

Orgenesis Inc.
Form 10-K
February 19, 2014

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: **November 30, 2013**

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)

<u>Nevada</u>	<u>98-0583166</u>
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
<u>21 Sparrow Circle, White Plains, NY 10605</u>	
(Address of principal executive offices) (Zip Code)	

Registrant's telephone number, including area code **914-949-0631**

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

Title of Each Class	Name of each exchange on which registered
<u>None</u>	<u>N/A</u>

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

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

Edgar Filing: Orgenesis Inc. - Form 10-K

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**]

Edgar Filing: Orgenesis Inc. - Form 10-K

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 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 No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes No

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, 2013, 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 \$25,016,766.32, based on the average bid and asked price for the registrant's common stock on the OTC Bulletin Board on May 31, 2013 of \$0.91 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:

51,394,621 shares of common stock as of February 3, 2014.

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

TABLE OF CONTENTS

<u>PART I</u>	
<u>ITEM 1. BUSINESS</u>	<u>1</u>
<u>ITEM 1A. RISK FACTORS</u>	<u>12</u>
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	<u>18</u>
<u>ITEM 2. PROPERTIES</u>	<u>18</u>
<u>ITEM 3. LEGAL PROCEEDINGS</u>	<u>18</u>
<u>ITEM 4. MINE SAFETY DISCLOSURES.</u>	<u>18</u>
<u>PART II</u>	<u>18</u>
<u>ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>18</u>
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	<u>22</u>
<u>ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>22</u>
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>26</u>
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>27</u>
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>27</u>
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	<u>27</u>
<u>ITEM 9B. OTHER INFORMATION</u>	<u>28</u>
<u>PART III</u>	<u>28</u>
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	<u>28</u>
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	<u>35</u>
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	<u>35</u>
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	<u>43</u>
<u>ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	<u>43</u>

<u>PART IV</u>	<u>44</u>
<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	<u>44</u>
<u>SIGNATURES</u>	<u>47</u>

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 this report include 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 and the risks set out below, any of which may cause our 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 exists about our ability to continue as a going concern;
- we may need to raise additional funds in the future which may not be available on acceptable terms or at all;
- if we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operation;
- we may not be able to successfully implement our business plan;

- conditions in Israel and the surrounding Middle East may materially adversely affect our subsidiary's operations and personnel;
- the ability of our subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by our subsidiary may be subject to taxes;
- THM may cancel the License Agreement;
- if we are unable to successfully acquire, develop or commercialize new products, our operating results will suffer;
- our expenditures may not result in commercially successful products;
- third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products;
- extensive industry regulation has had, and 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 .

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 current report on Form 10-K and unless otherwise indicated, the terms we, us and our refer to Orgenesis Inc. and our wholly owned subsidiaries: Orgenesis Ltd. (the Subsidiary), Orgenesis SPRL (the Belgium Subsidiary) and Orgenesis Maryland Inc. (the US 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 our subsidiary, 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 effected 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 the State of Nevada, correcting the par value of 1,750,000,000 shares of common stock which 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 annual 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

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 Tel Hashomer 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 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 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 a therapeutic agent (i.e., PDX-1, or additional pancreatic transcription factors in 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. 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. Prof. Ferber has developed this technology, as a researcher in Tel Hashomer, and has established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells in liver and convert them into pancreatic beta cell like cells. Furthermore, those cells were found to be resistant to the autoimmune attack.

We intend to develop 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

Pursuant to a licensing agreement dated February 2, 2012 with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (**Tel Hashomer** or **THM**), a private company duly incorporated under the laws of the State of Israel having its registered office at Tel Hashomer, 52621, Israel, on February 2, 2012, our 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 a treatment for diabetes (the **Licensed Information**), with the right to sublicense and to make commercial use of the Licensed Information and any other intellectual property rights related thereto, all in order to develop, manufacture, produce, use, market, commercialize, lease, sell, distribute, export, import and otherwise utilize new technology for regeneration of functional insulin-producing cells so as to sell a new therapeutic mix, new functional AIP cells, and to provide the treatment process and protocols (the **Products**). This licensed portfolio is based on the ground-breaking work and two decades of research by the world renowned researcher, Prof. Sarah Ferber as a researcher in Tel Hashomer.

As consideration for the Licensed Information, our Subsidiary will pay the following to THM:

A royalty (the **Royalty**) of 3.5% of net sales.

16% of all sublicensing fees.

An annual fee (the **Annual Fee**) of \$15,000, which commenced on January 1, 2012 and shall be paid once every year thereafter. The Annual Fee is non-refundable, but it shall be credited each year due, against the Royalty, to the extent that such are payable, during that year.

Milestone payments as follows:

- o \$50,000 on the date of initiation of phase I clinical trials in human subjects;
- o \$50,000 on the date of initiation of phase II clinical trials in human subjects;

- o \$150,000 on the date of initiation of phase III clinical trials in human subjects;

3

- o \$750,000 on the date of initiation of issuance of an approval for marketing of the first Product by the FDA or any other equivalent authority; and
- o \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time (the **Sales Milestone**).

In the event that a third party closes an acquisition of all or substantially all of the issued and outstanding share capital of our company or our Subsidiary or our company or our Subsidiary consolidates with another corporation (an **Exit**), THM shall be entitled to choose, according to its sole discretion, whether to receive one of the following:

a one-time payment based, as applicable, on the value of either 5,563,809 shares of our common stock at the time of the Exit; or

the value of 1,000 common shares of our Subsidiary at the time of the Exit.

If, THM chooses not to receive any consideration as a result of an Exit, THM 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 THM to perform all of our obligations pursuant to the License Agreement. If THM chooses to receive the consideration as a result of an Exit, the Royalty payments will cease.

We agreed to provide our Subsidiary during the three year period following the date of the License Agreement an amount not less than \$750,000, or, if the entire warrants issued in connection with a private placement that closed on February 2, 2012 are exercised within said period, an aggregate amount (including the above \$750,000) of not less than \$1,100,000.

We agreed to submit to THM a commercially reasonable plan which shall include all research and development activities as required for the development and manufacture of the Products, including preclinical and clinical activities until an FDA or any other equivalent regulatory authority's approval for marketing and including all regulatory procedures required to obtain such approval for each Product (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, THM 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 anticipate that we will submit the Development Plan in February 2014.

Without derogating from THM's rights under any applicable law, THM 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 THM has provided us with written notice of such material breach and THM's intention to terminate, and we have not cured such breach within 180 days of receiving such written notice from THM. Our failure to comply with sections relating to the following are deemed to be a material breach of the License Agreement:

- o granting of sublicenses;

- o confidentiality provisions;
- o perform payments to THM; and
- o 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 THM.
- 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 THM to the Licensed Information anywhere in the world.

We may terminate the License Agreement and return the Licensed Information to THM 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 THM.

Development

Our goal is to advance an initial product to clinical stage that is a one overall clinical treatment for the diabetic patient. The diabetic patient serves as the donor of his own therapeutic tissue. We anticipate producing AIP cells by sending a standard liver biopsy taken from the patient to our central laboratory where we intend to produce, from the biopsy, a sufficient amount of cells and deliver it back to the clinical center. Then, the AIP cells will be transplanted back to the patient's liver in a standard infusion procedure.

On March 22, 2012, we announced the entry into an agreement between Tel Hashomer and our Israeli subsidiary to perform a study of liver cells into pancreatic cells, at the facilities and using the equipment and personnel of the Chaim Sheba Medical Center of Israel under the supervision of our Chief Scientific Officer, Prof. Sarah Ferber. We will pay Tel Hashomer the amount of New Israeli Shekel 279,000 (approximately US \$74,231.40) plus VAT per year. The agreement will continue until Tel Hashomer completes its study or until we terminate the agreement with a 90 days written notice. On May 1, 2013 the Subsidiary renewed the research agreement for the total annual consideration of approximately \$92,000.

On April 24, 2012, we entered into an agreement with Granzer Regulatory Consulting & Services (**Granzer**) to provide services with regard to regulatory and development aspects in connection with pharmaceutical products in the area of chemistry and pharmacy toxicology, clinical and regulatory. We pay Granzer between 125-300 Euro per hour up to a maximum of 2,400 Euro per day for their services.

On October 18, 2012, we entered into a service agreement with the Fraunhofer Institute for Interfacial Engineering and Biotechnology (**Fraunhofer IGB**) to develop a pilot process to manufacture human autologous insulin-producing cell transplants based on the Orgenesis technology. It is anticipated that the subsequent establishment of a fully GMP-compliant production process will, in turn, enable us to obtain authorization for the production of clinical grade material to be used in a first-in-man study of our diabetes treatment product candidate. According to the agreement, we must pay per achieved phase, which are defined in the agreement, a total consideration of 260,000 Euro for all services. Under the terms of the agreement, we have discretion whether to conclude all the phases or only part of them.

