UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: **November 30, 2017**

or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number **000-54329**

ORGENESIS INC.

((Exact name of registrant as specified in its charter)

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

20271 Goldenrod Lane, Germantown, MD 20876
((Address of principal executive offices) (Zip Code)

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

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

Securities registered pursuant to section 12(g) of the Act:
Common stock, par value $0.0001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes [ ] No [**X**]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes [ ] No [**X**]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes [**X**] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes [**X**] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ] Accelerated filer [ ]

Non-accelerated filer [ ] Smaller reporting company **[X]**
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b -2 of this chapter). [ ]

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 10,273,644 shares of common stock outstanding as of February 28, 2018. The aggregate market value of the common stock held by non-affiliates of the registrant as of May 31, 2017 was $41,903,396, as computed by reference to the closing price of such common stock on OTCQB on such date.

ORGENESIS INC.
2017 FORM 10-K ANNUAL REPORT
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FORWARD-LOOKING STATEMENTS

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

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Form 10-K. Certain statements made in this discussion are "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements. Unless otherwise indicated or the context requires otherwise, the words “we,” “us,” “our,” the “Company” or “our Company” or “Orgenesis” refer to Orgenesis Inc., a Nevada corporation, and our subsidiaries, MaSTherCell, S.A. (“MaSTherCell”), Orgenesis SPRL (the “Belgian Subsidiary), Orgenesis Ltd. (the “Israeli Subsidiary”), Orgenesis Maryland Inc. and Cell Therapy Holdings S.A. Forward-looking statements made in an 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 one of our principal competitive advantages is our cell trans-differentiation technology being developed by our Israeli Subsidiary and being able to compete favorably and profitably as a Contract Development and Manufacturing Organization (“CDMO”) in the regenerative medicine sector;

CDMO business

- our ability to grow the business of MaSTherCell, which we acquired in our fiscal year 2015, as our principal contract development and manufacturing (CDMO) business;
- 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 our CDMO business;
- our expectations regarding our 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;
- our ability to contract 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; and

Cellular Therapy business (“CT”)

- 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 belief that our diabetes-related treatment seems to be safer than other options;
- expectations regarding the ability of our Israeli Subsidiary and our Belgian Subsidiary to obtain additional and maintain intellectual property protection for our technology 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 relationship with Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") and the risk that THM may cancel the License Agreement;
- expenditures not resulting in commercially successful products;

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, 2017, 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 service and research company in the field of the regenerative medicine industry with a focus on cell therapy development and manufacturing for advanced medicinal products serving the regenerative medicine industry. In addition, we are focused on developing novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes.

A large number of diseases continue without adequate conventional therapies. Cell therapy has a unique therapeutic effect as it is based on augmenting, repairing, replacing or regenerating organs and tissues - leveraging the human body's capacity to heal. It therefore holds the promise to be able to cure diseases that present both a major health care and economic burden, such as cancer, diabetes and cardiovascular diseases. But if the regenerative market is to realize its full potential, manufacturing and logistics need to be in place to ensure these products' safety, potency and consistency at economically sustainable costs. We have built up our long term strategy on this industry assessment.

Our vertically integrated manufacturing capabilities are being used to serve emerging technologies of cell therapy clients in such areas as cell-based cancer immunotherapies and neurodegenerative diseases and also to optimize our abilities to scale-up our licensed and proprietary technologies for clinical trials and eventual commercialization of our proposed diabetes treatment. Our hybrid business model of combining our own proprietary cell therapy trans-differentiation technologies for the treatment of diabetes and a revenue-generating contract development and manufacturing service business provides us with unique capabilities and supports our mission of accelerating the development and ultimate marketing of breakthrough life-improving medical treatments.

We seek to differentiate our company from other cell therapy companies by our Belgian-based CDMO subsidiary, MaSTherCell, and a world-wide network of Contract Development and Manufacturing Organizations ("CDMO") joint venture partners who have built a unique and fundamental base platform of know-how and expertise for manufacturing in a multitude of cell types. The goal is to industrialize cell therapy for fast, safe and cost-effective production in order to provide rapid therapies for any market around the world. Our strategy is to have all of our services compliant with GMP requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III through commercialization.

MaSTherCell currently operates facilities qualified under cGMPs in Belgium. We acquired MaSTherCell in March 2015. Formed in 2011 as a spin-off from the Université Libre de Bruxelles ("ULB") and starting operational activities in 2013, we believe that MaSTherCell has assembled a recognized team of experts and talents in the cell therapy industry and has attracted world-class customers. MaSTherCell is developing technologies for other cell therapy companies such as cell-based cancer immunotherapies and neurodegenerative diseases. Our vertical integration responds to the main challenges faced by most biotechnology companies such as cost of goods sold and logistics.

MaSTherCell has built its unique and disruptive value proposition by providing two types of services to its customers: (i) process and assay development and optimization services and (ii) current Good Manufacturing Practices (cGMP) contract manufacturing services as practiced in Europe. These services offer a double advantage to MaSTherCell's customers. First, customers can continue allocating their financial and human resources on their therapy offerings, while relying on a trusted partner for their production process development. Second, it allows customers to leverage MaSTherCell' s expertise in cell therapy manufacturing and all related aspects. As the industry continues to mature and a growing number of cell therapy companies approach commercialization, we believe that MaSTherCell is well positioned to serve as an external manufacturing source for cell therapy companies. Additionally, all of these capabilities offered to third-parties will be mobilized for our internal development projects, allowing us to be in a position to bring new products to the patients faster and in a cost-effective way.

Our trans-differentiation technologies for treating diabetes, which we will refer to as our cellular therapy ("CT") business, is based on a technology licensed by our Israeli Subsidiary that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and transdifferentiating them into "pancreatic beta cell-like" Autologous Insulin Producing ("AIP") cells for patients with Type 1 Diabetes. Moreover, those cells were found to be resistant to autoimmune attack and to produce insulin in a glucose-sensitive manner in relevant animal models which significantly broadens the potential of the technology for other therapeutics areas. Our trans-differentiation technology for diabetes is from the work of Prof. Sarah Ferber, our Chief Science Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") in Israel. Our development plan calls for conducting additional preclinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating clinical trials. In parallel, we work on establishing the GMP manufacturing process which development is already accomplished.

We operate our CDMO and the CT businesses as two separate business segments.

CDMO Business

Industry Background

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 manufacturing and production of the cells necessary for their respective treatments. Of the companies active in this market, only a small number have established their own GMP manufacturing facilities due to the high costs and expertise required to develop and maintain such production centers. In addition to the limitations imposed by 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 the 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 specializes in developing solutions and manufacturing cell therapies.

Companies can establish their own process and GMP manufacturing facility or engage a contract manufacturing organization for each step. A contract manufacturing organization (CMO), sometimes called a contract development and manufacturing organization (CDMO), is an entity that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from cell therapy development through cell therapy manufacturing for and end-to-end solution. Due to the complexity, global outreach needs, redundancy and operational costs of manufacturing biologics and cell therapies, the CDMO business is expanding. With more than 854 companies in the field of the regenerative medicine worldwide (versus 580 in 2015) and 934 clinical trials underway by the end of the third quarter of 2017 (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 regenerative medicine, including the growth of autologous CAR T-cell therapies, led to a significant increase in investment in the industry. As its name implies, the backbone of CAR T-cell therapy is T-cells, often called the workhorses of the immune system because of their critical role in orchestrating the immune response and killing cells infected by pathogens. The therapy requires drawing blood from patients and separating out the T-cells. Next, using a disarmed virus, the T-cells are genetically engineered to produce receptors on their surface called chimeric antigen receptors, or CARs. Treatments work by extracting a cancer patient's T-cells, genetically modifying them outside the body to make them more effective at hunting down and killing tumors, and then re-injecting them into the patient.

Two landmark U.S. FDA approvals in CAR T-cell therapy significantly impacted the cell therapy industry. In August 2017, Novartis's CAR T-cell therapy, Kymriah, was approved for relapsed/refractory acute lymphoblastic leukemia for pediatric and young adult patients, making it the first cell-base immunotherapy to move across the finish line in the United States. 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 are the most concrete step towards building confidence and support for the future potential approvals of many more cellular therapies that address a wide range of diseases.

The complexity of manufacturing individual cell therapy treatments poses a fundamental challenge for CAR T-cell therapy-based companies as they enter the field, potentially casting a spotlight on improved large-scale manufacturing processes such as MaSTherCell's. Manufacturing and delivery are more complex in CAR T 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, as well as monitoring 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.

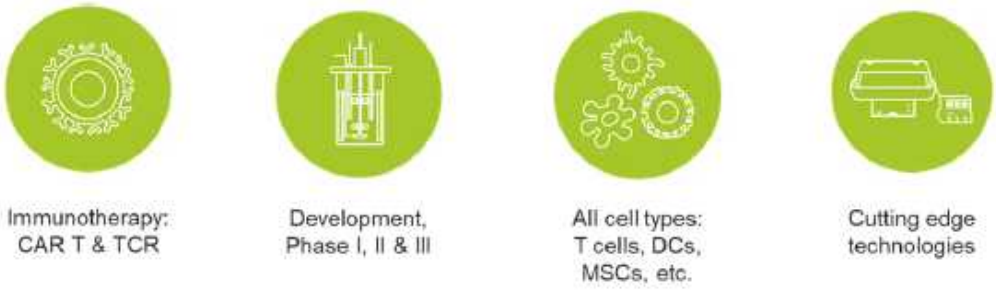
Our vertical integration of development and manufacturing and logistics services through MaSTherCell provide the basis for generating a recurring revenue stream, as well as carefully managing our fixed cost structure to maximize optionality and drive down production cost. We believe that operating our 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's Business

Our Belgian-based subsidiary, MaSTherCell, 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 plans to fill this gap by providing two types of services to its customers: (i) process and assay development services and (ii) current Good Manufacturing Practices (cGMP) contract manufacturing services. These services offer a double advantage to MaSTherCell's customers. First, customers can continue allocating their financial and human resources on their product/therapy, while relying on a trusted partner for their process development/production. Second, it allows customers to benefit from MaSTherCell's expertise in cell therapy manufacturing and all related aspects.

MaSTherCell continues to invest in its manufacturing capabilities to offer a "one-stop-shop" service to its customers from pre-clinical up to commercial. 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). 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 vertical integration of development, manufacturing and logistics services through MaSTherCell 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 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 has built-up a team of more than 92 industry experts dedicated to support process development and manufacturing efforts in a fast, safe and cost-effective way. MaSTherCell'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 relies on a team of dedicated experts both from academic and industry backgrounds. It operates through state-of-the-art facilities located approximately 40 minutes from Brussels, which have 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 that was extended to gene therapies.

Third Party Investment in MaSTherCell

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 "Agreement") pursuant to which SFPI completed an equity investment in MaSTherCell in the aggregate amount of €5million (approximately $5.9 million), for approximately 16.7% of MaSTherCell. The equity investment included the conversion of the then outstanding loan of €1 million (approximately $1.1 million) plus accrued interest in the approximate amount of €70 thousand (approximately $77,000), previously made by SFPI to MaSTherCell (the "Loan Amount").

Under the Agreement, an initial subscription amount of €2 million (approximately $2.3 million) has been paid and the outstanding Loan Amount was converted. The balance of approximately €2 million is payable as needed by MaSTherCell and called in by the board of directors of MaSTherCell. The proceeds of the investment will be used to expand MaSTherCell's facilities in Belgium by the addition of five new cGMP manufacturing cleanrooms. MaSTherCell expects that this expansion will position it as the European hub for the Company's continental activities and strengthen its leading position in cell and gene manufacturing. The state-of-the-art design enables MaSTherCell to offer full flexibility for production and process development.

Under the Agreement, SFPI will be represented by one board member of the five board members of MaSTherCell. In addition, SFPI is entitled to designate one independent board member to the MaSTherCell board who is acceptable to us. The Agreement provides that, under certain specified circumstances where MaSTherCell breaches the terms of the Agreement, SFPI is entitled to put its equity interest in MaSTherCell to us at a price equal to the subscription price paid by SFPI, plus a specified annual premium ranging from 10% to 25%, depending on the year following the subscription in which the put is exercised. If the Company elects to terminate the Agreement before its scheduled term of seven years (or to not renew the agreement upon its scheduled termination), SFPI is entitled to put its MaSTherCell equity interest to us at fair market value (as determined by SFPI and the Company). Additionally, at any time during the first three years following the investment, SFPI is entitled to exchange its equity interest in MaSTherCell into shares of common stock, at a rate equal to the subscription price paid by SFPI divided by $6.24 (subject to adjustment for certain capital events, such as stock splits).

Following the SFPI investment in MaSTherCell, in November 2017, MaSTherCell announced the expansion by 600m² of its facility in Belgium with a dedicated, late-stage clinical and commercial cGMP unit, anticipated to be operational by the fourth quarter of 2018. This new expansion will enable 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.

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 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.

Orgenesis is building up a leading international CDMO focusing on cell manufacturing and a strong pipeline of regenerative medicine products. Capitalizing on MaSTherCell's experience and expertise, we have established collaboration agreement for the CDMO activity with the main focus, initially, in South Korea and Israel. The goal is a potential 50/50 partnership, which allows us the potential of full ownership in the future.

We have leveraged the recognized quality expertise and experience in cell process development and manufacturing of MaSTherCell, and our international joint ventures, in Israel and Korea, 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 of highly specialized employees, while also possibly requiring new regulatory approvals. Therefore, we believe we are well positioned to continue expanding our revenue for the following reasons:

(1) A higher number of companies in later phases of clinical trials;
(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.

Our CDMO Partners Around the World

We have leveraged the experience and expertise of MaSTherCell to build out a global network of CDMO centers. We believe that this international footprint will give a unique competitive advantage to MaSTherCell with harmonized manufacturing between the respective regional footprints.

To date we have set up CDMO facilities in South Korea and set the basis for process development in Israel. These have been set up as collaborative joint ventures where we have invested significant amounts as convertible loans. Under the arrangements, we have the ability to convert our loans into 50% of the equity in the entities. The joint venture documents also allow us a call option on the equity holdings of our partners such, if and when we determine to acquire ownership and control of these facilities.

Korea

On March 14, 2016, we and CureCell Co., Ltd. ("CureCell") entered into a Joint Venture Agreement (the "CureCell JVA") pursuant to which the parties are collaborating in the contract development and manufacturing of cell therapy products in Korea. Under the CureCell JVA, CureCell has procured, at its sole expense, a GMP facility and appropriate staff in Korea for the manufacture of cell therapy products. We shared with CureCell our knowhow in the field of cell therapy manufacturing, which know-how does not include the intellectual property included in the license from the THM to our Israeli Subsidiary. The parties pursue the joint venture through CureCell (the "JV Company"), with each party having 50% from the participating interest of the JV Company subject to the fulfillment by each party of his obligations under the CureCell JVA.

Under the CureCell JVA, the Company and CureCell each undertook to remit, within two years of the execution of the CureCell JVA, a minimum amount of $2 million to the JV Company, of which $1 million is to be in cash and the balance may be in an in-kind investment, the scope and valuation of which shall be preapproved in writing by CureCell and the Company. The Company's funding was made by way of a convertible loan. The CureCell JVA provides that, under certain specified conditions, we can require CureCell to sell to us its participating (including equity) interest in the JV Company in consideration for the issuance of our common stock based on the then valuation of the JV Company. As of November 30, 2017, we remitted to CureCell $2.1 million.

Israel

On May 10, 2016, we and ATVIO Biotech Ltd., an Israeli company, ("ATVIO") entered into a joint venture agreement pursuant to which the we are collaborating in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in Israel. We are pursuing the joint venture through ATVIO, in which we are holding a 50% participating interest therein, with the remaining 50% participating interest being held by the other shareholders of ATVIO. To date, ATVIO has procured, at its sole expense, a GMP facility and has been recruiting employees in Israel. Subject to the work plan that was approved by ATVIO and us, we have remitted to ATVIO a total of $1 million to defray the costs associated with the setting up and the maintenance of the GMP facility. Our funding was made by way of a convertible loan to ATVIO, which shall be convertible, at our option at any time, into 50% of the then outstanding equity capital immediately following such conversion.

Our global manufacturing network is envisioned as offering a global one-stop-shop manufacturing and logistics services and breakthrough technologies enabling promising therapies to more rapidly reach the market in a more cost-effective way.

On January 22, 2018 we announced a strategic organizational regrouping of our CDMO global manufacturing services offerings. The planned CDMO regrouping will utilize the global MaSTherCell brand for its unique technology and innovation activity located in Israel and serving the global cell & gene therapy markets. The primary purpose of the strategic regrouping is to create a more efficient CDMO corporate organization that can optimally utilize resources and more efficiently broaden, streamline and harmonize the CDMO service offerings on a global basis utilizing the quality and standards of MaSTherCell. In connection with this and in order to align our CDMO activities, we plan to transfer to a newly formed and wholly-owned Delaware-based holding company, named MaSTherCell Global Inc., our interests in MaSTherCell S.A., as well as in our joint venture partners in Israel and Korea. When successfully concluded, of which no assurance can be provided, each of MaSTherCell S.A., At-Vio Biotech Ltd. and CureCell Co. Ltd., will be direct subsidiaries of MaSTherCell Global Inc.

United States and Other Parts of the World

We are currently in advanced negotiations with a prospective strategic partner in the U.S. and will continue to explore discussions with other strategic partners throughout the world to set up CDMO facilities in other geographic locations. While we expect to utilize similar structures as our other joint venture partners, we can provide no assurance that such efforts will be successful in these other joint venture endeavors.

Our Competitive Advantages

We offer the following benefits to our CDMO clients:

We enable our clients to go faster to the market in a cost-effective way. MaSTherCell continues to invest in its manufacturing capabilities to offer a "one-stop-shop" service to its customers from pre-clinical up to commercial. 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. MaSTherCell works alongside its customers to transform the promises of their cell-based therapies into a robust and scalable process, compliant with GMP requirements. Its 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. MaSTherCell continues 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 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.

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. 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 to implement its QMS model in a quick and efficient way. This truly international footprint will give a unique competitive advantage to MaSTherCell, 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, MaSTherCell 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 (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 the client's needs and facilitates a long term revenue generating relationship.

Competition in the CDMO Field

MaSTherCell competes 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), Pharmacell BV (acquired by Lonza), WuxiAppTec (WuXi PharmaTech (Cayman) Inc.), Cognate Bioservices Inc., Apceth GmbH & Co. KG, Eufets GmbH, Fraunhofer Gesellschaft, Cellforcure SASU, Cell Therapy Catapult Limited and Molmed S.p.A. MaSTherCell's services differ from these companies 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
- Flexible and tailored approach: MaSTherCell's philosophy is to build a true partnership with its clients and adapt itself to the clients' needs, which entails no "off-the-shelf process" nor in-house technology platform, but a dedicated person in plant (of 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.

MaSTherCell strengthens its leading position by its "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 MaSTherCell operates with a lean organization focused solely on cell therapy. Quality is a critical aspect of our industry, and we believe that MaSTherCell has 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, MaSTherCell is the only CDMO located in Belgium 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.

Cell Therapy Business

Background

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 β-cells that severely reduces β-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 β-cell failure and a significant reduction in β-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 β-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, incurring staggering health, social, and economic impact. Diabetes is currently the fourth or fifth leading cause of death in most developed countries. Diabetes has been declared an epidemic in many developing and newly industrialized nations.

Cell therapy is the prevention or treatment of human disease by the administration of cells that have been selected, multiplied and manipulated outside the body (ex vivo). To date, the most common type of cell therapy has been the replacement of mature, functioning cells through blood and platelet transfusions. Since the 1970s, first bone marrow and then blood and umbilical cord-derived stem cells have been used to restore bone marrow, as well as blood and immune system cells damaged by chemotherapy and radiation used to treat many cancers. These types of cell therapies are standard of practice world-wide and are typically reimbursed by insurance. Various cell therapies are in clinical development for an array of human diseases, including autoimmune, oncologic, neurologic and orthopedic diseases, among other indications. Orgenesis, as well as other companies, are developing cell therapies that are designed to address cancers, ischemic repair and immune modulation. While no assurances can be given regarding future medical developments, we believe that the field of cell therapy holds the promise to address several medical conditions and minimize or ameliorate the pain and suffering from many common diseases and/or from the process of aging.

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 Subsidiary and our Belgian Subsidiary, 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 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.

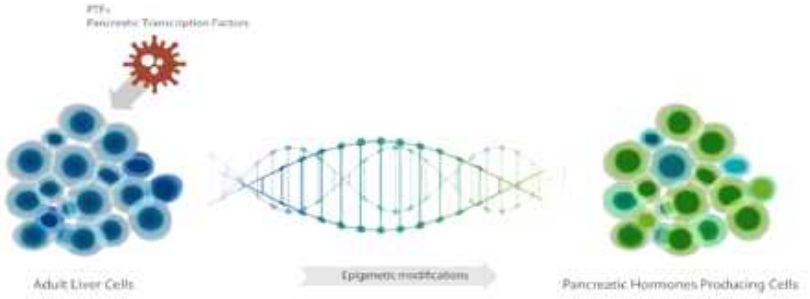
Pancreatic islet auto transplantation is a means of reducing the risk of brittle diabetes following total pancreatectomy. In 1977, researchers at the University of Minnesota School of Medicine pioneered the first Total Pancreatectomy with Islet Autologous Transplant (TP-IAT) for the treatment for induced 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.

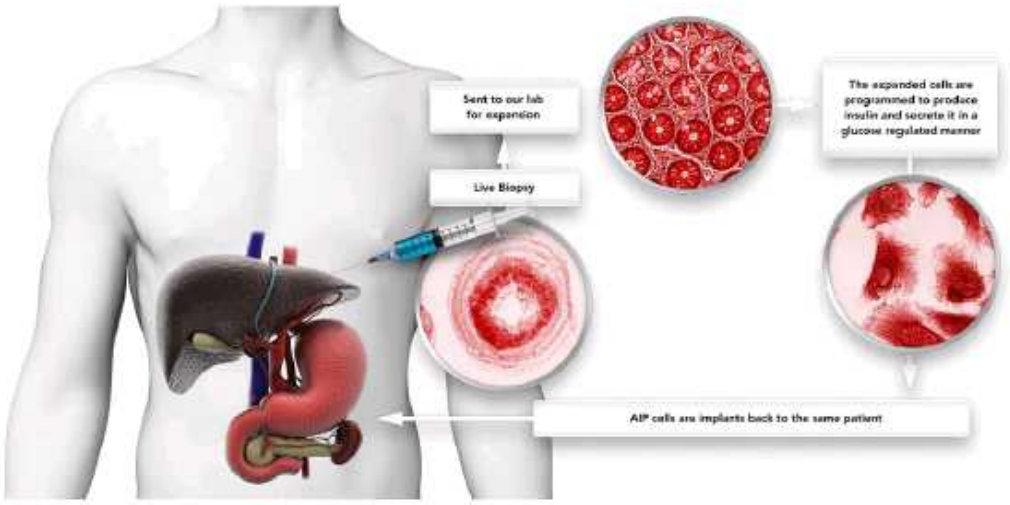
Our Solution

We are developing and bringing to clinical stage a technology that is based on the published work of Prof. Sarah Ferber, our Chief Science 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 "License Agreement"). See "The THM License Agreement" for details relating to this License Agreement.

