Orgenesis Inc.
Form 10-K
February 19, 2015

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, 2014**

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.)

21 Sparrow Circle, White Plains, NY 10605
(Address of principal executive offices) (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of each exchange on which registered
None	**N/A**

Securities registered pursuant to section 12(g) of the Act:

Shares of common stock with a par value of $0.0001
(Title of class)

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. [X]

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 [ ]	
(Do not check if a smaller reporting company)	Smaller reporting company **[X]**

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes **[ ]** No [**X**]

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter.

As of May 31, 2014, being the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was approximately $15,813,210, based on the average bid and asked price for the registrant s common stock on the OTCQB on May 31, 2014 of $0.50 per share.

APPLICABLE ONLY TO CORPORATE REGISTRANTS

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date: **55,970,565 shares of common stock as of February 19, 2015.**

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) any annual report to security holders; (2) any proxy or information statement; and (3) any prospectus filed pursuant to Rule 424(b) or (c) of the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980). **Not Applicable**

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PART I

ITEM 1. BUSINESS

Forward-Looking Statements

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may , should , expects , plans , anticipates , believes , estimates , predicts , potential negative of these terms or other comparable terminology. Forward-looking statements made in an annual report on Form 10-K includes statements about:

- our plans to identify and acquire products that we believe will be prospective for acquisition and development;
- our intention to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- our belief that our treatment seems to be safer than other options;
- our belief that our major competitive advantage is in our cell transformation technology;
- our marketing plan;
- our plans to hire industry experts and expand our management team;
- 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 beliefs regarding the future of our competitors;
- our expectation that the demand for our products will eventually increase; and
- our expectation that we will be able to raise capital when we need it.

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, 2014, 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 include, by way of example and not in limitation:

- general economic and business conditions;
- substantial doubt about our ability to continue as a going concern;
- our needs to raise additional funds in the future which may not be available on acceptable terms or at all;
- our inability to successfully recruit and retain qualified personnel in order to continue our operations;
- our ability to successfully implement our business plan;
- conditions in Israel and the surrounding Middle East which may materially adversely affect our Israeli Subsidiary s operations and personnel;
- the ability of our Israeli Subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by our Israeli Subsidiary may be subject to taxes;
- any probability that Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (THM) may cancel the License Agreement;
- if we are unable to successfully acquire, develop or commercialize new products;
- our expenditures not resulting in commercially successful products;
- third parties claiming that we may be infringing their proprietary rights that may prevent us from manufacturing and selling some of our products;
- the impact of 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
- other factors discussed under the section entitled Risk Factors set forth in this Annual Report on Form 10-K for the year ended November 30, 2014.

These risks may cause our company s or our 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. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

As used in this Annual Report on Form 10-K and unless otherwise indicated, the terms we , us , our , or the Compa refer to Orgenesis Inc. and our wholly-owned Subsidiaries, Orgenesis Ltd. (the Israeli Subsidiary), Orgenesis SPRL (the Belgian Subsidiary), and Orgenesis Maryland, Inc. (the U.S. Subsidiary). Unless otherwise specified, all dollar amounts are expressed in United States dollars.

Corporate Overview

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 Orgenesis Inc., a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we changed our name from Business Outsourcing Services, Inc. to Orgenesis Inc.

Effective August 31, 2011, we implemented a 35 to 1 forward stock split of our authorized and issued and outstanding common stock. As a result, our authorized capital has increased from 50,000,000 shares of common stock with a par value of $0.0001 to 1,750,000,000 shares of common stock with a par value of $0.0001. On February 27, 2012, we filed a Certificate of Correction with the Secretary of State of the State of Nevada, correcting the par value of 1,750,000,000 shares of common stock that was incorrectly stated as $0.001 to 1,750,000,000 shares of common stock with a par value of $0.0001. Unless otherwise noted, all references in this quarterly report to number of shares, price per share or weighted average number of shares outstanding have been adjusted to reflect the stock split on a retroactive basis.

Our Current Business

We are developing a technology that we are bringing to the clinical stage 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.

On August 5, 2011, we entered into a letter of intent with Prof. Sarah Ferber and Ms. Vered Caplan according to which, inter alia, Prof. Ferber has agreed to use commercially reasonable efforts to cause THM to license us all of the assets associated with Methods Of Inducing Regulated Pancreatic Hormone Production and Methods of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues .

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned Israeli Subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license patents and knowhow related to the development of autologous insulin producing (AIP) cells. Based on the licensed knowhow and patents, our intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using therapeutic agent (i.e., PDX-1, and additional pancreatic transcription factors in an adenovirus-vector) that efficiently converts 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. The development of AIP cells is based on the licensed patents and knowhow of THM and Prof. Ferber. We believe that our major competitive advantage is in our cell transformation technology.

This technology was licensed based on the published work of Prof. Ferber who has developed this technology, as a researcher in THM, and has established a proof of concept 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. Furthermore, those cells were found to be resistant to the autoimmune attack and to produce insulin in a glucose-sensitive manner.

We intend to grow our business by further developing the technology to a clinical stage. We intend to dedicate most of our capital to research and development with no expectation of revenue from product sales in the foreseeable future.

The License Agreement

On February 2, 2012, our Israeli Subsidiary entered into a licensing agreement with Tel Hashomer - Medical Research, Infrastructure and Services Ltd (the Licensor). According to the agreement, the 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).

As consideration for the licensed information, the Israeli Subsidiary will pay the following to the Licensor:

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 shall be paid 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; and
d) $750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA.
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, 2014, we have 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 Licensor shall be entitled to choose whether to receive from the Company a one-time payment based, as applicable, on the value of either 5,563,809 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.

If the Licensor chooses not to receive any consideration as a result of an Exit, Licensor shall be entitled 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 the Licensor to perform all of our obligations pursuant to the License Agreement. If the Licensor chooses to receive the consideration as a result of an Exit, the royalty payments will cease.

We agreed to submit to the Licensor 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 (a Development Plan), within 18 months from the date of the License Agreement. We must develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the Development Plan. In the event we fail to fulfill the terms of the Development Plan, the Licensor shall be entitled to terminate the License Agreement with a one-year prior written notice, provided that during such year we do not cure the breach of the Development Plan. We submitted the Development Plan in May 2014.

Without derogating from the Licensor s rights under any applicable law, the Licensor shall be entitled to terminate the License Agreement in each of the following events:

We materially change our business.

We breach any of our material obligations under the License Agreement, provided that the Licensor has provided us with written notice of such material breach and the Licensor s intention to terminate, and we have not cured such breach within 180 days of receiving such written notice from the Licensor. Our failure to comply with sections relating to the following are deemed to be a material breach of the License Agreement:

- granting of sublicenses;
- confidentiality provisions;
- performance of payments to the Licensor; or
- indemnity and insurance.

We breach any of our obligations thereunder other than material breaches, and such breach remains uncured for 200 days after written notice from the Licensor.

We become insolvent; file a petition or have a petition filed against us, under any laws relating to insolvency; enter into any voluntary arrangement for the benefit of our creditors; or appoint or have appointed on our behalf a receiver, liquidator or trustee of any of our property or assets, under any laws relating to insolvency; and such petition, arrangement or appointment is not dismissed or vacated within 90 days.

We have ceased to carry on our business for a period of more than 60 days.

We have challenged, challenge, or cause any third party to challenge, the intellectual property rights or other rights of the Licensor to the licensed information anywhere in the world.

We may terminate the License Agreement and return the licensed information to the Licensor only in the following events:

- the development and/or manufacture of the licensed information is not successful according to the scientific criteria acceptable in the relevant field of the invention;
- if the registration and/or defense of a patent is not successful, in any country for reasons not dependent upon us;
- the development and/or manufacture of the licensed information is not approved by the proper regulation procedures as mandated under the relevant laws for reasons not dependent upon us; or
- an external specialist in the field of the product(s) determined in a reasoned and explained written opinion that there is insufficient market demand for the products and such written opinion was provided to the Licensor.

On March 22, 2012, the Israeli Subsidiary entered into a research service agreement with the Licensor. According to the agreement, the Licensor will perform a study at the facilities and use the equipment and personnel of the Chaim Sheba Medical Center (the Hospital), for the consideration of approximately $74,000 for a year. On May 1, 2013, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately $92,000, and on May 4, 2014, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately $114,000.

Development

Our goal is to advance a unique product that combines cell-based therapy and regenerative medicine, Autologous Insulin Producing (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 Type 1 Diabetes patients with long-term insulin independence. 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 central

facility 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.

Marketing

Our intention is to market and sell AIP cellular therapy as a stand-alone product, and to provide supporting education and services to treating 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 the NA, EU and Asian regions.

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. Currently, leading companies in this field include Novo Nordisk, Takeda Pharmaceutical, Eli Lilly, GlaxoSmithKline, Sanofi Aventis and Merck. We would anticipate initiation of such collaborations upon successful completion of Phase 1 clinical trials, and to be inclusive of:

- Upfront payments
- Co-development funding
- Milestone payments
- Royalties upon sales

Future Products

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).

Market

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). I n T1D, the onset of the disease follows an autoimmune attack of -cells that severely reduces -cell mass. T1D usually has an early onset and is sometimes also called juvenile diabetes. In T2D, the pathogenesis involves insulin resistance, insulin deficiency and enhanced gluconeogenesis, while late progression stages eventually leads to -cell failure and a significant reduction in -cell function and mass. T2D often occurs later in life and is sometimes called adult onset diabetes. Both T1D and late-stage T2D result in marked hypoinsulinemia, reduction in -cell function and mass and lead to severe secondary complications, such as myocardial infarcts, limb amputations, neuropathies and nephropathies and even death. In both cases, patients become insulin-dependent, requiring either multiple insulin injections per day or reliance on an insulin pump.

We believe that diabetes will be one of the most challenging health problems in the 21st century, and will have a staggering health, societal, and economic impact. Diabetes is currently the fourth or fifth leading cause of death in most developed countries. There also is substantial evidence that it is an epidemic in many developing and newly industrialized nations.

Competition

Insulin therapy is used for Insulin-Dependent Diabetes Mellitus (IDDM) patients who are not controlled with oral medications, but 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.

Threats from Pancreas Islet Transplantation and Cell Therapies

Transplant procedure

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. Physicians 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 called the Edmonton protocol are now widely used instead.

Studies and reports

Since reporting their findings in the June 2000 issue of the *New England Journal of Medicine*, researchers at the University of Alberta in Edmonton, Canada, have continued to use and refine a procedure called the Edmonton protocol to transplant pancreatic islets into selected patients with type 1 diabetes that is difficult to control.

In 2005, the researchers published 5-year follow-up results for 65 patients who received transplants at their center and reported that about 10 percent of the patients remained free of the need for insulin injections at 5-year follow-up. Most recipients returned to using insulin because the transplanted islets lost their ability to function over time, potentially due to the immune suppression protocol, which prevents the immune rejection of the implanted cells. The researchers noted, however, that many transplant recipients were able to reduce their need for insulin, achieve better glucose stability, and reduce problems with hypoglycemia, also called low blood sugar level.

In its 2006 annual report, the Collaborative Islet Transplant Registry, which is funded by the National Institute of Diabetes and Digestive and Kidney Diseases, presented data from 23 islet transplant programs on 225 patients who received islet transplants between 1999 and 2005. According to the report, nearly two-thirds of recipients achieved "insulin independence"—defined as being able to stop insulin injections for at least 14 days—during the year following transplantation. However, other data from the report showed that insulin independence is difficult to maintain over time. Six months after their last infusion of islets, more than half of recipients were free of the need for insulin injections, but at 2-year follow-up, the proportion dropped to about one-third of recipients. The report described other benefits of islet transplantation, including reduced need for insulin among recipients who still needed insulin, improved blood glucose control, and greatly reduced risk of episodes of severe hypoglycemia.

In a 2006 report of the Immune Tolerance Network's international islet transplantation study, researchers emphasized the value of transplantation in reversing a condition known as hypoglycemia unawareness. People with hypoglycemia unawareness are vulnerable to dangerous episodes of severe hypoglycemia because they are not able to recognize that

their blood glucose levels are too low. The study showed that even partial islet function after transplant can eliminate hypoglycemia unawareness.

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.

Human Embryonic Stem Cells (ESC)

The use of ESC is still in its preliminary research stage and there are ethical and legal issues involved in the use of such cells. Many issues concerning cancerous tumor risks have not been resolved.

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. 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.

Research and Development Expenditures

We incurred $1,549,450 in research and development expenditures in the last fiscal year ended November 30, 2014. We intend to dedicate most of our capital to research and development with no expectation of revenue from product sales in the foreseeable future.

Employees

As of November 30, 2014, we had 1 full time employee and 6 part time employees. We intend to hire additional staff and to engage consultants in general administration. We also intend to engage experts in healthcare and in general business to advise us in various capacities.

Subsidiaries

On October 11, 2011, the Company incorporated a wholly-owned subsidiary in Israel, Orgenesis Ltd. (the “Israeli Subsidiary”), which is engaged in research and development. On February 2, 2012, the Israeli Subsidiary entered into an agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the “Licensor”). The Israeli Subsidiary was granted a worldwide, royalty-bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

On July 31, 2013, the Company incorporated a wholly-owned subsidiary in Maryland, Orgenesis Maryland Inc. (the “U.S. Subsidiary”), which was formed as the U.S. center for research and development and manufacturing scale-up for

our technology. The U.S. Subsidiary received a grant from TEDCO which is being used for pre-clinical research and will oversee initiation and conduct of our Phase 1 clinical trial program.

On October 11, 2013, Orgenesis Ltd. incorporated a wholly-owned subsidiary in Belgium, Orgenesis SPRL (the "Belgian Subsidiary"), which will be engaged in development and manufacturing activities together with clinical development studies in Europe, and later on to be the Company s center for our activities in Europe. The Belgian Subsidiary has not commenced operations yet. The incorporation of Orgenesis SPRL followed a strategic decision in May 2013 to work with Pall Life Science Belgium BVBA (formerly ATMI BVBA), a Belgian Company, to supply disposable bioreactors as the major component in our product manufacturing. Also, we made another strategic decision in September 2013 to work with Masthercell SPRL, a Belgium company, as our CMO (Contract Manufacturing Organization) in order to develop a manufacturing process and to manufacture our product. Both companies are located in Belgium.

Intellectual Property

We have licensed the intellectual property rights related to AIP cells as follows:

Title	Country	Status	Application No.	Application Date	Patent Number	Issue Date
Cell Populations, Methods of Transdifferention and Methods of Use Thereof	Patent Cooperation Treaty	Published	PCT/IB2014/ 002164	June 13, 2014		
Methods of Transdifferention and Methods of Use Thereof	United States of America	Pending	62/098,050	December 30, 2014		
Methods of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	United States of America	Granted	09/584,216	May 31, 2000	6,774,120	August 10, 2004
Methods of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	United States of America	Pending	13/339,958	December 29, 2011		
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	United States of America	Pending	14/330,965	July 14, 2014		
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	United States of America	Granted	10/852,994	May 24, 2004	8,119,405	February 21, 2012

Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Australia	Granted	50974/00	June 1, 2000	779,619	June 9, 2005

Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Canada	Granted	2,371,995	June 1, 2000	2,371,995	January 21, 2014
In Vitro Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues, Pharmaceutical Compositions Related Thereto	Germany	Granted	00935435.8	June 1, 2000	60034781.8-08	May 9, 2007
In Vitro Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues, Pharmaceutical Compositions Related Thereto	European Patent Office	Granted	00935435.8	June 1, 2000	1180143	May 9, 2007
In Vitro Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues, Pharmaceutical	France	Granted	00935435.8	June 1, 2000	1180143	May 9, 2007

Compositions Related Thereto In Vitro Methods of						
Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues, Pharmaceutical Compositions Related Thereto	United Kingdom	Granted	00935435.8	June 1, 2000	1180143	May 9, 2007
In Vitro Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues, Pharmaceutical Compositions Related Thereto	Italy	Granted	00935435.8	June 1, 2000	29390BE/2007	May 9, 2007
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Australia	Granted	2004236573	May 12, 2004	2004236573	February 4, 2010
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet	United States of America	Granted	10/843,801	May 12, 2004	8,778,899	July 15, 2014

Tissues						

Government Regulations

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.

Within the last decade, many studies published in leading scientific journal confirmed the capacity of reprogramming adult cells from many of our mature organs to either alternate organs or to stem like cells . The most widely used autologous cell replacement protocol is the one 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: 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*. 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 begin;
- Obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce the 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, or cGMP regulations and standards;
- Submission to FDA of a Biologics License Application, or 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.

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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 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).

Clinical trials

Typically, both in the U.S. and the European Union, 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 and 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.

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

There is substantial doubt about our ability to continue as a going concern.

We have not generated any revenue from operations since our inception. We expect that our operating expenses will increase over the next twelve months to continue our development activities. We estimate our average monthly expenses over the next twelve months to be approximately $491,000, including general and administrative expenses

and research and development. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As of the date of this filing, we had cash and cash equivalents of approximately $485,284. We do not expect to raise capital through debt financing from traditional lending sources since we are not currently producing revenue and cannot assure a lender that we will be able to successfully achieve commercial revenues from the development of our technology. Therefore, we only expect to raise money through equity financing via the sale of our common stock. If we cannot raise the money that we need in order to continue to operate our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail. If we are unsuccessful in raising additional financing, we may need to curtail, discontinue or cease operations.

During 2014, we have received certain grant funding and have relied and expect to continue to rely on such funding to further our clinical development in the future.

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. Under the agreement, TEDCO has agreed to give us an amount not to exceed $406,431 to 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 July 22, 2014, our U.S. Subsidiary received an advance payment of $203,215 on account of the grant. Through November 30, 2014, an amount of $118,305 out of the $203,215 was spent.

On November 17, 2014, our Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a €2.015 million support program for the research and development of a potential cure for Type 1 Diabetes. The Financial support is composed of a 1,085,000 Euros (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of 930,000 Euros (60% of budgeted costs) of the experimental development part of the research program. The grants will be paid to us over a period of approximately 3 years. The grants are subject to certain conditions with respect to our work in the Walloon Region, our own investment in these projects and certain other conditions. On December 9 and 16, 2014, we received €651,000 and €558,000 under the grant, respectively, to have relied on grant funding in 2014 may need to raise additional funds in the future that may not be available on acceptable terms or at all.

On December 21, 2014, we received a notification from the Israel-U.S. Binational Industrial Research and Development Foundation ("BIRD") that our Israeli Subsidiary, and our research and development partner, have been approved by BIRD's Board of Governors for a conditional grant of $800,000 for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the "Project"). A Cooperation and Project Funding Agreement (CPFA) must be signed for the Project with the BIRD Foundation within three months, or by March 31, 2015. Up to the date of this report, we have not received these funds and may be unable to obtain these funds if we are not able to provide sufficient information to BIRD or if our CPFA is not accepted by such date.

We may need to raise additional funds in the future that may not be available on acceptable terms or at all.

We may consider issuing additional debt or equity securities in the future to fund clinical trials, for potential acquisitions or investments, to refinance existing debt, or for general corporate purposes. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. We may not be able to obtain financing on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities or respond to competitive pressures.

We are an early-stage company with a limited operating history, which may hinder our ability to successfully meet our objectives.