We will provide Fraunhofer IGB with required information and cell material to perform certain experiments set out in work packages. Times for each of the work packages are dependent on a close collaboration with us providing sufficient amounts of cell material in time, method transfer and performing functional studies with cell material produced by the Fraunhofer IGB.

We will access and pay for the work packages on a case-by-case arrangement. Agreements on new work packages to be included during the project and the elimination of work packages can be made during the tenure. Payments by us are due on the receipt of the final work package reports from Fraunhofer IGB by work package.

The agreement will continue until Fraunhofer IGB completes all their work packages or, should no essential work progress be achieved within a significant period of time, then each contracting party shall be entitled to terminate the contract with one month notice.

On May 6, 2013, the Subsidiary entered into a Process Development Agreement with ATMI BVBA, a Belgium company which is a wholly owned subsidiary of Advanced Technology Materials, Inc. (**ATMI**), a US publicly traded company. According to the agreement, ATMI will provide services in cell research. We will use ATMI's unique technology while we will provide to ATMI the required materials for the purpose of the study. According to the agreement, we will pay per achieved phase, as defined in the agreement with total consideration of 606,500 Euro for all services.

Marketing

Our intention is to sell a new therapeutic mix, the new functional AIP cells, and to provide the treatment process and protocols. We may also provide bio-banking of pancreatic precursor cells for future use.

Once we obtain the CE Mark for the AIP cell therapy, our goal is to initiate sales in the Asian and European markets. We believe that at that stage, we should start to implement our long term strategy.

Our long term strategy is to collaborate with international companies involved in the diabetes treatment market after completing phase II clinical trials or after initiation of sales activity. Leading companies in this area include Novo Nordisk, Tekada Pharmaceutical, Eli Lilly, GlaxoSmithKline, Sanofi Aventis and Merck. We aim to collaborate with international companies who currently do not play a role in the diabetes therapy market, but are interested in expanding their product line and entering new markets. The agreements will define the terms under which the strategic partners will be granted the rights to further develop, test, obtain regulatory approval, and market the new therapeutic mix in pre-defined geographical territories. We anticipate continuing to support the research and development (**R&D**) process as necessary, based on our R&D team's extensive knowhow.

Based on industry benchmarks and history, we believe that we are most likely to sign a licensing deal that will generate revenues through the following acceptable mechanisms:

- Upfront payment;
- Milestone payments; and
- Royalties upon sales.

Future Products

Future products may be less invasive using more accessible cells of a diabetic patient.

Market

Diabetes Mellitus (DM) is a metabolic disorder caused usually by a combination of hereditary and environmental factors, and results in abnormally high blood sugar levels (hyperglycemia). DM occurs as a result of impaired insulin production by the pancreatic islet cells. The most common types of the disease are type-1 DM (T1DM) and type-2 DM (T2DM). In T1DM, the onset of the disease follows an autoimmune attack of β -cells thus severely reducing β -cell mass. In T2DM, the pathogenesis involves insulin resistance, insulin deficiency and enhanced gluconeogenesis, while late progression stages eventually leads to β -cell failure and a significant reduction in β -cell function and mass. Thus, both T1DM and late-T2DM result in marked hypoinsulinemia, reduction in β -cell function and mass and lead to severe secondary complications, such as myocardial infarcts, limb amputations, neuropathies and nephropathies and even death.

We believe that Diabetes Mellitus (DM) 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 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 some 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 antidiabetic drugs has been evolving rapidly. A look at the diabetes market reveals that it was 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

Researchers use specialized enzymes to remove islets from the pancreas of a deceased donor. Because the islets are fragile, transplantation occurs soon after they are removed. Typically a patient receives at least 10,000 islet equivalents per kilogram of body weight, extracted from two donor pancreases. Patients often require two transplants to achieve insulin independence. Some transplants have used fewer islet equivalents taken from a single donated pancreas.

Transplants are often performed by a 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.

In an experimental procedure called islet transplantation, islets are taken from the pancreas of a deceased organ donor. The islets are purified, processed, and transferred into another person. Once implanted, the beta cells in these islets begin to make and release insulin.

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 T1DM 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.

Our Advantages

We believe that our singular focus on the acquisition, development, and commercialization of AIP cells has a competitive advantage over other technologies, since it has the potential of providing an approach which may:

- release the patient from the daily involvement in monitoring blood glucose levels, numerous insulin injections and watching food intake and exercise;
- allow continuous control of blood glucose levels which prevents diabetes related complications;
- provide an unlimited source of therapeutic tissue and overcomes the shortage in tissues available for islet cells transplantation;
- generate an autologous transplant, thus avoiding the risk of transplant rejection;
- protect the patient from recurrent auto-immune attacks on the transplanted beta-cells, thus avoiding the need of immunosuppressant treatment; and
- provide a minimally invasive procedure.

We are aware of no other company focused exclusively 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 \$1,452,456 in research and development expenditures in the last fiscal year. 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

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. As of November 30, 2013, we had two full time employee and four part time employees located in Israel.

Subsidiaries

On October 11, 2011, we incorporated our wholly owned subsidiary, Orgenesis Ltd., a company governed by the laws of Israel. The majority of our research and development operations are conducted in Israel.

On July 31, 2013, we incorporated a wholly-owned subsidiary in Maryland named Orgenesis Inc., which will be engaged in research and development. The US subsidiary has not commenced its operation yet.

On October 11, 2013, Orgenesis Ltd. incorporated a wholly-owned subsidiary in Belgium, Orgenesis SPRL. We established a subsidiary in Belgium in order to coordinate the process development and manufacturing activities together with the clinical studies in Europe, and later on to be our center for our activities in Europe.

The incorporation of Orgenesis SPRL followed a strategic decision in May 2013 to work with ATMI 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. In addition, we are already conducting some portion of our process development with Fraunhofer IGB in Germany and all those activities will be coordinated through Orgenesis SPRL.

Intellectual Property

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

Title	Country	Status	Serial No.	Patent No.	Filing Date	Issue Date
Methods of Inducing Regulated Pancreatic Hormone Production	Australia	Granted	50974/00	779619	01-June-2000	09-June-2005
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Australia	Granted	2004236573	2004236573	12-May-2004	04-Feb-2010
Methods of Inducing Regulated Pancreatic Hormone Production	Canada	Pending	2371995		01-June-2000	
Methods of Inducing Regulated Pancreatic Hormone Production	European Patent Convention	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	European Patent Convention	Published	04732369.6		12-May-2004	

Edgar Filing: Orgenesis Inc. - Form 10-K

Methods of Inducing Regulated Pancreatic Hormone Production	France	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production	Germany	Granted	00935435.8	60034781.8-08	01-June-2000	09-May-2007

Title	Country	Status	Serial No.	Patent No.	Filing Date	Issue Date
Methods of Inducing Regulated Pancreatic Hormone Production	Italy	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Japan	Published	2010- 261850		12-May-2004	
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Japan	Published	2010- 288937		01-June-2000	
Methods of Inducing Regulated Pancreatic Hormone Production	United Kingdom	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	United States of America	Granted	09/584216	6,774,120	31-May-2000	10-Aug-2004
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	United States of America	Published	10/843801		12-May-2004	
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	United States of America	Published	13/339958		29-Dec-2011	
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	United States of America	Granted	10/852994	8,119,405	24-May-2004	21-Feb-2012
Methods of Producing Pancreatic Beta-cells and Methods of use thereof	United States of America	Pending	61/746651		28-Dec-2012	

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 genetic information which 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 need cells 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 which destroys their bone marrow cells. However, the cell therapy protocol for cancer patients delineated above does not require extensive cell culture, in vitro. 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 biological products under the *Public Health Service Act* and the *Food, Drug and Cosmetic Act*. The FDA generally requires the following steps for pre-market approval or licensure of a new biological product:

- Pre-clinical laboratory and animal tests conducted in compliance with the Good Laboratory Practice, or GLP, requirements to assess a drug's biological activity and to identify potential safety problems, and to characterize and document the product's chemistry, manufacturing controls, formulation, and stability;
- Submission to the FDA of an Investigational New Drug, or IND application, which must become effective before clinical testing in humans can 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 the 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. The FDA may also require post marketing testing and surveillance of approved products, or place other conditions on the approvals.