Toward this goal, we are working to advance a unique product that combines cell-based therapy and regenerative medicine, (AIP) cells, 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. By using therapeutic agents (i.e., PDX-1, and additional pancreatic transcription factors in an adenovirus-vector) that efficiently convert a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. We believe that this provides major competitive advantage to the cell transformation technology of our Israeli Subsidiary.

As consideration for the license, our Israeli Subsidiary has agreed to pay the following to THM:

1) A royalty of 3.5% of net sales;
2) 16% of all sublicensing fees received;
3) An annual license fee of $15,000, which commenced on January 1, 2012 and is due once every year thereafter (the “Annual Fee”). The Annual Fee is non-refundable, but it shall be credited each year due, against the royalty noted above, to the extent that such are payable, during that year; and
4) Milestone payments as follows:

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

As of November 30, 2017, 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 the Company and/or consolidation of the Israeli Subsidiary or the Company into or with another corporation (“Exit”), under the License Agreement, THM is entitled to elect, at its sole option, whether to receive from the Company a one-time payment based, as applicable, on the value at the time of the Exit of either 463,651 shares of common stock of the Company 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 License Agreement to continue to receive all the rights and consideration it is entitled to pursuant to the 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 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 License Agreement. Under the 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 License Agreement, THM is entitled to terminate the 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 License Agreement and return the licensed information to THM.

In 2016 and 2017, the Israeli Subsidiary entered into a research service agreement with the Licensor. According to the agreements, the Israeli Subsidiary will perform a study at the facilities and use the equipment and personnel of the Sheba Medical Center, with annual consideration of approximately $88 thousand and $131 thousand, respectively.

Marketing

Our plan is to market and sell AIP cellular therapy as a stand-alone product and to provide supporting education and services to physicians and the healthcare providers that support them. In addition, we expect to provide appropriate and supportive services to the distribution networks that make our product available to treating physicians and facilities. Once marketing authorization is granted, we plan to market our product in North America, Europe and Asia.

As part of our long-term strategy, we will consider clinical development and commercialization collaborations and/or partnerships with international companies involved in the diabetes therapeutic area.

Competition

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 global diabetes market comprising the insulin, insulin analogues and other anti-diabetic drugs has been evolving rapidly. Today's overall diabetes market 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.

CT Subsidiaries and Collaboration Agreements

Subject to raising the necessary funding, we intend to advance our cell therapy business by furthering this licensed technology to a clinical stage. 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 believe that operating our own manufacturing facility will provide the Company 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.

We carry out our CT business through three wholly-owned and separate subsidiaries. This corporate structure allows us to simply the accounting treatment, minimize taxation and optimize local grant support. Our CT subsidiaries are as follows:

- United States: Orgenesis Maryland Inc. – This is the center of activity for North America currently focused on 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.

We have embarked on a strategy of collaborative arrangement with strategically situated third parties around the world. We believe that these parties have the expertise, experience and strategic location to advance our clinical development business.

On March 14, 2016, our Israeli Subsidiary, entered into a collaboration agreement with CureCell Co., Ltd. ("CureCell"), initially for the purpose of applying for a grant from the Korea Israel Industrial R&D Foundation ("KORIL") for pre-clinical and clinical activities related to the commercialization of our AIP cell therapy product in Korea (the "KORIL Grant"). Subject to receiving the KORIL Grant, the parties agreed to carry out, at their own expense, 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 and information licensed from THM. Subject to obtaining the requisite approval needed to commence commercialization in Korea, the Israeli 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 AIP product solely for commercialization of the Israeli 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 for adipose-derived AIP product, subject to CureCell procuring all of the regulatory approvals required for commercialization in Japan. As of the date of this filing, none of the requisite regulatory approvals for conducting clinical trials had been obtained.

Grant Funding

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

On March 20, 2012, MaSTherCell was awarded an investment grant from the DGO6 for €1,421 thousand. This grant is related to the investment in the production facility with a coverage of 32% of the investment planned. A first payment of €568 thousand was received in August 2013. In December 2016, the DGO6 paid to MaSTherCell €669 thousand on account of the grant, and the remaining grant amount has been declined.

On November 17, 2014, Our Belgian Subsidiary, received the formal approval from the DGO6 for a €2.015 thousand ($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 €1,085 thousand (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of €930 thousand (60% of budgeted costs) of the experimental development part of the research program. In December 2014, the Belgian Subsidiary received advance payment on amount of €1,209 thousand under the grant. The grants are subject to certain conditions with respect to the Belgian Subsidiary's work in the Walloon Region. In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. In 2017 we received from the DGO6 approval for Euro 1.8 million costs invested in the project, out of which Euro 1,192 thousand was funded by the DGO6. During 2017 we repaid to the DGO6 the down payments of €17 thousand. In addition, the final recoverable advance under this project is €150 thousand, out of which €15 thousand was paid by the Belgian Subsidiary during 2017.

On April 2016, our Belgian Subsidiary received the formal approval from DGO6 for a budgeted €1,304 thousand ($1,455 thousand) support program for the development of a potential cure for Type 1 Diabetes. The financial support was awarded to our Belgian Subsidiary as a recoverable advance payment at 55% of budgeted costs, or for a total of €717 thousand ($800 thousand). The grant will be paid over the project period. On December 19, 2016, our Belgian Subsidiary received a first payment of €359 thousand ($374 thousand). In 2017, the DGO6 approved a no cost extension for the program until August 31, 2017. The total expenses under the program through November 30, 2017 were €787 thousand ($900 thousand). In addition, the DGO6 is also entitled to a (i) revocable advance of €215 thousand ($250 thousand) and (ii) a royalty upon revenue being generated from any commercial application of the technology.

On October 8, 2016, our Belgian Subsidiary received the formal approval from the DGO6 for a budgeted €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 our Belgian Subsidiary at 55% of budgeted costs, a total of €6.8 million ($7 million). The grant will be paid over the project period. On December 19, 2016, our Belgian Subsidiary received a first payment of €1.7 million ($1.8 million). The total expenses under the program through November 30, 2017 were €1,224 thousand ($1,451 thousand).

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

On September 9, 2015, our 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 our 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 rate of 5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the BIRD Project during a period of 18 months starting on March 1, 2015 and up to the date the Israeli Subsidiary received $200 thousand under the grant. On July 28, 2016, BIRD approved an extension until May 31, 2017 and the final report was submitted to BIRD. The total expenses under the program through November 30, 2017 were $717 thousand.

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

On May 26, 2016, our Israeli Subsidiary entered into a pharma Cooperation ad Project Funding Agreement (CPFA) with KORIL and CureCell. 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 June 1, 2016. On June 2016, we received $160 thousand under the grant. The total expenses under the program through November 30, 2017 were $368 thousand.

Maryland Technology Development Corporation

On June 30, 2014, our U.S. Subsidiary entered into a grant agreement with Maryland Technology Development Corporation ("TEDCO"). TEDCO was created by the Maryland State Legislature in 1998 to facilitate the transfer and commercialization of technology from Maryland's research universities and federal labs into the marketplace and to assist in the creation and growth of technology-based businesses in all regions of the State. TEDCO is an independent organization that strives to be Maryland's lead source for entrepreneurial business assistance and seed funding for the development of start-up 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 "TEDCO Grant"). The TEDCO Grant was used solely to finance the costs to conduct the research project entitled AIP during a period of two years.

On July 22, 2014 and September 21, 2015, the U.S subsidiary received an advance payment of $406 thousand on account of the grant. On June 21, 2016, TEDCO approved an extension until June 30, 2017. Through November 30, 2017, the Company utilized $356 thousand.

Research and Development Expenditures

We incurred $3,326 and $2,637 thousand in research and development expenditures in the fiscal years ended November 30, 2017 and 2016, respectively, of which $848 thousand and $480 thousand was covered by grant funding.

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 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 four (4) United States and seven (7) foreign issued patents, three (2) pending applications in the United States, eleven (11) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and one (1) international PCT patent application, relating to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell phenotype and function, and their use in the treatment of degenerative pancreatic disorders including diabetes, pancreatic cancer, and pancreatitis.

Granted U.S. patents which are directed to methods of making trans-differentiated cells will expire between 2021 and 2024, excluding any patent term extensions that might be available following the grant of marketing authorizations. Granted patents outside of the United States directed to making trans-differentiated cells and their uses will expire between 2020 and 2024. We have pending patent applications for methods of making our product, the product itself, and methods of using the product that, if issued, would expire in the United States and in countries outside of the United States between 2034 and 2035, 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. These pending patent applications are directed to the following specific compositions and methods: a method of producing a transdifferentiated population of cells, a population of transdifferentiated cells, a method of treating a degenerative pancreatic disorder in a subject in need, a method of isolating a population of cells that have an enriched capacity for transcription factor induced trans-differentiation, an isolated population of cells having enriched trans-differentiation capacity, a method of increasing trans-differentiation efficiency in a population of cells, a population of liver cells enriched for cells predisposed to trans-differentiation, and a method of manufacturing a population of human insulin producing cells and the population of cells produced by the recited manufacturing method.

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 seems to be of the highest benefit. We believe that it seems to be 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 since 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 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 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 FDA of a Biologics License Application (BLA) for marketing that includes adequate results of pre-clinical testing and clinical trials;
- 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. FDA may also require post marketing testing and surveillance of approved products or place other conditions on the approvals.

In addition, prior to the general regulatory process of a new biologic products, we expect to pursue an Orphan Drug Designation for treatment of Patients with Established Diabetes Mellitus (DM) Induced by Total pancreatectomy). The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated.

Obtaining Orphan drug designation will provide the following financial incentives:

- Tax Credits – 50% of clinical trials costs;

- Waiver of marketing application user fees – over $2 million; and
- 7-year Marketing Exclusivity if first approved.

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 Good Manufacturing Practices, or 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; and
- Submission to EMEA for a Marketing Authorization (MA);
- 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 ten 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, 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.

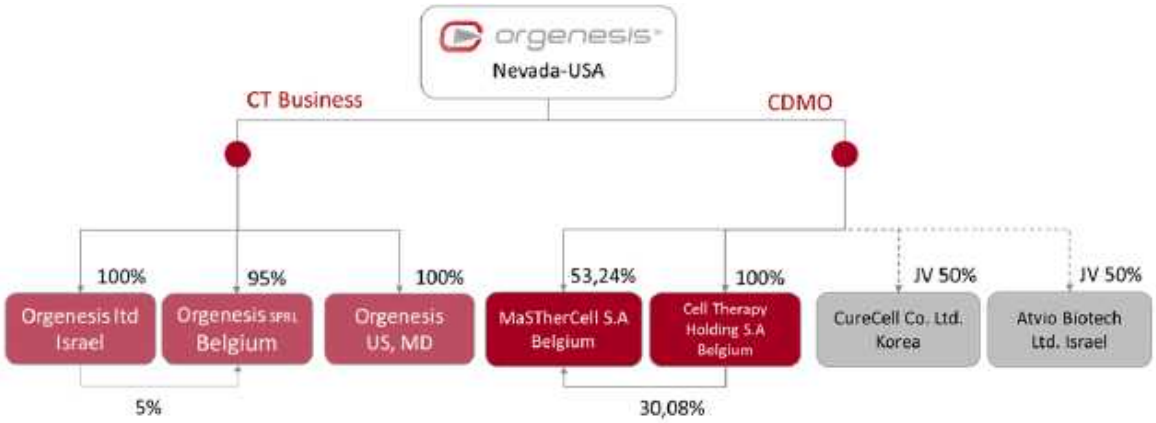
Employees

As of November 30, 2017, we had 103 full-time 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 is covered by collective bargaining agreements. We believe that our relations with our employees are good.

Subsidiaries

Orgenesis Inc. is a Nevada corporation, and our subsidiaries currently consist of MaSTherCell, S.A. ("MaSTherCell"), Orgenesis SPRL (the "Belgian Subsidiary), Orgenesis Ltd. (the "Israeli Subsidiary"), Orgenesis Maryland Inc. and Cell Therapy Holdings S.A.

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 made available free of charge though our Internet website (http://www.orgenesis.com) as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. 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 Securities and Exchange Commission.

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.

We currently have sufficient resources for next 12 months from the date of issuance of these financial statements. 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, seek out strategic CDMO acquisitions or commence clinical trials for our diabetes solution or respond to competitive pressures. As of November 30, 2017, we had available cash resources of $3.5 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.

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 have no history of profitability, 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, 2017 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 auditors agreed with our assessment, and the auditor's report for the year ended November 30, 2017 does not include a going concern emphasis on the matter. However, management is still required to assess our ability to continue as a going concern. We had a net loss of $12.4 million for the year ended November 30, 2017. During the same period, cash used in operations was $3.8 million, the working capital deficiency and accumulated deficit as of November 30, 2017 was $9.6 million and $44.1 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.

As of November 30, 2017, we owed significant amounts of money under convertible loan agreements and, unless these amounts are converted into common stock or we raise significant working capital, we may not be able to pay them when due.

As of November 30, 2017, we owed approximately $8.7 million in principal amount and accrued interest under convertible loan agreements with third party lenders with varying maturity dates, the latest of which is August 22, 2019. The operative agreements provide that the holders of these notes can voluntarily convert them into shares of our common stock at fixed pre-arranged rates. As of the date of this filing, noteholders holding approximately $6.1 million of these convertible notes had agreed to convert all outstanding principal and interest into units, consisting of one share of our common stock at $6.24 and a warrant for one share of common stock at an exercise price of $6.24 per share. However, unless these balance of the outstanding amounts are converted (whether mandatorily or voluntarily) or we raise sufficient working capital, we may not be able to repay these notes at their stated maturity. Non-payment of these amounts will entitle the holders to take action to recovered payment, which may result in attachments or liens on our asset. Any of these developments will have a material adverse effect on our business, financial condition and prospects.

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, 2017, we had 103 full-time employees. Of these employees, approximately 92 were employed by our subsidiary, MaSTherCell. 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.

In addition, as previously disclosed, our agreements with each of CureCell Co., Ltd. and Atvio Biotech Ltd., our Korea and Israel-based CDMO partners, provide that we can obtain 50% equity ownership in these entities by converting advances made to them into 50% of their outstanding equity capital and also that we can compel the underlying equity holders to transfer their equity holding to us for consideration consisting of our equity shares, thereby allowing us to consolidate these entities into our corporate structure. This lack of long-term experience working together may adversely impact our senior management team's ability to effectively manage our business and growth.

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, 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.

Any proposed internal corporate reorganization we may consider and decide to implement at a future date could be subject to various risks and uncertainties and may involve significant time and attention, all of which could disrupt or adversely affect our business.

Orgenesis is engaged in two separate businesses, the CDMO business and our trans-differentiation technologies to treat diabetes, or what we call as out CT business. The CDMO business is spearheaded by our Belgian-based subsidiary, MaSTherCell, as well as various CDMO joint ventures that we currently have in Korea and Israel. The CT business is carried out at the Israeli Subsidiary level, as well as through Orgenesis SPRL, our Belgian Subsidiary, and Orgenesis Maryland Inc., a Maryland corporation. We may at some point in the future consider and possibly implement a corporate reorganization or restructure of these two separate businesses segments, including without limitation, third party asset transfer, merger or divestiture, spin-off or split-out. While we currently have no definitive plan for any such action, we may, consider any such initiative if our Board of Directors deems it to be in the best interests of our company. Any such initiative, however, will require significant time and attention from management, which may distract management from the operation of our business and the execution of our other initiatives. Additionally, any such initiative may result in unforeseen and adverse tax consequences to us or may result in significant changes to our shareholder base if we are no longer engaged in either one of these business segments. Any such difficulties or developments could potentially have a material adverse effect on our financial condition, results of operations or cash flow.

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 four (4) United States (US) patents, one of which is directed to a composition comprising a vector comprising a promoter linked to PDX-1 and having a term of 2021, and the other three have a term of 2023 and are directed 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. Further, we have exclusive rights to four (4) foreign issued patents (1 in Europe (validated in Germany, France, Italy, and Great Britain) with a term of 2020; two (2) in Australia with a term of 2020 and 2024; and one (1) in Canada with a term of 2020. We also have five (5) pending applications in the United States, which if granted would have a term of 2034-2035; and twenty three (23) pending applications in foreign jurisdictions: Europe, Australia, Brazil, Canada, China, Columbia, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore which if they were to grant would have a term of 2034-2035, which are directed to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell phenotype and function, and their use in the treatment of degenerative pancreatic disorders including diabetes, pancreatic cancer, and pancreatitis.

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

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

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

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

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

- decreased demand for our products;
- injury to our reputation;

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

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

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

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

Risks Related to Our CDMO Business

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

Cell therapy is in its early stages and is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace, making it difficult for their own funding to enable them to continue their business. In addition to providing in-house process development and manufacturing expertise for our own product candidates in development, MaSTherCell 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's revenues may vary dramatically change from period to period making it difficult to forecast future results.

MaSTherCell recorded revenues of approximately $10 million for the year ended November 30, 2017, representing an increase of 58% over the same period last year. The nature and duration of MaSTherCell's and our joint venture CDMO partners' 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.

MaSTherCell's contract manufacturing services are dependent upon a single fully operational facility located in Gosselies (Belgium). A catastrophic loss of the use of all or a portion of MaSTherCell's 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.

Risks Related to Our Trans-Differentiation Technologies for Diabetes

THM is entitled to cancel the License Agreement.

Pursuant to the terms of the 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 License Agreement, THM shall be entitled to terminate the 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 License Agreement, our CT business may be materially adversely affected. THM may also terminate the License Agreement if the Israeli Subsidiary breaches an obligation contained in the License Agreement and does not cure it within 180 days of receiving notice of the breach. Any termination or cancellation of the 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 or 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.

For Europe, the European Medicines Agency ("EMA") will regulate our future products. 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 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 2018. 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, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates will require substantial additional funding and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

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

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

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

If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Our product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including the biopsy of tissue from a patient's liver, propagation of the patient's liver cells from that liver tissue to obtain the desired dose, trans-differentiating those cells into insulin-producing cells ex vivo and ultimately infusing the cells back into a patient's body. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of liver cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, failures in process testing and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity and tractability of all reagents and viruses involved in the process with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

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

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

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

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

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

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

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

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

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

We currently have no sales, marketing, or commercial therapeutic product distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If we are unable 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 science 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 or 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, 2017, our stock price has fluctuated from a low of $2.76 to a high of $11.76 (adjusted to account for the 1:12 reverse split implemented in November 2017). This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

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

Entity	Property Description
Orgenesis Inc./Orgenesis Maryland Inc.	These are the principal offices: • Located at 20271 Goldenrod Lane, Germantown, MD 20876. • Occupy office space at the Germantown Innovation Center. • Cost is $200 per month on a month-to-month contract.
MaSTherCell SA, Cell Therapy Holding SA and Orgenesis SPRL	All activities located in Gosselies, Belgium, in the I-Tech Incubator 2. Property consists of:

	• Operational production and Office area represent +/- 1,911 m² • Monthly costs are approximately €20 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; it represents 180m² for a monthly cost of €2 thousand and termination lease agreement on January 31, 2019 • The new production area designed during 2016 is to be built in 2017-2018 and operational end of 2018.
Orgenesis Ltd.	• The development lab is located in Nasher, Israel. Monthly costs are NIS 10 thousand. • The offices are located in the Science Park of Nes Tziona. Annual costs are approximately €20 thousand

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

Our common stock has been listed on the OTCQB under the trading symbol "ORGS."

The following table shows the quarterly high and low bid prices or sales prices for our common stock over the last two completed fiscal years and subsequent interim periods, as quoted on the OTCQB Platform. The prices represent quotations by dealers without adjustments for retail mark-ups, mark-downs or commissions and may not represent actual transactions.

The prices have been adjusted to reflect the 1 for 12 reverse stock split of our common stock that became effective on November 16, 2017.

	High	**Low**
Year Ended November 30, 2018		
First Quarter [1]	$ 10.75	$ 4.00
Year Ended November 30, 2017		
Fourth Quarter	$ 7.80	$ 2.76
Third Quarter	$ 7.56	$ 3.84
Second Quarter	$ 11.76	$ 6.60
First Quarter	$ 10.68	$ 3.39
Year Ended November 30, 2016		
Fourth Quarter	$ 5.16	$ 3.41
Third Quarter	$ 6.18	$ 3.40
Second Quarter	$ 4.80	$ 2.82
First Quarter	$ 4.92	$ 3.13

[1] December 1, 2017 – February 27, 2018

As of February 28, 2018, there were 76 holders of record of our common stock, and the last reported sale price of our common stock on the OTCQB on February 27, 2018 was $8.09. 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 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 three months ended November 30, 2017, our financing activities consisted of the following:

Between September and November 2017, we issued in private placement to accredited or offshore investors 160,265 shares of common stock and three-year common stock purchase warrants for an additional 160,265 shares of our common stock, exercisable at a per share exercise price of $6.24 for aggregate gross proceeds of $1,000,053.

Between September and November 2017, we issued in private placement to accredited or offshore investors our convertible promissory notes in the aggregate principal amount of $1.1 million which are convertible into closing on $1.1 million, in private placement debt offerings through the issuance our convertible promissory notes with maturity dates of twenty-four months, convertible as of November 30, 2017 into 176,282 shares of our common stock and 176,282 three-year warrants to purchase up to an additional 176,282 shares of our common stock at a per share exercise price of $6.24.

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) of the Securities Act or Regulation S under such Securities Act. Except with respect to securities sold under 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 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 discussion should be read in conjunction with our financial statements and the notes related to those statements. Some of our discussion is forward-looking and involves risks and uncertainties. For information regarding risk factors that could have a material adverse effect on our business, refer to the "risk factors" section of this annual report.

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."

Our strategy is to accelerate the development of breakthrough life-improving medical treatments through a hybrid business model combining proprietary technologies in our CT and CDMO businesses.

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. Through Orgenesis Ltd., we became engaged in our CT business.

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, the Company's revenues are generated through MaSTherCell.

Corporate Overview

We are a service and research company in the field of the regenerative medicine industry with a focus on cell therapy development and manufacturing for advanced medicinal products serving the regenerative medicine industry. In addition, we are focused on developing novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes, with a revenue generating contract development and manufacturing service business to serve the regenerative medicine industry.