We are an early-stage company with only a limited operating history upon which to base an evaluation of our current business and future prospects. As a result, the revenue and income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business. Errors may be made in predicting and reacting to relevant business trends, and we will be subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our

business, results of operations and financial condition to suffer.

Because some of our directors and officers are not residents of the United States, investors may find it difficult to enforce, within the United States, any judgments obtained against some of our directors and officers.

Some of our directors and officers are not residents of the United States, and all or a substantial portion of their assets is located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against some of our directors and officers, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof.

If we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operations.

In order to successfully implement and manage our business plan, we will depend upon, among other things, successfully recruiting and retaining qualified personnel having experience in the pharmaceutical industry. Competition for qualified individuals is intense. We may not be able to find, attract and retain qualified personnel on acceptable terms. If we are unable to find, attract and retain qualified personnel with technical expertise, our business operations could suffer.

Future growth could strain our resources, and if we are unable to manage our growth, we may not be able to successfully implement our business plan.

We hope to experience rapid growth in our operations, which will place a significant strain on our management, administrative, operational and financial infrastructure. Our future success will depend in part upon the ability of our executive officers to manage growth effectively. This will require that we hire and train additional personnel to manage our expanding operations. In addition, we must continue to improve our operational, financial and management controls and our reporting systems and procedures. If we fail to successfully manage our growth, we may be unable to execute upon our business plan.

Risks Relating to our Operations in Israel

Conditions in Israel and the surrounding Middle East may materially adversely affect our Subsidiaries' operations and personnel.

Our Israeli Subsidiary has significant operations in Israel, including research and development. Since the establishment of the State of Israel in 1948, a number of armed conflicts and terrorist acts have taken place, which in the past, and may in the future, lead to security and economic problems for Israel. In addition, certain countries in the Middle East adjacent to Israel, including Egypt and Syria, recently experienced, and some continue to experience, political unrest and instability marked by civil demonstrations and violence, which in some cases resulted in the replacement of governments and regimes. Current and future conflicts and political, economic and/or military conditions in Israel and the Middle East region may affect our operations in Israel. The exacerbation of violence within Israel or the outbreak of violent conflicts involving Israel may impede our Israeli Subsidiary's ability to engage in research and development, or otherwise adversely affect its business or operations. In addition, our Israeli Subsidiary's employees in Israel may be required to perform annual mandatory military service and are subject to being called to active duty at any time under emergency circumstances. The absence of these employees may have an adverse effect on our Israeli Subsidiary's operations. Hostilities involving Israel may also result in the interruption or curtailment of trade between Israel and its trading partners, which could materially adversely affect our results of operations.

The ability of our Israeli Subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by our Israeli Subsidiary may be subject to taxes.

The ability of our Israeli Subsidiary to pay dividends is governed by Israeli law, which provides that dividends may be paid by an Israeli corporation only out of its earnings as defined in accordance with the Israeli Companies Law of 1999, provided that there is no reasonable concern that such payment will cause our Israeli Subsidiary to fail to meet its current and expected liabilities as they come due. Cash dividends paid by our Israeli Subsidiary to our company may result in our Israeli Subsidiary having to pay taxes on any dividends it declares.

Risks Relating to the Biopharmaceutical Business

Our Licensor may cancel the License Agreement.

Pursuant to the terms of the License Agreement with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. ("THM"), we must develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the Development Plan. In the event we fail to fulfill the terms of the Development Plan, THM shall be entitled to terminate the License Agreement by providing us with written notice of such a breach and if we do not cure such breach within one year of receiving the notice. If THM cancels the License Agreement, our business may be materially adversely affected. THM may also terminate the License Agreement if we breach an obligation contained in the License Agreement and do not cure it within 180 days of receiving notice of the breach.

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 expenditures may not result in commercially successful products.

We cannot be sure our business expenditures will result in the successful acquisition, development or launch of product that will prove to be commercially successful or will improve the long-term profitability of our business. If such business expenditures do not result in the successful acquisition, development or launch of a commercially successful line of products, our results of operations and financial condition could be materially adversely affected.

Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our future products.

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. In addition, if we infringe on the rights of others, we could lose our right to develop, manufacture or market products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on commercially reasonable terms, or at all. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our future products, and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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 ("EMEA") will regulate our future products. Regulatory approval by the EMEA 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.

We have never generated any revenue from 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 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 Type 1 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 Type 1 Diabetes. Based on licensed knowhow 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 Type 1 Diabetes, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA 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; and
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance;

When we are able to 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 the first half of 2015. 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;
- 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; as 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; or 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 beyond the net proceeds of this offering 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 or our third-party manufacturers 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, 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 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 our manufacturing strategy will involve the use of one or more CMOs as well as establishing our own capabilities and infrastructure, including a manufacturing facility. We expect that development of our own manufacturing facility 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. However, we have no experience as a company in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. 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 or our CMOs 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 CMOs 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.

We expect to rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture supplies and process our product candidates, which is and will need to be done on a patient-by-patient basis. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

On July 3, 2014, our Belgian Subsidiary entered into a service agreement with MaSTherCell, pursuant to which MaSTherCell will function as our CMO and conduct certain clinical tests related to diabetes treatment research. The term of the service agreement will run until all work is completed (or by either party providing 30 days' written notice of termination) in order to develop a manufacturing process and to manufacture our product. While we anticipate that MaSTherCell will be able to sufficiently support our needs as a CMO, we may need to find other CMOs to meet our clinical and manufacturing needs, of which there are a limited number of third-party manufacturers. This exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any manufacturers. This approval would require new testing and good manufacturing practices compliance inspections by FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;
- Other manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- Our third-party manufacturers might be unable to timely manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- Our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our products, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products;
- Our third-party manufacturers could breach or terminate their agreement with us;
- Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- Our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; or
- Our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

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.

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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, 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 cGMP 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, 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 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 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 in particular, 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 management, particularly our chief science officer, Prof. Sarah Ferber, our chief executive officer, Vered Caplan and the chief executive officer of our U.S. Subsidiary, Scott Carmer. 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, 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.

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, 2014, we had 1 full-time employee and 6 part time employees. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. Our efforts to manage our growth are complicated by the fact that all of our executive officers other than our chief executive officer have joined us since August 2014. 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 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 and 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.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. As more fully described in the section "Subsequent Events" in the footnotes to our financial statements, on November 6, 2014, we entered into a share exchange agreement with MaSTherCell SA and Cell Therapy Holding SA (collectively "MaSTherCell") and each of the shareholders of MaSTherCell, which provides for the acquisition by our company of all of the issued and outstanding shares of MaSTherCell from the shareholders of MaSTherCell in exchange for the issuance of $24,593,000 in value of shares of common stock in the capital of our company. MasTHerCell SA and Cell Therapy Holding SA are private limited liability companies incorporated in Belgium. MaSTherCell is a technology-driven, customer-oriented Contract Development and Manufacturing Organization (CDMO) specialized in cell therapy development for advanced medicinal products. MaSTherCell's mission is to help customers bring highly potent cell therapy products faster to the market. As of the date of this filing, the share exchange agreement has not closed yet. Any other potential acquisitions or strategic partnerships may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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 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.

Risks Relating 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 authorize the issuance of up to 1,750,000,000 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.

Trading of our stock is restricted by the Securities Exchange Commission's penny stock regulations, which may limit a stockholder's ability to buy and sell our common stock.

The Securities and Exchange Commission has adopted regulations which generally define "penny stock" to be any equity security that has a market price (as defined) less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors". The term "accredited investor" refers generally to institutions with assets in excess of $5,000,000 or individuals with a net worth in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 jointly with their spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the Securities and Exchange Commission, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock.

FINRA sales practice requirements may also limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, the Financial Industry Regulatory Authority ("FINRA") has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information

about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our stock.

Our common stock is illiquid and the price of our common stock may be negatively impacted by factors that are unrelated to our operations.

Although our common stock is currently listed for quotation on the QB, there is no market for our common stock. Even when a market is established and trading begins, trading through the OTCQB is frequently thin and highly volatile. There is no assurance that a sufficient market will develop in our stock, in which case it could be difficult for stockholders to sell their stock. The market price of our common stock could fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of our competitors, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. In addition, the stock market is subject to extreme price and volume fluctuations. 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.

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. 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

Executive Offices and Registered Agent

Our principal offices are located at 21 Sparrow Circle, White Plains, New York, 10605, where we pay $300 per month on a month-to-month contract. We also occupy virtual office space at the Germantown Innovation Center located at 20271 Goldenrod Lane, Germantown, Maryland 20876, where we pay $200 per month on a month-to-month contract. Once we attain the necessary funding, increase our employee base, and establish the protocol for our manufacturing facilities here in the U.S., we will look for more suitable facilities to meet our growing needs. We believe that our current arrangement will be suitable until such time that these factors take place.

Our registered agent is Business Filing Incorporated located at 311 S. Division Street, Carson City, Nevada, 89703.

Intellectual Property

The description of our intellectual property is in Item 1. Business under the section entitled "Intellectual Property".

ITEM 3. LEGAL PROCEEDINGS

We face a potential claim by a former employee regarding termination of employment payments. No claims have been filed and the Company believes that we would not be liable for any amounts to this former employee. Other than this issue, we know of no material pending legal proceedings to which our company or our Subsidiaries is a party or of which any of our properties, or the properties of our Subsidiaries, is the subject. In addition, we do not know of any such proceedings contemplated by any governmental authorities.

We know of no material proceedings in which any of our directors, officers or affiliates, or any registered or beneficial stockholder is a party adverse to our company or our Subsidiaries or has a material interest adverse to our company or

our Subsidiaries.

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 is quoted on the OTCQB under the symbol ORGS . Set forth below are the range of high and low bid quotations for the period indicated as reported by the OTC Markets Group (www.otcmarkets.com). The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

Quarter Ended	Bid High	Bid Low
November 30, 2014	$ 0.90	$ 0.46
August 31, 2014	$ 1.00	$ 0.34
May 31, 2014	$ 0.78	$ 0.44
February 28, 2014	$ 0.80	$ 0.41
November 30, 2013	$ 0.70	$ 0.70
August 31, 2013	$ 0.95	$ 0.56
May 31, 2013	$ 1.20	$ 0.63
February 28, 2013	$ 0.80	$ 0.35
November 30, 2012	$ 1.01	$ 0.47
August 31, 2012	$ 1.05	$ 0.31
May 31, 2012	$ 1.66	$ 0.69
February 29, 2012	$ 0.70	$ 0.13
November 30, 2011(1)	$ 0.30	$ 0.01
August 31, 2011(1)	$ 6.00	$ 0.55
May 31, 2011(1)	$ 1.25	$ 1.25
February 28, 2011(1)	$ 0.56	$ 0.17

(1) After taking into account a 35:1 stock split.

Transfer Agent

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

Holders of Common Stock

As of February 19, 2015, there were 29 shareholders of record of our common stock. As of such date, 55,970,565 shares were issued and outstanding.

Registration Rights

On May 6, 2013, we entered into a subscription agreement with Pall Life Science Belgium BVBA (formerly ATMI BVBA) ("Pall"), pursuant to which Pall purchased 1,526,718 units of our securities at a price of $0.8515 per unit for total consideration of $1,300,000. Each unit consists of one share of our common stock and one common share purchase warrant. Each warrant may be exercised pursuant to the terms of the warrant certificate for a period of two years from issuance at an exercise price of $1.00, subject to adjustments as set out in the warrant certificate. In connection with the subscription agreement, we also entered into a registration rights agreement dated May 6, 2013, whereby we agree to provide notice to Pall that we will register their shares if we file a registration statement with the Securities and Exchange.

On December 13, 2013, we entered into an investment agreement (the "Investment Agreement") with Kodiak. Although we are not mandated to sell shares under the Investment Agreement, the Investment Agreement gives us the option to sell to Kodiak, up to $3,000,000 worth of our common stock over a twelve-month period. The $3,000,000 was stated as the total amount of available funding in the Investment Agreement because this was the maximum amount that Kodiak agreed to offer us in funding. There is no assurance that the market price of our common stock will remain at its current price or increase substantially in the future. The number of common shares that remains issuable may not be sufficient, dependent upon the share price, to allow us to access the full amount contemplated under the Investment Agreement. Therefore, we may not have access to the remaining commitment under Investment Agreement unless the market price of our common stock remains at its current price or increases from its current level. On January 7, 2014, we filed a registration statement for 8,000,000 shares issuable pursuant to the Investment Agreement.

On March 28, 2014 and on June 11, 2014, we filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall ; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represented 14% of the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to increase our working capital and do not anticipate paying any cash dividends in the foreseeable future.

In the event that we obtain authorization to issue any preferred stock and issue such stock, we must not declare, pay or set apart for payment any dividend or other distribution (unless payable solely in shares of our common stock or other class of stock junior to our preferred stock as to dividends or upon liquidation) in respect of our common stock, nor must we redeem, purchase or otherwise acquire for consideration shares of any of the foregoing, unless dividends, if any, payable to holders of our preferred stock for the current period (and in the case of cumulative dividends, if any, payable to holders of our preferred stock for the current period and in the case of cumulative dividends, if any, for all past periods) have been paid, are being paid or have been set aside for payment, in accordance with the terms of our preferred stock, as fixed by our board of directors.

Other than as stated above, there are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. The Nevada Revised Statutes, however, do prohibit us from declaring dividends where, after

giving effect to the distribution of the dividend:

- we would not be able to pay our debts as they become due in the usual course of business; or
- our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

Recent Sales of Unregistered Securities

In December 2012, the Company entered into a subscription agreement with Derby for the issuance of 500,000 units for a total consideration of $500,000. Each unit is comprised of one share of the Company's common stock and two non-transferrable warrants. In connection with this agreement, the 1,000,000 warrants issued to Derby were expired on November 30, 2014.

In May 2013, the Company entered into a subscription agreement with Pall, pursuant to which Pall purchased 1,526,718 units at a price of $0.8515 per unit for total consideration of $1,300,000. Each unit consisted of one share of the Company's common stock and one warrant. On March 28, 2014, on June 11, 2014 and on July 31, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC, covering the shares under the subscription agreement, which allows Pall to sell the shares (including shares that will be issued to Pall as a result of the exercise of the warrants).

On December 13, 2013, the Company entered into a $3,000,000 common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beach-based institutional investor ("Kodiak"). The purchase agreement is conditioned, among other things, by filing a registration statement with the SEC covering the shares that may be issued to Kodiak under the terms of the common stock purchase agreement. After the SEC has declared the registration statement related to the transaction effective (March 18, 2014; See below), the Company has the right at its sole discretion over a period of one year to sell shares of common stock under the terms set forth in the agreement in the total amount of up to $3,000,000. Proceeds from this transaction will be used to fund research and development and working capital. Pursuant to the common stock purchase agreement, the Company issued to Kodiak 250,000 shares of common stock of the Company at no consideration. The Company valued the shares at their fair value of $135,000 and recorded the charge as financing cost. The Company's ability to put shares to Kodiak and obtain funds under the equity line is limited by the terms and conditions in the common stock purchase agreement, including restrictions on when the Company may exercise its put rights, restrictions on the amount the Company may put to Kodiak at any one time, which is determined in part by the trading volume of the Company's common stock, and a limitation on its ability to put shares to Kodiak.

During the first quarter of 2014, the Company issued 1,128,849 units in a non-brokered private placement for total consideration of $587,001. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years. In July 2014, 96,154 warrants were exercised.

During 2014, the Company issued 836,538 units at a purchase price of $0.52 to investors in non-brokered private placements for a total consideration of $385,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years.

During 2014, the Company entered into a debt settlement agreement with two creditors, whereby it settled a debt in the amount of $37,406 by the issuance of 71,934 share of its common stock at a price per share of $0.52.

On March 28, 2014 and on June 11, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 (See Note 4b(4) above) and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall ; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of

the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of November 30, 2014:

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	Nil	Nil	Nil
Equity compensation plans not approved by security holders	18,013,818	0.33	Nil
Total	18,013,818	0.33	Nil

Effective May 23, 2012, our board of directors adopted and approved the Global Share Incentive Plan (2012) (the Plan). The purpose of the Plan is to enhance the long-term stockholder value of our company by offering opportunities to our directors, officers, key employees, independent contractors and consultants to acquire and maintain stock ownership in our company in order to give these persons the opportunity to participate in our company s growth and success, and to encourage them to remain in the service of our company. A total of 12,000,000 shares of our common stock are available for issuance under the Plan. As of February 19, 2015, the Plan has not been approved by our shareholders.

On December 23, 2012, the Company appointed Mr. Sav DiPasquale as the Company s President and Chief Executive Officer. As part of his compensation he was to receive stock options at an exercise price of $0.001 per share upon the performance as follows: (i) 982,358 performance shares to be issued upon the completion of a fundraising and (ii) 1,473,537 stock options to be issued as to 25% on each of the first, second, third and fourth anniversaries of the date of his employment agreement. On October 23, 2013, 255,413 performance options were granted to Mr. Dipasqale based on section (i) as mentioned above, the fair value of these options as of the date of grant was $165,850. On December 23, 2013, Mr. DiPasquale, resigned, as of this date 368,393 out of 1,473,537 were vested, the fair value of these options as of the date of grant was $217,347. According to Mr. DiPasquale s employment agreement, all vested options expire 90 days after the date of termination of employment. On February 16, 2014, Mr. DiPasquale exercised 623,806 options at a price of $0.001 per share.

On July 16, 2013, 250,000 options were granted to Dr. David Sidransky, a member of our board of directors, at an exercise price of $0.75 per share. The options vest in five equal annual installments from the date of grant and expire on July 16, 2023.

On August 1, 2014, the Company granted an aggregate of 200,000 stock options to an employee that are exercisable at $0.50 per share, with 50,000 vesting quarterly over one year. The fair value of these options as of the date of grant was $80,531 using the Black and Scholes option-valuation model. In addition, the Company granted an aggregate of 200,000 stock options to an employee that are exercisable at $0.50 per share, with 25,000 vesting quarterly over two years.

On August 22, 2014, the Company approved an aggregate of 2,762,250 stock options to the Company s Chief Executive Officer that are exercisable at $0.0001 per share. Out of the total approved, 414,304 options vested immediately and 1,242,996 options will vest quarterly over 4 years. The rest of the options were not granted yet.

On August 1, 2014, the Company granted an aggregate of 650,000 stock options to an employee that is exercisable at $0.50 per share, with 40,625 vesting quarterly over four years.

In December 2014, the Company granted an aggregate of 1,641,300 stock options to the Company s Chief Executive Officer of the U.S. Subsidiary that is exercisable at $.001 per share. The grant and its associated fair value will record in fiscal first quarter 2015.

Issuer Purchases of Equity Securities

During the fiscal year ended November 30, 2014, we did not purchase any of our equity securities.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Notice Regarding Forward Looking Statements

The information contained in Item 7 contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results may materially differ from those projected in the forward-looking statements as a result of certain risks and uncertainties set forth in this report. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual results will not be different from expectations expressed in this report.

