outstanding at the beginning of the year	399,380	7.47	441,621	6.24
Changes during the year:				
Granted	102,763	4.92	16,668	4.80
Expired	-	-	(58,909)	8.28
Forfeited	(15,500)	-	-	-
Cancelled	(16,669)	7.02		
Options outstanding at end of the year	469,974	5.75	399,380	7.47
Options exercisable at end of the year	436,640	5.75	379,712	5.76

The following table presents summary information concerning the options granted and exercisable to consultants and service providers outstanding as of November 30, 2018 (in thousands, except per share data):

<b>Exercise Price \$</b>	<b>Number of Outstanding Options</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value* \$</b> (in thousands)	<b>Number of Exercisable Options</b>	<b>Aggregate Exercisable Options Value \$</b> (in thousands)
3.36	136,775	7.41	362	136,775	460
3.6	83,334	7.25	201	83,334	300
4.42	10,325	9.02	16	10,325	46
4.8	16,667	8.03	20	16,667	80
5.3	35,000	9.79	25	20,000	106
5.99	25,005	9.9		13,337	80
6	90,000	5.67		90,000	540
6.4	8,333	9.13		1,667	11
7.32	8,334	3.98		8,334	61
8.34	8,600	9.61		8,600	72
11.52	8,334	4.35		8,334	96
16.8	39,267	3.37		39,267	660
	469,974	6.83	624	436,640	2,512



Costs incurred with respect to options granted to consultants and service providers for the year ended November 30, 2018 and 2017 was \$331 thousand and \$322 thousand, respectively. As of November 30, 2018, there was \$157 thousand of unrecognized compensation costs related to non-vested consultants and service providers, to be recorded over the next 3.13 years.

F-40

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*d. Warrants and Shares Issued to Non-Employees*

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

2) In December 2017, the Company entered into investor relations services, marketing and related services agreements. Under the terms of the agreement, the Company agreed to grant the consultants a total of 195,000 shares of restricted common stock, out of which the first 50,000 shares will vest after 30 days from the signing date, and 145,000 shares are to vest monthly over 15 months commencing February 2018. As of November 30, 2018, 140,000 shares were vested. The fair value of the shares as of the date of grant was \$1,439 thousand.

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

4) During the year ended November 30, 2017, the Company granted to several consultants 53,148 warrants each exercisable at \$6.24 or \$10.20 per share for three years. The fair value of those options as of the date of grant using the Black-Scholes valuation model was \$211 thousand, out of which \$169 thousand is related to 38,001 warrants granted as a success fee with respect to the issuance of the convertible notes.

**NOTE 16 TAXES**

*a. Corporate taxation in the U.S.*

The applicable corporate tax rate for the Company and the U.S. subsidiaries is 21% following the U.S. Tax Cuts and Jobs Act (the TCJA), excluding state tax and local tax. On December 22, 2017, the TCJA was signed into law, which among other changes reduced the federal corporate income tax rate from 35% to 21%, effective January 1, 2018.

As of November 30, 2018, the Company has an accumulated tax loss carryforward of approximately \$19 million (as of November 30, 2017, approximately \$12.8 million). Under U.S. tax laws, subject to certain limitations, carryforward tax losses expire 20 years after the year in which incurred. Utilization of the U.S. net operating losses may be subject to substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

*b. Corporate taxation in Israel*

The Israeli Subsidiaries are taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2018 and 2017 are 23% and 24% respectively.

As of November 30, 2018, the Israeli Subsidiaries has an accumulated tax loss carryforward of approximately \$7.3 million (as of November 30, 2017, approximately \$5.8 million). Under the Israeli tax laws, carryforward tax losses have no expiration date.

*c. Corporate taxation in Belgian*

The Belgian Subsidiaries are taxed according to Belgian tax laws. The corporate tax rate applicable to 2020, 2019-2018 and 2017 are 25%, 29.58% and 34%.

F-41

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As of November 30, 2018, the Belgian Subsidiaries has an accumulated tax loss carryforward of approximately \$5.9 million (€5.2 million), (as of November 30, 2017 \$15.8 million). Under the Belgian tax laws there is are limitation on accumulated tax loss carryforward deductions of Euro 1 million per year.