Our vertically integrated manufacturing capabilities are being used to serve to emerging technologies of other cell therapy markets in such areas as cell-based cancer immunotherapies and neurodegenerative diseases and also to optimize our abilities to scale-up our technologies for clinical trials and eventual commercialization of our proposed diabetes treatment. Our hybrid business model of combining our own proprietary cell therapy trans-differentiation technologies for the treatment of diabetes and a revenue-generating contract development and manufacturing service business provides us with unique capabilities and supports our mission of accelerating the development and ultimate marketing of breakthrough life-improving medical treatments.

We seek to differentiate our company from other cell therapy companies through MaSTherCell and a world-wide network of CDMO joint venture partners who have built a unique and fundamental base platform of know-how and expertise for manufacturing in a multitude of cell types. The goal is to industrialize cell therapy for fast, safe and cost-effective production in order to provide rapid therapies for any market around the world. All these services are already compliant with GMP requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III through commercialization.

We have leveraged the recognized expertise and experience in cell process development and manufacturing of MaSTherCell, and our international joint ventures, in Israel and Korea, to build a global and fully integrated bio-pharmaceutical company in the cell therapy development and manufacturing area. We believe that cell therapy companies need to be global in order to truly succeed. In furtherance of that belief, we intend to expand our establishment of CDMO facilities to the United States and other international markets. 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. All of these capabilities offered to third-parties will be mobilized for our internal development projects, allowing us to be in a position to bring new products to the patients faster and in a cost-effective way.

Our trans-differentiation technologies for treating diabetes, which we refer to as our cellular therapy ("CT") business, is based on a technology licensed by our Israeli Subsidiary, that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and transdifferentiating them into "pancreatic beta cell-like" Autologous Insulin Producing ("AIP") cells for patients with Type 1 Diabetes. Moreover, those cells were found to be resistant to autoimmune attack and to produce insulin in a glucose-sensitive manner in relevant animal models which significantly broadens the potential of the technology for other therapeutics areas. Our trans-differentiation technology for diabetes is from the work of Prof. Sarah Ferber, our Chief Science Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") in Israel. Our development plan calls for conducting additional preclinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating clinical trials. In parallel, we work on establishing the GMP manufacturing process which development is already accomplished.

We operate our CDMO and the CT business as two separate business segments.

Revenue History

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 manufacturing and production of the cells necessary for their respective treatments. Of the companies active in this market, only a small number have established their own GMP manufacturing facilities due to the high costs and expertise required to develop and maintain such production centers. In addition to the limitations imposed by a limited number of trained personnel and high infrastructure/operational costs, we believe that the industry faces a need for custom innovative process development and manufacturing solutions. In this context, we have grown total revenue from $6.4 million in our fiscal year 2016 to $10.1 million for fiscal year 2017. The increased revenues derive from an increase in the volume of the services provided by our CDMO segment, namely our Belgian-based subsidiary, MaSTherCell, through its customer service contracts with existing customers and the entry into new customer service contracts with leading biotech companies, as well as from revenues generated from existing manufacturing agreements.

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, 2017, MaSTherCell had backlog of approximately $9.5 million, consisting of services that we expect to deliver into fiscal year 2018. 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.

Recent Developments

Following the SFPI investment in MaSTherCell in November 2017, MaSTherCell decided to expand its facilities with a dedicated, late-stage clinical and commercial unit, anticipated to be operational by the end of 2018. This new asset will provide the most up-to-date commercial capabilities in Europe with five state-of-the-art advanced therapy manufacturing units and extended Good Manufacturing Practice (GMP)-accredited quality control (QC) laboratories.

Additionally, we announced a strategic organizational regrouping of our CDMO global manufacturing services offerings. The planned CDMO regrouping will utilize the global MaSTherCell brand, except for At-Vio Biotech Ltd. ("At-Vio"), for its unique technology and innovation activity located in Israel and serving the global cell and gene therapy markets. The primary purpose of the strategic regrouping is to create a more efficient CDMO corporate organization that can optimally utilize resources from the parent, Orgenesis Inc., and more efficiently broaden, streamline and harmonize the CDMO service offerings on a global basis utilizing the quality and standards of our flagship Belgian-based subsidiary, MaSTherCell S.A.

Critical Accounting Policies and Use of Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, bad debts, investments, intangible assets and income taxes. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates.

We have identified the accounting policies below as critical to our business operations and the understanding of our results of operations.

Business Combination

We allocated the purchase price of the business we acquired 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 from us to make significant estimates and assumptions, especially at the acquisition date with respect to intangible assets. Direct transaction costs associated with the business combination are expensed as incurred. The allocation of the consideration transferred in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date. We included the results of operations of the business that we acquired in the consolidated results prospectively from the date of acquisition when control was obtained.

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 over their estimated period of useful life, which is determined by identifying the period over which the cash flows are expected to be generated.

Goodwill

Goodwill represents the excess of the purchase price of an 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 goodwill 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.

As of November 30, 2017, the fair value of the reporting unit, our CDMO, exceeded the carrying value by approximately $10.4 million. A decrease in the terminal year growth rate of 1% and an increase in the discount rate of 1% would reduce the fair value of the reporting unit by approximately $1.1 million and $2.3 million, respectively. These changes would not result in an impairment. Given the small amount that the fair value exceeded the carrying value of the reporting unit, a negative change in the future to the income approach based on discounted cash flows of a number of assumptions (including the expected cash flows, discount rate, growth rate and terminal rate) will result in an impairment. Given that the reporting unit is still in its growth stage, there can be no assurance that an impairment may not occur in the near future.

Impairment of Long-lived Assets

We are reviewing the 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 indicators for impairment charges in 2017 and 2016 and, therefore, no fair value assessment was performed.

Revenue Recognition

We recognize the 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. We determine that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. In addition, we determine that services have been delivered in accordance with the arrangement. We assess 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 May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09") "Revenue from Contracts with Customers." ASU 2014-09 will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. On July 9, 2015, the FASB deferred the effective date of the standard by one year, which results in the new standard being effective for the Company at the beginning of its first quarter of fiscal year 2018. In addition, during March, April and May 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net), ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing and ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients, respectively, which clarified the guidance on certain items such as reporting revenue as a principal versus agent, identifying performance obligations, accounting for intellectual property licenses, assessing collectability and presentation of sales taxes. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. As applicable for the Company, the effective date for adopting the ASU is for the year ending November 30, 2019. The Company is currently evaluating the impact of adopting ASU 2014-09 on its financial position, results of operations and related disclosures and has not yet determined whether the effect of the revenue portion will be material.

We also incur revenue from selling of some consumables which are incidental to the services provided as foreseen in the clinical services contracts. Such revenue is recognized upon delivery of the processed cells in which they were consumed.

Results of Operations

Comparison of the Year Ended November 30, 2017 to the Year Ended November 30, 2016

Our loss before income tax for the year ended November 30, 2017 are summarized as follows in comparison to our expenses for the year ended November 30, 2016:

	Year ended November 30,	
	2017	**2016**
	(in thousands)	
Revenues	$ 10,089	$ 6,397
Cost of revenues	6,807	7,657
Research and development expenses, net	2,478	2,157
Amortization of intangible assets	1,631	1,620
General and administration expenses	9,189	6,240
Share in losses of associated company	1,214	123
Financial expenses , net	2,447	1,260
Loss before income taxes	$ 13,677	$ 12,660

Revenues

Our revenues for the year ended November 30, 2017 are summarized as follows in comparison to its revenues for the year ended November 30, 2016:

	Year ended November 30,	
	2017	2016
	(in thousands)	
Services	$ 8,024	$ 4,683
Goods	2,065	1,714
Total	$ 10,089	$ 6,397

All revenues were derived from our subsidiary, MaSTherCell. Manufacturing activities increased by $3,692 thousand, or 58%, reflecting our revenue diversification by source in the CDMO segment. We believe this reflects the market recognition of our CDMO business and our expertise and responsiveness to industry needs. Considering the vertical integration of research and manufacturing segments, the revenues from other group companies related to manufacturing activities for its CT business were $1,395 thousand.

In 2017, MaSTherCell benefited from the extension of manufacturing activities with its existing clients, together with agreements with leading pharmaceutical companies like Servier and CRISPR. In January 2017, MaSTherCell signed a master service agreement with Servier for the development of a manufacturing platform for allogeneic cell therapies. Under the master service agreement, MaSTherCell is developing a CAR-T cell therapy manufacturing platform, which will enable industrial and commercial manufacturing of Servier's cell therapy products. This is a critical step in the development of these products for later stage clinical trials.

In June 2017, MaSTherCell signed an agreement with CRISPR to develop and manufacture allogeneic CAR-T therapies. MaSTherCell will be responsible for the development and cGMP manufacturing of CTX101 for use in clinical studies. CTX101 is an allogeneic CAR T-cell therapy currently in development by CRISPR Therapeutics for the treatment of CD19 positive malignancies.

Expenses

Cost of Revenues

	Year Ended November 30, (in thousands)	
	2017	2016
Salaries and related expenses	$ 2,642	$ 3,356
Professional fees and consulting services	-	967
Raw Material	2,692	1,769
Depreciation and amortization expenses	986	1,299
Other expenses	487	266
Total	$ 6,807	$ 7,657

As with our revenues, all costs of revenues are derived from our Belgian Subsidiary, MaSTherCell. Cost of revenues for the year ended November 30, 2017 decreased by 11%, or $850 thousand, compared to 2016. This decrease is driven by the salaries and related expenses for the year ended November 30, 2017 in an amount of $2,624 thousand, as compared to $3,356 thousand during the same periods in 2016. It is primarily attributable to a decrease in salaries and related expenses associated with an internal transformation program implemented in MaSTherCell in the second quarter of 2017 to evolve from an organization based on project to a matrix organization supported by transversal departments focusing on value creation. As part of the program, we changed the business positions of certain employees from laboratory managers to general manager positions in order to reflect the current period’s business activity. Subsequently, these changes in business positions resulted in a shift of costs into general and administration expenses.

Raw materials for the year ended November 30, 2017 increased by 52%, or $923 thousand, compared to the year ended November 30, 2016. This was due to the increase in the volume of our manufacturing and process development services.

Amortization and depreciation expenses for the year ended November 30, 2017 decreased by 24%, or $313 thousand, as compared to the year ended November 2016. This was primarily attributable to the increase in the production facility useful life from 10 to 20 years and due to an increase in the classification of depreciation expenses to research and development expenses related to assets used in our CT business. We increased the level of investment in tangible assets of MaSTherCell in 2017 by $1,038 thousand, including $326 thousand in assets related to the expansion plan of its facilities.

Research and Development Expenses

We are a vertically integrated biopharmaceutical company combining proprietary technologies and manufacturing services. If process development and manufacturing activities are primarily reflected in revenues and costs of revenues, the research and development of our proprietary technologies are accounted as specific expenses. Our research and development expenses for the year ended November 30, 2017 are summarized as follows in comparison to our research and development expenses for the year ended November 30, 2016:

	Year Ended November 30, (in thousands)	
	2017	2016
Salaries and related expenses	$ 1,181	$ 1,040
Stock-based compensation	711	327
Professional fees and consulting services	854	400
Depreciation expenses, net	110	
Lab expenses	287	691
Other research and development expenses	183	179
Less – grants	(848)	(480)
Total	$ 2,478	$ 2,157

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 year ended 2017, we focused our CT business on two major developments of our proprietary technology platform: (i) three-dimensional (3D) cell culture systems and (ii) process development of our technology for the sourcing of the starting material (liver sampling and cell collection) for the development of the autologous insulin producing (AIP) cells. In furtherance of these two developments, salaries and related expenses increased for the year ended November 30, 2017 compared to 2016, primarily due to the expansion of our development team in Israel and Belgium.

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. We believe that we will be able to retain qualified personnel through, among other things, the issuance of stock-based compensation. Stock-based compensation for the year ended November 30, 2017 increased by $384 thousand compared to the same period in 2016, due to new grants of stock options to employees during fiscal year 2017.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses for the year ended November 30, 2017 are summarized as follows in comparison to our selling, general and administrative expenses for the year ended November 30, 2016:

	Year Ended November 30, (in thousands)	
	2017	2016
Salaries and related expenses	$ 2,862	$ 241
Stock-based compensation	1,155	2,334
Accounting and legal fees	1,773	786
Professional fees	2,017	845
Rent and related expenses	859	798
Business development	599	397
Expenses related to a JV	-	497
Other general and administrative expenses	(76)	342
Total	$ 9,189	$ 6,240

Selling, general and administrative expenses increased by $2,949, or 47%, in year ended November 30, 2017, primarily attributable to (i) a decrease in stock based compensation in the 2017 periods attributable to the termination of the vesting period of options and shares awarded to executive officers and consultants in 2016; (ii) an increase in corporate governance costs in order to remediate specific material weaknesses; (iii) an increase in salaries and related expenses resulting from the retention of new senior management at our Belgian Subsidiary and new accounting staff in our financial department in our Israeli Subsidiary; (iv) an increase in professional fees resulting from the appointment of an independent third party to assess our risk management framework to manage enterprise risk and work on corporate governance; (v) and increase in accounting and legal expenses associated with exploring new strategic collaboration arrangements, new capital raising initiatives, repayment of bonds issued by MaSTherCell; (vi) an increase in legal expenses associated with the preparation of applications for new patents under our CT business; (vii) an increase in expenses related to expanding our CDMO network, namely expenses related to a joint venture which primarily consisted of salary expenses and set up related cost of the new production facility in Korea under our joint venture with CureCell Co. Ltd.

Financial Expenses, net

	Year Ended November 30, (in thousands)	
	2017	2016
(Decrease) in fair value of financial liabilities measured at fair value	$ (902)	$ 332
Warrants granted to bondholder and shares and units granted to creditor	1,497	208
Interest expense on loans and convertible loans	1,233	694
Foreign exchange loss, net	562	31
Other expenses (income)	57	(5)
Total	$ 2,447	$ 1,260

Financial income for the year ended November 30, 2017 increased by $1,188 thousand or 94%, compared to the same period in 2016. The increase in financial expenses is mainly attributable to an increase (i) of $1.3 million in the Stock-based compensation related to restricted shares and warrants issued in accordance with the terms of the convertible loan agreements (ii) of 0.5 million in interest expense on loans and convertible loans due to $6.2 million new convertible loans invested in our company during the year ended 2017. In addition, the increase was partly offset due to a decrease in fair value of embedded derivative following total repayments of $1.8 million principal amount and accrued interest of convertible loan during the year ended 2017.

Working Capital Deficiency

	November 30,	
	2017	2016
	(in thousands)	
Current assets	$ 7,295	$ 4,205
Current liabilities	16,914	14,500
Working capital deficiency	$ (9,619)	$ (10,295)

Current assets increased by $3 million, which was primarily attributable to an increase of $2.3 million in cash mainly derived from SFPI investment and $0.7 million in receivables from a related party due to advance payments under services agreements for virus production by Atvio.

Current liabilities increased by $2.4 million, which was primarily attributable to an increase (i) of $1.5 million in advanced payments on account of grant in connection with the new grant approved by the DGO6 to support a clinical study in Germany and Belgium (ii) of $2.3 million in deferred income paid upfront by our customers under new agreements signed in the CDMO segment. The increase in deferred income is a result of a greater number of customer contracts during the fiscal year and, as a result, a greater number of required upfront payments from customers. The increase was partly offset by (i) a net decrease of $2.5 million due to repayments of loans and convertible bonds and loans received (ii) a decrease of $0.5 million in accounts payable due to repayments to old debtors and (iii) $1.3 million in employees and related payables.

Liquidity and Financial Condition

	Year Ended November 30,	
	2017	2016
	(in thousands)	
Net loss	$ (12,367)	$ (11,113)
Net cash used in operating activities	(3,833)	(3,783)
Net cash used in investing activities	(3,404)	(1,536)
Net cash provided by financing activities	8,365	2,123
Decrease in cash and cash equivalents	$ 1,128	$ (3,196)

Since inception, we have funded our operations primarily through the sale of our securities and, more recently, through revenue generated from the activities of MaSTherCell, our Belgian Subsidiary. As of November 30, 2017, we had negative working capital of $9.6 million, including cash and cash equivalents of $3.5 million.

Net cash used in operating activities was approximately $3.8 million for the year ended November 30, 2017, we successfully expanded our global activity of the CDMO division while maintaining the same level of cash used in operating activities as a result of the increased revenues at our subsidiary, MaSTherCell, thereby significantly increasing gross profit and generating cash to pay our ongoing operating expenses.

Net cash used in investing activities for the year ended November 30, 2017 increased by $1.9 million, or 122%, compared to the same period in 2016, mainly due to completion of our obligation under the JV's agreements with Atvio and CureCell in total amount of $2.4 million.

During the fiscal year ended November 30, 2017, our financing activities consisted of (i) closing on $5.3 million net of transaction costs in private placement equity offerings through the issuance of 828,409 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 or $7.68 and (ii) closing on $5.9 million in private placement debt offerings consisting of convertible promissory notes with maturity dates of between six and twenty-four months.

Liquidity & 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;
- Restrictions on our ability to continue receiving government funding for our CT 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 in order to remain competitive or acquire other businesses and technologies and in order 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 in order to fund our operating needs.

From December 1, 2017 to the date of this report on Form 10-K, we raised an aggregate of $3 million in private placements of our securities with accredited investors. In addition, $720,000 was raised through convertible loans which are convertible at any time by the holders into units of our securities at a conversion price per unit of $6.24, with each unit comprised of one share of common stock and a warrant for an additional share of common stock exercisable for three years from the date of issuance at a per share exercise price of $6.24.

For the fiscal year ended November 30, 2017, we had been funding operations primarily from the proceeds from private placements of our convertible debt and equity securities and from revenues generated by MaSTherCell. From December 2016 through November 2017, we received, through MaSTherCell, proceeds of approximately $8.9 million in revenues and accounts receivable from customers and $11.4 million from the private placement to accredited investors of our equity and equity linked securities and convertible loans, out of which $4.5 million is from the institutional investor with whom we entered into definitive agreements in January 2017 for the private placement of units of our securities for aggregate subscription proceeds to us of $16 million. The subscription proceeds are payable on a periodic basis through August 2018.

The equity investment in November 2017 by SFPI in MaSTherCell of €5.9 million (approximately $6 million), which includes the conversion of €1 million in an outstanding loan by SFPI to MaSTherCell, will cover costs associated with an expansion of MaSTherCell's manufacturing and production capabilities.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's 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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our chief executive and financial officers (our principal executive officer and principal financial and accounting officer, respectively) to allow timely decisions regarding required disclosure based on the definition of "disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of November 30, 2017. In designing and evaluating the Company's disclosure controls and procedures, the Company's management recognizes that controls and procedures are designed on a risk-based approach and, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. The Company's management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The continuous improvement of the Company's disclosure controls and procedures is based on material weaknesses identification in the Company's internal control over financial reporting.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of November 30, 2017, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at reasonable assurance level due to a material weakness in internal control over financial reporting, as further described below.

Management's Annual Report on Internal Controls Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. 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.

Our system of internal control over financial reporting is 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation.

We conducted risk assessment on five corporate criteria – Strategic, management, regulatory, IT, operational and financial – resulting in a risk-based management of the company and establishment of a remediation plan based on company risk aversion. This plan is designed to strengthen the effectiveness of our internal controls over financial reporting as of November 30, 2017. Based on this evaluation, which is based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework (2013), management concluded that the material weakness in internal control over financial reporting described below existed as of November 30, 2017.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The limitation of the Company's 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 implying:

(i) Improved but insufficient segregation of duties with control objectives; and
(ii) Insufficient controls over period end financial disclosure and reporting processes.

Our management believes the weaknesses identified above have not had any material effect on our financial results.

Remediation Plan

During the fiscal year ended November 30, 2017, we continued to expand upon our implementation of a risk management, resource planning and internal control system, which are all intended to strengthen our overall control environment. Management has taken additional steps to address the causes of the above weaknesses and to improve our internal control over financial reporting, including the re-design of our accounting processes and control procedures and the identification of gaps in our skills base and the expertise of our staff as required to meet the financial reporting requirements of a public company. In particular, during the first quarter of fiscal year 2017, we retained qualified independent third-party personnel, to conduct a comprehensive review of our internal controls and formalization of our review and approval processes in order. The appointed qualified independent third party assessed the Company's risk management framework to manage enterprise risk. During the third quarter, the appointed qualified independent third party designed a remediation plan which, among other things, is designed to prevents fraudulent transaction. The risk based approach identified by the Company reflects the awareness of an acceptable level of risk to manage the Company, considering the strategy, resources and regulatory environment.

This measure led to an overarching remediation plan and program brief to be followed by a detailed action plan for each major risk selected. Subsequently, it is expected to lead to an improvement in our internal controls which will enable us to expedite our month-end close process, thereby facilitating the timely preparation of financial reports and to strengthen our segregation of duties at the Company. We are also hired a full time Chief Financial Officer at MaSTherCell in September 2017 and a full-time controller in our Israeli subsidiary. Finally, we are exploring implementing a new initiative to ease and automate data gathering from all affiliated companies (data warehousing) and implement quantitative and qualitative controls.

We are committed to maintaining a strong internal control environment, and believe that these remediation efforts will represent significant improvements in our control environment. Our management will continue to monitor and evaluate the relevance of our risk-based approach and the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary and as funds allow.

Changes in Internal Control Over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes.

Other than these changes mentioned, during the quarter ended November 30, 2017, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our Directors and Executive Officers. The age of each Director and Executive Officer listed below is given as of February 28, 2018.

Name	Age	Position
Vered Caplan	49	Chief Executive Officer, President and Director
Neil Reithinger	48	Chief Financial Officer, Secretary and Treasurer
Prof. Sarah Ferber	63	Chief Scientific Officer
Denis Bedoret	37	General Manager of MaSTherCell
David Sidransky (1)	56	Director
Guy Yachin (1)	50	Director
Yaron Adler (1)	46	Director
Hugues Bultot	52	Director
Ashish Nanda	53	Director

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

Set forth below are brief accounts of the business experience during the past five years of each of our directors and executive officers of the Company.

Vered Caplan - Chairman of the Board of Directors, Chief Executive Officer and President

Ms. Caplan has been the Chairman of the Board of Directors and Chief Executive Officer since August 14, 2014, prior to which she was Interim President and CEO since December 23, 2013. Since 2008, Ms. Caplan has been Chief Executive Officer of Kamedis Ltd., a company focused on utilizing plant extracts for dermatology purposes. From 2004 to 2007, Ms. Caplan was Chief Executive Officer of GammaCan International Inc., a company focused on the use of immunoglobulins for treatment of cancer. During the previous five years, Ms. Caplan has been a director of the following companies: Opticul Ltd., a company involved with optic based bacteria classification; Inmotion Ltd., a company involved with self-propelled disposable colonoscopies; Nehora Photonics Ltd., a company involved with noninvasive blood monitoring; Ocure Ltd., a company involved with wound management; Eve Medical Ltd., a company involved with hormone therapy for Menopause and PMS; and Biotech Investment Corp., a company involved with prostate cancer diagnostics. Ms. Caplan has 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.