We desire to take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This filing contains a number of forward-looking statements that reflect management s current views and expectations with respect to our business, strategies, products, future results and events, and financial performance. All statements made in this filing other than statements of historical fact, including statements addressing operating performance, clinical developments which management expects or anticipates will or may occur in the future, including statements related to our technology, market expectations, future revenues, financing alternatives, statements expressing general optimism about future operating results, and non-historical information, are forward looking statements. In particular, the words believe, expect, intend, anticipate, estimate, may, variations of such words, and similar expression forward-looking statements, but are not the exclusive means of identifying such statements, and their absence does not mean that the statement is not forward-looking. These forward-looking statements are subject to certain risks and uncertainties, including those discussed below. Our actual results, performance or achievements could differ materially from historical results as well as those expressed in, anticipated, or implied by these forward-looking statements. We do not undertake any obligation to revise these forward-looking statements to reflect any future events or circumstances.

Readers should not place undue reliance on these forward-looking statements, which are based on management s current expectations and projections about future events, are not guarantees of future performance, are subject to risks, uncertainties and assumptions (including those described below), and apply only as of the date of this filing. Our actual results, performance or achievements could differ materially from the results expressed in, or implied by, these forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks to be discussed in this Annual Report on Form 10-K and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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Use of Generally Accepted Accounting Principles (GAAP) Financial Measures

We use United States GAAP financial measures in the section of this report captioned Management s Discussion and Analysis or Plan of Operation (MD&A), unless otherwise noted. All of the GAAP financial measures used by us in this report relate to the inclusion of financial information. This discussion and analysis should be read in conjunction with our financial statements and the notes thereto included elsewhere in this annual report. All references to dollar amounts in this section are in United States dollars, unless expressly stated otherwise. Please see our Risk Factors for a list of our risk factors.

Overview

This subsection of MD&A provides an overview of the important factors that management focuses on in evaluating our businesses, financial condition and operating performance, our overall business strategy and our financial results for the periods covered.

Results of Operations

Comparison of the Twelve Months Ended November 30, 2014 and the Twelve Months Ended November 30, 2013

Revenue

We have not earned any revenues since our inception and we do not anticipate earning revenues in the near future.

Expenses

Our expenses for the twelve months ended November 30, 2014 are summarized as follows in comparison to our expenses for twelve months ended November 30, 2013:

	Year Ended November 30,	
	2014	**2013**
Research and development expenses	$ 1,549,450	$ 1,452,456
General and administration expenses	3,027,180	4,008,046
Financial expenses, net	927,471	78,657
Loss	$ 5,504,101	$ 5,539,159

Research and Development Expenses

	Year Ended November 30,	
	2014	**2013**
Salaries and related expenses	$ 779,746	$ 395,710
Stock-based compensation	766,070	475,877
Professional fees and consulting services	126,103	378,826
Lab expenses	609,081	51,743
Other research and development expenses	197,271	150,300
Less - grant	(928,821)	-
Total	$ 1,549,450	$ 1,452,456

The increase in salaries and related expenses and in stock-based compensation in the twelve months ended November 30, 2014, compared to the same period last year is mainly due to a change in the mix of employees from general and administrative to research and development activities. The increase in lab expenses during the twelve months ended November 30, 2014, compared to the same period last year is related to expansion of research and development operations in 2014, mainly in our Belgian Subsidiary. The grant deduction is due to a grant approved from DGO6 in our Belgian Subsidiary for our research and development activities in November 2014.

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General and Administrative Expenses

	Year Ended November 30,	
	2014	2013
Salaries and related expenses	$ 330,134	$ 415,163
Stock-based compensation	1,720,983	2,636,090
Accounting and legal fees	476,095	283,493
Professional fees	212,244	296,753
Business development	143,387	187,827
Other general and administrative expenses	144,337	188,720
Total	$ 3,027,180	$ 4,008,046

The decrease in salaries and related expenses and in stock-based compensation for the twelve months ended November 30, 2014, compared to the same period last year is due to the prior year having higher employee compensation cost and stock-based compensation for a number of employees and consultant whose options had fully vested. In addition, the decrease resulted from a change in mix of employees from general and administrative to research and development activities.

Financial Expenses, Net

	Year Ended November 30,	
	2014	2013
Increase (decrease) in fair value of warrants and embedded derivative	$ (180,000)	$ (133,316)
Interest expense on convertible loans	691,090	172,510
Funding fees to Kodiak	135,000	-
Foreign exchange loss, net	9,740	33,761
Bank commissions, net	11,910	5,702
Issuance of warrants as induced conversion	259,731	-
Total	$ 927,471	$ 78,657

The increase in interest expense in the twelve months ended November 30, 2014, compared to the same period last year is mainly attributable to additional convertible loans received during 2014, including the main convertible loan received equal to $1,500,000. The funding fees to Kodiak is due to represent the fair value of 250,000 shares of common stock issued to Kodiak as part of a stock purchase agreement with Kodiak. The issuance of warrants reflects issuance of beneficial warrants that were granted in March 2014.

Liquidity and Financial Condition

Working Capital Deficiency

	November 30, 2014	November 30 2013
Current assets	$ 2,229,526	$ 97,737
Current liabilities	4,663,320	986,409
Working capital deficiency	$ (2,433,794)	$ (888,672)

The increase in current assets is mainly due to an increase in cash from the investment from Nine Investments Limited totaling $1,500,000 and a grant in amount of $810,516 received in the Belgian Subsidiary during the twelve months ended November 30, 2014. The increase in current liabilities was due to an increase in expenses which resulted in an increase of accounts payable, accrued expenses and employees and related payables of $1,404,598 during the twelve months ended November 30, 2014, in addition to an increase in convertible loans and accrued interest of $2,173,318.

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Cash Flows

	Year Ended November 30,	
	2014	**2013**
Net cash used in operating activities	$ (1,429,247)	$ (1,989,348)
Net cash provided by (used) in investing activities	2,509	(10,172)
Net cash provided by financing activities	2,736,708	2,050,000
Increase in cash and cash equivalents	$ 1,309,970	$ 50,480

The decrease in net cash used in operating activities in the twelve months ended November 30, 2014, compared to the same period last year is mainly related to the increase in our current liabilities such as accounts payable, accrued expenses and employees and related payables during the twelve month period ended November 30, 2014, compared to the same period last year. This amount was offset by an increase in payable and receivable on account of grant due to grants which received in the Belgian and U.S Subsidiaries. The increase in cash provided by financing activities in the twelve months ended November 30, 2014 compared to the comparable period in 2013 is mainly due to an increase in convertible loans of $1,500,000 which was offset by a decrease in capital received through sales of common stock and warrants.

Recent Corporate Developments

Since the commencement of the year through November 30, 2014, we experienced the following corporate developments:

Private Placement

During the first quarter of 2014, the Company issued 1,128,849 units in a non-brokered private placement for total consideration of $587,001. Each unit consisted of one share of the Company s common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company s common stock at an exercise price of $0.52 per share for a period of three years.

Convertible Loans with Mediapark A.G.

On March 22, 2013, we entered into a convertible loan agreement with Mediapark A.G., a Marshall Islands company (Mediapark), pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the Convertible Loan) in the aggregate principal amount of $250,000. On December 6, 2013, we entered into a similar convertible loan agreement with Mediapark in the aggregate principal amount of $100,000. The agreement stated that if we complete an equity financing prior to the maturity date of the loan in an amount greater than $350,000, Mediapark would convert all of our outstanding indebtedness into equity securities on the same terms as the current financing. Due to meeting this provision, on March 3, 2014, both loans in the aggregate amount of $370,772 (principle and interest) outstanding as of that date were converted into 713,023 shares of common stock at a price of $0.52 and 713,023 warrants to acquire additional shares of our common stock at a price of $0.52 per share for a period of three years in full payment of our indebtedness. The warrants were recorded as financial expenses.

Chief Executive Officer

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, has been appointed 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 on the following key terms:

(b) a base salary of NIS 49,585 (as of August 22, 2014, equates to approximately $14,100) per month, retroactive to January 1, 2014;

(c) a monthly contribution based on Ms. Caplan s previous month s salary equal to either:

(i) 13.33% to a Managers Insurance policy; or

(ii) 14.33% to a comprehensive pension plan;

(e) the grant of stock options to be granted by our company, as follows:

(i) Options to purchase 1,657,300 shares of our company s common stock (representing approximately three percent (3%) of our company s issued and outstanding shares of common stock, which will vest as follows: (i) options to purchase 414,304 shares of common stock shall vest immediately on the date of grant and (ii) options to purchase the balance of 1,242,996 shares of common stock shall vest on a quarterly basis over a period of four years from the date of grant (i.e., initially, 77,687 of the options shall vest three months following the grant date).

(ii) Options to purchase 1,104,950 shares of our company s common stock, representing approximately two percent (2%) of our company s issued and outstanding common stock, which will vest pursuant to performance milestones to be determined by our Compensation Committee no later than December 31, 2014. As of the date of this filing, while the Compensation Committee has not yet determined the milestones or the expectations regarding such milestones, it expects to do so by the end of the Company s first fiscal quarter.

(iii) All of the options are to have an exercise price equal to the par value per share of our common stock and all of them will expire on the 10th anniversary of the grant date.

The employment agreement, which replaces a previous employment agreement with Ms. Caplan dated April 1, 2012, contains other customary terms, covering matters such as non-competition; confidentiality; indemnity and insurance; use of leased car; and vacation, health and other benefits.

Chief Financial Officer

Effective August 1, 2014, Joseph Tenne resigned as our Chief Financial Officer, Treasurer and Secretary. Mr. Tenne s resignation was not as a result of any disagreement with our company operations, policies or practices. Mr. Tenne remained as Chief Financial Officer of our Israeli Subsidiary, Orgenesis Ltd., until September 1. On September 1, the Company entered into an agreement with Dorit Kreiner who replaced Mr. Tenne as Chief Financial Officer of Orgensis Ltd. Mr. Tenne remains as a director of Orgenesis Ltd.

On August 1, 2014, we appointed Neil Reithinger as our Chief Financial Officer, Treasurer and Secretary with the following terms:

(a) payment of a monthly salary of $1,500;
(b) payment of an annual bonus as determined by our company in its sole discretion;
(c) participation in our company s pension plan;
(d) a grant of 200,000 stock options exercisable at the market price of $0.50 for a period of 5 years and which are subject to vesting provisions; and
(e) Reimbursement of expenses.

In addition, on August 1, 2014, we entered into a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, (Eventus) pursuant to which Eventus has agreed to provide financial consulting and shareholder communication services to our company. In consideration for Eventus services, we have agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement is for a period of one year from August 1, 2014 and shall automatically renew for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Neil Reithinger.

Chief Executive Officer of our Subsidiary, Orgenesis Maryland, Inc.

On July 23, 2014, our Subsidiary, Orgenesis Maryland, Inc. entered into an employment agreement with Scott Carmer, to be effective July 1, 2014. In consideration for acting as our Subsidiary s Chief Executive Officer, we will

pay Mr. Carmer the following compensation:

(a) an annual salary of $250,000;

(b) an annual bonus of up to $100,000 subject to the discretion of our board of directors and a further bonus as determined by meeting certain milestones; and

(c) a grant of shares or options.

Prospectuses

The Company filed prospectuses dated March 28, 2014, June 11, 2014 and July 31, 2014 pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall ; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

Consulting Agreement with Aspen Agency Limited

On April 3, 2014, we entered into a consulting agreement with Aspen Agency Limited, a Hong Kong corporation ("Aspen"), pursuant to which Aspen has agreed to provide investment banking, investor relations and business development services to the Company. In consideration for Aspen's services, the Company agreed to issue to Aspen 3,000,000 stock options in two separate tranches of 1,000,000 and 2,000,000, with the second tranche vesting if they exercise the first tranche, to acquire shares of the Company's common stock at an exercise price of $0.52 per share, for a period of three years. The term of the consulting agreement was from April 3, 2014 and will run for an indefinite period unless terminated by either party providing 30 days written notice. The fair value of the options was $744,000 and was recorded on April 3, 2014 as additional paid-in capital in the balance sheet with a corresponding expense in general and administrative expenses. On October 23, 2014, we entered into a termination agreement with Aspen in which both parties agreed to terminate the consulting agreement and to cancel the first tranche of options. By way of cancellation of the first tranche of options, the second tranche was cancelled as well.

Private Placement with Mediapark A.G.

On April 24, 2014, we issued 384,615 units to one investor in a non-brokered private placement, at a purchase price of $0.52 per unit for proceeds of $200,000. Each unit consists of one share of our common stock and one nontransferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of $0.52 per share for a period of three years.

Convertible Loans with Nine Investments Ltd.

On May 29, 2014, we entered into a convertible loan agreement with Nine Investments Limited, a Hong Kong company ("Nine Investments"), pursuant to which Nine Investments loaned us $1,500,000 which we subsequently transferred to our Belgian Subsidiary, Orgenesis SPRL, to fund a research project to develop new medical technologies and cell therapies for the treatment of diabetes. We received the funds on June 4, 2014 (the "Closing Date"). Interest is calculated at 8% semi-annually and is payable, along with the principal on or before December 31, 2014 subject to acceleration for specific events including: (i) if a grant of money to Orgenesis SPRL is not approved by Department De La Gestion Financiere Direction De L'analyse Financiere ("DGO6") within 90 days after the loan proceeds are advanced; and (ii) if the Company raises, in the aggregate, gross proceeds of more than $400,000 between the date of the loan and the maturity date, but only to the extent of gross proceeds so raised that are in excess

of $400,000.

Nine Investments may convert all or part of the loan into shares of its common stock at $0.40 per share. The conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment in the event and in the manner following: (i) if and whenever the Company's common shares at any time outstanding shall be subdivided into a greater or consolidated into a lesser number of common shares, or in case of any capital reorganization or of any reclassification of the capital of the Company or in case of the consolidation, merger or amalgamation of the Company with or into any other company or of the sale of the assets of the Company as or substantially as an entirety or of any other company, the conversion price shall be decreased or increased proportionately; and (ii) in the event the Company issues any shares of common stock or securities convertible into shares at a price less than the conversion price, the conversion price shall be reduced for any unpaid or unconverted loan amount to the new issuance price.

As consideration for entering into the loan agreement, on June 5, 2014, the Company issued to Nine Investments 500,000 shares of its common stock.

Maryland Technology Development Corporation Research Grant

On June 30, 2014, the Company's Subsidiary, Orgenesis Maryland, Inc., 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 Subsidiary an amount not to exceed $406,431 (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 July 22, 2014, the Subsidiary received an advance payment of $203,216 on account of the grant. Through November 30, 2014, an amount of $118,305 out of the $203,216 was spent. The amount of grant that was spent through November 30, 2014 was recorded as a deduction of research and development expenses in the statement of operations. The excess of $84,911 is presented on the balance sheet as of November 30, 2014 as a short-term liability.

Service Agreement with MaSTherCell S.A.

On July 3, 2014, the Company's Belgian Subsidiary, Orgenesis SPRL (the "Belgian Subsidiary") entered into a service agreement with MaSTherCell, pursuant to which MaSTherCell will conduct certain clinical tests related to diabetes treatment research. The Belgian Subsidiary will pay MaSTherCell for its services Euro 962,500 with 30% payable upon the date of approval of the DGO6 grant with the balance being invoiced monthly. Services will commence upon approval of the DG06. The term of the service agreement will run until all work is completed or by either party providing 30 days' written notice of termination.

Exercise of Warrants and Issuance of New Warrants

In July 2014, one of our investors exercised warrants to purchase 96,154 shares of our common stock at an exercise price of $0.52 for a total consideration of $50,000. The Company issued him 192,308 new warrants. Each warrant entitles the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years.

Private Placement with Non-U.S. Investors

In July 2014, we issued 144,230 units to one investor in a non-brokered private placement, at a purchase price of $0.52 per unit for proceeds of $75,000. Each unit consists of one share of our common stock and one nontransferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of $0.52 per share for a period of three years.

In August 2014, the Company issued 115,385 units at a purchase price of $0.52 per unit to one investor in a non-brokered private placement for total consideration of $60,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years.

Debt Settlement Agreements

On June 30, 2014, we entered into a debt settlement agreement with one of our creditors, whereby we settled a debt in the amount of $24,011 by the issuance of 46,175 shares of our common stock at a price per share of $0.52.

On July 14, 2014, we entered into a debt settlement agreement with one of our creditors, whereby we settled a debt in the amount of $13,395 by the issuance of 25,759 shares of our common stock at a price per share of $0.52.

Convertible Loans with Non-U.S. Investors

On September 1, 2014, the Company entered into a convertible loan agreement for $50,000. The loan bears an annual interest rate of 6% and matures on February 28, 2015, unless converted earlier. The lender shall have the right to convert all or any portion of the outstanding principal amount and all accrued but unpaid interest thereon into shares of common stock of the Company at a conversion price of $0.40 per share.

On September 15, 2014, the Company entered into a convertible loan agreement for $100,000. The loan bears an annual interest rate of 6% and matures on March 15, 2015, unless converted earlier. The lender shall have the right to convert all or any portion of the outstanding principal amount and all accrued but unpaid interest thereon into shares of common stock of the Company at a conversion price of $0.40 per share.

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

On November 17, 2014, our Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DG06) for a €2.015 million support program for the research and development of a potential cure for Type 1 Diabetes. The Financial support is composed of a 1,085,000 Euros (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of 930,000 Euros (60% of budgeted costs) of the experimental development part of the research program. The grants will be paid to us over a period of approximately 3 years. The grants are subject to certain conditions with respect to our work in the Walloon Region, our own investment in these projects and certain other conditions. On December 9 and 16, 2014, we received €651,000 and €558,000 under the grant, respectively.

Going Concern

The audited consolidated financial statements contained in this annual report on Form 10-K have been prepared assuming that the Company will continue as a going concern. The Company have accumulated losses for the period from inception (June 5, 2008) through November 30, 2014, of $16,179,076 as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following November 30, 2014. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives in order to finance our research and development activities and general and administrative expenses. These alternatives include raising funds through public or private equity markets and either through institutional or retail investors. Although there is no assurance that the Company will be successful with our fund raising initiatives, management believes that the Company will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

The consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability. If the Company raises additional funds through the issuance of equity, the percentage ownership of current shareholders could be reduced, and such securities might have rights, preferences or privileges senior to its common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms,

the Company may not be able to take advantage of prospective business endeavors or opportunities, which could significantly and materially restrict its future plans for developing its business and achieving commercial revenues. If the Company is unable to obtain the necessary capital, the Company may have to cease operations.

Cash Requirements

Our plan of operation over the next 12 months is to:

- initiate regulatory activities in Europe and the United states;
- locate suitable facility on the U.S. for tech transfer and manufacturing scale-up;
- purchase equipment needed for our cell production process;
- hire key personnel including, but not limited to, a chief medical officer, chief science officer and chief operating officer;
- collaborate with clinical centers and regulations to carry out clinical studies and clinical safety testing;
- identify optional technologies for scale up of the cells production process; and
- initialize efforts to validate the manufacturing process (in certified labs).

We estimate our operating expenses for the next 12 months as of November 30, 2014 to be as follows:

Research and development	$ 4,300,000
Manufacturing and scale-up	2,700,000
General and administrative	1,600,000
Total	$ 8,600,000

As more fully described in Note 2 to our financial statements herein, on November 6, 2014, we entered into a share exchange agreement with MasTHerCell and each of the shareholders of MaSTherCell, which provides for the acquisition by our company of all of the issued and outstanding shares of MaSTherCell from the shareholders of MaSTherCell in exchange for the issuance of $24,593,000 in value of shares of common stock in the capital of our company. MasTHerCell SA and Cell Therapy Holding SA are private limited liability companies incorporated in Belgium, are generating limited revenue and are not profitable. While the above cash requirements do contemplate our expected cash needs for the scale-up of manufacturing for our products in the U.S. Market in conjunction with MaSTherCell, they do not contemplate the potential cash needs of MaSTherCell s current operations in their existing markets once acquired by us.