Regulatory Process in Europe

The European Union (EU) has approved a regulation specific to cell and tissue therapy product, the Advanced Therapy Medicinal Product (ATMP) regulation. For products such as our AIP 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, the FDA or EMA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data which 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

The worldwide economic downturn may reduce our ability to obtain the financing necessary to continue our business and may reduce the number of viable products and businesses that we may wish to acquire. If we cannot raise the funds that we need or find a suitable product or business to acquire, we may go out of business and investors will lose their entire investment in our company.

Since 2008, there has been a downturn in general worldwide economic conditions due to many factors, including the effects of the subprime lending and general credit market crises, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions, increased unemployment and liquidity concerns. In addition, these economic effects, including the resulting recession in various countries and slowing of the global economy, will likely result in fewer business opportunities as companies face increased financial hardship. Tightening credit and liquidity issues will also result in increased difficulties for our company to raise capital for our continued operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable. If we cannot raise the funds that we need or find a suitable product or business to acquire, we will go out of business. If we go out of business, investors will lose their entire investment in 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 incorporation. We expect that our operating expenses will increase over the next 12 months. We estimate our average monthly expenses over the next 12 months to be approximately \$320,000, including general and administrative expenses, research and development. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As of December 31, 2013, we had cash and cash equivalents of approximately \$400,402. As we cannot assure a lender that we will be able to successfully develop our pharmaceutical assets, we will almost certainly find it difficult to raise debt financing from traditional lending sources. 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 unable to meet our debt service obligations and other financial obligations, we could be forced to restructure or refinance, seek additional equity capital or sell our assets. We might then be unable to obtain such financing or capital or sell our assets on satisfactory terms. If the Company is unsuccessful in raising additional financing, it may need to curtail, discontinue or cease operations.

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

We may consider issuing additional debt or equity securities in the future to fund 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 market such issuances 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 are 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 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 subsidiary's ability to engage in research and development, or otherwise adversely affect its business or operations. In addition, our 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 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 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 such 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 subsidiary having to pay taxes on any dividends it declares.

Risks Relating to the Pharmaceutical Business

THM may cancel the License Agreement.

Pursuant to the terms of the License Agreement, we are required to submit to THM the 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, 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. We anticipate that we will submit the Development Plan in February 2014.

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 new products and businesses in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- there are still 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;

- 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 this 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 successful acquisition, development or launch of commercially successful brand 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 (**EMA**) will regulate our future products. Regulatory approval by the EMA will be subject to the evaluation of data relating to the quality, efficacy and safety of our future products for its proposed use. The time taken to obtain regulatory approval varies between countries. Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

Further trials and other costly and time-consuming assessments of the product may be required to obtain or maintain regulatory approval. Medicinal products are generally subject to lengthy and rigorous pre-clinical and clinical trials and other extensive, costly and time-consuming procedures mandated by regulatory authorities. We may be required to conduct additional trials beyond those currently planned, which could require significant time and expense.

The pharmaceutical industry is highly competitive.

The pharmaceutical industry has an intensely competitive environment that will require an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of products to healthcare professionals in private practice, group practices and payers in managed care organizations, group purchasing organizations and Medicare & Medicaid services. We are smaller than almost all of our competitors. Most of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. It is possible that developments by our competitors will make any products or technologies that we acquire non-competitive or obsolete.

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 which are unrelated to our operations.

Although our common stock is currently listed for quotation on the OTC Bulletin Board, there is no market for our common stock. Even when a market is established and trading begins, trading through the OTC Bulletin Board 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. We are presently benefitting from free rental space until such time as our operations ramp up. Once we attain the necessary funding and increase our employee base, we will look for more spacious facilities to meet our growing needs. We believe that this arrangement will be suitable for the next 12 months.

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 rights is under the section entitled "Business Intellectual Property".

ITEM 3. LEGAL PROCEEDINGS

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 OTC Bulletin Board of the Financial Industry Regulatory Authority 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. 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, 2013	\$0.7	\$0.7
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

Note

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

Transfer Agent

The shares of our common stock are issued in registered form. 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, 2014, there were 11 holders of record of our common stock. As of such date, 51,394,621 shares were issued and outstanding.

Registration Rights

On May 6, 2013, we entered into a subscription agreement with ATMI, pursuant to which ATMI 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 ATMI that we will register their shares if we file a registration statement with the Securities and Exchange. We have accepted funds for a private placement of units for a price of \$0.52 per unit. If this financing closes, the exercise price commission of the warrants issued to ATMI will be reduced to \$0.52. For further information see note 14(4).

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 12 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.

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

Since the beginning of our fiscal year ended November 30, 2013, we have not sold any equity securities that were not registered under the Securities Act of 1933 that were not previously reported in a quarterly report on Form 10-Q or in a current report on Form 8-K.

Securities authorized for issuance under equity compensation plans

The following table summarizes certain information regarding our equity compensation plans as of November 30, 2013:

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	9,417,427	0.48	2,582,573

Total	9,417,427	0.48	2,582,573
--------------	-----------	------	-----------

20

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.

On February 2, 2012, we granted 2,781,905 options to Prof. Sara Ferber, our Chief Scientific Officer, at an exercise price of \$0.0001 per share. The options vest in twelve equal monthly installments from the date of grant and expire on February 2, 2022. The options which were granted to Prof. Sara Ferber are not part of our Plan and are not reflected in the table above.

On February 2, 2012, we granted 2,781,905 options to Mr. Jacob BenArie, our Chief Executive Officer, at an exercise price of \$0.69 per share. The options vest in twelve equal quarterly installments from the date of grant and expire on February 2, 2022.

On April 14, 2012, we granted 471,200 options to Dr. G. Alexander (Zan) Fleming, our advisor, at an exercise price of \$1.40 per share. The options vest in five equal annual installments from the date of grant and expire on April 14, 2022.

On June 4, 2012, we granted 471,200 options to Mr. Guy Yachin, a member of our board of directors, at an exercise price of \$0.85 per share. The options vest in five equal annual installments from the date of grant and expire on June 4, 2022.

On June 4, 2012, we granted 706,904 options to Mr. Dov Weinberg, our Chief Financial Officer, at an exercise price of \$0.69 per share. The options vest in four equal semi-annual installments from the date of grant and expire on February 2, 2022.

On July 8, 2012, we granted 706,890 options to Mr. Yaron Eldar, a member of our board of directors, at an exercise price of \$0.79 per share. The options vest in five equal annual installments from the date of grant and expire on July 8, 2022.

On July 8, 2012, we granted 235,630 options to Ms. Etti Hanochi, a member of our board of directors, at an exercise price of \$0.79 per share. The options vest in five equal annual installments from the date of grant and expire on July 8, 2022.

On July 10, 2012, we granted 3,338,285 options to Ms. Vered Kaplan, the Chairman of our board of directors at an exercise price of \$0.001 per share. The options vest in two equal annual installments from the date of grant and expire on February 2, 2022.

On July 16, 2013, we granted 250,000 options 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 November 21, 2012, we granted 100,000 options to Camillo Ricordi, a consultant to our company, at an exercise price of \$0.61 per share. The options vest in five equal annual installments from the date of grant and expire on November 21, 2022.

On August 2, 2013, we granted 100,000 options to Prof. Skyler, a member of our advisory board, 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.

On December 23, 2012, we granted 1,473,537 restricted shares to Sav Dipasquale, our chief executive officer. The restricted shares vest in four equal annual installments from the date of grant. In addition, On October 23, 2013, we granted 255,413 options to Mr. Dipasquale, at an exercise price of \$0.001 per share. The options are fully vested on the date of grant and expire on October 23, 2023. According to Mr. Dipasquale's employment agreement, all vested options expire 90 days after the date of cessation of employment. Mr. DiPasquale resigned on December 23, 2013 and his options expire on March 23, 2014.

Issuer Purchases of Equity Securities

During the fiscal year ended November 30, 2013, 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

The following discussion should be read in conjunction with our financial statements and the related notes that appear elsewhere in this annual report on Form 10-K. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward looking statements. Factors that could cause or contribute to such differences include those discussed below and elsewhere in this annual report on Form 10-K.

Our audited financial statements are stated in United States Dollars and are prepared in accordance with United States Generally Accepted Accounting Principles.

Results of Operations

The following summary of our results of operations should be read in conjunction with our audited financial statements for the year ended November 30, 2013.