We believe that Ms. Caplan's significant experience relating to our industry and a deep knowledge of our business, based on her many years of involvement with our company, makes her suitable to serve as a director of our company.

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 COO & 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 was appointed Chief Scientific Officer on February 2, 2012. Since 2017, Prof. Ferber has been the Principal Investigator of cell therapy for TMU DiaCure. From 2012 to present, she has been the Chief Scientific Offer of the Company. 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 and a degree in Cell Therapy Sciences from UTSW, Dallas,

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

Dr. Bedoret was appointed General Manager of MaSTherCell 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.

Dr. David Sidransky – Director

Dr. Sidransky was appointed as a director 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 April 2, 2012. 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.

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 was appointed as a director on April 17, 2012. In 1999 Mr. Adler co-founded IncrediMail Ltd. and served as its Chief Executive Officer 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.

Hugues Bultot – Director

Mr. Bultot was appointed as a director on March 2, 2015. Mr. Bultot is a technology entrepreneur with a 10-year track record in bioprocessing. From April 2014 to July 2017, Mr. Bultot was the Chief Executive Officer of MaSTherCell, a company he co-founded in 2011. Since January 2013, Mr. Bultot is the Founder and CEO of Univercells SA, a Belgian-based company focused on the development of the implementation of disruptive manufacturing science in order to make biologics accessible and affordable. Prior to founding MaSTherCell and Univercells, Mr. Bultot founded Artelis in 2005 with his partner, José Castillo, a Belgian biotech company that specialized in the development of disposable bioreactors for the vaccine and monoclonal antibodies industry and for cell therapy applications. Artelis was sold to ATMI in November 2010, which was subsequently acquired by Pall Corporation (NYSE: PLL) in February 2014. From 2006 until 2009, Mr. Bultot was a director with Ascencio, a Euronext-quoted real estate company where he was the head of the Audit Committee. Mr. Bultot founded Kitozyme in 2000, a company developing vegetal chitosan-based applications for the nutrition, wine-making, cosmetics and medical device industry where he developed the entire manufacturing chain, led the strategy and the operations and concluded numerous co-development agreements and financial rounds. Between 1994 and 1999, Mr. Bultot served as investment manager and COO of Synerfi, a private equity firm affiliated with Generale de Banque, a major Belgian banking institution. In these positions, he concluded several funding rounds and exited deals for start-ups and mature companies. Mr. Bultot holds a master's degree in law from UCL, Belgium and an executive master's degree in business administration from Solvay Business School, Belgium and in tax management from ICHEC in Belgium. Mr. Bultot followed the advanced management program at INSEAD in 1997 and several courses in tech entrepreneurship at MIT from 2009 to 2011. Mr. Bultot is also serving on the Board of Directors of Ovizio, a company specialized in holographic microscopy and of Vivaldi Biosciences, a company developing live-attenuated influenza vaccines for pediatric and elderly segments.

We believe Mr. Bultot is qualified to serve on our Board of Directors because of his success with early-stage enterprises, and knowledge and leadership skills for his role as a former Chief Executive Officer of MaSTherCell, our subsidiary.

Ashish Nanda – Director

Mr. Nanda was appointed a director on February 22, 2017. Since 1990, 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. Prior to that, from 1991 to 1994, Mr. Nanda held the position of Asst. Manager Corporate Banking at Emirates Banking Group where he was involved in establishing relationship 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 the Company and Image Securities fzc. ("Image"), so long as Image's ownership of the company is 10% or greater, it was granted the right to nominate a director to the Company's 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 six directors. 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.

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. Our Board of Directors has also established a Finance Committee. Each committee operates under a 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 www.orgenesis.com.

Audit Committee

The members of our Audit Committee are Messrs. Sidransky, Adler and Yachin. Mr. Yachin is also an "Audit Committee financial expert," as defined in applicable SEC rules.

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 the Company with copies of all such forms they file.

Based solely on review of the copies of such forms received by the Company with respect to 2017, or written representations from certain reporting persons, each of Ashish Nanda and Denis Bedoret did not timely file a Form 3.

Code of Business 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 code of business conduct and ethics are available, without charge, upon request in writing to Orgenesis Inc., 20271 Goldenrod Lane, Germantown, MD, 20876, Attn: Secretary and are posted on the investor relations section of our website, which is located at www.orgenesis.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We also intend to disclose any amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, on our website.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information for the last two completed fiscal years concerning compensation of the officers identified below (the "Named Executive Officers"):

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (1)	Non-equity Incentive Plan Compensa-tion ($)	Change in Pension Value and Non-qualified Deferred Compensation Earnings ($)	All Other Compensa-Tion ($) (2)	Total ($)
Vered Caplan *CEO & President*	2017	156,232*(3)*	150,000	-	685,318	-	-	63,262	1,054,842
	2016	150,077 *(3)*	-	-	500,649	-	-	50,304	701,030
Neil Reithinger *CFO, Treasurer & Secretary*	2017	112,652 *(4)*	-	-	136,148	-	-	-	248,799
	2016	108,596 *(4)*	-	-	-	-	-	-	108,596
Sarah Ferber *Chief Scientific Officer*	2017	128,907 *(5)*	-	-	-	-	-	43,328 *(5)*	172,235
	2016	112,353 *(5)*	-	-	-	-	-	39,808 *(5)*	152,161
Hugues Bultot *Former General Manager of MaSTherCell*	2017	22,513 *(6)*	-	-	-	-	-	-	22,513
	2016	168,029 *(6)*	-	-	-	-	-	-	168,029
Denis Bedoret, General Manager of MaSTherCell	2017	208,542 *(7)*	31,281	-	-	-	-	-	239,824
	2016	-		-	-	-	-	-	-

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for the Company that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our Common Stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 13 to this Annual Report on form 10-K for the year ended November 30, 2017.

(2) For 2017 and 2016, represents the compensation as described under the caption “All Other Compensation” below.

(3) Due to cash flow considerations, part of the amounts earned have been deferred periodically and, as of November 30, 2017, an aggregate of $246,461 has been deferred by agreement and accrued by the Company. See below under “Employment/Consulting Agreements – Vered Caplan.”

(4) Due to cash flow considerations, part of the amounts earned have been deferred periodically and, as of November 30, 2017, an aggregate of $111,813 has been deferred and accrued by agreement and accrued the Company. See below under “Employment/Consulting Agreements – Neil Reithinger.”

(5) Under her employment agreement with the Company, Prof. Ferber was entitled to additional salary and social benefits of $82,012 and $152,161 for the years ended November 30, 2017 and 2016, respectively. Due to cash flow considerations, Prof. Ferber has been deferring part of her salary and social benefits due thereon 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, 2017, such deferred amount totaled an aggregate of $582,371 for the years 2013 to 2017. Any increase in Prof. Ferber’s compensation amounts was due to currency fluctuations during the fiscal year ended November 30, 2017.

(6) We acquired MaSTherCell on March 3, 2015. Of the 2017 and 2016 amounts earned, $22,513 and $149,317 was paid, respectively, and $1,480 and $41,685 was deferred, respectively, by agreement and accrued by the Company. On July 6, 2017, Mr. Bultot resigned as General Manager of MaSTherCell. See below under "Employment/Consulting Agreements – Hugues Bultot."

(7) On July 6, 2017, the Board of directors of MaSTherCell appointed Denis Bedoret, Ph.D. as General Manager and day-to-day Manager of MaSTherCell, effective as of July 11, 2017. Of the 2017 amounts earned, $208,542 was paid and $31,281was deferred by agreement by the Company.

All Other Compensation

The following table provides information regarding each component of compensation for 2017 and 2016 included in the All Other Compensation column in the Summary Compensation Table above. Represents amounts paid in New Israeli Shekels (NIS) and converted at average exchange rates for the year.

Name	Year	Automobile and Communication Related Expenses $ (1)	Israel-related Social Benefits $ (2)	Total $ (3)
Vered Caplan	2017	21,921	41,371	63,262
	2016	13,231	37,073	50,304
Prof. Sarah Ferber	2017	5,144	38,183	43,328
	2016	5,019	34,789	39,808

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

(2) 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, 2017

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of November 30, 2017.

	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Vered Caplan (1)	551,458	206,923	278,191	$0.0012, $4.80 & $7.20	02/02/2022 to 01/06/27
Neil Reithinger (2)	47,917	52,084	-	$6.00 & $4.80	08/01/2024 & 12/09/26
Prof. Sarah Ferber	231,826	-	-	$0.0012	02/02/2022

(1) On December 9, 2016, the Board of Directors granted Ms. Caplan 166,667 options for shares of common stock with an exercise price of $4.80 that are exercisable quarterly over two years from date of grant. On June 6, 2017, the Compensation Committee granted Ms. Caplan options for 83,334 shares of common stock at an exercise price of $7.20 that vest in two equal installments of 41,667 options, each on December 6, 2017 and June 6, 2018.

(2) On December 9, 2016 the Board of Directors granted Mr. Reithinger 83,334 options for Common Shares that vest on a quarterly basis over two years at an exercise price of $4.80 per share.

Option Exercises and Stock Vested in 2017

There were no option exercises by our named executive officers during our fiscal year ended November 30, 2017.

Employment/Consulting Agreements

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 replaces 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 continues 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 is entitled to a signing bonus of $150,000 upon execution of the Amended Caplan Employment Agreement. Ms. Caplan continues to have the social benefits described above. 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% (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 of by us 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 1,000,000 shares of the Company's common stock at a per share exercise price equal to the Fair Market Value (as defined in 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 3,000,000 shares of common stock (on a pre-split basis) 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.

The Initial Option shall vest in two equal tranches upon the six and twelve month anniversary of the grant date. The Additional Option shall vest in tranches of 500,000 shares of common stock (on a pre-split basis) every six months from the date of grant, provided that Ms. Caplan remains employed by Company on the vesting date; provided, further, however, that the Options shall vest fully immediately prior to a Change of Control (as defined in the 2017 Plan), or as otherwise provided for in the 2017 Plan.

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 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. As of November 30, 2017, Mr. Reithinger is owed $22,610 in accrued salary. 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's 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, 2017, Eventus was owed $89,203 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 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, 2017, such deferred amount totaled an aggregate of $582,371. 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%) or (ii) Severance pay under Israeli law pursuant to which the Company contributes 8 1/3% (iii) Education fund pursuant to which the Company contributes 7.5 % (with Prof. Farber contributing 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 contains customary provisions regarding confidentiality of information, non-competition and assignment of inventions.

Denis Bedoret

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

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, 2017.

Name	Salary Continuation	Bonus	Accrued Vacation Pay	Total Value
Vered Caplan	$ -	$ -	$ 22,383	$ 22,383
Prof. Sarah Ferber	$ -	$ -	$ 191,722	$ 191,722

Director Compensation

The following table sets forth for each director certain information concerning his compensation for the year ended November 30, 2017:

	Fees Earned or Paid in Cash ($)[1]	Stock Awards ($)	Option Awards ($)[2]	Non-equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All other Compensation ($)	Total ($)
Vered Caplan	38,130	-	-	-	-	-	38,130
Guy Yachin	31,130	-	139,590	-	-	-	170,720
Yaron Adler	905	-	139,590	-	-	-	140,495
Dr. David Sidransky	1,055	-	139,590	-	-	-	140,645
Hugues Bultot	680	-	139,590	-	-	-	140,270
Ashish Nanda	-	-	-	-	-	-	-

(1) None of these amounts were paid to the directors.

(2) 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 13 (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 February 2, 2012, we entered into a compensation agreement with Ms. Vered Caplan (the "Caplan Compensation Agreement"). Pursuant to the Caplan Compensation Agreement, Ms. Caplan will serve as a director of our company for a gross salary of NIS (Israeli Shekel) 10,000 per month, which is approximately $2,689.

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.

On June 18, 2015, we entered into an agreement with Hugues Bultot to serve as a member of our Board of Directors. In consideration for Mr. Bultot's services, we will 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.

Newly Adopted Compensation Policy for Non-Employee Directors.

On March 5, 2017, the Board of Directors adopted a compensation policy for non-employee directors which is intended to replace the non-employee director compensation terms discussed above. By its terms, the policy becomes effective when (and if) the Company uplists its securities to a National Exchange in the United States. Under the newly 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 2,083 shares of common stock. 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. All of the foregoing share amounts have been adjusted to post-split amounts. Once the new policy becomes effective, such policy will replace the compensation currently paid to the directors and non –employee directors will no longer receive any payment on respect of service on the Board of Directors.

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, 2017.

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

The following table sets forth, as of February 27, 2018, the number of shares of our common stock owned by (i) each person who is known by us to own of record or beneficially five percent (5%) or more of our outstanding shares, (ii) all five percent (5%) or greater shareholders as a group, (iii) each of our directors, (iv) each of our executive officers and (v) all of our directors and executive officers as a group. Unless otherwise indicated, each of the persons listed below has sole voting and investment power with respect to the shares of our common stock beneficially owned. The address of our directors and officers is c/o Orgenesis Inc., at 20271 Goldenrod Lane, Germantown, MD 20876.

Security Ownership of Certain Beneficial Holders

Name and Address of Beneficial Owner	**Amount and Nature of Beneficial Ownership [(1)]**	**Percent[(1)]**
Oded Shvartz 130 Biruintei Blvd. Pantelmon Ilfov, Romania	1,830,658 Direct	17.82%
Universite Libre De Bruxelles Avenue Franklin D. Roosevelt 50 1050 Brussels, Belgium	1,021,980 Direct (2)	9.95%
Image Securities fzc. 2310, 23rd floor, Tiffany Towers, JLT Dubai, UAE	721,160 Direct (3)	7.02%

Name and Address of Beneficial Owner	**Amount and Nature of Beneficial Ownership (1)**	**Percent(1)**
Vered Caplan c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	633,380 Direct (4)	5.81%
Neil Reithinger 14201 N. Hayden Road, Suite A-1 Scottsdale, AZ 85260	58,334 Direct (5)	<1%
Prof. Sarah Ferber c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	231,826 Direct (6)	2.21%
Dr. Denis Bedoret c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	-	<1%
Guy Yachin c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	60,101 Direct (7)	<1%
Dr. David Sidransky c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	41,668 Direct (8)	<1%
Yaron Adler c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	114,999 Direct (9)	1.11%
Hugues Bultot Avenue Victor Jacobs 78 1040 Brussels, Belgium	635,593 (10)	6.04%
Ashish Nanda c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	- (3)	-
Directors & Executive Officers as a Group (9 persons)	1,775,901 Direct	15.26%

Notes:

(1) Percentage of ownership is based on 10,273,644 shares of our common stock outstanding as of February 27, 2018, after giving effect to a 12 for 1 reverse stock split effective November 16, 2017. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission 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) To the Company's knowledge, Messrs. Pierre Gurdjian and Yves Englert have voting and dispositive power over these securities. The foregoing disclosure is based on a report on Schedule 13D filed on December 13, 2017.

(3) Does not include options to purchase an additional 1,842,943 shares of common stock to which the shareholder committed to purchase from the Company periodically over through August 2018, at the per unit purchase price of $6.24. The warrants are exercisable over a three year period from the date of issuance at a per share exercise price of $6.24. Mr. Ashish Nanda has voting and dispositive power over these securities.

(4) Consists of options for 508,380 shares of common stock with an exercise price of $0.0012 that are fully vested, options for 83,334 shares of common stock with an exercise price of $4.80 and options for 41,667 shares of common stock at an exercise price of $7.20. Does not include options for 83,334 shares of common stock with an exercise price of $4.80 that are exercisable quarterly after December 9, 2017 and 41,667 shares of common stock with an exercise price of $7.20 are exercisable on June 6, 2018.

(5) Consists of options for 16,667 shares of common stock with an exercise price of $6.00 that are fully vested and options for 41,667 shares of common stock with an exercise price of $4.80. Does not include options for 41,667 shares of common stock with an exercise price of $4.80 that are exercisable quarterly after December 9, 2017.

(6) Consists of options for 231,826 shares of common stock with an exercise price of $0.0012 that are fully vested.

(7) Consists of options for 39,267 shares of common stock with an exercise price of $10.20 that are fully vested and options for 20,834 shares of common stock with an exercise price of $4.80. Does not include options for 20,834 shares of common stock with an exercise price of $4.80 that are exercisable quarterly after December 9, 2017.

(8) Consists of options for 20,834 shares of common stock with an exercise price of $9.00 that are fully vested and options for for 20,834 shares of common stock with an exercise price of $4.80. Does not include options for 20,834 shares of common stock with an exercise price of $4.80 that are exercisable quarterly after December 9, 2017.

(9) Consists of options for 58,908 shares of common stock with an exercise price of $9.48 that are fully vested, options for 20,834 shares of common stock with an exercise price of $4.80 and 9,616 warrants for shares of common stock with an exercise price of $6.24. Does not include options for 20,834 shares of common stock with an exercise price of $4.80 that are exercisable quarterly after December 9, 2017.

(10) Consists of options for 20,834 shares of common stock with an exercise price of $6.36 that are fully vested, options for 20,834 shares of common stock with an exercise price of $4.80 and an option, under a private agreement with Universite Libre de Bruxelles (ULB), to purchase 204,396 common shares at an exercise price of $0.1454 per share from ULB, under which Mr. Bultot has not yet received such shares from ULB. Does not include options for 20,834 shares of common stock with an exercise price of $4.80 that are exercisable quarterly after December 9, 2017.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of November 30, 2017:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	83,334	$7.20	1,666,666
Equity compensation plans not approved by security holders (2)	1,921,101	$5.29	494,880
Total	2,004,435	$5.34	2,161,546

(1) Consists of the 2017 Equity Incentive Plan. For a short description of this plan see Note 13 to our 2017 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended November 30, 2017.

(2) Consists of the Global Share Incentive Plan (2012). For a short description of this see Note 13 to our 2017 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended November 30, 2017.

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

Transactions with Related Persons

Except as set out below, as of November 30, 2017, 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.

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 are payable on a periodic basis through August 2018. Each periodic payment of subscription proceeds will be evidenced by the Company's standard securities subscription agreement. During the year ended November 30, 2017, Image remitted to the Company $4.5 million, 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. 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 2017 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

Our Board of Directors has determined that four of our six directors are independent directors within the meaning of the independence requirements of the NASDAQ Listing Rules. The independent directors are Messrs. Adler, Sidransky, Yachin and Nanda

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, 2017. The following table sets forth the fees billed to the Company for professional services rendered by PwC for the years ended November 30, 2017 and 2016:

Services	**2017**	**2016**
Audit fees	$ 211,000	$ 160,964
Audit related fees	22,000	31,193
Tax fees	-	9,250
Total fees	**$ 233,000**	**$ 201,407**

Audit Fees

The audit fees were paid for the audit services of our annual and quarterly reports.

Tax Fees

The tax fees were paid for reviewing various tax related matters.

Pre-Approval Policies and Procedures

Our Audit Committee preapproves all services provided by our independent registered public accounting firm. All of the above services and fees were reviewed and approved by the Board of Directors before the respective services were rendered. Our Board of Directors has considered the nature and amount of fees billed by PwC and believes that the provision of services for activities unrelated to the audit is compatible with maintaining their respective independence.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibits required by Regulation S-K

No.	Description
3.1	Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S-1 filed on April 2, 2009)
3.2	Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.3	Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.4	Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.5	Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.6	Certificate of Correction dated February 27, 2012 (incorporated by reference to an exhibit to a current report on Form 8-K/A filed on March 16, 2012)
3.7	Certificate of Change Pursuant to Nevada Revised Statutes Section 78.209, as filed by Orgenesis Inc. on November 13, 2017 (incorporated by reference to an exhibit to a current report on Form 8- K filed on November 16, 2017)
10.2	Convertible Loan Agreement dated December 6, 2013 with Mediapark Investments Limited (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
10.3	Investment Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
10.4	Registration Rights Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
10.5	Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on March 4, 2014)
10.6	Form of warrant (incorporated by reference to our current report on Form 8-K filed on March 4, 2014)
10.7	Consulting Agreement dated April 3, 2014 with Aspen Agency Limited (incorporated by reference to our current report on Form 8-K filed on April 7,2014)
10.8	Stock Option Agreement dated April 3, 2014 with Aspen Agency Limited (incorporated by reference to our current report on Form 8-K filed on April 7,2014)
10.9	Form of subscription agreement with form of warrant (incorporated by reference to our current report on Form 8-K filed on April 28, 2014)
10.10	Convertible Loan Agreement dated May 29, 2014 with Nine Investments Limited (incorporated by reference to our current report on Form 8-K filed on May 30, 2014)
10.11	Services Agreement between Orgenesis SPRL and MaSTherCell SA dated July 3, 2014 (incorporated by reference to our current report on Form 8-K filed on July 7, 2014)
10.12	Financial Consulting Agreement dated August 1, 2014 with Eventus Consulting, P.C. (incorporated by reference to our current report on Form 8-K filed on August 5, 2014)
10.13	Personal Employment Agreement dated August 1, 2014 by and between Orgenesis, Inc. and Neil Reithinger (incorporated by reference to our current report on Form 8-K filed on August 5, 2014)
10.14	Personal Employment Agreement dated as of July 23, 2014 by and between Orgenesis Maryland Inc. and Scott Carmer (incorporated by reference to our current report on Form 8-K filed on August 6, 2014)
10.15	Release Agreement dated November 26, 2016 by and between Orgenesis Maryland Inc., Orgenesis Inc. and Scott Carmer (incorporated by reference to our current report on Form 8-K filed on November 23, 2016)
10.16	Executive Employment Agreement dated March 30, 2017 between Orgenesis Inc. and Vered Caplan (incorporated by reference to our quarterly report on From 10-Q filed on July 24, 2017)

No.	Description
10.17	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 our quarterly report on Form 10-Q filed on July 24, 2017)
10.18	Share Exchange Agreement dated November 6, 2014 with MaSTherCell SA and Cell Therapy Holding SA (collectively "MaSTherCell") and each of the shareholders of MaSTherCell (incorporated by reference to our current report on Form 8-K filed on November 10, 2014)
10.19	Addendum No. 1 to Share Exchange Agreement dated March 2, 2015 with MaSTherCell SA, Cell Therapy Holding SA and their shareholders (incorporated by reference to the Company's current report on Form 8-K filed on March 5, 2015)
10.20	Escrow Agreement dated February 27, 2015 with the shareholders of MaSTherCell SA and Cell Therapy Holding SA and bondholders of MaSTherCell SA and Securities Transfer Corporation (incorporated by reference to the Company's current report on Form 8-K filed on March 5, 2015)
10.21	Orgenesis Inc. Board of Advisors Consulting Agreement dated March 16, 2015 (incorporated by reference to the Company's current report on Form 8-K filed on March 17, 2015)
10.22	Addendum No. 2 to Share Exchange Agreement dated March 2, 2015 with MaSTherCell SA, Cell Therapy Holding SA and their shareholders (incorporated by reference to the Company's current report on Form 8-K filed on November 13, 2015)
10.23	Joint Venture Agreement dated March 14, 2016 with CureCell Co., Ltd. (incorporated by reference to our annual report on From 10-K for the year ended November 30, 2016, as filed on February 28, 2017)
10.24	Joint Venture Agreement dated as of May 10, 2016 between Orgenesis Inc. and Atvio Biotech Ltd. (incorporated by reference to our quarterly report on From 10-Q filed on April 19, 2017)
10.25	Private Placement Subscription Agreement dated January 26, 2017 between Orgenesis Inc. and Image Securities FZC (incorporated by reference to our quarterly report on From 10-Q filed on April 19, 2017)
10.26	Amendment No. 1 dated February 9, 2017 to the Private Placement Subscription Agreement between Orgenesis Inc. and Image Securities fzc. (incorporated by reference to our quarterly report on From 10-Q filed on April 19, 2017)
10.27	2017 Equity Incentive Plan (incorporated by reference from the Proxy Statement on Schedule 14A filed on March 30, 2017)
21.1*	List of Subsidiaries of Orgenesis Inc.
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1*	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2*	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
99.1	Global Share Incentive Plan (2012) (incorporated by reference to our current report on Form 8K filed on May 31, 2012)
99.2	Appendix – Israeli Taxpayers Global Share Incentive Plan (incorporated by reference to our current report on Form 8K filed on May 31, 2012)
99.3*	Audit Committee Charter
99.4*	Compensation Committee Charter

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101 CAL	XBRL Taxonomy Extension Calculation Linkbase
101 DEF	XBRL Taxonomy Extension Definition Linkbase
101 LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

*Filed herewith

ITEM 16. SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary.