Future Financing

We will require additional funds to implement our growth strategy for our business. In addition, while we have received various grants that have enabled us to fund our clinical developments, these funds are largely restricted for use for other corporate operational and working capital purposes. Therefore, we will need to raise additional capital to both supplement our clinical developments that are not covered by any grant funding and to cover our operational expenses. These funds may be raised through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of our shares. There can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. If we are not able to obtain the additional financing on a timely basis should it be required, or generate significant material revenues from operations, we will not be able to meet our other obligations as they become due and we will be forced to scale down or perhaps even cease our operations.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in the notes to our consolidated financial statements included herein for the fiscal year ended November 30, 2014. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Research and Development

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.

Fair Value Measurement

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

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

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

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

Embedded Derivatives

The Company entered into convertible debentures agreement in which a derivative instrument is embedded . Embedded derivative is 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, stand-alone instrument with the same terms would qualify as a derivative instrument. As to embedded derivatives arising from the issuance of convertible debentures, see Note 4(b).

Volatility in Stock-Based Compensation

The volatility is based on historical volatilities of companies in comparable stages as well as the historical volatility of companies in the industry and, by statistical analysis of the daily share-pricing model. The volatility of stock-based compensation granted after November 30, 2013 is based on historical volatility of the Company for the last two years.

Warrants classified as liabilities

Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the statement of financial position. The liability is measured both initially and in subsequent periods at fair value, with changes in fair value charged to finance expenses, net.

The fair value of the warrants is determining by using a Monte Carlo type model based on a risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issue dates, then for each path to use the Black-Scholes model to estimate the value of the warrants on the last issue date including all the

changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant delay in this input would result a higher fair value measurement.

Recently Adopted Accounting Pronouncements

In June 2014, the FASB issued ASU 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (ASU 2014-10). The amendments in ASU 2014-10 remove an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity. The revised consolidation standards are effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period, with early application permitted. The Company has elected to early adopt the provisions of ASU 2014-10 for these consolidated financial statements.

Newly Issued Accounting Pronouncements

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. ASU 2014-15 defines management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter, although early adoption is permitted. This guidance is not expected to have an impact on the financial statements of the Company. If any event occurs in future periods that could affect our ability to continue as going concern, we will provide appropriate disclosures as required by ASU 2014-15.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF NOVEMBER 30, 2014

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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 (the Company) as of November 30, 2014 and 2013, and the related consolidated statements of comprehensive loss, changes in capital deficiency and cash flows for each of the years then ended. 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 audit.

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 audit provides 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 at November 30, 2014 and 2013, and the results of their comprehensive loss, changes in capital deficiency and cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1a to the financial statements, the Company has recurring losses for the period from inception through November 30, 2014 and presently the Company does not have sufficient cash and other resources to meet its requirements in the following twelve months. These factors raise substantial doubt as to the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1a. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Tel-Aviv, Israel Kesselman & Kesselman
February 19, 2015 Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
In U.S. Dollars

	As of the Year Ended	
	November 30, 2014	**November 30, 2013**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,314,052	$ 50,827
Short term bank deposits	-	10,002
Prepaid expenses and other account receivable	104,958	36,908
Receivables on account of grant	810,516	-
TOTAL CURRENT ASSETS	2,229,526	97,737
FUNDS IN RESPECT OF RETIREMENT BENEFIT OBLIGATION	6,377	3,630
PROPERTY AND EQUIPMENT, net	13,049	12,854
TOTAL ASSETS	$ 2,248,952	$ 114,221
Liabilities net of capital deficiency		
CURRENT LIABILITIES:		
Short-term bank credit	$ 14,084	$ -
Accounts payable	1,083,910	138,775
Accrued expenses	374,673	386,122
Employees and related payables	626,012	155,100
Related parties	42,362	42,362
Advance payment on account of grant	84,911	-
Convertible loans	2,437,368	264,050
TOTAL CURRENT LIABILITIES	4,663,320	986,409
LONG-TERM LIABILITIES		
Warrants liability	559,954	1,157,954
Retirement benefit obligations	4,974	4,272
TOTAL LONGTERM LIABILITIES	564,928	1,162,226
COMMITMENTS (Note 2)		
TOTAL LIABILITIES	$ 5,228,248	$ 2,148,635
CAPITAL DEFICIENCY:		
Common stock of $0.0001 par value, 1,750,000,000 shares authorized, 55,970,565 and 51,144,621 shares issued and outstanding as of November 30, 2014 and November 30, 2013, respectively	5,597	5,114
Additional paid-in capital	13,152,551	8,635,447
Receipts on account of shares to be allotted	60,000	-
Accumulated other comprehensive loss	(18,368)	-
Accumulated deficit	(16,179,076)	(10,674,975)
TOTAL CAPITAL DEFICIENCY	(2,979,296)	(2,034,414)
TOTAL LIABILITIES NET OF CAPITAL DEFICIENCY	$ 2,248,952	$ 114,221

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
In U.S. Dollars

	For the Year Ended	
	November 30, 2014	**November 30, 2013**
OPERATING EXPENSES:		
Research and development, net	1,549,450	$ 1,452,456
General and administrative	3,027,180	4,008,046
OPERTING LOSS	4,576,630	5,460,502
FINANCIAL EXPENSES, net	927,471	78,657
NET LOSS	$ 5,504,101	$ 5,539,159
OTHER COMPREHENSIVE LOSS -		
Translation adjustments	18,368	-
TOTAL COMPREHENSIVE LOSS	5,522,469	$ 5,539,159
LOSS PER SHARE:		
Basic	$ 0.10	$ 0.11
Diluted	$ 0.11	$ 0.11
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING USED IN COMPUTATION OF LOSS PER SHARE:		
Basic	54,162,596	50,483,814
Diluted	54,721,969	50,483,814

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN CAPITAL DEFICIENCY
In U.S. Dollars

	Common Stock		Additional	Receipts on account	Accumulated Other	Accumulate
	Number	Par Value	Paid-in Capital	of share to be allotted	Comprehensive Loss	Deficit
BALANCE AT DECEMBER 1, 2012	49,117,903	$ 4,912	$ 4,850,348	$ -	$ -	$ (5,135,8
Changes during the Year ended November 30, 2013						
Stock-based compensation related to options granted to employees and directors			2,795,655			
Stock-based compensation related to options granted to service providers			316,312			
Issuances of shares and warrants	2,026,718	202	666,988			
Receipts on account of shares to be issued			6,144			
Net loss for the year						(5,539,1
BALANCE AT NOVEMBER 30, 2013	51,144,621	$ 5,114	$ 8,635,447	$ -	$ -	$ (10,674,9
Changes during the Year ended November 30, 2014						
Stock-based compensation related to options granted to employees			1,199,583			

and directors						
Stock-based compensation related to options and shares granted to service providers	913,333	92	1,287,378			
Issuances of shares and warrants	2,479,628	248	1,214,159	60,000		
Conversions of convertible loans into shares and warrants	713,023	71	630,432			
Exercise of stock options into shares	623,806	62	562			
Exercise of warrants into shares and warrants	96,154	10	49,990			
Beneficial conversion feature of convertible loans			135,000			
Comprehensive loss for the year					(18,368)	(5,504,10
BALANCE AT NOVEMBER 30, 2014	55,970,565	$ 5,597	$ 13,152,551	$ 60,000	$ (18,368)	$ (16,179,07

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
In U.S. Dollars

	For the Year Ended	
	November 30, 2014	**November 30, 2013**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,504,101)	$ (5,539,159)
Adjustments to reconcile net income to net cash used in operating activities:		
Stock-based compensation related to options granted to employees	1,199,583	2,795,655
Stock-based compensation related to options granted to service providers	1,287,470	322,456
Increase in accrued retirement benefits obligations	702	2,719
Depreciation expenses	4,551	3,257
Change in fair value of warrants and embedded derivative	(180,000)	(133,316)
Financial expense	1,085,821	172,510
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other accounts receivable	(73,506)	(8,659)
Increase in accounts payable	1,016,291	2,984
Increase (decrease) in accrued expenses	(11,365)	312,984
Increase in employee and related party payables	470,912	79,221
Increase in payables and receivables on account of grant	(725,605)	-
Net cash used in operating activities	(1,429,247)	(1,989,348)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(4,746)	(7,838)
Proceeds from short Term Deposits	10,002	-
Investment in short term Deposits	-	-
Amounts funded in respect of retirement benefits obligation	(2,747)	(2,334)
Net cash provided by (used in) investing activities	2,509	(10,172)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowings on short-term line of credit	14,084	-
Proceeds from issuance of shares and warrants	922,000	1,800,000
Proceeds from exercise of stock options	624	-
Proceeds from exercise of warrants into shares and warrants	50,000	-
Proceeds from issuance of convertible loans together with shares	1,750,000	250,000
Net cash provided by financing activities	2,736,708	2,050,000
NET CHANGE IN CASH	1,309,970	50,480
EFFECT ON EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(46,745)	-
CASH AT BEGINNING OF PERIOD	50,827	347
CASH AT END OF PERIOD	1,314,052	50,827
SUPPLEMENTAL INFORMATION:		

Non-cash investing and financing activities:				
Common stock issued for rendered services	$	37,406	$	-
Common stock and warrants issued for conversion of loans and accrued interest	$	630,503	$	-

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

ORGENESIS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 DESCRIPTION OF BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES

a. General

Orgenesis Inc. (the Company) was incorporated in the state of Nevada on June 5, 2008. The Company is developing a technology that it is bringing to the clinical stage 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.

On October 11, 2011, the Company acquired a wholly owned Subsidiary in Israel, Orgenesis Ltd. (the Israeli Subsidiary), which is engaged in research and development. On February 2, 2012, the Israeli Subsidiary entered into an agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the Licensor). The Israeli Subsidiary was granted a worldwide, royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

On July 31, 2013, the Company incorporated a wholly owned Subsidiary in Maryland, Orgenesis Maryland Inc. (the U.S. Subsidiary), which is engaged in research and development.

On October 11, 2013, Orgenesis Ltd. incorporated a wholly owned Subsidiary in Belgium, Orgenesis SPRL (the Belgian Subsidiary), which will be engaged in development and manufacturing activities together with clinical development studies in Europe, and later on to be the Company s center for the Company's activities in Europe.

On November 6, 2014, the Company entered into a share exchange agreement with MasTHerCell SA and Cell Therapy Holding SA (collectively Masthercell) and each of the shareholders of Masthercell, which provides for the acquisition by the Company of all of the issued and outstanding shares of Masthercell from the shareholders of Masthercell in exchange for the issuance of $24,593,000 in value of shares of common stock in the capital of the Company. Masthercell is a private limited liability company incorporated in Belgium. Under the share exchange agreement, a total of $24,593,000 in value of common stock of Orgenesis is to be issued at the average of all closing trading prices for Orgenesis common shares as traded on the OTC stock market for the 30 trading days immediately preceding the closing date, but will be priced at no more than $0.80 and no less than $0.50. In the event that Orgenesis has not achieved a post-closing financing and a valuation which meets the agreed threshold within eight (8) months of the closing date, then the Masthercell shareholders may, by notice to Orgenesis, unwind the transaction in exchange for return of all of the Consideration Shares plus any amount that Orgenesis has advanced or invested in Masthercell. In the event that some or all of Masthercell s current outstanding convertible bonds are not converted to shares, the consideration payable in share of the Company's common stock will be reduced by the amount that is then owed to the Bondholders. The share exchange agreement contemplates that on or prior to the closing of the acquisition, the parties will conduct due diligence on each other and Masthercell will provide its audited financial statements, among other things. The closing of the share exchange agreement is subject to the satisfaction of certain conditions precedent, including (without limitation) receipt of legal opinions, there being no material changes in the affairs of either Orgenesis or Masthercell, all parties representations continuing to be true at closing, and other conditions which are listed in the Agreement. Due to conditions precedent to closing, including those set out above, and the risk that the conditions precedent may not be satisfied, there is no assurance that the Company will close the share exchange agreement and complete the acquisition of all of the issued and outstanding shares of Masthercell.

Unless otherwise indicated, the term Company refer to Orgenesis Inc. and its wholly owned Subsidiaries. As of the date of this filing, the foregoing terms do not include Masthercell. Unless otherwise specified, all dollar amounts are expressed in United States dollars.

On November 17, 2014, the Company's Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a €2.015 million (approximately $2.5 million) support program for the research and development of a potential cure for Type 1 Diabetes. The grants are subject to certain conditions with respect to the Company's work in the Walloon Region, the Company's own investment in these projects and certain other conditions. On December 9 and 16, 2014, the Company's received €651,000 and €558,000 under the grant, respectively.

On December 21, 2014, the Company's Israeli Subsidiary received a notification from the Israel-U.S. Binational Industrial Research and Development Foundation (“BIRD”) that the Company's Israeli Subsidiary and the Company's research and development partner, have been approved by BIRD's Board of Governors for a conditional grant of $800,000 for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the “Project”). Up to the date of this report, the Company has not yet received these funds.

Going Concern and Management’s Plan

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (June 5, 2008) through November 30, 2014, of $16,179,076, as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following November 30, 2014. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives for operations, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets.

The consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company’s continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability. If the Company raises additional funds through the issuance of equity, the percentage ownership of current shareholders could be reduced, and such securities might have rights, preferences or privileges senior to its common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, the Company may not be able to take advantage of prospective business endeavors or opportunities, which could significantly and materially restrict its future plans for developing its business and achieving commercial revenues. If the Company is unable to obtain the necessary capital, the Company may have to cease operations.

b. 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 statements 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, embedded derivatives and warrants issued.

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

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.

e. Principles of Consolidation

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

f. Functional Currency

The currency of the primary economic environment in which the operations of the Company and part of its Subsidiaries are conducted is in the U.S. dollar ("$" or "dollar"). The functional currency of the Belgian Subsidiary, which has only commenced operations, is the Euro ("€" or "Euro"). 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 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 carried to financial income or expenses, as appropriate.

g. 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. It is the Company's policy to classify interest and penalties on income taxes as interest expense or penalties expense. The Company have provided a full valuation allowance with respect to its deferred tax assets.

2) The Company follow 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 intent and ability to hold these investments.

i. Stock Based Compensation

The Company account for employee stock based compensation in accordance with the guidance of ASC Topic 718, 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 follow ASC Topic 505-50, for stock options and warrants 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.

j. Warrants Classified as a Liability

Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the balance sheet. The liability is measured both initially and in subsequent periods at fair value, with changes in fair value charged to finance expenses, net. See Note 8(a).

k. Fair Value Measurement

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

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

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

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

l. Property and Equipment

Property and equipment are recorded at cost and depreciated by the straight line method over the estimated useful lives of the assets. Annual rates of depreciation are as follows:

Computers	33%
Lab equipment	15%
Office furniture	6%

m. 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 shares 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 debentures, which are included under the if converted method when dilutive. The computation of diluted net loss per share for the year ended November 30, 2014 includes common share equivalents due to warrants. See Note 3(c).

n. Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally cash and cash equivalents and other receivables. The Company held these instruments with highly rated financial institutions and the Company have not experienced any credit losses in these accounts and do not believe the Company is exposed to any significant credit risk on these instruments.

o. 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 4(c).

p. Derivatives

Embedded derivative 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. As to embedded derivatives arising from the issuance of convertible debentures, see Note 4(b).

q. Comprehensive loss

Other comprehensive loss, represents adjustments of foreign currency translation.

r. Recently Adopted Accounting Pronouncements

In June 2014, the FASB issued ASU 201410, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (ASU 201410). The amendments in ASU 201410 remove an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity. The revised consolidation standards are effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period, with early application permitted. The Company has elected to early adopt the provisions of ASU 201410 for these consolidated financial statements.

s. Newly Issued Accounting Pronouncements

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. ASU 2014-15 defines management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter, although early adoption is permitted. This guidance is not expected to have an impact on the financial statements of the Company. If any event occurs in future periods that could affect the Company s ability to continue as going concern, the Companywill provide appropriate disclosures as required by ASU 2014-15.

NOTE 2 COMMITMENTS

a. Tel Hashomer Medical Research, Infrastructure and Services Ltd.

On February 2, 2012, the Company s Israeli Subsidiary entered into a licensing agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the Licensor). According to the agreement, the 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.

As consideration for the licensed information, the Israeli Subsidiary will pay the following to the Licensor:

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 shall be paid 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; and
d) $750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA.
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, 2014, the Company have 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 Licensor shall be entitled to choose whether to receive from the Company a one-time payment based, as applicable, on the value of either 5,563,809 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.

On March 22, 2012, the Israeli Subsidiary entered into a research service agreement with the Licensor. According to the agreement, the Licensor will perform a study at the facilities and use the equipment and personnel of the Chaim Sheba Medical Center (the "Hospital"), for the consideration of approximately $74,000 for a year. On May 1, 2013 and in May 2014, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately $92,000 and $114,000 respectively.

b. Mintz, Levin, Ferris, Glovsky and Popeo, P.C.

On February 2, 2012, the Company entered into an agreement with its patent attorneys, Mintz, Levin, Ferris, Glovsky and Popeo, P.C. ("Mintz Levin") for professional services related to patent registration. In addition to an amount of $80,000 paid to Mintz Levin, the Company issued 1,390,952 shares of common stock. The Company will pay an additional $50,000 upon consummation of certain criteria that the company will meet. The Company has not reached any of the milestones.

On March 27, 2013, the Company signed an agreement with Mintz Levin in which 16% of the Company's fees will be converted to shares of common stock of the Company at market price. On July 14, 2014, $13,395 of fees incurred were converted into 25,759 shares of common stock.

c. Pall Life Science Belgium BVBA

On May 6, 2013, the Israeli Subsidiary entered into a Process Development Agreement with Pall Life Science Belgium BVBA (formerly ATMI BVBA), a Belgian Company which is a wholly owned Subsidiary of Pall Corporation ("Pall"), a U.S. publicly traded company. According to the agreement, Pall will provide services in cell research. The Company will use Pall's unique technology while the Company will provide to Pall the required materials for purpose of the study. According to the agreement, the Company will pay per achieved phase, as defined in the agreement, with a total consideration of Euro 606,500 for all services. As of November 30, 2014, the Company received services in total value of Euro 381,362.

d. MaSTherCell SA

On July 3, 2014 (prior to the initiation of the transaction detailed in note 1(a)), the Company's Belgian Subsidiary entered into a service agreement with MaSTherCell SA, pursuant to which MaSTherCell SA will conduct certain clinical tests related to diabetes treatment research. The Belgian Subsidiary will pay MaSTherCell SA for its services Euro 962,500 with 30% payable upon the date of approval of the DGO6 grant (as defined in Note 2(f)) with the balance being invoiced monthly. Services will commence upon approval of the DGO6.

The term of the service agreement will run until all work is completed or by either party providing 30 days' written notice of termination.