Our operating results for the year ended November 30, 2013 are summarized as follows in comparison to our operating results for the year ended November 30, 2012:

	Year ended November 30,	
	2013	2012
Research and Development Expenses	\$ 1,452,456	\$ 2,308,811
General and Administrative Expenses	4,008,046	2,679,748
Operating Loss	\$ 5,460,502	\$ 4,988,559
Financial Expense, Net	78,657	9,584
Net Loss For The Period	\$ 5,539,159	\$ 4,998,143

Revenue

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

Research and Development Expenses

	Year ended November 30,	
	2013	2012
Salaries and related expenses	\$ 395,710	\$ 166,108
Stock-based compensation	475,877	1,329,651
Professional fees and consulting services	378,826	102,863
Patents registrations	101,801	619,288

Edgar Filing: Orgenesis Inc. - Form 10-K

Other		100,242		90,901
Total	\$	1,452,456	\$	2,308,811

22

The decrease in total research and development expenses is mainly due to the decrease in stock-based compensation expenses and patents registration. The decrease in patent registration expenses is due to one-time non-cash compensation granted to our patents lawyers on February 2, 2012 in the amount of \$509,622. The decrease in stock-based compensation expenses is due to options that was granted to an employee in the prior period and was fully vested in February 2013. The increase in professional and consulting is mainly due to development services in Europe.

General and Administrative Expenses

	Year ended November 30,	
	2013	2012
Salaries and related expenses	\$ 415,163	\$ 192,973
Stock-based compensation	2,636,090	1,889,326
Accounting and legal	283,493	176,446
Professional fees	296,753	203,288
Business development	187,827	140,944
Travel	118,333	14,551
Others	70,387	62,220
Total	\$ 4,008,046	\$ 2,679,748

The increase in salaries and related expenses is mainly due to the appointment of our new Chief Executive Officer, who was recruited in December 2012.

The increase in accounting and legal fees is mainly due to cost related to the registration statement on Form S-1 which we filed on January 7, 2013.

The increase in Travel expenses is mainly due to our expanded operation including the establishment of our Belgium subsidiary.

Financial Expenses

	Year ended November 30,	
	2013	2012
Interest expenses due to loan	\$ 172,510	\$
Changes in fair value of warrants	(133,316)	-
Foreign exchange loss - net	33,761	7,069
Bank commissions - net	5,702	2,515
Total	\$ 78,657	\$ 9,584

The interest expenses due to the loan was offset by a change in the valuation of the convertible warrants which were granted as part of the loan. The valuation changed due to a decrease in the price of our shares. All the expenses incurred from granting the warrants were recorded as financial expenses.

Liquidity and Financial Condition

Working Capital

	November 30, 2013	November 30, 2012	Percentage Increase
Current Assets	\$ 97,737	\$ 38,598	153 %

Edgar Filing: Orgenesis Inc. - Form 10-K

Current Liabilities	\$	986,409	\$	327,170	201 %
Working Capital (Deficiency)	\$	(888,672)	\$	(288,572)	208 %

23

The increase in current liabilities was due to increase in activities and extended credit terms with suppliers and service providers.

Cash Flows

	Year ended November 30,	
	2013	2012
Net cash used in operating activities	(1,989,348)	(1,051,612)
Net cash used in investing activities	(10,172)	(20,977)
Net cash provided by financing activities	2,050,000	1,071,661
Increase (Decrease) in Cash and Cash Equivalents	50,480	(928)

The increase in cash is mainly due to the \$2,050,000 we raised during the year ended November 30, 2013 compared to the amount of \$1,071,661 that we raised in the same period last year. The increase in operating expenses is related to our expanded operations this year in comparison to the previous year.

Recent Financings

Agreements with Kodiak Capital Group, LLC

We have entered into a \$3 million common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beach-based institutional investor (**Kodiak**). On January 7, 2014, we filed a registration statement with the U.S. Securities & Exchange Commission (**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, we have the right at our sole discretion over a period of one year to sell up to \$3 million of common stock under the terms set forth in the agreement. Proceeds from this transaction will be used to fund our research and development and for working capital. In connection with the entering of the stock purchase agreement, we have paid a commitment fee by issuing 250,000 shares in restricted common shares of our company to Kodiak.

Our ability to put shares to Kodiak and obtain funds under the equity line is limited by the terms and conditions in the investment agreement dated December 13, 2013, including restrictions on when we may exercise our put rights, restrictions on the amount we may put to Kodiak at any one time, which is determined in part by the trading volume of our common stock, and a limitation on our ability to put shares to Kodiak. In addition, we do not expect the equity line to satisfy all of our funding needs, even if we are able and choose to take full advantage of the equity line.

Loan Agreement with Mediapark A.G.

On December 6, 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 **Debenture**) in the aggregate principal amount of US \$100,000. Interest is calculated semi-annually and is payable, along with the principal on or before December 6, 2014.

If the Debenture is not repaid at the maturity date, the holder may convert the loan and any accrued and unpaid interest into shares of our common stock at a price per share of 80% of the volume weighted average price for the five trading days prior to the date Mediapark provides us with written notice of conversion. The loan will be converted into the same terms as any shares and/or warrant financing of \$350,000 or more Orgenesis completes before maturity of the loan.

We currently have outstanding another 8% unsecured convertible loan with Mediapark in the amount of US \$250,000. Both loans will be convertible to equity in full if we complete a non-equity financing.

Going Concern

We have suffered recurring losses from operations and are dependent on our ability to raise capital from stockholders or other sources to meet our obligations and repay our liabilities arising from normal business operations when they become due. In their report on our audited financial statements for the year ended November 30, 2013, our independent registered public accounting firm included an explanatory paragraph regarding concerns about our ability to continue as a going concern. Our financial statements contain additional note disclosure describing the circumstances that lead to this disclosure by our independent registered public accounting firm.

Our primary objectives for the next 12 month period are to further develop the technology of producing AIP cells and to advance the technology so that it may be appropriate for clinical safety testing.

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

- initiate regulatory activities in Asia, Europe and USA;
- locate suitable centers and sign a collaboration agreement;
- collaborate with clinical centers, specifically those performing Pancreatic Islet transplantations, in order to carry out clinical studies;
- identify optional technologies for scale up of the cells production process (this activity will be carried out at subcontracted facilities of Sheba Medical Center);
- initialize efforts to validate the manufacturing process (in certified labs); and
- raise sufficient capital to perform initial clinical safety testing.

We estimate our operating expenses for the next 12 months as of November 30 2013 to be as follows:

Expense	Amount
Product development	\$2,965,321
General and administration	\$563,160
Business development	\$327,960
Total	\$3,856,441

Future Financing

We will require additional funds to implement our growth strategy for our new business. 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.

In December 2013, we accepted funds of \$445,000 for subscriptions of units of our company at a price of \$0.52 per unit. Each unit is comprised of one share of our common stock and one common share purchase warrant, which entitles the holder to purchase an additional share at a price of \$0.52 for a period of three years. There is no guarantee that we will be able to close this financing or future financings.

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 are material to stockholders.

Significant Accounting Policies

Our significant accounting policies are more fully described in the notes to our consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended November 30, 2013. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Income Taxes

Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to our deferred tax assets.

Stock-Based Compensation

We granted options to purchase shares of our common stock to employees and non-employees.

We account for share-based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the straight line method.

When stock based compensation is granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock based compensation issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the stock based compensation is measured on each reporting date, and the gains (losses) are recorded to earnings over the related service period using the straight-line method.

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 determined 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
(A development stage Company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2013

TABLE OF CONTENTS

	Page
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	<u>F-1</u>
CONSOLIDATED FINANCIAL STATEMENTS:	
<u>Consolidated balance sheets</u>	<u>F-2</u>
<u>Consolidated Statements of comprehensive loss</u>	<u>F-3</u>
<u>Consolidated Statements of changes in stockholders' deficiency</u>	<u>F-4</u>
<u>Consolidated Statements of cash flows</u>	<u>F-5</u>
<u>Notes to Consolidated financial statements</u>	<u>F-6 - F-26</u>

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of

ORGENESIS INC.

(A Development Stage Company)

We have audited the accompanying consolidated balance sheet of Orgenesis Inc. (A Development Stage Company) and its subsidiaries (the Company) as of November 30, 2013 and 2012, and the related consolidated statements of comprehensive loss, changes in stockholders' deficiency and cash flows for the years then ended and cumulatively, for the period from June 5, 2008 (inception date) to November 30, 2013. These financial statements are the responsibility of the Company's board of directors and 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, based upon our audit, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of November 30, 2013 and 2012, and the consolidated results of its operations and its cash flows for the years then ended and cumulatively, for the period from June 5, 2008 (inception date) to November 30, 2013, 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, 2013 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.