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
President, Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)
Date: February 28, 2018

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Accounting Officer)
Date: February 28, 2018

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/ Guy Yachin*
Guy Yachin
Director
Date: February 28, 2018

By: */s/ David Sidransky*
David Sidransky
Director
Date: February 28, 2018

By: */s/ Yaron Adler*
Yaron Adler
Director
Date: February 28, 2018

By: */s/ Ashish Nanda*
Ashish Nanda
Director
Date: February 28, 2018

By: */s/ Hugues Bultot*
Hugues Bultot
Director
Date: February 28, 2018

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF NOVEMBER 30, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of

ORGENESIS INC.

We have audited the accompanying consolidated balance sheets of Orgenesis Inc. and its subsidiaries as of November 30, 2017 and 2016, and the related consolidated statements of comprehensive loss, changes in equity (capital deficiency) and cash flows for each of the two years in the period ended November 30, 2017. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company and its subsidiaries as of November 30, 2017 and 2016, and the results of their operations and cash flows for each of the two years in the period ended November 30, 2017, in conformity with accounting principles generally accepted in the United States of America.

Tel-Aviv, Israel

February 28, 2018

/s/ Kesselman & Kesselman

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

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

	November 30,	
	2017	**2016**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,519	$ 891
Accounts receivable, net	1,336	1,229
Prepaid expenses and other receivables	841	779
Receivables from related party	691	-
Grants receivable	183	906
Inventory	725	400
Total current assets	7,295	4,205
NON CURRENT ASSETS:		
Call option derivative	339	-
Investments in associates, net	1,321	-
Property and equipment, net	5,104	4,573
Intangible assets, net	15,051	15,050
Other assets	78	75
Goodwill	10,684	9,584
Total non current assets	32,577	29,282
TOTAL ASSETS	$ 39,872	$ 33,487

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

	November 30,	
	2017	**2016**
Liabilities and equity		
CURRENT LIABILITIES:		
Short term bank credit	-	21
Accounts payable	3,914	4,554
Accrued expenses and other payables	1,435	1,205
Employees and related payables	2,961	1,680
Related parties	116	42
Advance payments on account of grant	1,719	243
Short-term loans and current maturities of long term loans	378	11, 11
Deferred income	3,611	1,273
Current maturities of convertible loans	2,780	2,541
Convertible bonds	-	1,818
Investments in associate, net	-	12
TOTAL CURRENT LIABILITIES	16,914	14,500
LONG-TERM LIABILITIES:		
Loans payable	2,118	3,291
Convertible loans	2,415	1,059
Retirement benefits obligation	6	5
Put option derivative	-	273
Deferred taxes	690	1,862
TOTAL LONG-TERM LIABILITIES	5,229	6,490
TOTAL LIABILITIES	22,143	20,990
COMMITMENTS		
REDEEMABLE NON CONTROLLING INTEREST	3,606	-
EQUITY:		
Common stock of $0.0001 par value, 145,833,334 shares authorized, 9,872,659 and 9,508,068 shares issued and outstanding as of November 30, 2017 and November 30, 2016, respectively	1	1
Additional paid-in capital	55,334	45,454
Receipts on account of shares to be allotted	1,483	-
Accumulated other comprehensive income (loss)	1,425	(1,205)
Accumulated deficit	(44,120)	(31,753)
TOTAL EQUITY	14,123	12,497
TOTAL LIABILITIES AND EQUITY	$ 39,872	$ 33,487

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,	
	2017	**2016**
REVENUES	$ 10,089	$ 6,397
COST OF REVENUES	6,807	7,657
GROSS PROFIT (LOSS)	3,282	1,260( )
RESEARCH AND DEVELOPMENT EXPENSES, net	2,478	2,157
AMORTIZATION OF INTANGIBLE ASSETS	1,631	1,620
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	9,189	6,240
SHARE IN LOSSES OF ASSOCIATED COMPANY	1,214	123
OPERATING LOSS	11,230	11,400
FINANCIAL EXPENSES, net	2,447	1,260
LOSS BEFORE INCOME TAXES	13,677	12,660
INCOME TAX BENEFIT	(1,310)	(1,547)
NET LOSS	$ 12,367	$ 11,113
LOSS PER SHARE:		
Basic	$ 1.28	$ 1.30
Diluted	$ 1.31	$ 1.30
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE:		
Basic	9,679,964	8,521,583
Diluted	9,714,252	8,521,583
COMPREHENSIVE LOSS -		
Net loss	$ 12,367	$ 11,113
Translation adjustments	(2,630)	(81)
TOTAL COMPREHENSIVE LOSS	$ 9,737	$ 11,032

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	Receipts on Account of Share to be	Accumulated Other	Accumulated	
	Number	Par Value	Capital	Allotted	Comprehensive Income (loss)	Deficit	Total
BALANCE AT DECEMBER 1, 2016	4,653,009	$ 1	$ 14,234	$ 1,251	$ (1,286)	$ (20,640)	$ (6,440)
Changes during the Year ended November 30, 2016:							
Stock-based compensation to employees and directors			1,103				1,103
Stock-based compensation to service providers	220,836	*	1,613				1,613
Warrants and shares issued due to extinguishment of a convertible loan	24,039	*	114				114
Beneficial conversion feature of convertible loans			257				257
Issuances of shares and warrants from investments and conversion of convertible loans	1,076,707	*	6,675	(1,251)			5,424
Reclassification of redeemable non-controlling interest **	3,533,477	*	21,458				21,458
Comprehensive loss for the year					81	(11,113)	(11,032)
BALANCE AT NOVEMBER 30, 2016	9,508,068	1	45,454	-	(1,205)	(31,753)	12,497
Changes during the Year ended November 30, 2017:							
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
Issuance of shares, cancellation of contingent shares, and receipts on account of shares and warrants to be allotted and	285,424	*	3,702	1,483			5,185
Comprehensive income (loss) for the year					2,630	(12,367)	(9,737)
BALANCE AT NOVEMBER 30, 2017	9,872,659	$ 1	$ 55,334	$ 1,483	$ 1,425	$ (44,120)	$ 14,123

*Represents an amount lower than $ 1 thousand
**Including outstanding contingent share, see Note 11(d)

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,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,367)	$ (11,113)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,364	2,869
Share in losses of associated company	1,214	123
Loss from extinguishment of a convertible loan	-	229
Depreciation and amortization expenses	2,598	2,923
Change in fair value of warrants and embedded derivatives	(826)	187
Change in fair value of convertible bonds	(192)	(84)
Interest expense accrued on loans and convertible loans (including amortization of beneficial conversion feature)	1,110	283
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable, net	33	(54)
Increase in inventory	(265)	(101)
Increase in other assets	(3)	(17)
Decrease (increase) in prepaid expenses and other accounts receivable	(107)	136
Increase in related parties, net	(583)	
Increase (decrease) in accounts payable	(933)	1,079
Increase in accrued expenses	92	399
Increase in employee and related payables	1,142	352
Increase in deferred income	1,044	53
Increase in advance payments and receivables on account of grant	2,156	499
Decrease in deferred taxes	(1,310)	(1,546)
Net cash used in operating activities	(3,833)	(3,783)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(975)	(1,425)
Investments in associates	(2,429)	(111)
Net cash used in investing activities	(3,404)	(1,536)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Short-term line of credit	(21)	21
Proceeds from issuance of shares and warrants	5,297	1,488
Loans received	-	1,121
Redeemable non-controlling interest	2,349	-
Repayment of short and long-term debt	(1,108)	(2,106)
Repayment of convertible loans	(4,051)	
Proceeds from issuance of convertible loans (net of transaction costs)	5,899	1,599
Net cash provided by financing activities	8,365	2,123
NET CHANGE IN CASH AND CASH EQUIVALENTS	1,128	(3,196)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	1,497	(81)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	891	4,168
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 3,519	$ 891
SUPPLEMENTAL NON-CASH FINANCING ACTIVITY		
Conversion of loans (including accrued interest) to common stock and warrants **of MaSTherCell**	$ 1,277	$ 1,028
Reclassification of redeemable non-controlling interest to equity	$ -	$ 21,458
SUPPLEMENTAL INFORMATION ON INTEREST PAID IN CASH	$ 903	$ 106

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

NOTE 1 – DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc., a Nevada corporation, is a service and research company in the field of regenerative medicine industry with a focus on cell therapy development and manufacturing for advanced medicinal products. In addition, the Company is focused on developing novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes. The consolidated financial statements include the accounts of Orgenesis Inc., its subsidiaries MaSTherCell S.A ("MaSTherCell"), its Belgian-based subsidiary and a contract development and manufacturing organization, or CDMO, specialized in cell therapy development and manufacturing for advanced medicinal products; 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").

The Company's goal is to industrialize cell therapy for fast, safe and cost-effective production in order to provide rapid therapies for any market around the world through a world-wide network of CDMOs joint venture partners. The Company's trans-differentiation technologies for treating diabetes, which will be referred to as the cellular therapy ("CT") business, is based on a technology licensed by Tel Hashomer Medical Research ("THM") to the Israeli Subsidiary that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and trans-differentiating (converting) them into "pancreatic beta cell-like" insulin-producing cells.

On March 14, 2016, the Company and CureCell Co., Ltd. ("CureCell") entered into a Joint Venture Agreement (the "CureCell JVA") pursuant to which the parties are collaborating in the contract development and manufacturing of cell therapy products in Korea. See also Note 5.

On May 10, 2016, the Company and Atvio Biotech Ltd., ("Atvio") entered into a Joint Venture Agreement (the "Atvio JVA") pursuant to which the parties agreed to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in Israel. See also Note 5.

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.

On November 16, 2017, the Company implemented a reverse stock split of its outstanding shares of common stock at a ratio of 1-for-12 shares. The reverse stock split has been reflected in this Annual Report on Form 10-K. See Note 11(a).

b. Liquidity

As of November 30, 2017, we have accumulated losses of approximately $44.1 million. Although we are now showing positive revenue and gross profit trends in our CDMO division, we expect to incur further losses in the CT division.

The Company has been funding operations primarily from the proceeds from private placements of the Company's convertible debt and equity securities and from revenues generated by MaSTherCell. From December 1, 2016 through November 30, 2017, the Company received, through MaSTherCell, proceeds of approximately $8.9 million in revenues and accounts receivable from customers and $11.4 million from the private placement to accredited investors of the Company's equity and equity linked securities and convertible loans, out of which $4.5 million are from the institutional investor with whom the Company entered into definitive agreements in January 2017 for the private placement of units of the Company's securities for aggregate subscription proceeds of $16 million. The subscription proceeds are payable on a periodic basis through August 2018. In addition, from December 1, 2017 through February 28, 2018, the Company raised $3.8 million from the proceeds of a private placement to certain accredited investors of equity and equity-linked securities and received, through MaSTherCell, proceeds of approximately $2.6 million in accounts receivable from its customers.

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 - SUMMARY OF 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. As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the valuation of stock-based compensation, valuation of financial instruments measured at fair value and valuation of impairment of goodwill and intangible assets.

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.

c. Cash Equivalents

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

d. Research and Development, net

Research and development expenses include costs directly attributable to the conduct of research and development 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.

e. Principles of Consolidation

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

f. Non Marketable Equity Investments

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

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

g. Functional Currency

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

h. Inventory

Inventory is stated at the lower of cost or net realizable value with cost determined under the first-in-first-out (FIFO) cost method. The entire balance of inventory at November 30, 2017 and 2016, consists of raw material.

i. 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:

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

Intangible assets and their useful lives are as follows:

	Weighted Average Useful Life (Years)	**Amortization Recorded at Comprehensive Loss Line Item**
Customer Relationships	7.75	Amortization of intangible assets
Brand	9.75	Amortization of intangible assets
Know-How	11.75	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.

j. 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 2017 and 2016.

k. 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 2017 and 2016.

l. 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.

The Company also incurs revenue from selling of some consumables which are incidental to the services provided as foreseen in the clinical services contracts. Such revenue is recognized upon delivery of the processed cells in which they were consumed.

m. 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 also Note 15).

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 15).

n. Income Taxes

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

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

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

o. Stock-based Compensation

The Company 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.

p. Redeemable Non-controlling Interest

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

q. Loss per Share of Common Stock

Net loss per share, basic and diluted, is computed on the basis of the net loss for the period divided by the weighted average number of common shares outstanding during the 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 under the Company's Global Share Incentive Plan (2012) and warrants which are included under the treasury share method when dilutive, and (ii) common shares to be issued under the assumed conversion of the Company's outstanding convertible loans, which are included under the if-converted method when dilutive (See Note 12).

r. Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of principally cash and cash equivalents 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, 2017, the Company has recorded an allowance of $897 thousand ($336 in the year ended November 30, 2016).

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.

s. Beneficial Conversion Feature ("BCF")

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

t. Other Comprehensive Loss

Other comprehensive loss represents adjustments of foreign currency translation. *u. Recently Issued Accounting Pronouncements*

a. Recently Issued Accounting Pronouncements- adopted by the Company

In July 2017, the FASB issued ASU 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480; Derivatives and Hedging (Topic 815)", ("ASU 2017-11"). This update was issued to address complexities in accounting for certain equity-linked financial instruments containing down round features. The amendment changes the classification analysis of these financial instruments (or embedded features) so that equity classification is no longer precluded. The amendments in ASU 2017-11 are effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company elected to early adopt the standard effective September 1, 2017, retrospectively. Following is the results of the adoption on the Company's consolidated financial statements previously reported:

Balance sheet and Shareholders' equity

	November 30, 2016		
	As reported Previously	Impact of adoption	As revised
	In thousands		
Price protection derivative	$ 76	$ (76)	$ -
Total current liabilities	14,576	(76)	14,500
Warrants	1,843	(1,843)	-
Total long-term liabilities	8,333	(1,843)	6,490
Total liabilities	22,909	(1,919)	20,990
Additional paid-in capital	41,605	3,838	45,443
Accumulated deficit	(29,834)	(1,919)	(31,753)
Total equity	$ 10,578	$ 1,919	$ 12,497

Statement of Comprehensive loss

	Year ended November 30, 2016		
	As reported Previously	Impact of adoption	As revised
	In thousands		
Financial expenses, net	$ (659)	$ 1,919	$ 1,260
Loss before income taxes	$ 10,741	$ 1,919	$ 12,660
Net loss	$ 9,194	$ 1,919	$ 11,113

b. *Recently Issued Accounting Pronouncements- not yet adopted by the Company*

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09") "Revenue from Contracts with Customers." ASU 2014-09 will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. On July 9, 2015, the FASB deferred the effective date of the standard by one year, which results in the new standard being effective for the Company at the beginning of its first quarter of fiscal year 2018. In addition, during March, April and May 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers : Principal versus Agent Considerations (Reporting Revenue Gross versus Net), ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing and ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients, respectively, which clarified the guidance on certain items such as reporting revenue as a principal versus agent, identifying performance obligations, accounting for intellectual property licenses, assessing collectability and presentation of sales taxes. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. As applicable for the Company, the effective date for adopting the ASU is for the year ending November 30, 2019. The Company is currently evaluating the impact of adopting ASU 2014-09 on its financial position, results of operations and related disclosures and has not yet determined whether the effect of the revenue portion will be material.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The pronouncement requires equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. ASU 2016-01 requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset, and eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost. These changes become effective for the Company's fiscal year beginning November 30, 2019. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), 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 this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. As applicable for the Company, the effective date for adopting the ASU is for the year ending November 30, 2019. 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. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 (ASU 2016-13) "Financial Instruments- Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. As applicable for the Company, the effective date for adopting the ASU is for the year ending November 30, 2020. The Company is currently in the process of evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements.

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2017-01, "Business Combinations (Topic 805) Clarifying the Definition of a Business" ("ASU 2017-01") which amended the existing FASB Accounting Standards Codification. The standard provides additional guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting, including acquisitions, disposals, goodwill, and consolidation. As applicable for the Company, the effective date for adopting the ASU is for the year ending November 30, 2019. The Company is currently assessing the impact that this updated standard will have on the consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which simplifies the goodwill impairment test by eliminating the need to determine the fair value of individual assets and liabilities of a reporting unit to measure goodwill impairment. The same impairment assessment applies to all reporting units including those with zero or negative carrying amounts. A goodwill impairment will represent the excess of a reporting unit's carrying amount over its fair value. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The amendments in ASU No. 2017-04 should be applied on a prospective basis. Disclosure of the nature and reason for the change in accounting principle upon transition is required. For public business entities, the amendments in this ASU are effective for annual or interim goodwill impairments tests in fiscal years beginning after December 15, 2019. As applicable for the Company, the effective date for adopting the ASU is for the year ending November 30, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

NOTE 3 - SEGMENT INFORMATION

The Chief Executive Officer ("CEO") is the Company's chief operating decision-maker ("CODM"). Following the acquisition of MaSTherCell, 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 activity is operated by MaSTherCell, which specializes in cell therapy development for advanced medicinal products. MaSTherCell is providing two types of services to its customers: (i) process and assay development services and (ii) GMP contract manufacturing services. The CDMO segment includes only the results of MaSTherCell.

CT Business

The CT Business activity is based on our 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 Type 1 Diabetes. This segment is comprised of all entities aside from MaSTherCell.

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

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

	CDMO	CT Business	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 11,484	$ -	$ (1,395)	$ 10,089
Cost of revenues	(6,356)		638	(5,718)
Gross profit	5,128	-	(757)	4,371
Research and development expenses, net		(2,517)	757	(1,760)
Operating expenses	(4,699)	(3,335)		(8,034)
Operating profit	429	(5,852)	-	(5,423)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(2,720)	(6)		
Segment performance	(2,291)	(5,858)		

Reconciliation of segment performance to loss for the year:

	Year ended November 30, 2017
	in thousands
Segment subtotal performance	(8,149)
Stock-based compensation	(3,364)
Financial income (expenses), net	(950)
Share in losses of associated companies	(1,214)
Loss before income tax	$ (13,677)

Segment data for the year ended November 30, 2016 is as follows:

	CDMO	CTB	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 6,853	$ -	$ (456)	$ 6,397
Cost of revenues	(6,915)		557	(6,358)
Gross profit	(62)	-	101	39
Research and development expenses, net		(1,725)	(101)	(1,826)
Operating expenses	(2,239)	(1,667)		(3,906)
Operating profit	(2,301)	(3,392)	-	(5,693)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(2,918)	(5)		
Segment performance	(5,219)	(3,397)	-	

Reconciliation of segment performance to loss for the year:

	Year ended November 30, 2016
	in thousands
Segment performance	(8,616)
Stock-based compensation	(2,661)
Financial income (expenses), net	(1,260)
Share in losses of associated company	(123)
Loss before income tax	$ (12,660)

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:

	Year Ended November 30, 2017	Year Ended November 30, 2016
	(in thousands)	
Customer A	$ 4,115	$ 3,754
Customer B	$ 47	$ 1,742
Customer C	$ 2,837	
Customer D	$ 2,055	

The CDMO business has substantially diversified revenues by source signing contracts with biotech companies in their respective cell-based therapy field. In January 2017, MaSTherCell entered into a service agreement with Les Laboratoires Servier ("Servier") for the development of its CAR T-cell therapy manufacturing platform and in June 2017, MaSTherCell entered into a service agreement with CRISPR Therapeutics AG ("CRISPR") for the development and manufacturing of allogeneic cell therapies.

NOTE 4 – PROPERTY AND EQUIPMENT

The following table represents the components of property and equipment:

	November 30,	
	2017	2016
	(in thousands)	
Cost:		
Production facility	$ 6,246	$ 4,403
Office furniture and computers	353	211
Lab equipment	2,039	1,491
	8,638	6,105
Less – accumulated depreciation	(3,534)	(1,532)
Total	$ 5,104	$ 4,573

Depreciation expense for the years ended November 30, 2017 and 2016 was $1,096 thousand and $1,160 thousand, respectively.

NOTE 5 – INVESTMENTS IN ASSOCIATES, NET

(a) On May 10, 2016, the Company and Atvio entered into the Atvio JVA pursuant to which the parties agreed to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in Israel. The parties pursue the joint venture through Atvio, in which the Company has a 50% participating interest therein in any and all rights and obligations and in any and all profits and losses.

Under the Atvio JVA, Atvio has procured, at its sole expense, a GMP facility and appropriate staff in Israel. The Company shares with Atvio the Company's know-how in the field of cell therapy manufacturing, which know-how will not include the intellectual property included in the license from the Tel Hashomer Hospital in Israel to the Israeli Subsidiary. Atvio's operations commenced in September 2016.