On November 6, 2014, the Company entered into a share exchange agreement with Masthercell which has not been closed as of the date of this filing. See also Note 1(a).

e. 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 Subsidiary an amount not to exceed $406,431 (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 July 22, 2014, the Subsidiary received an advance payment of $203,216 on account of the grant. Through November 30, 2014, an amount of $118,305 out of the $203,216 was spent. The amount of grant that was spent through November 30, 2014 was recorded as a deduction of research and development expenses in the statement of operations. The excess of $84,911 is presented on the balance sheet as of November 30, 2014 as a short term liability.

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

On November 17, 2014, the Company's Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a €2.015 million support program for the research and development of a potential cure for Type 1 Diabetes. The Financial support is composed of a 1,085,000 Euros (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of 930,000 Euros (60% of budgeted costs) of the experimental development part of the research program. The grants will be paid to us over a period of approximately 3 years. The grants are subject to certain conditions with respect to the Company's work in the Walloon Region, the Company's own investment in these projects and certain other conditions and contain a repayment provision upon attaining a favorable outcome. In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. On December 9 and 16, 2014, the Company received €651,000 and €558,000 under the grant, respectively, an amount of $810,516 recorded as deduction of research and development expenses.

NOTE 3 – CAPITAL DEFICIENCY

a. Share Capital

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

b. *Financings*

1) In December 2012, the Company entered into a subscription agreement with Derby for the issuance of 500,000 units for a total consideration of $500,000. Each unit is comprised of one share of the Company's common stock and two non-transferrable warrants (See also Note 8(a)). In connection with this agreement, the 1,000,000 warrants issued to Derby were expired on November 30, 2014.

2) In May 2013, the Company entered into a subscription agreement with Pall, pursuant to which Pall purchased 1,526,718 units at a price of $0.8515 per unit for total consideration of $1,300,000. Each unit consisted of one share of the Company's common stock and one warrant (See also Note 8(a)). On March 28, 2014, on June 11, 2014 and on July 31, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC, covering the shares under the subscription agreement, which allows Pall to sell the shares (including shares that will be issued to Pall as a result of the exercise of the warrants).

3) On December 13, 2013, the Company entered into a $3,000,000 common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beachbased institutional investor ("Kodiak"). The purchase agreement is conditioned, among other things, by filing a registration statement with the SEC covering the shares that may be issued to Kodiak under the terms of the common stock purchase agreement. After the SEC has declared the registration statement related to the transaction effective (March 18, 2014; See below), the Company has the right at its sole discretion over a period of one year to sell shares of common stock under the terms set forth in the agreement in the total amount of

up to $3,000,000. Proceeds from this transaction will be used to fund research and development and working capital. Pursuant to the common stock purchase agreement, the Company issued to Kodiak 250,000 shares of common stock of the Company at no consideration. The Company valued the shares at their fair value of $135,000 and recorded the charge as financing cost. The Company's ability to put shares to Kodiak and obtain funds under the equity line is limited by the terms and conditions in the common stock purchase agreement, including restrictions on when the Company may exercise its put rights, restrictions on the amount the Company may put to Kodiak at any one time, which is determined in part by the trading volume of the Company's common stock, and a limitation on its ability to put shares to Kodiak.

4) During the first quarter of 2014, the Company issued 1,128,849 units in a non-brokered private placement for total consideration of $587,001. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was $419,287 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 117%; risk free interest of 0.68%, and an expected life of three years.

5) On April 24, 2014, the Company issued 384,615 units at a purchase price of $0.52 to one investor in a non-brokered private placement for a total consideration of $200,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was $117,047 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 102%; risk free interest of 0.91%, and an expected life of three years.

6) On June 30, 2014, the Company entered into a debt settlement agreement with one creditor, whereby it settled a debt in the amount of $24,011 by the issuance of 46,175 share of its common stock at a price per share of $0.52. On July 14, 2014, the Company entered into a debt settlement agreement with another creditor, whereby it settled a debt in the amount of $13,395 by the issuance of 25,759 shares of its common stock at a price per share of $0.52.

7) In July 2014, one of the investors mentioned in Note 3(b)(4) exercised warrants to purchase 96,154 shares of the Company's common stock at an exercise price of $0.52 for a total consideration of $50,000. As an inducement to the investor to exercise the warrants, the Company issued the investor twice the number of warrants exercised, which was 192,308 new warrants, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was $60,023 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 103%; risk free interest of 0.98%, and an expected life of three years.

8) During the third quarter of 2014, the Company issued 259,615 units at a purchase price of $0.52 per unit to private investors in a non-brokered private placement for total consideration of $135,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of $0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was $88,472 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 101%-102%; risk free interest of 0.93% -0.95%, and an expected life of three years.

On March 28, 2014 and on June 11, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 (See Note 4b(4) above) and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall ; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represent 14% of the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

c. *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	
	2014	2013
	U.S. dollars except per share data	
Basic:		
Loss for the period	5,504,101	5,539,139
Weighted average number of Ordinary Shares outstanding	54,162,596	50,483,814
Loss per ordinary share	0.10	0.11
Diluted		
Loss for the period	5,504,101	
Gain from change in fair value of warrants	598,000	
Total Loss for the period	6,102,101	
Weighted average number of shares used in the computation of basic loss per share	54,162,596	
Number of dilutive shares related to warrants	559,373	
Weighted average number of Ordinary Shares outstanding	54,721,969	
Loss per Ordinary Share	0.11	*0.11

The effect of the warrants was anti-dilutive, therefore the diluted loss per share for the year ended November 30, 2013 is equal to the basic loss per share.

Diluted loss per share does not include 15,267,559 shares underlying outstanding options, 400,000 shares due to stock-based compensation to service providers, 2,682,256 shares issuable upon exercise of warrants and 701,796 shares upon conversion of loans for the year ended November 30, 2014, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 4 CONVERTIBLE LOAN AGREEMENTS

a. Mediapark A.G.

In March 2013, the Company entered into a loan and warrant subscription agreement with Mediapark A.G., a Marshall Islands Company (Mediapark). The Company received a loan (the Mediapark Loan) in the total amount of $250,000 and issued to Mediapark 100,000 warrants. Each warrant can be exercised into one share of common stock at a purchase price of $0.50 per share and is exercisable until March 22, 2015. See also Note 8(a). The warrants issued are detachable from the Mediapark Loan and classified as a liability due to downround protection (ratchet and anti-dilution provisions). Therefore the Company allocated the proceeds from Mediapark, first to the warrants based upon their fair value and the residual amount was allocated to the Mediapark Loan. As of the issuance day of the warrants, the fair value of the warrants was $65,192 based on Monte Carlo simulation model. See also Note 8(a).

The Mediapark Loan bears interest at an annual rate of 8%, which is calculated quarterly. The original maturity day of the Mediapark Loan was June 30, 2013. The Company had the right to extend the maturity date for an additional period of up to 90 days provided that it issues an additional 100,000 warrants (the Additional Warrants).

If the Company has not paid the Mediapark Loan in full at the maturity date or, if extended, at the extended maturity date, Mediapark has the right of conversion in respect of the total outstanding amount of the principal balance including accrued interest as of the conversion date into shares of common stock, at a price per share equal to the lower of: (i) $0.75, and (ii) the value of the weighted average price of the share during the five trading days prior to the date of conversion.

On June 30, 2013 the Company exercised its discretion to extend the maturity date of the Mediapark Loan to September 30, 2013. In return for extending the maturity date, the Company issued to Mediapark additional 100,000 warrants at an exercise price of $0.50 per share, which subject to anti-dilution provisions, until June 30, 2015. The fair value of the warrants was $48,800 based on Monte Carlo simulation model. See also Note 8(a).

On September 30, 2013, the Company extended again the maturity date of Mediapark Loan to December 31, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of $0.50 per share, which subject to anti-dilution provisions, until September 30, 2015. The fair value of the warrants was $46,000 based on Monte Carlo simulation model. See also Note 8(a).

On December 6, 2013, the Company entered into a new agreement on the Mediapark Loan, pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the “Mediapark Convertible Loan”) in the aggregate principal amount of $100,000. Interest is calculated semiannually and is payable, along with the principal, on or before December 6, 2014. According to the agreement, in the event that the Company completes an equity financing prior to the maturity date for gross proceeds of $350,000 or more, Mediapark will convert the Company’s indebtedness under the Mediapark Loan and the Mediapark Convertible loan into shares of common stock and/or warrants on the same terms as the new equity financing.

As a result of the issuance of 1,128,849 units described in Note 3(b)(4), the Mediapark Loan and the Convertible Loan described above in the aggregate amount of $370,772 (including principal and interest) outstanding as of March 3, 2014 were converted on that date to 713,023 shares of common stock of the Company at a conversion rate of $0.52 per share and to 713,023 warrants to acquire additional shares of the Company’s common stock at an exercise price of $0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was $259,731 using the Black Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 104%; risk free interest of 0.66%, and an expected life of three years. This amount recorded as financial expense.

b. Nine Investments Limited

On May 29, 2014, the Company entered into a convertible loan agreement with Nine Investments Limited, a Hong Kong company (“Nine Investments”), pursuant to which Nine Investments loaned the Company $1,500,000 which the Company subsequently transferred to its Belgian Subsidiary, Orgenesis SPRL, to fund a research project to develop new medical technologies and cell therapies for the treatment of diabetes. The Company received the funds on June 4, 2014 (the “Closing Date”). Interest is calculated at 8% semiannually and is payable, along with the principal on or before December 31, 2014 subject to acceleration for specific events including: (i) if a grant of money to Orgenesis SPRL is not approved by Department De La Gestion Financiere Direction De L’analyse Financiere (“DGO6”) within 90 days after the loan proceeds are advanced; and (ii) if the Company raises, in the aggregate, gross proceeds of more than $400,000 between the date of the loan and the maturity date, but only to the extent of gross proceeds so raised that are in excess of $400,000.

Nine Investments may convert all or part of the loan into shares of the Company's common stock at $0.40 per share. The conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment in the event and in the manner following: (i) if and whenever the Company’s common shares at any time outstanding shall be subdivided into a greater or consolidated into a lesser number of common shares, or in case of any capital reorganization or of any reclassification of the capital of the Company or in case of the

consolidation, merger or amalgamation of the Company with or into any other company or of the sale of the assets of the Company as or substantially as an entirety or of any other company, the conversion price shall be decreased or increased proportionately; and (ii) in the event the Company issues any shares of common stock or securities convertible into shares at a price less than the conversion price, the conversion price shall be reduced for any unpaid or unconverted loan amount to the new issuance price.

As consideration for entering into the loan agreement, on June 5, 2014, the Company issued to Nine Investments 500,000 shares of its common stock.

The Company allocated the proceeds from Nine Investments between the shares and the convertible loan based on the relative fair value. In addition, the conversion right is detachable from the loan and classified as a derivative due to down round protection (full ratchet and anti-dilution provisions). Therefore, the Company attributed, to the conversion right derivative, out of the proceeds allocated to the convertible loan based on its fair value. The allocation of conversion right and shares represents a discount to the loan and will be accreted until the maturity date of the loan (December 31, 2014).

The table below presents the fair value of the instruments issued as of the Closing Date and the allocation of the proceeds:

	Total Fair Value	Allocation of Proceeds
Loan component	$ 1,262,000	$ 746,000
Shares component	250,000	180,000
Embedded derivative component	574,000	574,000
Total	$ 2,086,000	$ 1,500,000

The Company estimated the fair value of the embedded derivative by using the Black-Sholes formula for option pricing using the following parameters: Share price $0.50; Exercise price $0.40; Volatility 94%; Dividend yield 0; Risk-free interest 0.05% and 80% likelihood for conversion. The bonus shares component was recorded as additional paid-in-capital and the fair value of the embedded derivative component is classified as a financial liability because the conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment and will be measured in subsequent periods at fair value with changes in fair value charged to financial expenses or income, net.

c. Other Non U.S. Investors

In September 2014, the Company entered into convertible loans agreements for $150,000. The loans bear an annual interest rate of 6% and mature in six months, unless converted earlier. The lender shall have the right to convert all or any portion of the outstanding principal amount and all accrued but unpaid interest thereon into shares of common stock of the Company at a conversion price of $0.40 per share. Since the stock price is greater than the effective conversion price (after allocation of the total proceeds) on the measurement date, the conversion features is considered "beneficial" to the holders and equal to $135,000. 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.

NOTE 5 STOCK BASED COMPENSATION

a. Global Share Incentive Plan

On May 23, 2012, the Company's board of directors adopted the global share incentive plan (2012) ("Global Share Incentive Plan (2012)"). Under the Global Share Incentive Plan (2012), 12,000,000 shares of common stock have been reserved for the grant of options, 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

1) On December 23, 2012, the Company appointed Mr. Sav DiPasquale as the Company s President and Chief Executive Officer. As part of his compensation he was to receive stock options at an exercise price of $0.001 per share upon the performance as follows: (i) 982,358 performance shares to be issued upon the completion of a fund raising and (ii) 1,473,537 stock options to be issued as to 25% on each of the first, second, third and fourth anniversaries of the date of his employment agreement. On October 23, 2013, 255,413 performance options were granted to Mr. Dipasqale based on section (i) as mentioned above. The fair value of these options as of the date of grant was $165,850. On December 23, 2013, Mr. DiPasquale, resigned. As of this date 368,393 out of 1,473,537 were vested, the fair value of these options as of the date of grant was $217,347. According to Mr. DiPasquale s employment agreement, all vested options expire 90 days after the date of termination of employment. On February 16, 2014, Mr. DiPasquale exercised 623,806 options at a price of $0.001 per share.

2) On July 16, 2013, 250,000 options were granted to Dr. David Sidransky, a member of the Company's board of directors, at an exercise price of $0.75 per share. The options vest in five equal annual installments from the date of grant and expire on July 16, 2023. The fair value of these options as of the date of grant was $167,561 using the Black-Scholes valuation model.

3) On August 1, 2014, the Company granted an aggregate of 200,000 stock options to an employee that are exercisable at $0.50 per share, with 50,000 vesting quarterly over one year and expire on August 1, 2019. The fair value of these options as of the date of grant was $80,531 using the Black and Scholes option valuation model. In addition, the Company granted an aggregate of 200,000 stock options to an employee that are exercisable at $0.50 per share, with 25,000 vesting quarterly over two years and expire on August 1, 2024. The fair value of these options as of the date of grant was $96,058 using the Black and Scholes option valuation model.

4) On August 22, 2014, the Company approved an aggregate of 2,762,250 stock options to the Company s Chief Executive Officer that are exercisable at $0.0001 per share. Out of the total approved, 414,304 options vested immediately with a fair value as of the date of grant of $260,981 using the Black-Scholes valuation model, 1,242,996 options will vest quarterly over 4 years, with a fair value as of the date of grant of $782,997 using the Black-Scholes valuation model, and 1,104,950 options were not granted yet. All the options expire on August 22, 2024.

5) On August 1, 2014, the Company granted an aggregate of 650,000 stock options to an employee that is exercisable at $0.50 per share, with 40,625 vesting quarterly over four years and expire on August 1, 2024. The fair value of these options as of the date of grant was $311,905 using the Black-Scholes valuation model.

6) In December 2014, the Company granted an aggregate of 1,641,300 stock options to the Company s Chief Executive Officer of the U.S. Subsidiary that is exercisable at $.001 per share.

The fair value of each stock option grant is estimated at the date of grant using the Black-Scholes valuation model. The volatility is based on historical volatilities of companies in comparable stages as well as the historical volatility of companies in the industry and, by statistical analysis of the daily share-pricing model. The volatility of stock-based compensation granted after November 30, 2013 is based on historical volatility of the Company for the last two years. The expected term is equal to the contractual life, based on management estimation for the expected dates of exercising of the options. The fair value of each option grant is estimated on the date of grant using the Black Scholes option pricing model with the following assumptions:

	Year Ended November 30,	
	2014	**2013**
Value of one common share	$ 0.53 - 0.63	$ 0.75
Dividend yield	0%	0%
Expected stock price volatility	100.5-100.6%	97.3%
Risk free interest rate	1.67-2.52%	2.55%
Expected term (years)	5 - 10	10

A summary of the Company's stock option granted to employees and directors as of November 30, 2014 and 2013 and changes for the years then ended is presented below:

	2014		2013	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	12,294,765	0.265	10,315,815	0.297
Changes during the year:				
Granted	2,707,300	0.194	1,978,950	0.96
Exercised	(623,806)	0.001		
Forfeited	(1,568,804)	0.205		
Options outstanding at end of the year	12,809,455	0.27	12,294,765	0.265
Options exercisable at end of the year	9,661,548	0.568	6,611,982	0.20

Costs incurred with respect to stock based compensation for employees and directors, for the years ended November 30, 2014 and 2013 were $1,199,583 and $2,795,655 , respectively. As of November 30, 2014, there was $1,810,693 of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 3.7 years.

The following table presents summary information concerning the options granted to employees and directors outstanding as of November 30, 2014:

Exercise Prices $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price $	Aggregate Intrinsic Value $
0.0001	4,439,205	8.126	0.0001	2,885,039
0.001	3,338,276	7.173	0.001	2,166,547
0.50	1,050,000	8.716	0.50	157,500
0.69	2,318,254	7.173	0.69	
0.75	250,000	8.625	0.75	
0.79	942,520	7.603	0.79	
0.85	471,200	7.510	0.85	
	12,809,455	7.780	0.270	5,209,086

The following table presents summary of information concerning the options exercisable as of November 30, 2014:

Exercise Prices $	Number of Exercisable Options	Total Exercise Value $
0.0001	3,273,896	327
0.001	3,338,285	3,338
0.50	115,625	57,813
0.69	2,318,254	1,599,595
0.75	50,000	37,500
0.79	377,008	297,836
0.85	188,480	160,208
	9,661,548	2,156,617

c. Options Granted to Non-Employees

1) On August 2, 2013, 100,000 options were granted to Prof. Jay S. Skyler, one of the Company's board advisors, at an exercise price of $0.96 per share. The options vest in five equal annual installments from the date of grant and expire on April 4, 2023. The fair value of these options as of the date of grant was $65,620 using the Black and Scholes option pricing model.

2) On August 1, 2014, the Company granted an aggregate of 1,080,000 stock options to a consultant that are exercisable at $0.50, with 216,000 vesting immediately and 216,000 for each of the next four years and expire on August 1, 2018. The fair value of these options as of the date of grant was $403,614 using the Black and Scholes option valuation model.