*d. Corporate taxation in Korea*

The basic Korean corporate tax rates are currently: 10% on the first KRW 200 million of the tax base, 20% up to KRW 20 billion , 22% up to KRW 300 billion and 25% for tax base above KRW 300 billion.

As of November 30, 2018, CureCell has an accumulated tax loss carryforward of approximately \$3.2 million (KRW 3,421 million).

*e. Deferred Taxes*

The following table presents summary of information concerning the Company s deferred taxes as of the periods ending November 30, 2018 and 2017 (in thousands):

	<b>November 30,</b>	
	<b>2018</b>	<b>2017</b>
	(U.S dollars in thousands)	
Net operating loss carry forwards	\$ 8,868	\$ 11,893
Research and development expenses	2,915	1,065
Employee benefits	181	180
Property and equipment	(47)	(61)
Deferred income	(117)	(292)
Intangible assets	(4,142)	(5,117)
Less: Valuation allowance	(9,235)	(8,358)
Net deferred tax liabilities	\$ (1,702)	\$ (690)

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forwards losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not considered more likely than not achievable, the Company and all its subsidiaries except MaSTherCell, Atvio and CureCell have recorded full valuation allowance.

The changes in valuation allowance are comprised as follows:

	<b>Year Ended November 30,</b>	
	<b>2018</b>	<b>2017</b>
	(U.S dollars in thousands)	
Balance at the beginning of year	\$ (8,358)	\$ (5,151)
Additions during the year	(877)	(3,207)
Balance at end of year	\$ (9,235)	\$ (8,358)

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

The main reconciling item between the statutory tax rate of the Company and the effective rate is the provision for full valuation allowance with respect to tax benefits from carry forward tax losses and changes in cooperate tax rate in the U.S and Belgium.

*g. Uncertain Tax Provisions*

ASC Topic 740, Income Taxes requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement

of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company. As of November 30, 2018, the Company has not accrued a provision for uncertain tax positions.

F-42

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**NOTE 17 - FAIR VALUE PRESENTATION**

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Observable inputs that are based on inputs not quoted on active markets but corroborated by market data.
- Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs, to the extent possible, and considers credit risk in its assessment of fair value.

As of November 30, 2017, the Company's liabilities that are measured at fair value and classified as level 3 fair value are as follows (in thousands):

	<b>November 30, 2017 Level 3</b>
Embedded derivatives convertible loans *	(37)
CALL/PUT option derivative	(339)

\* The embedded derivative is presented in the Company's balance sheets on a combined basis with the related host contract (the convertible loans).

The fair value is determined by using a Black-Scholes Model.

The following table presents the assumptions that were used for the models as of November 30, 2017:

	<b>Embedded Derivative</b>	<b>Put Option Derivative</b>
Fair value of shares of common stock	\$ 4.38	
Expected volatility	77%	54%
Discount on lack of marketability	-	12%
Risk free interest rate	1.21%-1.39%	1.44%
Expected term (years)	0.17-0.42	0.5
Expected dividend yield	0%	

The table below sets forth a summary of the changes in the fair value of the Company's financial liabilities classified as Level 3 for the year ended November 30, 2018:

	<b>Embedded Derivatives</b>	<b>Put Option Derivative</b>
Balance at beginning of the period	\$ 37	\$ (339)

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Repayment	(14)	-
Changes in fair value during the period	(23)	49
Option disposal	-	290
Balance at end of the period	\$ -	\$ -

F-43

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(\*) There were no transfers to Level 3 during the twelve months ended November 30, 2018.

The table below sets forth a summary of the changes in the fair value of the Company's financial liabilities classified as Level 3 for the year ended November 30, 2017:

	<b>Embedded Derivatives</b>	<b>Convertible Bonds</b>	<b>Put Option Derivative</b>
Balance at beginning of the year	\$ 240	\$ 1,818	\$ 273
Repayment	(876)	(1,827)	-
Changes in fair value during the period	662	22	(612)
Translation adjustments	11	(13)	-
Balance at end of the year	\$ 37	\$ -	\$ (339)

(\*) There were no transfers to Level 3 during the twelve months ended November 30, 2017.