Through November 30, 2017, 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 shall be convertible at the Company's option at any time into 50% of the then outstanding equity immediately following such conversion. The Company concluded that, based on the terms of the agreement, it has the ability to exercise significant influence in Atvio, but does not have control. Therefore, the investment is accounted for under the equity method.

In addition, at any time following the first anniversary year of the Effective Date the Company has the option to require the Atvio 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 shareholders have 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 are accounted as derivatives and measured at fair value and presented in the balance sheet in "put/call option derivative" line item (See Note 15).

(b) On March 14, 2016, Orgenesis Inc. and CureCell entered into the CureCell JVA, pursuant to which the parties are collaborating in the contract development and manufacturing of cell therapy products in Korea.

Under the CureCell JVA, CureCell has procured, at its sole expense, a GMP facility and appropriate staff in Korea for the manufacture of the cell therapy products. The Company will share with CureCell the Company's know-how in the field of cell therapy manufacturing, which know-how does not include the intellectual property included in the license from the THM to the Israeli subsidiary. As of November 30, 2017, all obligations were fulfilled by the parties and the JV Company was established under the CureCell JVA agreement and each party has 50% from the participating interest and in any and all profits and losses of the JV Company subject to the fulfillment by each Party of his obligations under the CureCell JVA.

Under the CureCell JVA, the Company and CureCell each undertook to remit, within two years of the execution of the CureCell JVA, minimum amount of $2 million to the JV Company, of which $1 million is to be in cash and the balance may be in an in-kind investment, the scope and valuation of which shall be preapproved in writing by CureCell and the Company. The Company's funding was made by way of a convertible loan. The CureCell JVA provides that, under certain specified conditions, the Company can require CureCell 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 the then valuation of the JV Company. Through November 30, 2017, the Company remitted to CureCell $2.1 million.

(c) The table below sets forth a summary of the changes in the investments for the years ended November 30, 2017 and 2016:

	November 30, 2017 (In thousands)	November 30, 2016 (In thousands)
Opening balance	$ (12)	$ -
Reclass from short-term receivables *	118	
Investments during the period	2,429	111
Share in losses	(1,214)	(123)
	$ 1,321	$ (12)

*As of November 30, 2016, prior to the formal incorporation of the CureCell JV company, the actual joint operations already began. The amounts transferred to CureCell by the Company on account of the investment and the share in loss were recorded as short-term receivables, and Company's share in the expenses incurred through balance sheet date was recorded by the Company as part of its selling, general and administrative expenses.

NOTE 6 – INTANGIBLE ASSETS AND GOODWILL

Changes in the carrying amount of the Company's goodwill for the years ended November 30, 2017 and 2016 are as follows:

	(in thousands)
Goodwill as of November 30, 2015	$ 9,535
Translation differences	49
Goodwill as of November 30, 2016	9,584
Translation differences	1,100
Goodwill as of November 30, 2017	$ 10,684

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 the CDMO unit.

As part of the first step of the two-step impairment test, the Company compared the fair value of the reporting units to their carrying values and determined that the carrying amount of the units do not exceed their fair values. 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 units 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 CDMO 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 16.6% and 15.3% . Based on the Company's assessment as of November 30, 2017 and 2016, respectively, the carrying amount of its reporting unit does not exceeds 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 $1.1 million and $2.3 million, 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 $3.3 million. These changes would not result in an impairment.

Other Intangible Assets

Other intangible assets consisted of the following:

	November 30, 2017	November 30, 2016
	(In thousands)	
Gross Carrying Amount:		
Know How	$ 17,998	16,158
Customer relationships	369	331
Brand name	1,418	1,272
	19,785	17,998
Accumulated amortization	4,734	2,948
Net carrying amount of other intangible assets	$ 15,051	15,050

Intangible asset amortization expenses were approximately $1.8 million for each of the years ended November 30, 2017 and 2016.

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

	2018	2019 to 2022
	(in thousands)	
Amortization expenses	$ 1,947	$ 7,790

NOTE 7– CONVERTIBLE LOAN AGREEMENTS

(a) During the year ended November 30, 2015 and 2014, the Company entered into six convertible loan agreements with new investors for a total amount of $1 million (the "Convertible Loans"). The loans bear an annual interest rate of 6%.

On April 27, 2016 and December 23, 2015, the holders of all the Convertible Loans converted the principal amount and the accrued interest in amount of $1,018 thousand into units, with each unit comprising one share of the Company's common stock and one three-year warrant to purchase an additional share of the Company's common stock at an exercise price of $6.24. Upon conversion of the Convertible Loans, the Company issued an aggregate of 163,904 shares of Common stock and three year warrants to purchase up to an additional 163,904 shares. Furthermore, in the event that the Company will issue any common shares or securities convertible into common shares in a private placement for cash at a price less than $6.24 on or before December 23, 2016, the Company will issue to the subscribers, for no additional consideration, additional common stock. As of the date of the approval of these financial statements, the shares anti-dilution protection mechanism described above, has expired and no shares were issued under this provision.

(b) On April 27, 2016, the Company entered into an assignment and assumption of debt agreement with Nine Investments Ltd. ("Nine Investments") and Admiral Ventures Inc. ("Admiral"). Pursuant to the terms of a Convertible Loan Agreement dated May 29, 2014, as amended on December 2014 (collectively, the "Loan Agreement"), Nine Investments assigned and transferred to Admiral all of the Company's obligations for the outstanding amount of the Loan Agreement. Additional amendments to the provisions of the Loan Agreement were included the following:

(1) Extending the due date of the loan of $1.5 million through September 30, 2016;
(2) The Company paid to Admiral an extension fee in the form of 288,461 units, each unit was comprised of one common share and one, three-year warrant converted into one common share at an exercise price of $6.24 per common share. The fair value of the warrants as of the grant date was $34 thousand. Using the Black-Scholes model, the shares were valued at the fair value of the Company's common stock as of April 27, 2016, or $3.36; and
(3) The Company shall accrue additional interest totalling $55 thousand for the period from January 31, 2015 to December 31, 2015. In addition, the interest rate shall be 12% per annum commencing from January 1, 2016.

The Company accounted for the above changes as an extinguishment of the old debt and issuance of a new debt. As a result, a loss of $229 thousand was recorded within financial expenses.

On February 27, 2017, the Company and Admiral entered into an agreement resolving the payment of amounts owed to Admiral. Under the terms of the 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 will make a monthly payment of $125 thousand on account of the remaining unpaid balance, and also remit 25% of all amounts received from equity financing raised above $1 million and 20% of such amounts above $500 thousand on account of amounts owed. The Company accounted for the above changes as a modification of the old debt. Upon an occurrence of a default, the loan bears interest at an annual rate of 15%.

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 $177 thousand.

(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 ($262 thousand). The loan bears a monthly interest rate of 2% and mature on May 1, 2017, unless converted earlier. The holder, at its option, may convert the outstanding principal amount and accrued interest under this note into shares of the Company's common stock at a per share conversion price of $6.24.

The Company allocated the principal amount of the convertible loan and the accrued interest thereon based on their fair value. The table below presents the fair value of the instrument issued as of November 2, 2016 and the allocation of the proceed (for the fair value as of November 30, 2017 and 2016, see Note 15):

	Total Fair Value (in thousands) November 2, 2016
Embedded derivative component	$ 40
Loan component	222
Total	$ 262

The transaction costs were approximately $29 thousand, out of which $8 thousand as stock based compensation due to issuance of warrants (See also Note 13(d)).

On April 27, 2017 and November 2, 2017, the Company entered into extension agreements through November 2, 2017 and May 2, 2018, respectively.

(d) During the years ended November 30, 2017 and 2016 the Company entered into several unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of $5 and $1.4 million, respectively. The loans bear an annual interest rate of 6% and mature in two years, unless converted earlier. Under certain conditions as defined in the agreements, the entire principal amount and accrued interest automatically convert into Units (as defined below).

Each $6.24 of principal amount and accrued interest due shall convert into a Unit, consisting of one share of Common Stock and one three-year warrant exercisable into an additional share of common stock at a per share exercise price of $6.24. In addition, in certain loans within 12 months of the issuance date hereof, the holder, at its option, may convert the outstanding principal amount and accrued interest either (i) Units as provided above, or (ii) shares of the Company’s common stock at a per share conversion price of $6.

Since the closing price of the Company's publicly traded stock is greater than the effective conversion price on the closing date, the conversion feature is considered "beneficial" to the holders and equal to $2.3 million and $257 thousand for the convertible notes received during the years ended November 30, 2017 and 2016, respectively. The 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.

The transaction costs for the convertible notes received during the year ended November 30, 2017 and 2016 were approximately $527 and $126 thousand, respectively, out of which $163 and $55 thousand are stock-based compensation due to issuance of warrants (See also Note 13(d)).

(e) During the year ended November 30, 2017, the Company entered into several unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of $0.8 million. The notes have mainly 6% interest rate and are scheduled to mature between six to nine months and one year unless converted earlier. At any time, all or a portion of the outstanding principal amount and accrued but unpaid interest thereon may be converted at the Holder’s option into shares of the Company common stock at a price of $6.24 per share. The Company also issued to the investors three-year warrants to purchase up to 145,509 shares of the Company’s Common Stock at a per share exercise price of $6.24.

Since the closing price of the Company’s publicly traded stock is greater than the effective conversion price on the measurement date, the conversion feature is considered "beneficial" to the holders and equal to $81 thousand. The 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.

(f) On January 23, 2017, the Company entered into unsecured convertible note agreement with a Non-U.S. institutional investor, on amount of $400,000 at per annum rate of 6% and with a maturity date of April 23, 2017.

The transaction costs were approximately $71 thousand, out of which $35 thousand as stock based compensation due to issuance of 6,410 warrants and 2,671 shares. The fair value of those warrants as of the date of grant was evaluated by using the Black-Scholes valuation model.

The principal amount and accrued interest were repaid by the Company on March 7, 2017 and, in accordance with the terms of the agreement, the Company issued to the investor 54,167 restricted shares of the Company's Common Stock. The fair value of the shares as of March 7, 2017, was $494 thousand and was recorded as financial expenses.

(g) 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 11(c)).

NOTE 8 – LOANS

a. *Terms of Long-term Loans*

	Principal Amount (in thousands)	Grant Year	Interest Rate	Year of Maturity	November 30, 2017	2016
					(in thousands)	
Long-term loan (*)	€ 1,400	2012	4.05%	2022	$ 899	$ 952
Long-term loan	€ 1,000	2013	6%-7.5%	2023	977	1,000
Long-term loan	€ 790	2012-2016	5.5%-6%	2020-2024	620	739
Long-term loan (**)	€ 1,000	2016	7%	2019	-	1,063
					$ 2,496	$ 3,754
Current portion of loans payable					(378)	(463)
					$ 2,118	$ 3,291

(*) The loan has a business pledge on the Company's assets at the same value.
(**) On November 15, 2017 the outstanding loan and the accrued interest in a total amount of $1.1 million were converted into MaSTherCell common shares. See also Note 10.

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

	Currency	Interest Rate	November 30, 2017	2016
			(in thousands)	
Current portion of loans payable	Euro	4.05%	$ 169	$ 145
Current portion of loans payable	Euro	6%-7.5%	70	135
Current portion of loans payable	Euro	5.5%-6%	139	183
			$ 378	$ 463
Short term-loans*	Euro	7%	-	648
			$ 378	1,111

(*) On various dates from September 14, 2015 through the year 2015, MaSTherCell received short term loans from management and shareholders for a total amount of €1,247 thousand, which bear an annual interest rate of 7%. No maturity dates were defined. As of November 30, 2017, MaSTherCell repaid the remaining amount of these loans.

NOTE 9 - COMMITMENTS

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

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

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

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

As of November 30, 2017, the Israeli Subsidiary has 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.

In 2016 and 2017, the Israeli Subsidiary entered into a research service agreement with the THM. According to the agreements, the Israeli Subsidiary will perform a study at the facilities and use the equipment and personnel of the Sheba Medical Center, with annual consideration of approximately $88 and $131 thousand, respectively.

b. *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 has approved an extension 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, 2017, the Company utilized $356 thousand. The amount of Grant that was utilized through November 30, 2017, was recorded as a deduction of research and development expenses in the statement of comprehensive loss.

c. *Department De La Gestion Financiere Direction De L'analyse Financiere ("DGO6")*

i. On March 20, 2012, MaSTherCell was awarded an investment grant from the DGO6 of Euro1,421 thousand. This grant is related to the investment in the production facility with a coverage of 32% of the investment planned. A first payment of Euro 568 thousand has been received in August 2013. In December 2016, the DGO6 paid to MaSTherCell Euro 669 thousand on account of the grant and the remaining grant amount has been declined.

ii. On November 17, 2014, the Belgian Subsidiary, received the formal approval from the DGO6 for a Euro 2.015 thousand ($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 approval for Euro 1.8 million costs invested in the project out of which Euro 1.192 founded by the DGO6. During 2017 the Company repaid to the DGO6 the down payments of Euro 17 thousand. As of November 30, 2017, an amount of $160 thousand was recorded as advance payments on account of grant.

iii. In April 2016, the Belgian Subsidiary received the formal approval from DGO6 for a budgeted Euro 1,304 thousand ($1,455 thousand) support program for the development of a potential cure for Type 1 Diabetes. The financial support is 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 a first payment of Euro 359 thousand ($374 thousand). Up through November 30, 2017, an amount of Euro 303 thousand was recorded as deduction of research and development expenses and an amount of $66 thousand was recorded as advance payments on account of grant.

iv. On October 8, 2016, the Belgian Subsidiary received the formal approval from the DGO6 for a budgeted 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, 2017, an amount of $558 was recorded as deduction of research and development expenses and an amount of $1,442 thousand was recorded as advance payments on account of grant.

d. *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. Up 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, 2017, an amount of $359 thousand was recorded as deduction of research and development expenses and $159 thousand as a receivable on account of grant.

e. *Korea-Israel Industrial Research and Development Foundation ("KORIL")*

On May 26, 2016, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with KORIL and CureCell. 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 Autologous Insulin Producing (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 June 1, 2016. On June 2016, the Israeli Subsidiary received $160 thousand under the grant.

Up through November 30, 2017, an amount of $184 thousand was recorded as deduction of research and development expenses and $24 thousand as a receivable on account of grant.

f. *Lease Agreement*

MaSTherCell has an operational lease agreement for the rent of offices for a period of 12 years expiring on November 30, 2027. The costs per year are €329 thousand (approximately $390 thousand).

The Israeli subsidiary has an operational lease agreement for the rent of development lab. The costs per year are NIS 120 thousand (approximately $35 thousand).

g. *Quality Manufacturing System ("QMS") License Agreement*

In December 2016, MaSTherCell and the Company entered into a license agreement pursuant to which MaSTherCell granted to the Company a worldwide (excluding Europe), perpetual, exclusive, royalty-free and sub-licensable right to MaSTherCell's quality manufacturing system for the Company and its affiliates' own internal quality assurance program and for the Company's CDMO activity. In consideration of the license, the Company has a financial obligation to pay to MaSTherCell Euro 2.5 million, payable by an initial and second payment of Euro 250,000, with the balance to be made by an in-kind contribution by the Company by no later than December 2018.

h. *Collaboration Agreement*

On March 14, 2016, the Israel subsidiary, entered into a collaboration agreement with CureCell Co., Ltd. ("CureCell"), initially for the purpose of applying for a grant from KORIL for pre-clinical and clinical activities related to the commercialization of Orgenesis Ltd.'s AIP cell therapy product in Korea ("KORIL Grant"). Subject to receiving the Koril Grant, the Parties agreed to carry out at their own expense 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 of the regulatory approvals required for commercialization in Japan. As of November 30, 2017, none of the requisite regulatory approvals for conducting clinical trials had been obtained (See also Note 5(b)).

i. On November 18, 2016, Mr. Scott Carmer, the Chief Executive Officer of the U.S Subsidiary, resigned from his position in order to pursue other interests. The Company's Chief Executive Officer assumed his position. In connection with his resignation the Company entered into a Release Agreement pursuant to which the Company agreed that Mr. Carmer will be able to exercise options to purchase up to 136,775 shares of the Company's common stock previously issued to him through their original exercise period and Mr. Carmer waived, released and forever discharge Company from any claims, demands, obligations, liabilities, rights, causes of action and damages. In furtherance thereof, on November 18, 2016, Mr. Carmer and the Company entered into a Strategic Advisory Agreement whereas he will continue to serve the Company as a non-employee advisor on its activities in the U.S. and internationally. The Company accounted for the above changes as a waiver of Mr. Carmer's accrued salary and modification of his options. As a result, a non-cash net income of $458 thousand was recorded within financial expenses in the year ended November 30, 2016.

NOTE 10 – REDEEMABLE NON CONTROLING INTEREST

On November 15, 2017 the Company, MaSTherCell and the Belgian Sovereign Funds Société Fédérale de Participations et d'Investissement ("SFPI") entered into a Subscription and Shareholders Agreement ("SFPI Agreement") pursuant to which SFPI is making an equity investment in MaSTherCell in the aggregate amount of Euro 5 million (approximately $5.9 million), for approximately 16.7% of MaSTherCell. The equity investment commitment included the conversion of the outstanding loan of Euro 1 million (approximately $1.1 million) plus accrued interest in the approximate amount of Euro 70 thousand (approximately $77 thousand), previously made by SFPI to MaSTherCell (the "Loan Amount").

Under the Agreement, an initial subscription amount of Euro 2 million ($2.3 million) has been paid and the outstanding Loan Amount been converted. The balance of approximately Euro 1.9 million ($2.2 million) is payable as needed by MaSTherCell and called in by the board of directors of MaSTherCell. The proceeds of the investment will be used to expand MaSTherCell's facilities in Belgium by the addition of five new cGMP manufacturing cleanrooms. This expansion will position MaSTherCell as the European hub for the Company's continental activities and strengthen its position in cell and gene manufacturing. The design enables MaSTherCell to offer full flexibility for production and process development. Under the Agreement, SFPI will be represented by one board member of the five board members of MaSTherCell. In addition, SFPI is entitled to designate one independent board member to the MaSTherCell board who is acceptable to the Company. The Agreement provides that, under certain specified circumstances where MaSTherCell breaches the terms of the Agreement, SFPI is entitled to put its equity interest in MaSTherCell to the Company at a price equal to the subscription price paid by SFPI, plus a specified annual premium ranging from 10% to 25%, depending on the year following the subscription in which the put is exercised. However, the agreement specifies that SFPI has a right to such put provision if the Company is not listed on NASDAQ within six months from the date the SFPI Agreement. If the Company elects to terminate SFPI Agreement before its scheduled term of seven years (or to not renew the agreement upon its scheduled termination), SFPI is entitled to put its MaSTherCell equity interest to the Company at fair market value (as determined by SFPI and the Company). Additionally, at any time during the first three years following the investment, SFPI is entitled to exchange its equity interest in MaSTherCell into shares of the Company's Common Stock, at a rate equal to the subscription price paid by SFPI divided by $6.24 (subject to adjustment for certain capital events, such as stock splits).

The Agreement contains customary representations, warranties and covenants by MaSTherCell, in respect of which the Company has undertaken to indemnify SFPI for the consequences of any breach thereof by MaSTherCell.

The SFPI investment was presented as redeemable non-controlling interest in the balance sheet in the amount of $3,606 thousand.

NOTE 11 – EQUITY

a. *Share Capital*

The Company's common shares are traded on the OTCQB Venture Market under OTC Market Group's OTCQB tier under the symbol "ORGS".

On November 16, 2017, the Company implemented a 1:12 reverse stock split (the "Reverse Split") of its authorized and outstanding shares of Common Stock. All share and per share amounts in these financial statements have been retroactively adjusted to reflect the reverse split as if it had been effected prior to the earliest financial statement period included herein. Following the Reverse Split, the number of authorized shares of common stock that the Company is authorized to issue from time to time is 145,833,334 shares.

b. *Financings*

1) During the year ended November 30, 2017 and 2016, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement (the "Private Placement") of (i) 107,249 and 2,860,578 units, respectively. 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 or $7.68. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of $699 thousand and $1,488 thousand, respectively. Furthermore, in certain events the subscribers received anti-dilution protection for issuance at less than their purchase price.

2) 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 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 are payable on a periodic basis through August 2018. Each periodic payment of subscription proceeds will be evidenced by the Company's standard securities subscription agreement.

During the year ended November 30, 2017 the investor remitted to the Company $4.5 million, in consideration of which, the investor is entitled to 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. The Company allocated the proceeds based on the fair value of the warrants and the shares. The table below presents the allocation of the proceeds as of the closing date:

		Total Fair Value (in thousands)
Warrants component	$	1,516
Shares component		2,984
Total	$	4,500

As of November 30, 2017, 320,516 shares have not been issued and therefore the Company has recorded $1,483 thousand in receipts on account of shares to be allotted in the statement of equity. In connection therewith, the Company undertook to pay a fee of 5% resulting in the payment of $225 thousand (classified as Additional Paid-in Capital in the statement of equity) and the issuance of 36,063 restricted shares of Common Stock. The fair value of the shares as of the date of grant was $253 thousand using the share price on the date of grant. See also note 20(b).

c. *Contingent Shares*

According to the share exchange agreement signed during 2015, the former shareholders of MaSTherCell received a "consideration of shares" of Orgenesis in exchange of their shares in MaSTherCell. At the time of MaSTherCell acquisition by Orgenesis, there was outstanding convertible bonds issued by MaSTherCell in an amount of $1.8 million (Euro 1.6 million).

In case MaSTherCell is repaying the principal amount and the accrued interest of the convertible bonds, the "consideration shares" received by the former shareholders will be reduced by the amount that was due to those bondholders who did not exchange their convertible bond. The consideration of shares will be released back to the Company proportionally to the holding of former shareholders. 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. In case of such release for cancellation of consideration shares, each former shareholder of MaSTherCell will give up for cancellation a part of its consideration shares that will be proportionate to such former shareholder's share in the total number of consideration share issued at acquisition closing.