The fair value of each stock option grant is estimated at the date of grant using the Black-Scholes valuation model. The volatility is based on historical volatilities of companies in comparable stages as well as the historical volatility of companies in the industry and, by statistical analysis of the daily share-pricing model. The volatility of stock-based compensation granted after November 30, 2013 is based on historical volatility of the Company for the last two years. The expected term is equal to the contractual life, based on management estimation for the expected dates of exercising of the options. The fair value of each option grant is estimated on the date of grant using the Black Scholes option pricing model with the following assumptions:

	Year Ended November 30,	
	2014	2013
Value of one common share	$ 0.53	$ 0.75
Dividend yield	0%	0%
Expected stock price volatility	101%	97.1%
Risk free interest rate	1.31%	2.63%
Expected term (years)	4	10

3) On April 3, 2014, the Company entered into a consulting agreement with Aspen Agency Limited, a Hong Kong corporation (Aspen), pursuant to which Aspen has agreed to provide investment banking, investor relations and business development services to the Company. In consideration for Aspen s services, the Company agreed to issue to Aspen 3,000,000 stock options in two separate tranches of 1,000,000 and 2,000,000, with the second tranche vesting if they exercise the first tranche, to acquire shares of the Company s common stock at an exercise price of $0.52 per share, for a period of three years. The term of the consulting agreement was from April 3, 2014 and will run for an indefinite period unless terminated by either party providing 30 days written notice. The fair value of the options was $744,000 and was recorded as additional paid in capital in the balance sheet with a corresponding expense in general and administrative expenses. On October 23, 2014, the Company entered into a termination agreement with Aspen in which both parties agreed to terminate the consulting agreement and to cancel the first tranche of options. By way of cancellation of the first tranche of options, the second tranche was cancelled as well. The fair value of each option grant is estimated on the date of grant using a hybrid model combining a Monte Carlo simulation and Black Scholes option pricing model with the following assumptions:

	Year Ended November 30, 2014
Value of one common share	$ 0.51
Dividend yield	0%
Expected stock price volatility	100%
Risk free interest rate	0.11-0.95%
Expected term (years)	1-3

A summary of the status of the stock options granted to nonemployees as of November 30, 2014, and2013 and changes for the years then ended is presented below:

	2014		2013	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	1,378,104	0.95	1,278,104	0.95
Changes during the year:				
Granted	2,080,000	0.51	100,000	0.96
Expired	(1,000,000)	0.52		
Options outstanding at end of the year	2,458,104	0.75	1,378,104	0.95
Options exercisable at end of the year	1,171,384	0.77	644,418	0.79

Costs incurred with respect to stock based compensation for consultants, for the year ended November 30, 2014 and 2013 was $922,970 and $316,312, respectively. As of November 30, 2014, there was $554,595 of unrecognized compensation costs related to non-vested nonemployees, to be recorded over the next 3.67 years.

The following table presents summary information concerning the options granted to nonemployees outstanding as of November 30, 2014:

Exercise Prices $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price $	Aggregate Instrinsic Value $
0.50	1,080,000	3.67	0.50	162,000
0.61	100,000	7.98	0.61	4,000
0.69	706,904	7.17	0.69	
0.96	100,000	8.34	0.96	
1.40	471,200	7.37	1.40	
	2,458,104	5.75	0.75	166,000

The following table presents summary of information concerning the options exercisable as of November 30, 2014:

Exercise Prices $	Number of Exercisable Options	Total Exercise Value $
0.50	216,000	108,000
0.61	40,000	24,400
0.69	706,904	487,764

0.96	20,000	19,200
1.40	188,480	263,872
	1,171,384	903,236

d. Shares Issued for Services

On June 25, 2014, the Company entered into a consulting agreement for professional services for a term of six months. Under the terms of the agreement, the Company agreed to pay the consultant $10,000 and 100,000 shares of restricted common stock. The shares were valued at the fair value of the Company s common stock as of November 30, 2014, which was $0.65 per share, and were recorded as an expense for the proportionate period to general and administrative expenses.

On September 4, 2014, the Company entered into a consulting agreement for professional services for a term of twelve months. Under the terms of the agreement, the Company agreed to pay the consultant 500,000 shares of restricted common stock, with a 250,000 vesting on date of grant and the balance vesting over 12 months. The shares were valued at the fair value of the Company s common stock with respect to the first vesting as of the date of grant on September 4, 2014, which was $0.64. With respect to the second vesting as of November 30, 2014, which was $0.65 per share, recorded an expense for the proportionate period to general and administrative expenses.

On November 1, 2014, the Company entered into a consulting agreement for professional services for a term of six months. Under the terms of the agreement, the Company agreed to pay the consultant 200,000 shares of restricted common stock, of which the first 50,000 shares shall vest immediately and the remaining 150,000 shares shall vest for the remaining term of the agreement with 50,000 shares on the first day of each fiscal quarter for the next three fiscal quarters, unless agreement is terminated sooner. The shares were valued at the fair value of the Company s common stock with respect to the first 50,000 as of the date of grant on November 1, 2014, or $0.59 per share, and were recorded as an expense to general and administrative expenses and with respect to each subsequent tranche as of November 30, 2014, which was $0.65 per share, were recorded as an expense for the proportionate period to general and administrative expenses.

On November 1, 2014, the Company entered into a consulting agreement for professional services for a term of six months. Under the terms of the agreement, the Company agreed to pay the consultant 113,333 shares of restricted common stock vesting on the date of grant. The shares were valued at the fair value of the Company s common stock as of November 1, 2014, which was $0.59 per share, and were recorded as an expense for the proportionate period to general and administrative expenses.

NOTE 6 PREPAID EXPENSES AND ACCOUNTS RECEIVABLE

	As of November 30,	
	2014	**2013**
Value added tax refundable	$ 70,326	$ 22,877
Prepaid expenses	26,023	12,765
Other receivables	8,609	1,266
Total	$ 104,958	$ 36,908

NOTE 7 PROPERTY AND EQUIPMENT, NET

The following table presents summary of the Company s property and equipment as of November 30, 2014 and 2013:

	Years Ended November 30,	
	2014	**2013**
Cost:		
Office furniture	$ 3,761	$ 3,761
Lab equipment	5,901	5,901
Computers	12,601	7,855
Total:	22,263	17,517
Less accumulated depreciation	(9,214)	(4,663)
	$ 13,049	$ 12,854

NOTE 8 - WARRANTS

As part of the Company s private placements and loan received as described in Notes 3 and 4, the Company issued warrants as follows:

a. Warrants Which are Subject to Exercise Price Adjustments

Grant Date	Number of Warrants	Exercise Price / Adjusted Exercise Price	Expiration Date	Number of Warrants Outstanding
March 2013	100,000	$ 0.40	March 22, 2015	100,000
May 6, 2013	1,526,718	$ 0.40	May 6, 2015	1,526,718

June 30, 2013	100,000	$	0.40	June 30, 2015	100,000
September 30, 2013	100,000	$	0.40	September 30, 2015	100,000
	1,826,718				1,826,718

As a result of an issuance to a service provider during the fourth quarter of 2014, each of the warrant exercise prices above was reduced to $0.40 per share.

The fair value parameters of such warrants are stated in the following table:

	November 30, 2014	November 30, 2013
Value of one common share	$ 0.65	$ 0.70
Dividend yield	0%	0%
Expected stock price volatility	100%	105%
Risk free interest rate	0.03 0.11%	0.13 0.28%
Expected term (years)	0.3 0.8	1 1.8
Expected capital raise date	March 2015	Q1 & Q4, 2014

b. Warrants Which are Not Subject to Exercise Price Adjustments included in equity

Grant Date	Number of Warrants	Exercise Price / Adjusted Exercise Price	Expiration Date	Number of Warrants Outstanding
April 2012	100,000	$ 1.00	April 2015	100,000
December 2013/ February 2014	1,128,849	$ 0.52	March 2017	1,032,695
March 2014	713,023	$ 0.52	March 2017	713,023
April 2014	384,615	$ 0.52	April 2017	384,615
July 2014	192,308	$ 0.52	July 2017	192,308
July 2014	144,230	$ 0.52	July 2017	144,230
August 2014	115,385	$ 0.52	August 2017	115,385
	2,778,410			2,682,256

NOTE 9 FAIR VALUE

As of November 30, 2014, and November 30, 2013, the Company s assets and liabilities that are measured at fair value and classified as level 3 are as follows:

	November 30, 2014	
	Level 3	Total
Warrants	$ 559,954	$ 559,954
Embedded derivative*	$ 992,000	$ 992,000

	November 30, 2013	
	Level 3	Total
Warrants	$ 1,157,954	$ 1,157,954

* Represented the conversion feature embedded in the convertible loan.

The fair value of each of the warrants described in Note 8(a) is determined by using a Monte Carlo simulation model based on a risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multistep dynamic model. The first step is to model the risk neutral distribution of the share value on the new issuance dates. Then for each path to use the Black-Scholes valuation model to estimate the value of the warrants on the last issuance date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the volatility and future expected issuance dates.

The fair value of the embedded derivative described in Note 4(b) is determined by using the Black-Scholes valuation model. Notwithstanding the anti-dilution provision, the Black Scholes formula produces a value that is substantially the same to the value under more flexible option valuation models such as the Monte Carlo simulation model due to an ineffectiveness of this protection feature over the relatively short term of the embedded derivative.

The following table presents the assumptions that were used for the models as of November 30, 2014:

	Warrants	Embedded Derivative
Fair value of shares of common stock	$ 0.65	$ 0.65
Expected volatility	100%	100%
Risk free interest rate	0.03% 0.11%	0.04%
Expected term (years)	0.3 0.8	0.08
Expected dividend yield	0%	0%

The table below sets forth a summary of the changes in the fair value of the Company s financial liabilities classified as Level 3 for the year ended November 30, 2014:

	Warrants	Embedded Derivative
Balance at beginning of period	$ 1,157,954	$
Additions		574,000
Changes in fair value during the period*	(348,000)	418,000
Changes in fair value related to warrants expired	(250,000)	
Balance at end of period	$ 559,954	$ 992,000

*There were no transfers to Level 3 during 2014.

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, 2013:

	Warrants
Balance at beginning of period	$ -
Additions	1,291,270
Changes in fair value during the period	(133,316)
Balance at end of period	$ 1,157,954

The Company have performed a sensitivity analysis of the results to changes in the assumptions for capital raising projections and expected volatility with the following parameters: Capital raising projection with a variance of +/- 3 months with warrant fair value base of $0.60 and range of $0.58 to $0.63; Expected volatility assumption of a base of $0.60 and 90% at $0.57 and 110% at $0.62.

The sensitivity of the embedded derivative fair value to changes in the expected volatility assumption is a base of $992 and 90% at $987 and 110% at $998.

NOTE 10 RESEARCH AND DEVELOPMENT EXPENSES, net

	Year Ended November 30,	
	2014	**2013**
Salaries and related expenses	$ 779,746	$ 395,710
Stock based compensation	766,070	475,877
Professional fees and consulting services	126,103	378,826
Lab expenses	609,081	51,743

Other research and development expenses		197,271		150,300
Less grant		(928,821)		
Total	$	1,549,450	$	1,452,456

NOTE 11 GENERAL AND ADMINISTRATIVE EXPENSES

	Year Ended November 30,	
	2014	2013
Salaries and related expenses	$ 330,134	$ 415,163
Stock based compensation	1,720,983	2,636,090
Accounting and legal fees	476,095	283,493
Professional fees	212,244	296,753
Business development	143,387	187,827
Other general and administrative expenses	144,337	188,720
Total	$ 3,027,180	$ 4,008,046

NOTE 12 FINANCIAL EXPENSES, NET

	Year Ended November 30,	
	2014	2013
Decrease in fair value of warrants and embedded derivative	$ (180,000)	$ (133,316)
Interest expense on convertible loans	691,090	172,510
Funding fees to Kodiak	135,000	-
Foreign exchange loss, net	9,740	33,761
Bank commissions, net	11,910	5,702
Issuance of warrants as induced conversion	259,731	-
Total	$ 927,471	$ 78,657

NOTE 13 TAXES

a. The Company

The Company is taxed according to tax laws of the United States. The income of the Company is taxed in the United States at a rate of up to 34%.

b. The Israeli Subsidiary

The Israeli Subsidiary is taxed according to Israeli tax laws. The regular corporate tax rate in Israel for 2014 is 26.5% .

On August 5, 2013, the Law for Change of National Priorities (Legislative Amendments for Achieving the Budgetary Goals for 2013-2014), 2013 was published in Reshumot (the Israeli government official gazette), enacting, among other things, the following raising the corporate tax rate beginning in 2014 and thereafter to 26.5% (instead of 25%).

c. The Belgian Subsidiary

The Belgian Subsidiary is taxed according to Belgian tax laws. The regular corporate tax rate in Belgium for 2014 is 33.99% .

e. Tax Loss Carryforwards

1) The Company. As of November 30, 2014, the Company had net operating loss (NOL) carry forwards equal to $2,690,625 that is available to reduce future taxable. The Company s NOL carry forward is equal to $137,673 and 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 prechange NOL may not exceed the general Section 382 limitation, which is the fair market value of the prechange entity multiplied by the long term tax exempt rate.

2) Israeli Subsidiary. As of November 30, 2014, the Israeli Subsidiary had approximately $3,273,419 of NOL carry forwards that are available to reduce future taxable income with no limited period of use.

3) Belgian Subsidiary. As of November 30, 2014, the Belgian Subsidiary had approximately 169,682 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, 2014 and 2013:

	As of November 30,	
	2014	**2013**
Net operating loss carry forwards	$ 1,625,660	$ 1,013,024
Research and development expenses	229,673	182,668
Holiday and recreation pay	15,530	15,496
Severance pay accruals	(372)	1,132
Less: Valuation allowance	$ (1,870,491)	$ (1,212,320)
Net deferred tax assets	-	-

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 more likely than not achievable, the Company recorded a full valuation allowance.

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 due to the uncertainty of the realization of such tax benefits (see above).

g. Tax Assessments

1) The Company. As of November 30, 2014 the Company has not received final tax assessment for the years 2010 to 2013.

2) Israeli Subsidiary. As of November 30, 2014 the Israeli Subsidiary has not received final tax assessment for the years 2012 to 2013.

3) Belgian Subsidiary. As of November 30, 2014, the Belgian Subsidiary has not received final tax assessment since commencement.

h. Uncertain Tax Provisions

As of November 30, 2014, the Company have not accrued a provision for uncertain tax positions.

NOTE 14 - RELATED PARTY TRANSACTIONS

	2014	2013
Management and consulting fees to the Chairman of the Board	$ 33,755	$ 140,037
Compensation to the nonexecutive directors (except the Chairman of the Board)	$ 39,240	$ 40,648

With respect to options granted and salary paid to the Company s Chief Executive Officer, see Note 5(b)(4).

With respect to options granted to the Company s board members, see Note 5(b).

On June 2, 2012, the Company signed a promissory note with Guilbert Cuison, one of the Company's shareholders. According to the note, the Company will return the loan granted by the shareholder within thirty days from the date the Company completes on equity financing resulting in gross proceeds to the Company of at least $3,000,000. Since the date of this promissory note the Company has successfully raised $3,000,000 in financing and expects to negotiate with this shareholder as to when the Company will be able to pay the note.

NOTE 15 - SUBSEQUENT EVENTS

On November 17, 2014, the Company s Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a €2.015 million support program for the research and development of a potential cure for Type 1 Diabetes. The Financial support is composed of a 1,085,000 Euros (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of 930,000 Euros (60% of budgeted costs) of the experimental development part of the research program. The grants will be paid to us over a period of approximately 3 years. The grants are subject to certain conditions with respect to the Company s work in the Walloon Region, the Company s own investment in these projects and certain other conditions and contain a repayment provision upon attaining a favorable outcome. In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. On December 9 and 16, 2014, the Companyreceived €651,000 and €558,000 under the grant, respectively.

On December 21, 2014, the Company received a notification from the Israel-U.S. Binational Industrial Research and Development Foundation (BIRD) that its wholly owned Subsidiary, Orgenesis Ltd., and its research and development partner, have been approved by BIRD's Board of Governors for a conditional grant of $800,000 for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project). A Cooperation and Project Funding Agreement (CPFA) must be signed for the Project with the BIRD Foundation within three months, or by March 31, 2015.

On December 31, 2014, the Company executed an amendment to convertible loan agreement with Nine Investments Limited to extend the due date of the loan of $1,500,000 from December 31, 2014 to January 31, 2015. As of February 19, 2015, the Company is working on a second amendment to extend the loan to a new date, but such second amendment has not been finalized.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, 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 our management, including our interim president and chief executive officer (who is our principal executive officer) and our chief financial officer, treasurer, and secretary (who is our principal financial officer and principal accounting officer) to allow for timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management is required to apply its judgment in evaluating the costbenefit relationship of possible controls and procedures. The ineffectiveness of our disclosure controls and procedures was due to material weaknesses identified in our internal control over financial reporting, described below.

Management s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting. In order to evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the SarbanesOxley Act of 2002. Our management, with the participation of our principal executive officer and principal financial officer has conducted an assessment, including testing, using the criteria in Internal Control Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). 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. Based on this evaluation, our management concluded our internal control over financial reporting was not effective as of November 30, 2014. The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses which are indicative of many small companies with small staff:

(i) inadequate segregation of duties consistent with control objectives; and
(ii) ineffective controls over period end financial disclosure and reporting processes.

Our company plans to take steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this annual report, we have not been able to remediate the material weaknesses identified above. To remediate such weaknesses, we plan to implement the following changes during our fiscal year ending November 30, 2015:

(i) appoint additional qualified personnel to address inadequate segregation of duties and ineffective risk management;
(ii) adopt sufficient written policies and procedures for accounting and financial reporting.

The remediation efforts set out in (i) is largely dependent upon our company securing additional financing to cover the costs of implementing the changes required. If we are unsuccessful in securing such funds, remediation efforts may be adversely affected in a material manner. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within our company have been detected. These

inherent limitations include the realities that judgments in decisionmaking can be faulty and that breakdowns can occur because of simple error or mistake.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended November 30, 2014 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

Directors and Executive Officers, Promoters and Control Persons

As of February 19, 2015, our directors and executive officers, their age, positions held, and duration of such, are as follows:

Name	Position Held with Company	Age	Date First Elected or Appointed
Vered Caplan (1)	President, Chief Executive Officer and Chairperson of the Board of Directors	46	August 14, 2014 February 2, 2012
Scott Carmer (2)	Chief Executive Officer of Subsidiary, Orgenesis Maryland Inc.	50	July 23, 2014
Neil Reithinger (3)	Chief Financial Officer, Treasurer and Secretary	44	August 1, 2014
Sarah Ferber (4)	Chief Scientific Officer	60	February 2, 2012
Guy Yachin	Director	47	April 2, 2012
David Sidransky	Director	54	July 18, 2013
Etti Hanochi	Director	41	April 6, 2012
Yaron Adler	Director	44	April 17, 2012

Notes

(1) Ms. Caplan was appointed Interim President and CEO on December 23, 2013 and then appointed President and CEO on August 14, 2014.

(2) Mr. Carmer was appointed CEO of our Subsidiary, Orgenesis Maryland Inc., on July 23, 2014.

(3) Mr. Reithinger was appointed CFO, Treasurer and Secretary on August 1, 2014.

(4) Professor Ferber was appointed Chief Scientific Officer on February 2, 2012.

Business Experience

The following is a brief account of the education and business experience of our directors and executive officers during the past five years, indicating their principal occupation during the period, and the name and principal business of the organization by which they were employed**.**

Vered Caplan President and Chief Executive Officer and Chairperson of the Board of Directors

Vered Caplan was appointed President and CEO on August 14, 2014, prior to which she was Interim Presdient and CEO since December 23, 2013. Since 2008, Ms. Caplan has been Chief Executive Officer of Kamedis, a company focused on utilizing plant extracts for dermatology purposes. From 2004 to 2007, Ms. Caplan was Chief Executive Officer of GammaCan, 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 selfpropelled 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 TelAviv University specializing in signal processing; management for engineers from TelAviv University specializing in business development; and a B.Sc. in mechanical engineering from the Technion specialized in software and cad systems.

Scott Carmer – CEO of Orgenesis Maryland Inc.