The Company has performed a sensitivity analysis of the results for the Put Option Derivative fair value as of November 30, 2017 with the following parameters:

	<b>Base -50%</b>	<b>Base</b>	<b>Base+50%</b>
		(in thousands)	
Sensitivity analysis due to changes in the assumptions expected volatility	\$ 335	\$ 339	\$ 379
Sensitivity analysis due to changes in Atvio's FV	252	339	440

#### NOTE 18 RESEARCH AND DEVELOPMENT EXPENSES, NET

	<b>Year Ended November 30,</b>	
	<b>2018</b>	<b>2017</b>
	(in thousands)	
Total expenses	\$ 7,386	\$ 3,326
Less grants	(922)	(848)
Total	\$ 6,464	\$ 2,478

#### NOTE 19 FINANCIAL EXPENSES, NET

	<b>Year ended November 30,</b>	
	<b>2018</b>	<b>2017</b>
	(in thousands)	
Decrease in fair value of warrants and financial liabilities measured at fair value	\$ 48	\$ (902)
Stock-based compensation related to warrants granted due to issuance of credit facility	180	1,497
Interest expense on convertible loans	2,753	1,233
Foreign exchange loss, net	129	562
Other income	7	57
Total	\$ 3,117	\$ 2,447

#### NOTE 20- RELATED PARTIES TRANSACTIONS



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

F-44

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**For the year ended November 30,**  
**2018** **2017**

	(in thousands)	
Management and consulting fees to Board Members	\$ 52	\$ 25
Stock Based Compensation expenses to Board Members	304	393
Compensation of executive officers	1,119	419
Stock Based Compensation expenses to executive officers	1,479	821
Interest Expenses on convertible loan from director	\$ 13	\$ 55

b. Related Parties presented in the consolidated balance sheets

**Year ended November 30,**  
**2018** **2017**

	(in thousands)	
Convertible Loan from director	\$ -	\$ 167
Executive officers payables	1,164	358
Loan to Related Party. See Note 11(e)	1,007	-
Non-executive directors payable	\$ 41	\$ 316

**NOTE 21 - SUBSEQUENT EVENTS**

a. In December 2018, the Company entered into unsecured convertible loan agreements with accredited or offshore investors for an aggregate amount of \$250 thousand. The loans bear an annual interest rate of 2% and mature in three years unless converted earlier under the same terms as the convertible loans presented in Note 8(a).

b. During December 2018, the Company advanced a total of \$0.5 million to Hemogenyx Pharmaceuticals PLC and Immugenx PLC. See Notes 11(f) and 11(g).

c. On February 4, 2019, the Indian Joint Venture transferred the first payment of \$1 million for services under the India JVA. See also Note 11(e).

d. In December 2018, the Company entered into a Controlled Equity Offering Sales Agreement (“Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”) pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company’s common stock having an aggregate offering price of up to \$25.0 million. The Company will pay Cantor a commission rate equal to 3.0% of the aggregate gross proceeds from each sale. The Company has not yet sold any shares pursuant to the Sales Agreement.

e. During December 2018, the Company received authorization from the Direction des Programmes de recherche in Belgium that based on a program and budget of \$1.5 million in the field of gene-therapy research for diabetes 1 treatment, the Company could receive up to \$ 350 thousand by June 2021.

f. During January 2019, Masthercell Global executed a lease agreement for production facilities in the United States. Under the terms of the agreement, Masthercell Global leased approximately 32,000 square feet for 180 months. Masthercell Global advanced \$1.6 million on account of a security deposit, tenant improvement allowance and prepaid base rent. The annual rental increases over the lease period from approximately \$726 thousand to \$962 thousand.

g. In December 2018 and January 2019, the Board of Directors of Masthercell Global approved option grants for the purchase of 61,111 options in Masthercell Global under the Masthercell Global option plan to Masthercell Global executives, at an exercise price of \$13.52.