During January 2017 MaSTherCell repaid all but one of its bondholders and the aggregate payment amounted to $1.7 million (Euro1.5 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 7(g)).

d. *Warrants*

(1) Warrants which are subject to exercise price adjustments

Issuance Date	Number of Warrants Issued and Outstanding	Exercise Price / Adjusted Exercise Price	Expiration Date
October 2015	16,026	$6.24	March 2018
November 2015	657,597	$6.24	November 2018
December 2015	175,924	$6.24	December 2018
February 2016	16,026	$6.24	February 2019
March 2016	64,103	$6.24	March 2019
April 2016	40,859	$6.24	April 2019
May 2016	24,039	$6.24	May 2019
June 2016	72,117	$6.24	June 2019
	1,066,691		

(2) Warrants which are not subject to exercise price adjustments

Grant Month	Number of Warrants Issued and Outstanding	Exercise Price / Adjusted Exercise Price	Expiration Month
November 2013	16,668	$6	November 2018
October 2015	196,543	$6.24	October 2018
December 2015	2,552	$6.24	December 2018
April 2016	24,039	$6.24	April 2019
July 2016	10,016	$6.24	July 2019
August 2016	17,973	$6.24	August 2019
September 2016	641	$6.24	September 2019
October 2016	642	$6.24	October 2019
November 2016	70,033	$6.24	November 2019
December 2016	95,887	$6.24	December 2019
January 2017	76,655	$6.24	January 2020
February 2017	220,863	$6.24,$10.2	February 2020
March 2017	37,003	$6.24	March 2020
April 2017	123,896	$6.24,$7.8	April 2020
May 2017	100,162	$6.24	May 2020
June 2017	100,162	$6.24	June 2020
July 2017	80,129	$6.24	July 2020
August 2017	115,492	$6.24	August 2020
September 2017	7,697	$6.24	September 2020
October 2017	100,162	$6.24	October 2020
November 2017	86,539	$6.24	November 2020
	1,483,754		

NOTE 12 – LOSS PER SHARE

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

	Year Ended November 30,	
	2017	2016
	(in thousands, except per share data)	
Basic:		
Loss for the year	$ 12,367	$ 11,113
Weighted average number of common shares outstanding	9,679,964	8,521,583
Basic loss per common share	$ 1.28	$ 1.30
Diluted:		
Loss for the year	$ 12,367	11,113
Changes in fair value of embedded derivative and interest expenses on convertible bonds	392	
Loss for the year	$ 12,759	$ 11,113
Weighted average number of shares used in the computation of basic loss per share	9,679,964	8,521,583
Number of dilutive shares related to convertible bonds		
Number of dilutive shares related to warrants	34,289	
Weighted average number of common shares outstanding	9,714,252	8,521,583
Diluted loss per common share	$ 1.31	$ 1.30

Diluted loss per share does not include 2,004,435 shares underlying outstanding options, 2,088,239 shares issuable upon exercise of warrants and 1,057,785 shares upon conversion of convertible notes for the year ended November 30, 2017, because the effect of their inclusion in the computation would be anti-dilutive.

Basic loss per share for the year ended November 30, 2016, does not include 681,124 contingent shares.

Diluted loss per share does not include 1,420,446 shares underlying outstanding options, 1,620,965 shares issuable upon exercise of warrants, 32,212 shares due to stock-based compensation to service providers and 655,269 shares upon conversion of convertible notes for the year ended November 30, 2016, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 13 – 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.

In addition, the Company has one stock option plan, the Global share incentive plan (2012) (the "Plan"), under which, the Company had reserved a pool of 12,000,000 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.

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, 2017, and 2016:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Employees	2016	255,855	$0.0012-$4.32	vest immediately-2 years	$697	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:

	Year Ended November 30,	
	2017	2016
Value of one common share	$4.68,$7.2	$0.28-$0.36
Dividend yield	0%	0%
Expected stock price volatility	93.8%-95.4%	87.4%-89%
Risk free interest rate	1.89%-1.76%	1.32%-1.33%
Expected term (years)	5	5

A summary of the Company's stock options granted to employees and directors as of November 30, 2017 and 2016 and changes for the years then ended is presented below:

	2017		2016	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	978,853	1.92	861,773	1.92
Changes during the year:				
Granted	691,673	5.28	253,855	2.24
Expired	(38,106)	7.58		
Forfeited	(27,365)	4.8		
Re-designation to non- employee (see Note 9i)			(136,775)	3.36
Options outstanding at end of the year	1,605,055	3.11	978,853	1.92
Options exercisable at end of the year	1,135,107	2.57	879,759	1.71

The following table presents summary information concerning the options granted and exercisable to employees and directors outstanding as of November 30, 2017:

Exercise Price $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value $	Number of Exercisable Options	Aggregate Exercisable Options Value $
			(in thousands)		(in thousands)
0.0012	462,015	5.78	2,079	442,593	1
0.012	278,191	4.18	1,249	278,191	3
4.32	25,000	8.43	113	9,375	41
4.8	583,338	9.03		235,938	1,133
6	33,334	6.67		33,334	200
6.36	20,834	2.55		20,834	133
7.2	83,334	9.51		-	-
9	20,834	5.63		16,667	150
9.48	58,908	4.61		58,908	558
10.2	39,267	4.51		39,267	401
	1,605,055	6.82	3,444	1,135,107	2,620

Costs incurred with respect to stock-based compensation for employees and directors for the years ended November 30, 2017 and 2016 were $1,536 thousand and $1,103 thousand, respectively. As of November 30, 2017, there was $1,273 thousand of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 1.1 years.

c. *Options Granted to Non- Employees*

Below is a table summarizing all the compensation granted to consultants and service providers during the years ended November 30, 2017 and 2016:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employees	2016	83,333*	$3.6	Quarterly over a period of one year	$187	4 years
Non-employees	2017	16,668	$4.8	Quarterly over a period of one year	$68	10 years

* The options had been immediately vested prior to such one-year period if there was an acquisition of 40% or more of the Company or upon funding of $5 million, the criteria have not been completed in the first year.

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 term is the mid-point between the vesting date and the maximum contractual term for each grant equal to the contractual life. The fair value of each option grant is based on the following assumptions:

	June 1, 2017	December 9, 2016	March 1, 2016
Value of one common share	$7.44	$4.8	$3.6
Dividend yield	0%	0%	0%
Expected stock price volatility	95%	94%	87%
Risk free interest rate	1.76%	1.89%	1.19%
Expected term (years)	5	5	4

A summary of the status of the stock options granted to consultants and service providers as of November 30, 2017, and 2016 and changes for the years then ended is presented below:

	2017		2016	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	441,621	6.24	221,512	9.00
Changes during the year:				
Granted	16,668	4.80	83,334	3.60
Expired	58,909	8.28		
Re-designation to non-employee (see Note 9i)			136,775	3.36
Options outstanding at end of the year	399,380	7.47	441,621	6.24
Options exercisable at end of the year	379,712	5.76	387,284	5.70

The following table presents summary information concerning the options granted and exercisable to consultants and service providers outstanding as of November 30, 2017 (in thousands, except per share data):

Exercise Price $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value* $	Number of Exercisable Options	Aggregate Exercisable Options Value $
			(in thousands)		(in thousands)
4.8	16,668	9.1		16,667	151
3.36	136,775	8.4	156	136,775	1,153
3.60	83,334	8.3	75	83,334	689
6.00	90,000	6.7		72,000	481
6.24	8,334	7.5		8,334	25
7.32	16,668	7.3		16,668	85
11.52	8,334	5.4		6,667	36
16.80	39,267	4.4		39,267	172
	399,380	7.47	$ 231	379,712	$ 2,792

Costs incurred with respect to options granted to consultants and service providers for the year ended November 30, 2017 and 2016 was $322 thousand and $2,543 thousand, respectively. As of November 30, 2017, there was $22 thousand of unrecognized compensation costs related to non-vested consultants and service providers, to be recorded over the next 2.55 years.

d. *Warrants Issued to Non-Employees*

1) During the year ended November 30, 2016, the Company granted to several consultants 89,288 warrants each exercisable at $6.24 per share for three years. The fair value of those options as of the date of grant using the Black-Scholes valuation model was $219 thousand, out of which $64 thousand is related to 22,621 warrants granted as a success fee with respect to the issuance of the convertible notes.

2) During the year ended November 30, 2017, the Company granted to several consultants 53,148 warrants each exercisable at $6.24 or $10.2 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.

e. *Shares Issued to Non-Employees*

1) On March 1, 2016, the Company entered into a consulting agreement for a period of one year. Under the terms of the agreement, the Company granted the consultant 20,834 shares of restricted common stock. The fair value of the shares as of the date of grant was $75 thousand. In addition, the Company had to pay a retainer fee of $10,000 per month, consisting of $5,000 cash per month and $5,000 shall be payable in shares of the Company's common stock at a value equal to the price paid for an equity capital raise of at least $3 million (the "financing"). The cash fee per month and shares shall be issued upon completion of the financing. The fair value of the shares as of November 30, 2016, was $34 thousand. The consultant has not met the financing criteria therefore the Company has not issued additional shares under this agreement.

2) On April 27, 2016, the Company entered into consulting agreements for a period of one year with two consultants. Under the terms of the agreements, the Company agreed to grant the consultants an aggregate of 100,001 shares of restricted common stock that vested on the grant date. The fair value of the shares as of the date of grant was $336 thousand.

3) On May 1, 2016, the Company entered into a consulting agreement for a period of one year. Under the terms of the agreement, the Company agreed to grant a consultant 83,334 shares of restricted common stock, of which the first 29,167 shares vested immediately, 29,167 shares are to vest 90 days following the agreement date and 25,000 shares are schedule to vested 180 days following the agreement date. The fair value of the shares as of the date of grants of these three tranches was $383 thousand.

NOTE 14 – TAXES

a. *The Company and the US Subsidiary*

The Company and the US Subsidiary are taxed according to tax laws of the United States. The income of the Company is taxed in the United States at a federal tax rate of up to 35% and state tax rate of 8.25% .

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (the "TCJA"), which among other changes reduces the federal corporate tax rate to 21%. The Company is currently evaluating the impact of the TCJA on its consolidated financial statements and does not expect any material impact.

b. *The Israeli Subsidiary*

The Israeli Subsidiary is taxed according to Israeli tax laws.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate in 2016 and thereafter, from 26.5% to 25%.

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. As a result, the corporate tax rate in 2017 was 24% and in 2018 and thereafter reduced to 23%.

c . The Belgian Subsidiaries

The Belgian Subsidiaries are taxed according to Belgian tax laws. The regular corporate tax rate in Belgium for 2016 and 2017 is 34%.

On 22 December 2017, the Belgian Parliament has approved the Belgian reform bill. The main impacts of this tax reform are:

- A decrease of the nominal tax rate from 34% to 30% in 2018 and 25% in 2020
- Limitation of deductions on the taxable basis (i.e. carried forward losses, notional interests…) meaning that there will be a minimum taxable basis (if profit above Euro 1 million)
- Tax supplements resulting from a tax audit will constitute a minimum tax base

d. *Tax Loss Carryforwards*

1) As of November 30, 2017, the Company had net operating loss (NOL) carry forwards equal to $12.8 million that is available to reduce future taxable income. Out of the Company's NOL carry forward, an amount of $138 thousand may be restricted under Section 382 of the Internal Revenue Code ("IRC"). IRC Section 382 applies whenever a corporation with an NOL experiences an ownership change. As a result of Section 382, the taxable income for any post change year that may be offset by a pre-change NOL may not exceed the general Section 382 limitation, which is the fair market value of the pre-change entity multiplied by the long-term tax exempt rate.

2) U.S. Subsidiary - As of November 30, 2017, the U.S. Subsidiary had approximately $276 thousand of NOL carry forwards that are available to reduce future taxable income with no limited period of use.

3) Israeli Subsidiary - As of November 30, 2017, the Israeli Subsidiary had approximately $5.8 million of NOL carry forwards that are available to reduce future taxable income with no limited period of use.

4) Belgian Subsidiaries - As of November 30, 2017, the Belgian Subsidiaries had approximately $15.8 million (€13.3 million) of NOL carry forwards that are available to reduce future taxable income, with no limited period of use.

e. *Deferred Taxes*

The following table presents summary of information concerning the Company's deferred taxes as of the periods ending November 30, 2017 and 2016 (in thousands):

	November 30,	
	2017	**2016**
	(U.S dollars in thousands)	
Net operating loss carry forwards	$ 11,819	$ 8,278
Research and development expenses	1,065	655
Employee benefits	180	152
Property and equipment	(61)	(355)
Convertible bonds		1
Deferred income	(292)	(325)
Intangible assets	(5,117)	(5,117)
Less: Valuation allowance	(8,284)	(5,151)
Net deferred tax liabilities	$ (690)	$ (1,862)

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 of its subsidiaries except MaSTherCell have recorded full valuation allowance.

The changes in valuation allowance are comprised as follows:

	Year Ended November 30,	
	2017	**2016**
	(U.S dollars in thousands)	
Balance at the beginning of year .	$ (5,151)	$ (2,982)
Additions during the year	(3,207)	(2,169)
Balance at end of year	$ (8,358)	$ (5,151)

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.

g. *Tax Assessments*

1) The Company - As of November 30, 2017, the Company has received a final tax assessment up to the year 2010.

2) U.S. Subsidiary and the Israeli Subsidiary - As of November 30, 2017, the U.S. Subsidiary and the Israeli Subsidiary have not received any final tax assessment.

3) Belgian Subsidiary - As of November 30, 2017, the Belgian Subsidiary has received a final tax assessment for the year 2014.

4) MaSTherCell - As of November 30, 2017, MaSTherCell has received a final tax assessment for the year 2013.

h. *Uncertain Tax Provisions*

As of November 30, 2017, the Company has not accrued a provision for uncertain tax positions.

NOTE 15 - 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, and 2016, the Company's liabilities that are measured at fair value and classified as level 3 fair value are as follows (in thousands):

	November 30, 2017	November 30, 2016
	Level 3	Level 3
Embedded derivatives convertible loans *(1)	(37)	240
CALL/PUT option derivative(1)	(339)	273
Convertible bonds(2)	$ -	$ 1,818

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

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

(2) The fair value of the convertible bonds described in Note 3 is determined by using a binomial model for the valuation of the embedded derivative and the fair value of the bond was calculated based on the effective rate on the valuation date (6%). The binomial model used the forecast of the Company share price during the convertible bond's contractual term. Since the convertible bond is in Euro and the model is in USD, the Company has used the Euro/USD forward rates for each period. In order to solve for the embedded derivative fair value, the calculation was performed as follows:

- Stage A - The model calculates a number of potential future share prices of the Company based on the volatility and risk-free interest rate assumptions.
- Stage B - the embedded derivative value is calculated "backwards" in a way that takes into account the maximum value between holding the bonds until maturity or converting the bonds.

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

	Embedded Derivative	Put Option Derivative
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 following table presents the assumptions that were used for the models as of November 30, 2016:

	Embedded Derivative	Put Option Derivative
Fair value of shares of common stock	$ 4.68	
Expected volatility	103%	63%
Discount on lack of marketability	-	-
Risk free interest rate	0.38%-0.62%	0.9%
Expected term (years)	0.08-0.42	
Expected dividend yield	0%	
Probability of external Investment in Atvio		20%
Orgenesis cost of debt		26%
Revenues Multiplier distribution		3.34

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:

	Embedded Derivatives	Convertible Bonds	Put Option Derivative
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 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, 2016:

	Embedded Derivatives	Convertible Bonds	Put Option Derivative
Balance at beginning of the year	$ 289	$ 1,888	$ -
Additions	40		273
Conversion	(10)		
Changes in fair value during the period	(87)	(84)	
Changes in fair value due to extinguishment of convertible loan	8		
Translation adjustments	11	14	
Balance at end of the year	$ 240	$ 1,818	$ 273

(*) There were no transfers to Level 3 during the twelve months ended November 30, 2016.

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:

	Base -50%	Base	Base+50%
		(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 16 – REVENUES

	Year Ended November 30,	
	2017	**2016**
	(in thousands)	
Services	$ 8,024	$ 4,683
Goods	2,065	1,714
Total	$ 10,089	$ 6,397

NOTE 17 – RESEARCH AND DEVELOPMENT EXPENSES, NET

	Year Ended November 30,	
	2017	**2016**
	(in thousands)	
Total expenses	$ 3,326	$ 2,637
Less grants	(848)	(480)
Total	$ 2, 478	$ 2,157

NOTE 18 – FINANCIAL EXPENSES (INCOME), NET

	Year ended November 30,	
	2017	**2016**
	(in thousands)	
Decrease in fair value of warrants and financial liabilities measured at fair value	$ (902)	$ (1,587)
Stock-based compensation related to warrants granted due to issuance of credit facility	1,497	208
Interest expense on convertible loans	1,233	694
Foreign exchange loss, net	562	31
Other income	57	(5)
Total	$ 2,447	$ (659)

NOTE 19- RELATED PARTIES TRANSACTIONS

1) Related Parties presented in the consolidated statements of comprehensive loss

	For the year ended November 30,	
	2017	2016
	(in thousands)	
Management and consulting fees to Board Members	$ 25	$ 85
Stock Based Compensation expenses to Board Members	393	242
Compensation of executive officers	419	318
Stock Based Compensation expenses to executive officers	821	501
Interest Expenses on convertible loan from director	$ 55	$ 2

2) Related Parties presented in the consolidated balance sheets

	Year ended November 30,	
	2017	2016
	(in thousands)	
Convertible Loan from director	$ 167	$ 112
Executive officers payables	358	308
Non-executive directors payable	$ 316	$ 280

3) The balances with Related Parties in the balance sheet are mainly related to on-going transactions between the Company and the associates companies. See also Note 5.

NOTE 20- SUBSEQUENT EVENTS

a. On December 6, 2017 the Board of Directors approved grant of 70,700 shares to several consultants and service providers.

b. On December 18, 2017, MaSTherCell received the approval of a new grant from Intitule ICONE with a financial support of Euro 1 million ($1.2 million) in program for development of iPS-derived Cortical Neurons. In December 2017, MaSTherCell received an advance payment of Euro 0.6 million ($0.7 million).

c. In December 2017 and February 2018, the institutional investor referred to in Note 11b(2), remitted to the Company $500 thousand in subscription proceeds entitling such investor to 80,128 shares of Common Stock and three-year warrants for an additional 80,128 shares. The Company has received as of February 28, 2018 a total of $5,000thousand out of the committed $16 million subscription proceeds.

d. In January 2018, the Company entered into investors relation services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to grant the consultants 100,000 shares of restricted common stock, of which the first 25,000 shares will vest immediately, and 75,000 shares are to vest monthly over 15 months commencing February 2018.

e. 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 $749,900 at the Company's own cost in accordance with a project schedule and related mutually acceptable project budget. In consideration for and subject to the fulfilment 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.

f. During December 2017 thorough February 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of (i) 408,454 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 $2.5 million

g. During December 2017 and January 2018, the Company entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of $720 thousand. The notes bear an annual interest rate of 6% and mature in six months or two years from the closing date, unless earlier converted subject to the terms defined in the agreements. The notes provide that the entire principal amount and accrued interest automatically convert into units as in the agreement under certain condition described in the agreement. In addition, the Company issued to certain investors 40,064 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.

Through February 27, 2018, $650 thousand in principal amount out of these convertible notes were converted into units of the Company's securities. See additional information in Note 20h.

h. During January and February 2018, holders of $6.8 million in principal and accrued interest of convertible notes with maturity dates between June 2018 and January 2020 converted these outstanding amounts, in accordance with the terms specified in such notes, into units of the Company's securities at a deemed per unit conversion rate of $6.24, with each unit comprised of: (i) one (1) share of the Company's Common Stock and (ii) one warrant, exercisable for a period of three years from the date of issuance, for an additional share of Common Stock, at a per share exercise price of $6.24. As a result of these conversions, the Company will issue 1,087,960 shares of Common Stock and three-year warrants for an additional 1,087,960 shares of common stock at a per share exercise price of $6.24.

Exhibit 21.1

ORGENESIS, INC.

List of Subsidiaries

- MaSTherCell, S.A.
- Orgenesis SPRL
- Orgenesis Ltd.
- Orgenesis Maryland Inc.
- Cell Therapy Holdings S.A.

Exhibit 31.1

ORGENESIS INC.
CEO CERTIFICATE
PURSUANT TO SECTION 302

I, Vered Caplan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Orgenesis Inc. for the year ended November 30, 2017;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

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

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

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

Date: February 28, 2018

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

Exhibit 31.2

ORGENESIS INC.
CFO CERTIFICATE
PURSUANT TO SECTION 302

I, Neil Reithinger, certify that:

1. I have reviewed this Annual Report on Form 10-K of Orgenesis Inc. for the year ended November 30, 2017;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

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

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

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

Date: February 28, 2018

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

Exhibit 32.1

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

In connection with this Annual Report on Form 10-K of Orgenesis Inc. (the "Company") for the year ended November 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: February 28, 2018

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

Exhibit 32.2

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

In connection with this Annual Report on Form 10-K of Orgenesis Inc. (the "Company") for the year ended November 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: February 28, 2018

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

ORGENESIS, INC.

AUDIT COMMITTEE CHARTER

I. PURPOSE

The Audit Committee shall provide assistance to the Board of Directors (the "Board") of Orgenesis, Inc. (the "Corporation") in fulfilling the Board's responsibility to the Corporation's shareholders relating to the Corporation's accounting, financial reporting practices, the system of internal control, the audit process, the quality and integrity of its financial reports, and the Corporation's process for monitoring compliance with laws and regulations and the Corporation's code of conduct.

The Audit Committee's responsibility is oversight. Management of the Corporation has the responsibility for the Corporation's financial statements as well as the Corporation's financial reporting process, principles, and internal controls. The independent auditor is responsible for performing an audit of the Corporation's annual financial statements, expressing an opinion as to the conformity of such annual financial statements with generally accepted accounting principles, reviewing the Corporation's quarterly financial statements and other procedures. Each member of the Audit Committee shall be entitled to rely on (i) the integrity of those persons within the Corporation and of the professionals and experts (such as the independent auditor) from which it receives information, (ii) the accuracy of the financial and other information provided to the Audit Committee by such persons, professionals or experts absent actual knowledge to the contrary and (iii) representations made by management of the independent auditor as to any non-audit services provided by the independent auditor to the Corporation.

II. AUTHORITY

The Audit Committee has the authority to conduct or authorize investigations into any matters within its scope of responsibility. Its primary duties and responsibilities are to:

- Appoint, compensate, and oversee the work of any registered public accounting firm (referred to herein as the "independent auditor") employed by the Corporation and, if necessary, replace such independent auditor;
- Resolve any disagreements between management and the auditor regarding financial reporting;
- Pre-approve all auditing and non-audit services;
- Retain independent counsel, accountants, or others to advise the Audit Committee or assist in the conduct of an investigation;
- Seek any information it requires from employees—all of whom are directed to cooperate with the Audit Committee's requests—or external parties;
- Meet with the Corporation's officers, the independent auditor, or outside counsel, as necessary; and
- Oversee that management has established and maintained processes to assure compliance by the Corporation with all applicable laws, regulations and corporate policy.

The Audit Committee intends to fulfill these responsibilities primarily by carrying out the activities enumerated in Section IV of this Charter.

III. MEMBERSHIP AND PROCEDURES

A. Membership and Appointment

The Audit Committee shall be comprised of not fewer than three members of the Board, as shall be determined from time to time by the Board. The members of the Audit Committee shall hold office until their resignations or until their successors shall be duly elected and qualified.