Scott Carmer was appointed CEO of our U.S. Subsidiary on July 23, 2014. Prior to that, he served as Senior Vice President, MedImmune Specialty Care (Division of AstraZeneca) for AstraZeneca from February 2013 to December 2013. Previously he served as Executive Vice President, Chief Commercial Officer of MedImmune (which was acquired by AstraZeneca) from 2010 to 2013. Mr. Carmer was Vice President, Rheumatology Sales & Marketing for Genentech, Inc. from 2006 to 2010. Prior to that, Mr. Carmer was with Amgen, Inc. from 2001 to 2006. Mr. Carmer has not held any directorships in the last five years. Mr. Carmer obtained a B.S. in Biology from the University of Kentucky in 1987.

Neil Reithinger, CPA Chief Financial Officer, Secretary, and Treasurer

Neil Reithinger was appointed CFO, 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 Ph.D. Chief Scientific Officer

Prof. Sarah Ferber was appointed Chief Scientific Officer on February 2, 2012. 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. She completed a postdoctoral fellowship at the Joslin Diabetes Lab at Harvard Medical School. Prof. Ferber's breakthrough discovery suggested that humans carry their own 'stemcells' throughout adulthood, thus obviating the need for embryonic stem cells for generating an organ in need. Most of the research was conducted in Prof. Ferber's lab, in the Endocrine Research Lab at the Sheba Medical Center, and currently employs 11 scientists. Prof. Sarah Ferber received TEVA, LINDNER, RUBIN and WOLFSON awards for this research. Prof. Ferber's research work has been funded over the past 10 years by the JDRF, the Israel Academy of Science foundation (ISF) and DCure.

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Guy Yachin – Director

Guy Yachin was appointed a director on 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, Guy served as CEO of MGVS, 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. 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, and provided seed funding and guidance to more than a dozen biomedical startups such as Remon Medical Technologies, Enzymotec and NanoPass. 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 and business experiences as described above.

David Sidransky – Director

David Sidransky was appointed 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 peerreviewed 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, Roche, Amgen and Veridex, LLC (a Johnson & Johnson diagnostic company), among others, and is currently on the board of KV Pharmaceutical, Rosetta Genomics and Champions Oncology, Inc. Dr. Sidransky served as Director (20052008) of the American Association for Cancer Research (AACR). He was the chairperson of AACR International Conferences (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. We believe Mr. Sidransky is qualified to serve on our board of directors because of his education and business experiences as described above.

Etti Hanochi Director

Etti Hanochi (CPA Isr.) was appointed a director on April 6, 2012. Ms. Hanochi joined Nextage Ltd. as a Partner in 2010. Ms. Hanochi has extensive experience in mergers and acquisition transactions, accounting and tax consultations. Ms. Hanochi has broad experience in implementing internal procedures and controls and specializes in US GAAP. Under the role of Chief Financial Officer at Nextage, Ms. Hanochi has acted as VP Finance and CFO of several hightech companies, including Intucell (acquired by Cisco in January 2013) and XtremIO (acquired by EMC in May 2012). Prior to joining Nextage Ltd., Ms. Hanochi worked as a Senior Manager at Ernst & Young for almost 11 years for many HiTech public and private companies. She holds a B.A in Accounting and a Management degree from the Management College, an MBA from TelAviv University, a Master's degree in Law from BarIlan University and is a Certificated Public Accountant. We believe Ms. Hanochi is qualified to serve on our board of directors because of her education and business experiences, including her experience as a director of similar companies, as described above.

Yaron Adler, Director

Yaron Adler was appointed a director on April 17, 2012. In 1999 Mr. Adler cofounded 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 productionengineering 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. He has a B.A. in computer sciences and economics from TelAviv University. We believe Mr. Adler is qualified to serve on our board of directors because of his education and business experiences as described above.

Family Relationships

There are no family relationships between any director or executive officer.

Significant Employees

We do not have other significant employees.

Committees of Board of Directors

Board of Advisors

On April 14, 2012, we formed a Board of Advisors committee. From time to time, we add members to our Board of Advisors. These individuals are comprised of distinguished scientists whose experience, knowledge and counsel help in the development of our company and our technology. These Board of Advisors members may be compensated for their time in options to purchase shares of our common stock. Advisors do not have voting or observatory powers over the Board of Directors or management. Our Chief Executive Officer interacts with these advisors from time to time on matters related to our technological development. There are no formalized Board of Advisors meetings, and members have no other special powers or functions. Each individual on the Board of Advisors works parttime with us as requested.

Our Board of Advisors committee is currently comprised of Dr. Fleming, Prof. Ricordi and Dr. Jay Skyler, M.D.

Dr. Fleming

On April 14, 2012, we executed a consulting agreement with Dr. G. Alexander Fleming. Dr. Fleming has agreed to be appointed to our Board of Advisors committee, and in return we will pay Dr. Fleming an hourly fee of $300 for attending inperson meetings and $200 for attending meetings via conference call. We also granted Dr. Fleming 471,200 stock options. The options will be subject to our stock option plan and will have vesting provisions. Dr. Fleming will also be reimbursed for outofpocket expenses incurred for carrying out consulting business.

Dr. Fleming is a board certified endocrinologist with medical and research training at Emory, Vanderbilt, and National Institutes of Health. He served as reviewer and supervisory medical officer for 12 years at the FDA and brings extensive clinical experience and regulatory responsibility in the therapeutic area of diabetes and other general metabolic, bone, and endocrine disorders, growth and development, nutrition, lipidlowering compounds, and reproductive indications. He led reviews of landmark approvals including those of the first statin, insulin analog, metformin, PPARagonist, and growth hormone for nonGH deficiency indications. He was responsible for the regulation of the earliest biotech products including human insulin and growth hormone. Dr. Fleming helped to shape a number of FDA policies and practices related to therapeutic review and regulatory communication and represented the FDA at the International Conference on Harmonisation (ICH) and the World Health Organization, where he was stationed in 199293.

Dr. Fleming serves on numerous scientific advisory boards, expert committees, and corporate boards. He has continued to promote dialogue and creativity within the community of therapeutic developers. Dr. Fleming has authored the book, “Optimizing Development of Therapies for Diabetes” and a wide variety of scientific and policy publications. He has served as an invited editorialist to The New England Journal of Medicine and as a commentator on National Public Radio.

Prof. Ricordi

On November 14, 2012, we executed a consulting agreement with Professor Camillo Ricordi. Prof. Ricordi has agreed to be appointed to our Board of Advisors committee and we will pay Prof. Ricordi an hourly fee of $300 for attending inperson meetings and $200 for attending meetings via conference call. We also granted Prof. Ricordi 100,000 stock options. The options will be subject to our stock option plan and will have vesting provisions. Prof. Ricordi will also be reimbursed for outofpocket expenses incurred for carrying out consulting business. The agreement is for an indefinite period unless terminated by either party with 30 days advance written notice to the other party.

Prof. Ricordi is the Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine, Professor of Biomedical Engineering, and Microbiology and Immunology at the University of Miami Diabetes Research Institute. He also serves as Director of the Diabetes Research Institute Cell Transplant Center and Responsible Head of the NIHfunded cGMP Human Cell Processing Facility.

Dr. Skyler

On April 9, 2013, we executed a consulting agreement with Dr. Jay Skyler. Prof. Skyler has agreed to be appointed to our Board of Advisors committee, and we will pay Dr. Skyler an hourly fee for attending inperson meetings and meetings via conference call. We also granted Dr. Skyler 100,000 stock options exercisable at current market prices. The options will be subject to our stock option plan and will have vesting provisions. Dr. Skyler will also be reimbursed for outofpocket expenses incurred for carrying out consulting business.

Dr. Skyler's career in diabetes spans over four decades, where his research interests have concentrated in clinical aspects of diabetes, particularly improving the care of Type 1 diabetes. Dr. Skyler is a Professor of Medicine, Pediatrics and Psychology at the University of Miami Miller School of Medicine and Deputy Director for Clinical Research and Academic Programs at the Diabetes Research Institute. He also is an Adjunct Professor of Pediatrics at the Barbara Davis Center for Childhood Diabetes, University of Colorado at Denver. He is a past President of the American Diabetes Association, the International Diabetes Immunotherapy Group, and the Southern Society for Clinical Investigation, and was a VicePresident of the International Diabetes Federation. He served as a member of the Endocrinology, Diabetes, and Metabolism Subspecialty Examining Board of the American Board of Internal Medicine, as Chairman of the Council of Subspecialty Societies of the American College of Physicians (ACP) and a member of the ACP Board of Regents. A frequent national and international lecturer, Dr. Skyler has been an author, editor and coeditor of numerous books, monographs, chapters and articles. Dr. Skyler was founding EditorinChief of Diabetes Care.

Nominating Committee

Our board of directors is of the view that it is appropriate for us not to have a standing nominating committee because the current size of our board of directors does not facilitate the establishment of a separate committee. Our board of directors has performed, and will perform adequately, the functions of a nominating committee. The directors who perform the functions of a nominating committee are independent. The determination of independence of directors has been made using the definition of “independent director” contained under Rule 4200(a)(15) of the Rules of the Financial Industry Regulatory Authority. Our board of directors has not adopted a charter for the nomination committee. There has not been any defined policy or procedure requirements for stockholders to submit recommendations or nomination for directors. Our board of directors does not believe that a defined policy with regard to the consideration of candidates recommended by stockholders is necessary at this time because we believe that, given the early stages of our development, a specific nominating policy would be premature and of little assistance until our business operations are at a more advanced level. There are no specific, minimum qualifications that our board of directors believes must be met by a candidate recommended by our board of directors. The process of identifying and evaluating nominees for director typically begins with our board of directors soliciting professional firms and other industry professionals with whom we have an existing business relationship, such as law firms, accounting firms or

financial advisory firms, for suitable candidates to serve as directors. It is followed by our board of director's review of the candidates' resumes and interview of candidates. Based on the information gathered, our board of directors then makes a decision on whether to recommend the candidates as nominees for director. We do not pay any fee to any third party or parties to identify or evaluate or assist in identifying or evaluating potential nominees. Our company does not have any defined policy or procedural requirements for stockholders to submit recommendations or nominations for directors. Our directors believe that, given the stage of our development, a specific nominating policy would be premature and of little assistance until our business operations develop to a more advanced level.

A stockholder who wishes to communicate with our board of directors may do so by directing a written request addressed to our Chief Executive Officer, at the address appearing on the first page of this annual report.

Audit Committee

On December 27, 2012, our company s board of directors formed an audit committee and adopted an Audit Committee Charter. According to its charter, the Audit Committee shall consist of at least one member, and a majority of members shall meet the independence requirements of Rule 10A3 of the Securities Exchange Act of 1934, as amended (the 1934 Act). Also, one of the members shall qualify as an audit committee financial expert as defined by Rule 309 of the 1934 Act. The Audit Committee Charter describes the primary functions of the Audit Committee, including the following:

1. the appointment, remuneration and termination of our auditors;

2. reviewing and discussing with management our audited financial statements and reviewing with management and our auditors our financial statements;

3. reviewing the performance of and fees paid to the auditors; and

4. meeting separately and periodically, with our auditors.

Currently, the board of directors has appointed Etti Hanochi, Guy Yachin and Vered Caplan to act as members on our audit committee.

Audit Committee and Audit Committee Financial Expert

The Audit Committee member who is a financial expert is Etti Hanochi, who is also independent director. Ms. Hanochi has been a member of our board of directors since April 2012, and is a Partner at Nextage Ltd. (Israel), a privately held global financial services organization. Previously, she worked as a Senior Manager for Ernst & Young for nearly 11 years, focused mainly on hi-tech companies, both public and private. She has gained vast experience in M&A transactions, accounting and tax consultation which includes broad experience in implementing internal procedures and controls with a specialty in US GAAP. She holds a B.A. in Accounting and a Management degree from the Management College and an MBA from Tel-Aviv University, a Master s degree in Law from BarIlan University and is a Certificated Public Accountant.

Compensation Committee

On December 27, 2012, our company adopted a Compensation Committee Charter and appointed Etti Hanochi and Vered Caplan to act as members on our Compensation Committee. Etti Hanochi is an independent director. The role of the Compensation Committee is to:

1. review and recommend to our board of directors the appropriate compensation level for our executive officers;

2. oversee our compensation and benefit plans, policies and practices, including its executive compensation plans and incentivecompensation and equitybased plans;

3. monitor and evaluate, at their sole discretion, matters relating to the compensation and benefits structure of our company; and

4. take such other actions within the scope of the Compensation Committee s Charter as our board of directors may assign to the Compensation Committee from time to time or as the Compensation

Committee deems necessary or appropriate.

Term of Office

Our directors cease to hold office immediately before their election at an annual general meeting or their appointment by the unanimous resolution of our shareholders, but are eligible for reelection or reappointment. Notwithstanding the foregoing, our directors hold office until their successors are elected or appointed, or until their deaths, resignations or removals. Our officers hold office at the discretion of our board of directors, or until their deaths, resignations or removals.

Potential Conflicts of Interest

We are not aware of any conflicts of interest with our directors and officers.

Director Independence

Our board of directors consists of Vered Caplan, David Sidransky, Guy Yachin, Etti Hanochi and Yaron Adler. Our securities are quoted on the OTCQB which does not have any director independence requirements. Under NASDAQ Marketplace Rule 5605(a)(2), a director is not considered to be independent if he or she is also an executive officer or employee of the company. Using this definition of independence, we have determined that all members of our board of directors, except for Vered Caplan, are each an independent director. Vered Caplan is not independent as she is also an executive officer.

Involvement in Certain Legal Proceedings

Our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;

4. being found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

5. being the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of: (i) any federal or state securities or commodities law or regulation; or (ii) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease anddesist order, or removal or prohibition order; or (iii) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

6. being the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any selfregulatory organization (as defined in Section 3(a)(26) of the Securities Exchange Act of 1934), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

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Section 16(a) Beneficial Ownership Compliance

Section 16(a) of the Securities Exchange Act, as amended, requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the Securities and Exchange Commission and to provide us with copies of those filings. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, during fiscal year ended November 30, 2014, the filing requirements applicable to its officers, directors and greater than 10% beneficial owners were complied.

Code of Ethics

We currently do not have a Code of Ethics.

Director Independence

Our board of directors consists of Vered Caplan, David Sidransky, Guy Yachin, Etti Hanochi and Yaron Adler. Our securities are quoted on the OTCQB which does not have any director independence requirements. Under NASDAQ Marketplace Rule 5605(a)(2), a director is not considered to be independent if he or she is also an executive officer or employee of the company. Using this definition of independence, we have determined that all members of our board of directors, except for Vered Caplan, are each an independent director. Vered Caplan is not independent as she is also an executive officer.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation

The following table summarizes the compensation of each named executive for the fiscal years ended November 30, 2014 and 2013 awarded to or earned by (i) each individual serving as our principal executive officer and principal financial officer of the Company and (ii) each individual that served as an executive officer of the Company at the end of such fiscal years who received compensation in excess of $100,000.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Nonequity Incentive Plan Compensation ($)	Change in Pension Value and Non Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Vered Caplan *CEO & President* [1]	2014 2013	185,596 N/A	Nil N/A	Nil N/A	567,948 N/A	Nil N/A	Nil N/A	Nil N/A	753,544 N/A
Sav DiPasquale *Former CEO & President* [2]	2014 2013	38,958 184,669	N/A Nil	Nil Nil	Nil 369,506	Nil Nil	Nil Nil	Nil Nil	38,958 554,175

Jacob BenArie *Former CEO & President* [3]	2014 2013	167,760 204,891	Nil Nil	Nil Nil	Nil 474,174	Nil Nil	32,842 24,552	Nil Nil	200,602 703,617
Scott Carmer *CEO of Orgenesis*	2014 2013	104,167 N/A	Nil N/A	Nil N/A	Nil N/A	Nil N/A	Nil N/A	Nil N/A	104,167 N/A

Maryland Inc. [4]									
Neil Reithinger	2014	6,000	Nil	Nil	26,697	Nil	Nil	Nil	32,697
CFO, Treasurer & Secretary [5]	2013	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Joseph Tenne									
Former CFO, Treasurer & Secretary [6]	2014	55,594	Nil	Nil	15,922	Nil	Nil	Nil	71,516
	2013	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Dov Weinberg									
Former CFO, Treasurer & Secretary [7]	2014	59,500	Nil	Nil	8,873	Nil	Nil	Nil	68,373
	2013	126,600	Nil	Nil	233,423	Nil	Nil	Nil	360,023
Sarah Ferber									
Chief Scientific Officer [8]	2014	286,160	Nil	Nil	Nil	Nil	34,309	Nil	320,469
	2013	200,604	Nil	Nil	268,861	Nil	34,706	Nil	504,171

Notes

(1) Ms. Caplan was appointed Interim President and CEO on December 23, 2013 and then appointed President and CEO on August 14, 2014.

(2) Mr. DiPasquale was appointed President and CEO on December 17, 2012 and resigned on December 23, 2013.

(3) Mr. BenArie was appointed President and CEO on February 2, 2012 and resigned on December 17, 2012. On December 17, 2012, Mr. BenArie was appointed as President and CEO of our Subsidiary, Orgenesis Ltd., and resigned that position on October 31, 2014.

(4) Mr. Carmer was appointed CEO of our Subsidiary, Orgenesis Maryland Inc., on August 4, 2014. His contractual salary is $250,000 annually, of which $104,167 was accrued as of November 30, 2014 and of which none was paid.

(5) Mr. Reithinger was appointed CFO, Treasurer and Secretary on August 1, 2014.

(6) Mr. Tenne was appointed CFO, Treasurer and Secretary on April 16, 2014 and resigned on August 1, 2014.

(7) Mr. Weinberg was appointed CFO, Treasurer and Secretary on February 2, 2012 and resigned on April 16, 2014.

(8) Professor Ferber was appointed Chief Scientific Officer on February 2, 2012.

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Compensation Discussion and Analysis

On February 2, 2012, we entered into a consultancy agreement with Weinberg Dalyo Inc. for financial consulting services for a consideration of $3,000 per month. Weinberg Dalyo Inc. is owned by our former Chief Financial Officer, Mr. Weinberg. During the period of this agreement, if the consultant locates an investor, which we enter into a binding investment agreement, the consultant is entitled to a bonus of 2% from the total investment in cash. Due to additional work by Mr. Weinberg regarding the quarterly and annual filings of our company, due diligence with investors and financial work regarding fund raising, we increased the compensation payable to Mr. Weinberg as follows: on January 31, 2013, to $9,000 per month, on April 30, 2013, to $10,000 per month, on May 31, 2013, to $11,000 per month, and on August 2013, to $12,500 per month. Mr. Weinberg resigned his position as CFO, Treasurer and Secretary on April 16, 2014.

On February 2, 2012, we entered into an employment agreement (the "Ferber Employment Agreement") with Prof. Sarah Ferber. Pursuant to the Ferber Employment Agreement, Prof. Ferber agreed to serve as our Chief Scientific Officer. Prof. Ferber will be paid a gross salary of NIS (Israeli shekel) 36,000 per month, which is approximately $9,572 based on an exchange rate of 1 NIS equals 0.2689 USD as of February 2, 2012. In the event we complete a financing of at least $1,000,000 (in addition to the $1.5 million private placement in February 2012), Prof. Ferber's salary will double. Prof. Ferber agreed to spend 50% of her entire business time and attention to the business of our company. We also granted Prof. Ferber stock options to purchase 2,781,905 shares of our common stock at a price per share equal to $0.0001. Prof. Ferber's salary was increased to NIS 72,000 per month in May 2013.