	<u>/s/ Kesselman & Kesselman</u>
Tel-Aviv, Israel	Kesselman & Kesselman
February 19, 2014	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*

F-1

ORGENESIS INC.
(A development stage Company)

CONSOLIDATED BALANCE SHEETS
U.S. dollars

	November 30, 2013	November 30, 2012
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 50,827	\$ 347
Short term deposits	10,002	10,002
Prepaid expenses and other accounts receivable (Note 6)	36,908	28,249
Total current assets	\$ 97,737	\$ 38,598
FUNDS IN RESPECT OF RETIREMENT BENEFIT OBLIGATION		
	\$ 3,630	\$ 1,296
	\$ 12,854	\$ 8,273
PROPERTY AND EQUIPMENT, NET (Note 7)		
Total assets	\$ 114,221	\$ 48,167
Liabilities net of Stockholders' deficiency		
CURRENT LIABILITIES:		
Accounts payable	\$ 138,775	\$ 135,791
Accrued expenses	386,122	73,138
Employees and related payables	155,100	75,879
Related parties	42,362	42,362
Loan (Note 4)	264,050	-
Total current liabilities	\$ 986,409	\$ 327,170
LONG-TERM LIABILITIES		
Warrants (Note 8)	\$ 1,157,954	\$ -
Retirement benefit obligations	4,272	1,553
Total long-term liabilities	\$ 1,162,226	\$ 1,553
Commitments (Note 2)		
Total liabilities	\$ 2,148,635	\$ 328,723
STOCKHOLDERS' DEFICIENCY:		
Common stock of \$0.0001 par value - authorized: 1,750,000,000 shares at		
November 30, 2013 and 2012; issued and outstanding: 51,144,621 and 49,117,903 shares at November 30, 2013 and 2012, respectively		
	5,114	4,912
Additional paid-in capital	8,635,447	4,850,348
Deficit accumulated during the development stage	(10,674,975)	(5,135,816)

Edgar Filing: Orgenesis Inc. - Form 10-K

Total Stockholders' deficiency	(2,034,414)	(280,556)
Total liabilities net of Stockholders' deficiency	\$ 114,221	\$ 48,167

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

F-2

ORGENESIS INC.
(A development stage Company)

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars

	Year ended November 30,		Period from June 5, 2008 (inception date) through November 30, 2013
	2013	2012	
RESEARCH AND DEVELOPMENT EXPENSES (Note 9)	\$ 1,452,456	\$ 2,308,811	\$ 3,761,267
GENERAL AND ADMINISTRATIVE EXPENSES (Note 10)	4,008,046	2,679,748	6,825,467
OPERATING LOSS	5,460,502	\$ 4,988,559	\$ 10,586,734
FINANCIAL EXPENSE, NET (Note 11)	78,657	9,584	88,241
NET LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	\$ 5,539,159	\$ 4,998,143	\$ 10,674,975
BASIC AND DILUTED LOSS PER COMMON STOCK	\$ 0.11	\$ 0.09	
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER STOCK:	50,483,814	54,265,224	

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

ORGENESIS INC.
(A development stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIENCY
U.S. dollars

	Common Stock Shares	\$	Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity Deficiency
Balance at June 5, 2008 (inception)	-	\$ -	\$ -	\$ -	\$ -
Changes during the period from June 5, 2008 through November 30, 2010					
Shares issued to founder on June 5, 2008 \$0.000357 Per Share	56,000,000	5,600	14,400	-	
Private Placement at \$0.00143 Per Share	24,500,000	2,450	32,550	-	
Net Loss for the period- Comprehensive loss	-	-	-	(65,321)	
Balance as of November 30, 2010	80,500,000	8,050	46,950	(65,321)	
Net Loss for the year- Comprehensive loss	-	-	-	(72,352)	
Balance as of November 30, 2011	80,500,000	8,050	46,950	(137,673)	
Changes during the Year ended November 30, 2012					
Shares cancelled	(33,873,049)	(3,387)	3,387	-	
Warrants and shares issued for cash, net of issuance expenses	1,100,000	110	1,071,551	-	
Stock-based compensation expenses related to options granted to employees	-	-	2,976,922	-	
Stock-based compensation expenses related to options granted to consultant	-	-	242,055	-	
Shares issued for services	1,390,952	139	509,483	-	
Net loss for the year- Comprehensive loss	-	-	-	(4,998,143)	
Balance as of November 30, 2012	49,117,903	4,912	4,850,348	5,135,816	
Changes during the Year ended November 30, 2013					
Stock-based compensation expenses related to options granted to employees and directors	-	-	2,795,655	-	
Stock-based compensation expenses related to options granted to consultants	-	-	316,312	-	
Warrants and shares issued for cash	2,026,718	202	666,988	-	
Shares to be issued for services rendered	-	-	6,144	-	
Net loss for the year- Comprehensive loss	-	-	-	(5,539,159)	
Balance as of November 30, 2013	51,144,621	\$ 5,114	\$ 8,635,447	\$ (10,674,975)	

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

ORGENESIS INC.
(A development stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars

	Year ended November 30,		Period from June 5, 2008 (inception date) through November 30, 2013
	2013	2012	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (5,539,159)	\$ (4,998,143)	\$ (10,674,975)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Write-off of website development costs	-	-	15,000
Stock-based compensation expenses related to options granted to employees	2,795,655	2,976,922	5,772,577
Stock-based compensation expenses related to options granted to consultants	316,312	242,055	558,367
Increase in accrued severance pay, Net	2,719	1,553	4,272
Shares issued for services rendered	6,144	509,622	515,766
Depreciation	3,257	1,406	4,663
Change in fair value of warrants liabilities	(133,316)	-	(133,316)
Interest expenses due to loan	172,510	-	172,510
Changes in operating assets and liabilities:			
Increase in prepaid expenses and accounts receivable	(8,659)	(27,184)	(36,908)
Increase in accounts payable	2,984	91,278	138,775
Increase in accrued expenses	312,984	68,138	386,122
Increase in related parties	-	6,862	42,362
Increase in employees and related payables	79,221	75,879	155,100
Net cash used in operating activities	(1,989,348)	(1,051,612)	(3,079,685)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(7,838)	(9,679)	(17,517)
Website development costs	-	-	(15,000)
Investment in short term deposits	-	(10,002)	(10,002)
Amounts funded in respect of retirement benefits obligations	(2,334)	(1,296)	(3,630)
Net cash used in investing activities	(10,172)	(20,977)	(46,149)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from Warrants and shares issued for cash	1,800,000	1,071,661	2,926,661
Proceeds from loan received and warrants issued for cash	250,000	-	250,000
Net cash provided by financing activities	2,050,000	1,071,661	3,176,661
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	50,480	(928)	50,827

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	347	1,275	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 50,827	\$ 347	\$ 50,827

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

F-5

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES:

a. General:

Orgenesis Inc. (the Company), incorporated in the state of Nevada on June 5, 2008 is developing a new technology for regeneration of functional insulin-producing cells, thus, enabling normal glucose regulated insulin secretion, via cell therapy.

On October 11, 2011, the Company incorporated a wholly-owned subsidiary in Israel, Orgenesis Ltd. (the Subsidiary), which is engaged in research and development.

On February 2, 2012, the Subsidiary entered into an agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the Licensor). The 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 named Orgenesis Inc., (the US Subsidiary) which will be engaged in research and development. The US subsidiary has not commenced its operation yet.

On October 11, 2013, Orgenesis Ltd. incorporated a wholly-owned subsidiary in Belgium, Orgenesis SPRL (the Belgium Subsidiary), which will be engaged in development and manufacturing activities together with the clinical studies in Europe, and later on to be our center for our activities in Europe. The Belgium subsidiary has not commenced its operation yet.

Unless the context indicates otherwise, the term Group refers to Orgenesis Inc. and its subsidiaries, Orgenesis Ltd (the Subsidiary), Orgenesis Inc. (The US subsidiary in Maryland) and Orgenesis SPRL (The Belgium Subsidiary).

The Group is engaged in research and development in the biotechnology field and is considered a development stage Company in accordance with ASC Topic 915 Development Stage Entities . 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, 2013, of \$10,674,975 as well as a negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following November 30, 2013. 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, 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. Although there is no assurance that the Company will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders, including via future exercise of 2,926,718 warrants for a total amount of \$1,543,893 as mentioned in note 3(b). During December 2013, the company raised capital of \$445,000. See note 14(4)

These 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 is unsuccessful in raising additional financing, it may need to curtail, discontinue or cease operations.

F-6

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Basis Of Presentation

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP).

c. 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 and warrants issued.

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 inter-Company 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 its subsidiaries are conducted is the US dollar (\$ or dollar). The Belgium Subsidiary has only commenced immaterial operations.

Most of the Group's expenses are incurred in dollars and source of the Group'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 non-monetary 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 non-monetary balance sheet items such as depreciation) historical exchange rates. The resulting transaction gains or losses are carried to financial income or expenses, as appropriate.

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

g. Income Taxes

1. 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 has provided a full valuation allowance with respect to its deferred tax assets.