All members of the Audit Committee shall be "independent," as such term is defined in Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in that each Audit Committee member may not, other than in his or her capacity as a director or member of any committee of the Board, (i) accept any consulting, advisory, or other compensatory fee from the Corporation or any subsidiary thereof; or (ii) be an affiliated person of the Corporation or any subsidiary thereof. In addition, all members of the Audit Committee shall qualify as "independent directors" for purposes of the listing standards of The NASDAQ Stock Market, as such standards may be changed from time to time; provided, that any non-independent director serving on the Audit Committee pursuant to the "exceptional and limited circumstances" exception available under NASDAQ rules may not serve on the Audit Committee for more than two (2) years; and provided, further, that such non-independent director may not be permitted to serve as Chairperson of the Audit Committee.

All members of the Audit Committee shall be financially literate by being familiar with basic finance and accounting practices and able to read and understand fundamental financial statements at the time of their appointment to the Audit Committee. Furthermore, at least one member of the Audit Committee shall be designated as the "financial expert" with financial sophistication as defined by having experience in finance or accounting, professional certification in accounting, or any other comparable experience or background, such as being or having been a CEO or CFO or other senior officer with financial oversight responsibilities. The Corporation shall disclose, in its annual report, whether or not, and if not, the reasons therefor, the Audit Committee includes at least one "audit committee financial expert," as defined by Item 407(d)(5)(ii) of Regulation S-K under the Securities Act of 1933, as amended (the "Securities Act").

B. Removal

The entire Audit Committee or any individual Audit Committee member may be removed without cause by the affirmative vote of a majority of the Board. Any Audit Committee member may resign effective upon giving oral or written notice to the Chairman of the Board, the Secretary of the Corporation, or the Board (unless the notice specifies a later time for the effectiveness of such resignation). The Board may elect a successor to assume the available position on the Audit Committee when the resignation becomes effective.

C. Chairperson

A chairperson of the Audit Committee (the "Chairperson") may be designated by the Board. In the absence of such designation, the members of the Audit Committee may designate the Chairperson by majority vote of the full Audit Committee membership. The Chairperson shall determine the agenda for and the length of meetings and shall have unlimited access to management and to information relating to the Audit Committee's purposes. The Chairperson shall establish such other rules as may from time to time be necessary and proper for the conduct of the business of the Audit Committee.

D. Meetings, Minutes and Reporting

The Audit Committee shall meet as required but not less than once per quarter. All Audit Committee members are expected to attend each meeting, in person or via tele- or video-conference. Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials.

The Audit Committee shall keep minutes of the proceedings of the Audit Committee. In addition to the specific matters set forth herein requiring reports by the Audit Committee to the full Board, the Audit Committee shall report such other significant matters as it deems necessary concerning its activities to the full Board. The Audit Committee may appoint a Secretary whose duties and responsibilities shall be to keep records of the proceedings of the Audit Committee for the purposes of reporting Audit Committee activities to the Board and to perform all other duties as may from time to time be assigned to him or her by the Audit Committee, or otherwise at the direction of an Audit Committee member. The Secretary need not be a member of the Audit Committee or a director and shall have no membership or voting rights by virtue of the position.

As part of its job to foster open communication, the Audit Committee should meet separately, at least annually, with management, the director of the internal auditing department and the independent auditor to discuss any matters that the Audit Committee or each of these groups believe should be discussed privately. In addition, the Audit Committee or at least its Chairperson should meet separately with the independent auditor, and management quarterly to review the Corporation's financial statements in accordance with Section IV below.

A majority of Committee members shall constitute a quorum for the transaction of business. The action of a majority of those present at a meeting at which a quorum is attained, shall be the act of the Committee. The Committee may delegate matters within its responsibility to subcommittees composed of certain of its members.

E. Delegation

The Audit Committee may, by resolution passed by a majority of the Audit Committee members, designate one or more subcommittees, each subcommittee to consist of one or more members of the Audit Committee. Any such subcommittee, to the extent provided in the resolutions of the Audit Committee and to the extent not limited by applicable law, shall have and may exercise all the powers and authority of the Audit Committee. Each subcommittee shall have such name as may be determined from time to time by resolution adopted by the Audit Committee. Each subcommittee shall keep regular minutes of its meetings and report the same to the Audit Committee or the Board when required.

F. Authority to Retain Advisors

In the course of its duties, the Audit Committee shall have the authority, at the Corporation's expense and without needing to seek approval for the retention of such advisors or consultants from the Board, to retain and terminate consultants, legal counsel, or other advisors, as the Audit Committee deems advisable, including the sole authority to approve any such advisors' fees and other retention terms.

IV. DUTIES AND RESPONSIBILITIES

The Audit Committee, in its capacity as a committee of the Board, shall be directly responsible for the appointment, retention, compensation, evaluation, oversight and, if necessary, termination of the independent auditor(s) employed by the Corporation (including resolution of disagreements between management and the auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work, and each independent auditor shall report directly to the Audit Committee.

The following shall be recurring duties and responsibilities of the Audit Committee in carrying out its purposes. These duties and responsibilities are set forth below as a guide to the Audit Committee, with the understanding that the Audit Committee may alter or supplement them as appropriate under the circumstances, to the extent permitted by applicable law.

A. Document Review & Reporting Process

1. Review and reassess, at least annually, the adequacy of this Charter, make recommendations to the Board and request approval for proposed changes, as conditions dictate, to update this Charter, and ensure appropriate disclosure as may be required by law or regulation.

2. Review with management and the independent auditor the Corporation's annual financial statements and Form 10-K prior to the filing of the Form 10-K or prior to the release of earnings, including a discussion with the independent auditor of the matters required to be discussed under the applicable Statements of Auditing Standards ("SAS").

3. Review with management and the independent auditor each Form 10-Q prior to its filing or prior to the release of earnings, including a discussion with the independent auditor of the matters required to be discussed under SAS. The Chairperson of the Audit Committee may represent the entire Audit Committee for purposes of this review.

4. Review with management and the independent auditor the effect of regulatory and accounting initiatives that may affect the Corporation, as well as the effect of any off- balance sheet structures and transactions on the Corporation's financial statements.

5. Regularly report to the Board about Audit Committee activities, issues, and related recommendations.

6. Provide an open avenue of communication between the internal auditing department, the independent auditor, and the Board.

7. Report annually to the shareholders, describing the Audit Committee's composition, responsibilities and how they were discharged, and any other information required by applicable rules and regulations, including approval of non-audit services.

8. Review any other reports the Corporation issues that relate to Audit Committee responsibilities.

9. Perform other activities related to this Charter as requested by the Board.

10. Institute and oversee special investigations as needed.

11. Confirm annually that all responsibilities outlined in this Charter have been carried out.

12. Evaluate the Audit Committee's and each member's performance and qualifications under applicable rules and regulations on a regular basis.

B. Financial Reporting Process

1. In consultation with the independent auditor and the chief audit executive, review the integrity of the Corporation's financial reporting processes and the coordination of the internal audit function with the independent auditor. The Audit Committee shall report regularly to and review with the full Board any issues that arise with respect to the quality or integrity of the Corporation's financial statements, compliance with legal or regulatory requirements, the performance and independence of the independent auditor, or the performance of the internal audit function.

2. Consider and approve, if appropriate, changes to the Corporation's auditing and accounting principles and practices as suggested by the independent auditor, management, or the internal auditing department.

3. Ensure that there exist regular systems of reporting to the Audit Committee by each of management, the independent auditor and the chief audit executive regarding any significant judgments made in management's preparation of the financial statements and any significant difficulties encountered during the course of the review or audit, including any restrictions on the scope of work or access to required information.

4. Regularly review any significant disagreements among management and the independent auditor or the internal auditing department in connection with the preparation of the financial statements.

5. Ensure and oversee timely reports from the independent auditor to the Audit Committee of (i) all critical accounting policies and practices; (ii) all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management officials of the Corporation, ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the independent auditor; and (iii) other material written communications between the independent auditor and the management of the Corporation, such as any management letter or schedule of unadjusted differences.

C. Financial Statements

1. Review significant accounting and reporting issues, including complex or unusual transactions (such as off-balance sheet structures, if any) and highly judgmental areas, and recent professional and regulatory pronouncements, and understand their impact on the financial statements.

2. Review with management and the independent auditor the results of the audit, including any difficulties encountered and any significant changes in the audit plan.

3. Review the annual financial statements, and consider whether they are complete, consistent with information known to the Audit Committee members, and reflect appropriate accounting principles.

4. Review other sections of the annual report and related regulatory filings before release and consider the accuracy and completeness of the information.

5. Review with management and the independent auditor all matters required to be communicated to the Audit Committee under generally accepted auditing standards.

6. Understand how management and the internal auditing department prepare interim financial statements, and the degree of involvement of the independent auditor in the review process.

7. Review interim financial statements with management and the independent auditor before filing with regulators, and consider whether financial statements are complete and consistent with the information known to the Audit Committee members.

D. Internal Controls

1. Discuss with management and the independent auditor policies and programs with respect to risk management and risk assessment and inquire about risks or exposures facing the Corporation.

2. Understand how the internal auditing department has implemented and maintains the Corporation's internal controls and understand the process for the independent auditor's review of the internal controls, and obtain reports on significant findings and recommendations regarding effectiveness of the controls, together with management's responses.

3. Consider and review with the independent auditor the effectiveness of the Corporation's internal control system, including information technology security and control.

4. Review management's annual internal control report which acknowledges management's responsibility for establishing and maintaining an adequate internal control structure and procedures for financial reporting; and contains an assessment of the effectiveness of the internal control structure.

E. Internal Audit

1. Review with management and the chief audit executive the charter, plans, activities, staffing, and organizational structure of the internal audit function.

2. Ensure there are no unjustified restrictions or limitations, and review and concur in the appointment, replacement, or dismissal of the chief audit executive.

3. Review the effectiveness of the internal audit function, including compliance with The Institute of Internal Auditors' *Standards for the Professional Practice of Internal Auditing.*

4. On a regular basis, meet separately with the chief audit executive to discuss any matters that the Audit Committee or the chief audit executive believes should be discussed privately.

F. Independent Auditor

1. Review the independent auditor's proposed scope and approach for the audit, including coordination with internal audit function.

2. Review the performance of the independent auditor, and exercise final approval on the appointment or discharge of the independent auditor. The Audit Committee has the sole authority and responsibility to select, evaluate, and where appropriate, replace the independent auditor. The independent auditor is ultimately accountable to the Audit Committee for such auditor's review of the financial statements and internal controls of the Corporation. The Audit Committee shall also exercise final approval on the compensation of the independent auditor.

3. Approve in advance all audit services and all permitted non-audit services, except where such services are determined to be *de minimis* under the Exchange Act. The Audit Committee may delegate, to one or more designated members of the Audit Committee, the authority to grant such pre-approvals. The decisions of any member to whom such authority is delegated shall be presented to the full Audit Committee at each of its scheduled meetings.

4. Review and ensure the independence of the auditor by:

   - receiving from, and reviewing and discussing with, the auditor, on a periodic basis, a formal written statement delineating all relationships between the auditor and the Corporation consistent with the applicable requirements of the Public Company Accounting Oversight Board;

   - reviewing, and actively discussing with the Board, if necessary, and the auditor, on a periodic basis, any disclosed relationships or services, including non-audit services, between the auditor and the Corporation or any other disclosed relationships or services that may impact the objectivity and independence of the auditor;

   - recommending, if necessary, that the Board take appropriate action to satisfy itself of the auditor's independence; and

   - ensuring that the lead or coordinating audit partner having primary responsibility for the audit, or the audit partner responsible for reviewing the audit does not perform audit services for the Corporation for more than five consecutive fiscal years.

5. Set clear policies for the hiring by the Corporation of employees or former employees of the Corporation's independent auditor.

6. On a regular basis, meet separately with the independent auditor to discuss any matters that the Audit Committee or independent auditor believes should be discussed privately.

G. Approval of Related Person Transactions

1. Review and approve, prior to the Corporation's entry into any such transactions, all transactions in which the Corporation is or will be a participant, which would be reportable by the Corporation under Item 404 of Regulation S-K promulgated under the Securities Act as a result of any of the following persons having or expected to have a direct or indirect material interest (a "Related Person Transaction"):

   - executive officers of the Corporation;

   - members of the Board;

   - beneficial holders of more than 5% of the Corporation's securities;

   - immediate family members[1] of any of the foregoing persons; and

   - any other persons whom the Board determines may be considered to be related persons as defined by Item 404 of Regulation S-K promulgated under the Securities Act.

2. In reviewing and approving such transactions, the Audit Committee shall obtain, or shall direct management to obtain on its behalf, all information that the Audit Committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by the Audit Committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of the Audit Committee. This approval authority may also be delegated to the Chairperson of the Audit Committee in some circumstances. No Related Person Transaction shall be entered into prior to the completion of these procedures.

[1] "Immediate family member" means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, and any person (other than a tenant or employee) sharing the household with the executive officer, director or 5% beneficial owner.

3. The Audit Committee or the Chairperson, as the case may be, shall approve only those Related Person Transactions that are determined to be in, or not inconsistent with, the best interests of the Corporation and its stockholders, taking into account all available facts and circumstances as the Audit Committee or the Chairperson determines in good faith to be necessary in accordance with principles of Delaware law generally applicable to directors of a Delaware corporation. No member of the Audit Committee shall participate in any review, consideration or approval of any Related Person Transaction with respect to which the member or any of his or her immediate family members has an interest.

4. The Audit Committee shall adopt any further policies and procedures relating to the approval of Related Person Transactions that it deems necessary or advisable from time to time.

H. Legal Compliance/General

I. Review, with the Corporation's counsel, any legal or regulatory matter that could have a significant impact on the Corporation's financial statements.

2. Review and approve the Corporation's investment policies.

3. Review the adequacy of the Corporation's insurance coverage.

4. Review the status of any material tax audits and proceedings, the Corporation's tax strategy and other material tax matters.

5. Maintain minutes or other records of meetings and activities of the Audit Committee.

6. When deemed necessary by the members of the Audit Committee, retain independent legal, accounting or other advisors or consultants to advise and assist the Audit Committee in carrying out its duties, without needing to seek approval for the retention of such advisors or consultants from the Board. The Audit Committee shall determine the appropriate compensation for any advisors retained by the Audit Committee. The Audit Committee may request any officer or employee of the Corporation or the Corporation's outside counsel or independent auditor to attend a meeting of the Audit Committee or to meet with any members of, or consultants to, the Audit Committee.

7. Establish procedures for (i) the receipt, retention, and treatment of complaints received by the Corporation from external parties regarding accounting, internal accounting controls, or auditing matters; and (ii) the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters, whether through the whistleblower hotline or other reporting channels. Ensure such procedures maintain the confidentiality and anonymity of persons reporting violations or suspected violations and ensure that the Corporation does not take retaliatory actions against those reporting.

8. Review the effectiveness of the system for monitoring compliance with laws and regulations and the results of management's investigation and follow-up (including disciplinary action) of any instances of noncompliance.

6. Review the findings of any examinations by regulatory agencies, and any auditor observations.

7. Review the process for communicating the code of conduct to the Corporation's personnel, and for monitoring compliance therewith.

8. Obtain regular updates from management and the Corporation's legal counsel regarding compliance matters.

9. Review with management the policies and procedures with respect to officers' expense accounts and perquisites.

10. Perform any other activities consistent with this Charter, the Corporation's by-laws, and governing law, as the Audit Committee or the Board deems necessary or appropriate.

V. COMPENSATION

Audit Committee members shall be compensated by the Corporation solely in the form of directors' fees. Audit Committee members may, however, receive greater fees than those received for Board service by other Board members, in light of their heightened responsibilities to the Corporation.

ORGENESIS, INC.

COMPENSATION COMMITTEE CHARTER

I. PURPOSE

The purpose of the Compensation Committee (the "Committee") of the Board of Directors (the "Board") of Orgenesis, Inc. (the "Corporation") is:

1. To discharge the responsibilities of the Board relating to compensation of the Corporation's directors, executive officers and key employees;

2. To assist the Board in establishing appropriate incentive compensation and equity-based plans and to administer such plans; and

3. To oversee the annual process of evaluation of the performance of the Corporation's management; and

4. To perform such other duties and responsibilities as enumerated in and consistent with this Charter.

II. MEMBERSHIP AND PROCEDURES

A. Membership and Appointment

The Committee shall be comprised of not fewer than two members of the Board, as shall be determined from time to time by the Board. The members of the Committee shall be elected by the Board, or the committee thereof responsible for nominations of directors, at the annual organizational meeting of the Board or such committee, as applicable, and shall hold office until their resignation or removal or until their successors shall be duly elected and qualified.

All members of the Committee shall qualify as "independent directors" for purposes of the listing standards of The NASDAQ Stock Market, as such standards may be changed from time to time. To the extent that the Board deems practicable and advisable, all members of the Committee shall also qualify as "non-employee directors" for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and as "outside directors" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended, as such standards and definitions may be revised or amended from time to time; provided, however, that notwithstanding anything contained herein to the contrary, if not all members of the Committee qualify as non- employee directors, any grant of equity compensation to directors and officers (as defined by Rule 16a-1(f) of the Exchange Act) shall be made by the full Board or a subcommittee of the Committee comprised of at least two members who qualify as non-employee directors.

B. Removal

The entire Committee or any individual Committee member may be removed without cause by the affirmative vote of a majority of the Board. Any Committee member may resign effective upon giving oral or written notice to the Chairman of the Board, the Secretary of the Corporation, or the Board (unless the notice specifies a later time for the effectiveness of such resignation). The Board may elect a successor to assume the available position on the Committee when the resignation becomes effective.

C. Chairperson

A chairperson of the Committee (the "Chairperson") may be designated by the Board. In the absence of such designation, the members of the Committee may designate the Chairperson by majority vote of the full Committee membership. The Chairperson shall determine the agenda for and the length of meetings and shall have unlimited access to management and to information relating to the Committee's purposes. The Chairperson shall establish such other rules as may from time to time be necessary and proper for the conduct of the business of the Committee.

D. Meetings, Minutes and Reporting

The Committee shall meet at least two times per year and at such other times as it deems necessary to carry out its responsibilities. All Committee members are expected to attend each meeting, in person or via tele- or video-conference.

The Committee shall keep full and complete minutes of the proceedings of the Committee. In addition to the specific matters set forth herein requiring reports by the Committee to the full Board, the Committee shall report such other significant matters as it deems necessary concerning its activities to the full Board. The Committee may appoint a Secretary whose duties and responsibilities shall be to keep records of the proceedings of the Committee for the purposes of reporting Committee activities to the Board and to perform all other duties as may from time to time be assigned to him or her by the Committee, or otherwise at the direction of a Committee member. The Secretary need not be a member of the Committee or a director and shall have no membership or voting rights by virtue of the position.

E. Delegation & Meetings

The Committee may, by resolution passed by a majority of the Committee members, designate one or more subcommittees, each subcommittee to consist of one or more members of the Committee. Any such subcommittee, to the extent provided in the resolutions of the Committee and to the extent not limited by applicable law, shall have and may exercise all the powers and authority of the Committee. Each subcommittee shall have such name as may be determined from time to time by resolution adopted by the Committee. Each subcommittee shall keep regular minutes of its meetings and report the same to the Committee or the Board when required.

A majority of Committee members shall constitute a quorum for the transaction of business. The action of a majority of those present at a meeting at which a quorum is attained, shall be the act of the Committee.

F. Authority to Retain Advisors

In the course of its duties, the Committee shall have the sole authority, at the Corporation's expense, to retain and terminate compensation consultants, legal counsel, or other advisors, as the Committee deems advisable, including the sole authority to approve any such advisors' fees and other retention terms.

III. DUTIES AND RESPONSIBILITIES

The following shall be recurring duties and responsibilities of the Committee in carrying out its purposes. These duties and responsibilities are set forth below as a guide to the Committee, with the understanding that the Committee may alter or supplement them as appropriate under the circumstances, to the extent permitted by applicable law.

1. Establish a compensation policy for executives designed to (i) enhance the profitability of the Corporation and increase stockholder value, (ii) reward executive officers for their contribution to the Corporation's growth and profitability, (iii) recognize individual initiative, leadership, achievement, and other contributions and (iv) provide competitive compensation that will attract and retain qualified executives.

2. Subject to variation where appropriate, the compensation policy for executive officers and other key employees shall include (i) base salary, which shall be set on an annual or other periodic basis, (ii) annual or other time or project based incentive compensation, which shall be awarded for the achievement of predetermined financial, project, research or other designated objectives of the Corporation as a whole and of the executive officers and key employees individually and (iii) long-term incentive compensation in the forms of equity participation and other awards with the goal of aligning, where appropriate, the long-term interests of executive officers and other key employees with those of the Corporation's stockholders and otherwise encouraging the achievement of superior results over an extended time period.

3. Review competitive practices and trends to determine the adequacy of the executive compensation program.

4. Review and consider participation and eligibility in the various components of the total executive compensation package.

5. Annually review and approve corporate goals and objectives relevant to CEO compensation, evaluate the CEO's performance in light of those goals and objectives, and recommend to the Board the CEO's compensation levels based on this evaluation.

6. Annually review and make recommendations to the Board with respect to compensation of directors, executive officers of the Corporation other than the CEO and key employees.

7. Approve employment contracts, severance arrangements, change in control provisions and other agreements.

8. Approve and administer cash incentives and deferred compensation plans for executives (including any modification to such plans) and oversight of performance objectives and funding for executive incentive plans.

9. Approve and oversee reimbursement policies for directors, executive officers and key employees.

10. Review matters relating to management succession, including, but not limited to, compensation.

11. Approve and oversee compensation programs involving the use of the Corporation's stock.

12. If the Corporation is required by applicable Securities and Exchange Commission ("SEC") rules to include a Compensation Discussion and Analysis ("CD&A") in its SEC filings, review the CD&A prepared by management, discuss the CD&A with management and, based on such review and discussions, recommend to the Board that the CD&A be included in the Corporation's Annual Report on Form 10-K, proxy statement, or any other applicable filing as required by the SEC.

13. Review all compensation policies and practices for all employees to determine whether such policies and practices create risks that are reasonably likely to have a material adverse effect on the Corporation.

14. Periodically review executive supplementary benefits and, as appropriate, the organization's retirement, benefit, and special compensation programs involving significant cost.

15. Form and delegate authority to subcommittees when appropriate.

16. Make regular reports to the Board.

17. Annually review and reassess the adequacy of this Charter and recommend any proposed changes to the Board for approval.

18. Annually evaluate its own performance.

19. Oversee the annual process of performance evaluations of the Corporation's management.

20. Fulfill such other duties and responsibilities as may be assigned to the Committee, from time to time, by the Board and/or the Chairman of the Board.