On March 14, 2012 we signed an employment agreement with Jacob BenArie, our former Chief Executive Officer to be effective from February 2, 2012. In return for acting as our Chief Executive Officer, we agreed to pay Mr. BenArie a fee of 40,000 New Israeli Shekels per month; reimburse any of outofpocket expenses; and to grant 2,781,905 stock options at a price of US $0.69 per option share. Mr. BenArie was eligible to receive bonuses based upon performance criteria to be determined by our board of directors. Mr. BenArie was also entitled to receive a onetime incentive bonus in an amount of USD 10,000 to be paid within 14 days of the date of signing the employment agreement.

On December 17, 2012, Mr. Jacob BenArie resigned as President and Chief Executive Officer. There were no disagreements between Mr. BenArie and our company. Mr. BenArie retains his position as President and Chief Executive Officer of our Israeli Subsidiary, Orgenesis Ltd., and resigned that position on October 31, 2014.

On January 3, 2013, we executed an employment term sheet with Mr. Sav DiPasquale to act as our President and Chief Executive Officer to be effective December 17, 2012 in consideration for, among other things, an annual gross salary of US$180,000. On February 17, 2013 we executed an employment agreement with Sav DiPasquale to act as our President and Chief Executive Officer, which formalized the term sheet dated December 17, 2012. As part of his compensation he was to receive stock options at an exercise price of $0.001 per share upon the performance as follows: (i) 982,358 performance shares to be issued upon the completion of a fundraising and (ii) 1,473,537 stock options to be issued as to 25% on each of the first, second, third and fourth anniversaries of the date of his employment agreement. The fair value of these shares as of the date of grant was $869,387. On October 23, 2013, 255,413 performance options were granted to Mr. Dipasqale based on his agreement. On December 23, 2013, Mr. DiPasquale, resigned. As a result of his resignation, all options that were not vested were forfeited. On January 2, 2014, the board of directors approved a grant of 368,393 options out of the 1,473,537 options mentioned above. The grant was based on Mr. DiPasquale's employment agreement. According to Mr. DiPasquale's employment agreement, all vested options expire 90 days after the date of termination of employment. On February 16, 2014, Mr. DiPasquale exercised 623,806 options at a price of $0.001 per share.

On April 16, 2014 we appointed Joseph Tenne as our Chief Financial Officer, treasurer and Secretary pursuant to an employment agreement with our Israeli Subsidiary with the following terms:

(a) a onetime lump sum signing bonus in a gross amount of NIS 20,000 (on April 15, 2014, equivalent to $5,767) payable together with Mr. Tenne's first month's salary;

(b) a base salary of NIS 40,000 (on April 15, 2014, equivalent to $11,534) per month commencing April 1, 2014;

(c) a monthly contribution based on Mr. Tenne's previous month's salary equal to either:

i. 13.33% to a Managers Insurance policy; or
ii. 14.33% to a comprehensive pension plan;
iii. a performance bonus payable at the discretion of the Board;

(d) the grant of a number of stock options to be negotiated within 30 days to purchase common shares of the Corporation at the current market price per Option Share for a period of 10 years, vesting quarterly over a period of 36 months;

On July 23, 2014, our U.S. Subsidiary entered into an employment agreement with Scott Carmer, to be effective July 1, 2014. In consideration for acting as our U.S. Subsidiary s Chief Executive Officer, we will pay Mr. Carmer the following compensation:

(a) an annual salary of $250,000;
(b) an annual bonus of up to $100,000 subject to the discretion of our board of directors and a further bonus as determined by meeting certain milestones; and
(c) a grant of shares or options.

Effective August 1, 2014, Joseph Tenne resigned as our Chief Financial Officer, Treasurer and Secretary. Mr. Tenne s resignation was not as a result of any disagreement with our company operations, policies or practices. Mr. Tenne remained as Chief Financial Officer of our Israeli Subsidiary until September 1, 2014. On September 1, 2014, the Company entered into an agreement with Dorit Kreiner who replaced Mr. Tenne as Chief Financial Officer of Orgensis Ltd. Mr. Tenne remains as a director of Orgenesis Ltd.

On August 1, 2014, we appointed Neil Reithinger as our Chief Financial Officer, Treasurer and Secretary with the following terms:

(a) payment of a monthly salary of $1,500;
(b) payment of an annual bonus as determined by our company in its sole discretion;
(c) participation in our company s pension plan;
(d) a grant of 200,000 stock options exercisable at the market price of $0.50 for a period of 5 years and which are subject to vesting provisions; and
(e) Reimbursement of expenses.

In addition, on August 1, 2014, we entered into a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, (Eventus) pursuant to which Eventus has agreed to provide financial consulting and shareholder communication services to our company. In consideration for Eventus services, we have agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement is for a period of one year from August 1, 2014 and shall automatically renew for additional oneyear periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Neil Reithinger.

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, has been appointed as our President and Chief Executive Officer. On August 22, 2014, our wholly-owned Israeli Subsidiary entered into a Personal Employment Agreement with Ms. Caplan on the following key terms:

(a) a base salary of NIS 49,585 (as of August 22, 2014, equates to approximately $14,100) per month, retroactive to January 1, 2014;

(b) a monthly contribution based on Ms. Caplan s previous month s salary equal to either:

(i) 13.33% to a Managers Insurance policy; or

(ii) 14.33% to a comprehensive pension plan;

(d) the grant of stock options to be granted by our company, as follows:

(i) Options to purchase 1,657,300 shares of our company s common stock (representing approximately three percent (3%) of our company s issued and outstanding shares of common stock, which will vest as follows: (i) options to purchase 414,304 shares of common stock shall vest immediately on the date of grant and (ii) options to purchase the balance of 1,242,996 shares of common stock shall vest on a quarterly basis over a period of four years from the date of grant (i.e., initially, 77,687 of the options shall vest three months following the grant date).

(ii) Options to purchase 1,104,950 shares of our company s common stock, representing approximately two percent (2%) of our company s issued and outstanding common stock, which will vest pursuant to performance milestones to be determined by our Compensation Committee no later than December 31, 2014. The Compensation Committee has not yet determined the milestones or the expectations regarding such milestones.

(iii) All of the options are to have an exercise price equal to the par value per share of our common stock and all of them will expire on the 10th anniversary of the grant date.

The employment agreement, which replaces a previous employment agreement with Ms. Caplan dated April 1, 2012, contains other customary terms, covering matters such as noncompetition; confidentiality; indemnity and insurance; use of leased car; and vacation, health and other benefits.

Outstanding Equity Awards at Fiscal YearEnd

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of November 30, 2014.

	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 ($)**	**Option Expiration Date**	**Number of Shares or Units of Stock that have not Vested (#)**	**Market Value of Shares or Units of Stock that have not Vested (#)**	**Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested (#)**	**Equity Incentiv Plan Awards Market or Payout Value o Unearne Shares, Units or Other Rights that Have not Vested ($)**
Vered Caplan	3,830,276	2,270,259	Nil	0.0001 to 0.001	07/10/22 to 08/22/24	Nil	Nil	Nil	Nil

Scott Carmer [1]	Nil	1,641,300	Nil	0.001	December 2024	Nil	Nil	Nil	Nil
Neil Reithinger	50,000	150,000	Nil	0.50	08/01/24	Nil	Nil	Nil	Nil
Sarah Ferber	2,781,905	Nil	Nil	0.0001	02/02/22	Nil	Nil	Nil	Nil

(1) In December 2014, the Company granted an aggregate of 1,641,300 stock options to the Company s Chief Executive Officer of the U.S. Subsidiary that is exercisable at $0.001 per share. The grant and its associated fair value will record in fiscal first quarter 2015.

Retirement or Similar Benefit Plans

There are no arrangements or plans in which we provide retirement or similar benefits for our directors or executive officers.

Resignation, Retirement, Other Termination, or Change in Control Arrangements

We have no contract, agreement, plan or arrangement, whether written or unwritten, that provides for payments to our directors or executive officers at, following, or in connection with the resignation, retirement or other termination of our directors or executive officers, or a change in control of our company or a change in our directors or executive officers responsibilities following a change in control.

Director Compensation

The following table sets forth for each director certain information concerning his compensation for the year ended November 30, 2014.

	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	NonEquity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All other Compensation ($)	Total ($)
Vered Caplan	33,755	Nil	567,948	Nil	8,542	Nil	610,245
Guy Yachin	6,000	Nil	72,696	Nil	Nil	Nil	78,696
Etti Hanochi	6,000	Nil	34,241	Nil	Nil	Nil	40,241
Yaron Adler	21,240	Nil	101,327	Nil	Nil	Nil	122,567
Dr. David Sidransky	6,000	Nil	33,510	Nil	Nil	Nil	39,510

All directors receive reimbursement for reasonable out of pocket expenses in attending board of directors meetings and for promoting our business. From time to time we may engage certain members of the board of directors to perform services on our behalf. In such cases, we intend to compensate the members for their services at rates no more favorable than could be obtained from unaffiliated parties.

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 agreed to serve as a director of our company for a gross salary of NIS (Israeli Shekel) 10,000 per month, which is approximately $2,689 based on an exchange rate of 1 NIS to 0.2689 USD as of February 2, 2012. We also agreed to grant to Ms. Caplan stock options to purchase 3,338,285 shares of our common stock at a price per share equal to $0.001. In the event we complete a financing of at least $2,000,000, Ms. Caplan will be paid a onetime bonus of $100,000. On May 6, 2013, we have completed a financing of over $2,000,000 and recorded an expense of $100,000.

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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 meeting at the rate of $300 for the first hour of attendance and $200 for each additional hour or portion of an hour. In addition, we paid Mr. Yachin a signing bonus of $5,000. We issued to Mr. Yachin 471,200 stock options subject to the terms of our stock option plan, at an exercise price set at the time of the grant, or $0.85. We will also reimburse Mr. Yachin s preapproved business expenses.

On April 6, 2012, we entered into an agreement with Etti Hanochi to serve as a member of our board of directors for consideration of $300 for the first hour of attendance at Board meetings, and $200 per each additional hour. We issued to Ms. Hanochi 235,630 stock options subject to the terms of our stock option plan at an exercise price set at the time of the grant, or $0.79. We will also reimburse any preapproved business expenses incurred by Ms. Hanochi.

On April 17, 2012, we entered into an agreement with Yaron Adler to serve as a member of our board of directors for a consideration for every board meeting on an hourly basis. In the event that our company receives an aggregate financing of at least $3,000,000 he will be entitled to a onetime payment in the amount of $15,000. In addition, we will pay for his attendance at Board meetings at the rate of $300 for the first hour of attendance and $200 for each additional hour or portion of an hour. We issued to Mr. Adler 706,890 stock options subject to the terms of our stock option plan, at an exercise price set at the time of the grant, or $0.79. We will also reimburse any preapproved business expenses incurred by Mr. Adler.

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 will pay for his attendance at Board meetings at the rate of $300 for the first hour of attendance and $200 for each additional hour or portion of an hour. We also issued to Dr. Sidransky 250,000 stock options subject to the terms of our stock option plan, at an exercise price set at the time of grant, or $0.75. We will also reimburse any preapproved business expenses incurred by Dr. Sidransky.

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

The following tables set forth, as of February 19, 2015, certain information with respect to the beneficial ownership of our common stock by each stockholder known by us to be the beneficial owner of more than 5% of our common stock and by each of our current directors and executive officers. Each person has sole voting and investment power with respect to the shares of common stock, except as otherwise indicated. Beneficial ownership consists of a direct interest in the shares of common stock, except as otherwise indicated.

In the following tables, we have determined the number and percentage of shares beneficially owned in accordance with Rule 13d3 of the Securities Exchange Act of 1934 based on information provided to us by our controlling stockholder, executive officers and directors, and this information does not necessarily indicate beneficial ownership for any other purpose. In determining the number of shares of our common stock beneficially owned by a person and the percentage ownership of that person, we include any shares as to which the person has sole or shared voting power or investment power, as well as any shares subject to warrants or options held by that person that are currently exercisable or exercisable within 60 days.

Security Ownership of Certain Beneficial Holders

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership[1]	Percent of Class
Common Stock	Oded Shvartz 130 Biruintei Blvd. Pantelmon	11,126,920 Direct [2]	19.9%

	Ilfov, Romania		
Common Stock	Gilbert A. Cuison Block 616 Bedok Reservoir Road #031108 Singapore 470616	5,420,485 Direct [(2)]	9.7%
Common Stock	Jerome P. Golez Block 117 Bihan Street #2029 Singapore 570117	5,500,015 Direct [(2)]	9.8%
	Total Beneficial Holders as a Group	22,047,420 Direct	39.4%

Security Ownership of Management

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership[1]	Percent of Class
Common Stock	Vered Caplan 6 Sharabi Street, Neve Tzedek TelAviv, Israel65147	3,907,963 Direct [3]	6.5%
Common Stock	Neil Reithinger 14201 N. Hayden Road, Suite A1 Scottsdale, AZ 85260	100,000 Direct [4]	<1%
Common Stock	Prof. Sarah Ferber Shderot Hahaskala 17b TelAviv, Israel 67890	2,781,905 Direct [5]	4.7%
Common Stock	Guy Yachin 7 Orchard Way N Potomac, MD 20854	188,480 Direct [6]	<1%
Common Stock	Etti Hanochi 18 Aharonovitch Sh Kfar Saba, L3	94,252 Direct[7]	<1%
Common Stock	David Sidransky	50,000 Direct[8]	<1%
Common Stock	Yaron Adler 19 Chelouche Street TelAviv, Israel 65154	282,756 Direct[9]	<1%
Common Stock	**Directors & Executive Officers as a group (8 persons)**	7,405,356 Direct	11.7%

Notes

(1)	Percentage of ownership is based on 55,970,565 shares of our common stock issued and outstanding as of February 19, 2015. 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)	Oded Shvartz currently holds 11,126,920 shares of common stock representing 14.15% of our share capital on a fully diluted basis. Guilbert Cuison and Jerome Golez have granted to Oded Shvartz a conditional option to acquire 10,840,970 shares of common stock at a price of $0.0003571 per share. The option is exercisable only if we issue shares, grant options, or warrants to purchase shares, or any other security or right convertible into shares of our company (collectively, New Securities). In that event, Oded Schwartz shall have the right to

	exercise the option by purchasing one option share for every four New Securities issued. The option is exercisable for a period of up to four years after February 2, 2012. Should the option be exercised in full, Oded Shvartz would own up to 21,967,890 common shares in the capital of our company.

(3)	Consists of 3,830,276 stock options exercisable either immediately or within the next 60 days.
(4)	Consists of 100,000 stock options exercisable either immediately or within the next 60 days.
(5)	Consists of 2,781,905 stock options exercisable either immediately or within the next 60 days.
(6)	Consists of 188,480 stock options exercisable either immediately or within the next 60 days.
(7)	Consists of 94,252 stock options exercisable either immediately or within the next 60 days.
(8)	Consists of 50,000 stock options exercisable either immediately or within the next 60 days.
(9)	Consists of 282,756 stock options exercisable either immediately or within the next 60 days.

Changes in Control

As of December 31, 2014, we are not aware of any arrangement that may result in a change in control of our company.

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

Transactions with Related Persons

Except as set out below, as of November 30, 2014, 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.

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 consists of Vered Caplan, Guy Yachin, Etti Hanochi, Yaron Adler and David Sidransky. Our securities are quoted on the OTC Markets Group which does not have any director independence requirements. Under

NASDAQ Marketplace Rule 5605(a)(2), a director is not considered to be independent if he or she is also an executive officer or employee of the company. Using this definition of independence, we have determined that all members of our board of directors, excluding Ms. Caplan, are each an independent director.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit and Accounting Fees

The following table sets forth the fees billed to the Company for professional services rendered by Kesselman & Kesselman, a member firm of PricewaterhouseCoopers (PwC) International Limited, independent registeredpublic accounting firm, for the years ended November 30, 2014 and November 30, 2013:

Services	2014	2013
Audit fees	$ 84,273	$ 73,220
Audit related fees		
Tax fees	5,000	10,000
All other fees		
Total fees	**$** 89,273	**$** 83,220

Audit Fees

The audit fees were paid for the audit services of our Annual and Quarterly reports and issuing consents for our registration statements.

Tax Fees

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

PreApproval Policies and Procedures

Our board of directors 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 SK

No.	Description
3.1	Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S1 filed on April 2, 2009)
3.2	Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8K filed on September 2, 2011)
3.3	Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8K 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 8K filed on September 21, 2011)
3.5	Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8K 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 8K/A filed on March 16, 2012)

No.	Description
10.1	Term sheet with Mediapark Investments Limited (incorporated by reference to our current report on Form 8K filed on December 16, 2013)
10.2	Convertible Loan Agreement dated December 6, 2013 with Mediapark Investments Limited (incorporated by reference to our current report on Form 8K 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 8K 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 8K filed on December 16, 2013)
10.5	Form of subscription agreement (incorporated by reference to our current report on Form 8K filed on March 4, 2014)
10.6	Form of warrant (incorporated by reference to our current report on Form 8K 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 8K 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 8K filed on April 7,2014)
10.9	Personal Employment Agreement dated April 16, 2014 by and between Orgenesis Ltd. and Joseph Tenne (incorporated by reference to our current report on Form 8K filed on April 16, 2014)
10.10	Form of subscription agreement with form of warrant (incorporated by reference to our current report on Form 8K filed on April 28, 2014)
10.11	Convertible Loan Agreement dated May 29, 2014 with Nine Investments Limited (incorporated by reference to our current report on Form 8K filed on May 30, 2014)
10.12	Services Agreement between Orgenesis SPRL and MaSTherCell SA dated July 3, 2014 incorporated by reference to our current report on Form 8K filed on July 7, 2014)
10.13	Financial Consulting Agreement dated August 1, 2014 with Eventus Consulting, P.C., (incorporated by reference to our current report on Form 8K filed on August 5,2014)
10.14	Personal Employment Agreement dated August 1, 2014 by and between Orgenesis, Inc. and Neil Reithinger (incorporated by reference to our current report on Form 8K filed on August 5, 2014)
10.15	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 8K filed on August 6, 2014)
10.16	Personal Employment Agreement dated August 22, 2014 by and between Orgenesis Ltd. and Vered Caplan (incorporated by reference to our current report on Form 8K filed on August 25, 2014)
10.17	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 8K filed on November 10, 2014)
21.1	List of Subsidiaries of Orgenesis Inc
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the SarbanesOxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the SarbanesOxley Act of 2002

32.1*	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the SarbanesOxley Act of 2002
32.2*	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the SarbanesOxley 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 (incorporated by reference to our current report on Form 8K filed on January 15, 2013)
99.4	Compensation Committee Charter (incorporated by reference to our current report on Form 8K filed on January 15, 2013)
101*	Interactive Data Files pursuant to Rule 405 of Regulation ST.

*Filed herewith

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 (Principal Executive Officer)
Date: February 19, 2015

By: /s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Accounting Officer)
Date: February 19, 2015

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 19, 2015

By: /s/ David Sidransky
David Sidransky
Director
Date: February 19, 2015

By: /s/ Yaron Adler
Yaron Adler
Director
Date: February 19, 2015

By: /s/ Etti Hanochi
Etti Hanochi
Director
Date: February 19, 2015