2. Uncertainty in income tax

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

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

h. Stock-Based Compensation

The Company accounts 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 follows ASC Topic 505-50, formerly EITF 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services, 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.

i. Warrants issued as part of capital raisings that are 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 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. See note 8.

F-8

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

j. Fair value measurement:

Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of November 30, 2013 the assets or liabilities measured at Level 3 fair value comprise of warrants. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible.

k. 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%

l. Loss per common stock

Basic and diluted net loss per common stock is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding. Outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The total number of common stock options and warrants excluded from the calculation of diluted net loss per share was 15,245,531 for the year ended November 30, 2013 (7,883,198 for the year ended November 30, 2012).

m. Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally cash and cash equivalent and bank deposits. The Company held these instruments with highly rated financial institutions. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to any significant credit risk on these instruments.

F-9

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

n. Newly issued and recently adopted Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02). This update requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, ASU 2013-02 requires presentation, either on the face of the income statement or in the notes, of significant amounts reclassified out of accumulated other comprehensive income by respective line items of net income, but only if the amounts reclassified are required to be reclassified in their entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross- reference to other disclosures that provide additional details about these amounts. The amendments in ASU 2013-02 will be effective prospectively for annual reporting periods beginning after December 15, 2012, and interim periods within those annual periods. ASU 2013-02 is effective for the Company on November 30, 2013. The adoption of ASU 2013-02 does not have a material effect on the consolidated financial statement presentation.

NOTE 2 COMMITMENTS

1. On February 2, 2012 the Subsidiary entered into a licensing agreement with the Licensor. According to the agreement, the 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.

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

- a. A royalty of 3.5% of net sales.
- b. 16% of all sublicensing fees received.
- c. 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.
- d. Milestone payments as follows:
 1. \$50,000 on the date of initiation of phase I clinical trials in human subjects;
 2. \$50,000 on the date of initiation of phase II clinical trials in human subjects;
 3. \$150,000 on the date of initiation of phase III clinical trials in human subjects;
 4. \$750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA.
 5. \$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, 2013 the Company has not reached these milestones.

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Subsidiary of the Company and/or consolidation of the 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 Subsidiary at the time of the Exit.

F-10

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 COMMITMENTS (continued):

2. On February 2, 2012 the Company entered into an agreement with Mintz, Levin, Ferris, Glovsky and Popeo, P.c. for professional services related to the patent registration. In addition to an amount of \$80,000 paid to this service provider, the Company issued 1,390,952 shares of common stock that will be held in escrow for two years. As a result of the escrow, the fair value of these shares issued for services were \$509,622 based on a 34.57% discount calculated, on the price per share on February 2, 2012. The Company will pay an additional \$50,000 upon consummation of the earlier of:
 1. The purchase of all the Company's common shares and/or amalgamation of the Company or the Subsidiary into or with another corporation.
 2. The Company sublicensing the technology to a non-affiliate of the Company.
 3. \$20,000 upon each of the following milestones (but in any event no more than \$50,000 in total):
 1. Initiation by the Company of phase I clinical trials for the Company's product in human subjects.
 2. Initiation by the Company of phase II clinical trials in human subjects.
 3. Initiation by the Company of phase III clinical trials in human subjects.

As of November 30, 2013 the Company has not reached these milestones.

3. On February 2, 2012, the Company entered into a consultancy agreement with Weinberg Dalyo Inc., for financial consulting services for a consideration of \$3,000 per month. During the period of this agreement, if the consultant locates an investor, which the Company enters into a binding investment agreement, the consultant is entitled to a bonus of 1.5% from the total investment in cash. During 2013 the fee has been updated to \$12,500 per month.
4. On February 2, 2012, the Subsidiary entered into an employment agreement (the Ferber Employment Agreement) with Prof. Sarah Ferber. Pursuant to the Ferber Employment Agreement, Prof. Ferber agrees 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 \$10,217 based on an exchange rate of 1 NIS equals \$0.2838 as of November 30, 2013. In the event the Company completes 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. On May 6 2013, the Company completed a financing of over \$1,000,000, therefore. Prof. Ferber will be paid a gross salary of NIS (Israeli shekel) 72,000 per month, which is approximately \$20,433 based on an exchange rate of 1 NIS equals \$0.2838 as of November 30, 2013.
5. On February 2, 2012, the Subsidiary entered into a compensation agreement (the Caplan Compensation Agreement) with Ms. Caplan. Pursuant to the Caplan Compensation Agreement, Ms. Caplan agrees to serve as a director of our Company. Ms. Caplan will be paid a gross salary of NIS (Israeli shekel) 10,000 per month, which is approximately \$2,838 based on an exchange rate of 1 NIS equals \$0.2838 as of November 30, 2013. In the event the Company completes a financing of at

least \$2,000,000, Ms. Caplan will be paid a onetime bonus of \$100,000. On May 6, 2013 the Company completed a financing of over \$2,000,000. Therefore the Company has recorded an expense of \$100,000.

6. On March 22, 2012 the 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 total consideration of approximately \$74,000 for a year. On May 1, 2013 the Subsidiary renewed the research agreement for the total annual consideration of approximately \$92,000.

F-11

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 COMMITMENTS: (continued):

7. On April 17, 2012 the Company entered into an agreement with Yaron Adler to serve as a director in the Company's board of directors for a consideration for every board meeting on an hourly basis. In the event the Company receives an aggregate financing of at least \$3,000,000 he will be entitled to a one-time payment in the amount of \$15,000. As of November 30, 2013 the milestone was not met. See also note 5(5).
8. On April 24, 2012 the Company entered into an agreement with Granzer Regulatory Consulting & Services (Granzer) to provide services with regard to regulatory and development aspects in connection with pharmaceutical products in the area of chemistry and pharmacy toxicology, clinical and regulatory. The Company shall pay for services at a range of 125-300 Euro per hour or 2,400 Euro per day.
9. On October 18, 2012 the Company entered into an agreement with Fraunhofer IGB to perform experiments and studies on transplants of liver cells in order to develop the manufacturing process in standards that will enable Orgenesis to use it in clinical trials. According to the agreement the Company will pay per achieved phase which are defined in the agreement for a total consideration of 260,000 Euro for all services. Under the terms of the agreement the Company has the discretions to continue at each phase. As of November 30, 2013 the Company completed the first phase which was evaluated at 70,000 Euro.
10. On December 23, 2012 the Company appointed a new CEO Mr. Sav DiPasquale to the Company, whose compensation will consist of an annual gross salary of \$180,000 and the eligibility to receive stock options, performance shares and an annual bonus at the discretion of the board of directors upon the performance as follows:
 - a. 982,358 Performance Shares will be issued upon the completion of a fundraising.
 - b. 1,473,537 Shares will be issued as to 25% on each of the first, second, third and fourth anniversaries of the date of the employment agreement. See note 14(3).

On October 23, 2013, 255,413 performance options were granted to Mr. Dipasquale based on his agreement. See also note 5(9) and note 14(3).
11. On March 27, 2013, the Company signed an agreement with Mintz Levin, its patent attorneys, in which 16% of its fees will be converted to shares of the Company at market price. A total of \$6,144 will be converted into common shares. As of November 30, 2013 the issuance of shares has not yet occurred.
12. On May 6, 2013 the Subsidiary entered into a Process Development Agreement with ATMI BVBA, a Belgium Company which is a wholly owned subsidiary of Advanced Technology Materials, Inc. (ATMI), a US publicly traded company. According to the agreement ATMI will provide services in cell research. The Company will use ATMI's unique technology while the Company will provide to ATMI 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 total consideration of Euro 606,500 for all

services. As of November 30, 2013, 80% of work plan 1 has been completed, which was valued at Euro 87,000.

F-12

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 STOCKHOLDERS' DEFICIENCY:

a. Share capital:

The Company's shares are traded on the Over-The-Counter Bulletin Board.

On August 31, 2011, the Company effected a 35 to 1 share split. As a result the issued and outstanding capital of the Company has been increased from 2,300,000 to 80,500,000 shares of common stock with par value of \$0.0001 per share. Share data and Per share data has been adjusted to reflect the stock split.

On February 2, 2012, two of the Company's shareholders cancelled 33,873,049 shares of common stock of the Company held by them in connection with the capital raising and other changes in the capital.

b. Financing:

1. In 2012, the Company completed a private placement with Derby Management LLC for total consideration of \$1,100,000 for 1,100,000 shares of common stock and 1,100,000 common stock warrants at purchase price of \$1.00 per share.
2. 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-transferable Common Stock warrants. Each Common Stock warrant ("December Warrants") can be exercised into one share at a purchase price of \$0.50 per warrant and is exercisable until November 30, 2014. See also Note 8.

In connection with this agreement, the 1,000,000 Warrants issued in July 2012 were cancelled.

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 STOCKHOLDERS' EQUITY (continued):

3. On May 2013, the Company entered into a subscription agreement with ATMI, pursuant to which ATMI purchased 1,526,718 units at a price of \$0.8515 per unit for total consideration of \$1,300,000. Each Unit consists of one share of the Company's Common Stock and one Common Stock warrant. Each Common Stock warrant ("May Warrants") can be exercised into one share at a purchase price of \$1 per warrant and is exercisable until May 6, 2015. As of the issuance day, the fair value of the warrants was \$704,590 based on Monte Carlo pricing-model. See also Note 8.

NOTE 4 LOAN

1. 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 Loan) in the total amount of \$250,000 and issued to the investor 100,000 warrants (March Warrant). Each Common Stock warrant can be exercised into one share at a purchase price of \$0.50 per warrant and is exercisable until March 22, 2015. See also Note 8.

The warrants issued are detachable from the loan and classified as a liability due to down-round protection (through ratchet and anti-dilution provisions), therefore the Company allocated the proceeds from Mediapark, first to the warrants based upon the fair value of the warrants, and the residual amount of proceeds was allocated to the Loan. As of the issuance day, the fair value of the warrants was \$65,192 based on Monte Carlo pricing-model. See also Note 8.

The loan bears interest at an annual rate of 8%, which is calculated quarterly. The Loan matured on June 30, 2013. The Company has the right to extend the maturity date for an additional period of up to 90 days provided it issues an additional 100,000 warrants ("Additional Warrants").

If the Company has not paid the Loan in full at the maturity date or, if extended, the extended maturity date, Mediapark has the right of conversion in respect of the total outstanding amount of the Loan including accrued interest as of the conversion date into common shares, at a price per common share equal to the lower of: (1) \$0.75 and (2) the value of weighted average price for the five trading days prior to the date of conversion.

2. On June 30, 2013 the Company exercised its discretion to extend the maturity date of the loan to September 30, 2013, In return for extending the maturity date, the Company issued to Mediapark additional Warrants at an exercise price of \$0.50 per warrant. The fair value of the warrants was \$48,800 based on Monte Carlo pricing-model. See also Note 8.
3. On September 30, 2013, the Company extended the maturity date of a loan from Mediapark 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 until September 30, 2015. The fair value of the warrants was \$46,000 based on Monte Carlo pricing-model. See also Note 8 and Note 14.2.

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 STOCK BASED COMPENSATION

1. 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 which will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years.

The fair value of each stock option grant is estimated at the date of grant using the Black and Scholes option pricing model. The volatility is based on historical volatilities of companies in comparable stages as well as companies in the industry historical volatility, by statistical analysis of the daily share pricing model. The expected term is equal to the contractual life, based on management estimation for the expected dates of exercising of the options.

2. On February 2, 2012, 2,781,905 options were granted to Prof. Sara Ferber, the Company's Chief Scientific Officer, at an exercise price of \$0.0001 per share. The options vest in twelve equal monthly installments from the date of grant and expire on February 2, 2022. The fair value of these options on the date of grant was \$1,557,867 using the Black and Scholes option-pricing model.
3. On February 2, 2012, 2,781,905 options were granted to Mr. Jacob BenArie, the Company's CEO, at an exercise price of \$0.69 per share, the options vest in twelve equal quarterly installments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant was \$1,404,819 using the Black and Scholes option-pricing model.
4. On June 4, 2012, 471,200 options were granted to Mr. Guy Yachin, the Company's member of the board of directors, at an exercise price of \$0.85 per share, the options vest in five equal annual installments from the date of grant and expire on June 4, 2022. The fair value of these options as of the date of grant was \$363,478 using the Black and Scholes option-pricing model.
5. On July 8, 2012, 706,890 options were granted to Mr. Yaron Eldar, the Company's member of the board of directors, at an exercise price of \$0.79 per share, the options vest in five equal annual installments from the date of grant and expire on July 8, 2022. The fair value of these options as of the date of grant was \$506,635 using the Black and Scholes option-pricing model.
6. On July 10, 2012, 3,338,285 options were granted to Ms. Vered Kaplan, the Company's Chairman of the Board at an exercise price of \$0.001 per share, the options vest in two equal annual installments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant was \$2,935,496 using the Black and Scholes option-pricing model.
- 7.

On July 8, 2012, 235,630 options were granted to Ms. Etti Hanochi, the Company's member of the board of directors, at an exercise price of \$0.79 per share, the options vest in five equal annual installments from the date of grant and expire on July 8, 2022. The fair value of these options as of the date of grant was \$171,207 using the Black and Scholes option-pricing model.

8. On July 16, 2013, 250,000 options were granted to Dr. David Sidransky, the Company's member of the 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 and Scholes option-pricing model.

F-15

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 STOCK BASED COMPENSATION (continued):

9. On October 23, 2013, 255,413 options were granted to Sav DiPasquale, the Company's CEO at an exercise price of \$0.001 per share, the options are fully vested on the date of grant and expire on October 23, 2023. The fair value of these options as of the date of grant was \$165,850 using the Black and Scholes option-pricing model.

According to Mr. Sav DiPasquale's employment agreement, Mr. DiPasquale is entitled to 1,473,537 shares, which will be issued on each of the first, second, third and fourth anniversaries of the date of the employment agreement. The fair value of these shares as of the date of grant was \$869,387. For further information regarding the options granted see note 14(3).

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:

	For options granted during the year ended November 30,	
	2013	2012
Expected option life (years)	10.0	10.0
Expected stock price volatility (%)	96.5-98.8	104-105
Risk free interest rate (%)	2.51-2.55	1.53-1.86
Expected dividend yield (%)	0.0	0.0

A summary of the Company's stock option granted to employees and directors as of November 30, 2013 and November 30, 2012 and changes for the years then ended is presented below:

	2013		2012	
	Number Of Options	Weighted Average exercise price \$	Number of options	Weighted Average exercise price \$
Options outstanding at the beginning of the year	10,315,815	0.297	-	-
Changes during the year:				
Granted	1,978,950	0.96	10,315,815	0.297
Expired	-	-	-	-
Options outstanding at end of the year	12,294,765	0.265	10,315,815	0.297
Options exercisable at end of the year	6,611,982	0.20	2,781,905	0.17

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 STOCK BASED COMPENSATION (continued):

Costs incurred in respect of stock based compensation for employees and directors, for the years ended November 30, 2013 and November 30, 2012 were \$2,795,655 and \$2,976,922, respectively. As of November 30, 2013, there were \$1,703,987 of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 2.4 years.

The following table presents summary information concerning the options granted to employees and directors outstanding as of November 30, 2013:

Exercise Prices \$	Number of outstanding options	Weighted average remaining contractual Life Years	Weighted average Exercise price \$	Aggregate intrinsic value \$
0.0001	2,781,905	8.17	0.0001	1,947,055
0.001	5,067,235	8.52	0.001	3,541,997
0.69	2,781,905	8.17	0.69	27,819
0.75	250,000	9.62	0.75	-
0.79	942,520	8.62	0.79	-
0.85	471,200	8.51	0.85	-
	12,294,765	8.39	0.265	5,516,871

The following table presents summary of information concerning the options exercisable as of November 30, 2013:

Exercise prices \$	Number of exercisable options	Total Exercise value \$
0.0001	2,781,905	278
0.001	1,924,556	1,925
0.69	1,622,778	1,119,717
0.79	188,504	148,918
0.85	94,240	80,104
	6,611,982	1,350,942

F-17

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 STOCK BASED COMPENSATION (continued):

Options granted to non-employees:

1. On April 14, 2012, 471,200 options were granted to Dr. G. Alexander (Zan) Fleming, the Company's advisor, at an exercise price of \$1.40 per share. The options vest in five equal annual installments from the date of grant and expire on April 14, 2022. The fair value of these options as of the date of grant is \$564,907 using the Black and Scholes option-pricing model.
2. On June 4, 2012, 706,904 options were granted to Mr. Dov Weinberg, the Company's CFO, at an exercise price of \$0.69 per share. The options vest in four equal semi - annual installments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant is \$500,678 using the Black and Scholes option-pricing model.
3. On November 21, 2012, 100,000 options were granted to Camillo Ricordi, a consultant for the Company, at an exercise price of \$0.61 per share. The options vest in five equal annual installments from the date of grant and expire on November 21, 2022. The fair value of these options as of the date of grant is \$64,513 using the Black and Scholes option-pricing model.
4. On August 2, 2013, 100,000 options were granted to Prof. 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.

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:

	For options granted during the year ended November 30 2013	For options granted during the year ended November 30, 2012
Expected option life (years)	10.0	10.0
Expected stock price volatility (%)	97.1	104- 110
Risk free interest rate (%)	2.63	1.51-1.62
Expected dividend yield (%)	0.0	0.0

F-18

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 STOCK BASED COMPENSATION (continued):

A summary of the status of the stock options granted to non-employees as of November 30, 2013 and November 30, 2012 and changes for the years then ended is presented below:

	2013		2012	
	Number of options	Weighted Average Exercise Price	Number of options	Weighted Average exercise price \$
Options outstanding at the beginning of the year	1,278,104	0.95	-	-
Changes during the year:				
Granted - at market price	100,000	0.96	1,278,104	0.95
Expired	-	-	-	-
Options outstanding at end of the year	1,378,104	0.95	1,278,104	0.95
Options exercisable at end of the year	644,418	0.79	176,726	0.69

Costs incurred in respect of stock based compensation for consultants, for the year ended November 30, 2013 and November 30, 2012 was \$316,312 and \$242,055 respectively. As of November 30, 2013, there were \$348,105 of unrecognized compensation costs related to non-vested non-employees, to be recorded over the next 3.26 years.

The following table presents summary information concerning the options granted to non employees outstanding as of November 30, 2013:

Exercise prices \$	Number of outstanding options	Weighted average remaining contractual Life Years	Weighted average Exercise price	Aggregate intrinsic value \$
0.61	100,000	8.98	0.61	9,000
0.69	706,904	8.17	0.69	7,069
0.9	100,000	9.34	0.96	-
1.4	471,200	8.37	1.4	-
	1,378,104	8.38	0.95	16,069

F-19

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 STOCK BASED COMPENSATION (continued):

The following table presents summary of information concerning the options exercisable as of November 30, 2013:

Exercise prices \$	Number of exercisable options	Total Exercise price \$
0.61	20,000	12,200
0.69	530,178	365,822
1.4	94,240	131,936
	644,418	509,958

NOTE 6 PREPAID EXPENSES AND ACCOUNT RECEIVABLE

	Year ended November 30,	
	2013	2012
VAT	\$ 22,877	\$ 15,441
Prepaid expenses	12,765	12,808
Other receivables	1,256	-
	\$ 36,908	\$ 28,249

NOTE 7 PROPERTY AND EQUIPMENT, NET

	Year ended November 30,	
	2013	2012
Cost:		
Office Furniture	\$ 3,761	\$ 2,841
Lab Equipment	5,901	-
Computers	7,855	6,838
	17,517	9,679
Less accumulated depreciation	4,663	1,406
	\$ 12,854	\$ 8,273

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8- WARRANTS:

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

1. In December 2012, the Company issued 1,000,000 non-transferable Common Stock warrants. Each Common Stock warrant ("December Warrants") can be exercised into one share at an exercise price of \$0.50 per warrant and is exercisable until November 30, 2014. In the event the Company will issue any Common Stock or securities convertible into the Common Stock at a price less than the purchase price of the shares, the price shall be reduced to the new issuance price.
2. In March 2013, the Company issued 100,000 warrants (March Warrants) in connection with the agreements with Mediapark. Each Common Stock warrant can be exercised into one share at an exercise price of \$0.50 per warrant and is exercisable until March 22, 2015. In the event the Company will issue any Common Stock or securities convertible into the Common Stock at a price less than the purchase price of the shares, the price shall be reduced to the new issuance price.
3. In May 2013, the Company issued 1,526,718 warrants ("May Warrants"). Each Common Stock warrant can be exercised into one share at an exercise price of \$1 per warrant and is exercisable until May 6, 2015. In the event the Company will issue any Common Stock or securities convertible into the Common Stock at a price less than \$0.8515, the price shall be reduced to the new issuance price. Please see Note 14(4).
4. On June 30, 2013, the Company exercised its discretion to extend the maturity date of the Mediapark Loan from September 30, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 additional Warrants at an exercise price of \$0.5. For additional information see Note 4.
5. On September 30, 2013, the Company exercised its discretion to extend the maturity date of a loan to Mediapark from December 31, 2013. In return for extending the maturity date, The Company issued to Mediapark 100,000 additional warrants, which can be exercised into shares at an exercise price of \$0.50 per share until September 30, 2015.

The fair value of each of the warrants described above is determined 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. As of November 30, 2013, these are the assumptions which were used for the model:

FV of Common Share	\$0.70
Expected Volatility	105%
Risk Free Interest Rate	0.13%-0.28%
Expected Term (years)	1.0-1.8

Expected Dividend Yield 0%

F-21

ORGENESIS INC.
(A development stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8- WARRANTS (continued):

Financial liabilities carried at fair value as of November 30, 2013 are classified in the table below:

		Fair value measurements at reporting date using	
		Level 3	Total
Warrants -			
November 30, 2013	\$	1,157,954	\$ 1,157,954

The following table summarizes the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs:

		November 30 2013
Carrying value at the beginning of the year		-
Additional warrant liabilities issued		1,291,270
Changes in fair value of warrant liabilities		(133,316)
Carrying value at the end of the year	\$	1,157,954

F-22

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 RESEARCH AND DEVELOPMENT EXPENSES

	Year ended November 30,	
	2013	2012
Salaries & related expenses	\$ 395,710	\$ 166,108
Stock-based compensation	475,877	1,329,651
Professional fees and consulting services	378,826	102,863
Patents registrations	101,801	619,288
Other	100,242	90,901
Total	\$ 1,452,456	\$ 2,308,811

NOTE 10 GENERAL AND ADMINISTRATIVE EXPENSES

	Year ended November 30,	
	2013	2012
Salaries & related expenses	\$ 415,163	\$ 192,973
Stock-based compensation	2,636,090	1,889,326
Accounting and Legal	283,493	176,446
Professional fees	296,753	203,288
Business development	187,827	140,944
Travel	118,333	14,551
Others	70,387	62,220
Total	\$ 4,008,046	\$ 2,679,748

NOTE 11 FINANCIAL EXPENSES, NET

	Year ended November 30,	
	2013	2012
Interest expenses due to loan	\$ 172,510	\$ -
Changes in fair value of warrants	(133,316)	-
Foreign exchange loss -net	33,761	7,069
Bank commissions - net	5,702	2,515
Total	\$ 78,657	\$ 9,584

F-23

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 TAXES ON INCOME

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 Subsidiary

The Subsidiary is taxed according to Israeli tax laws. The regular corporate tax rate in Israel for 2013 is 25%.

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. Tax losses carried forward to future years

1. The Company

As of November 30, 2013, the Company had net operating loss (NOL) carry-forwards equal to \$1,429,661 that is available to reduce future taxable.

The NOL carry-forward of the Company equal to \$137,673 may be restricted under Section 382 of the Internal Revenue Code (IRC). IRC Section 382 applies whenever a corporation with NOL experiences an ownership change. As a result of Section 382, the taxable income for any post change year that may be offset by a pre-change NOL may not exceed the general Section 382 limitation, which is the fair market value of the pre-change entity multiplied by the long-term tax exempt rate.

2. The Subsidiary

As of November 30, 2013, the Subsidiary had approximately \$1,585,993 of NOL carry-forwards that is available to reduce future taxable income with no limited period of use.

d. Deferred income taxes:

	As of November 30	
	2013	2012
In respect of:		
Net operating loss carry forward \$	1,013,024	\$ 344,307
R&D expenses	182,668	57,344
Holiday and recreation pay	15,496	3,968
Severance pay accruals	1,132	402
Less - Valuation allowance \$	1,212,320	\$ 406,021

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-24

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 TAXES ON INCOME (continued)

e. 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 in respect of tax benefits from carry forward tax losses due to the uncertainty of the realization of such tax benefits (see above).

f. Tax assessments

1. The Company

As of November 30, 2013 the Company has not received final tax assessment for the years 2010 to 2012.

2. The Subsidiary

As of November 30, 2013 the Subsidiary has not received final tax assessment.

g. As of November 30, 2013 the Company has not accrued a provision for uncertain tax positions.

NOTE 13 RELATED PARTIES

	Year ended November 30,	
	2013	2012
a. Management and consulting fees to the Chairman of the Board.	\$ 140,037	\$ 22,679
b. Compensation to the non- executive directors (except the Chairman of the Board)	\$ 40,648	\$ 27,344
c. With respect to options granted and salary paid to the Company's Chief Executive Officer, see Note 5(3).		
d. With respect to options granted to the Company's board members. See Note 5.		
e. 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.		

ORGENESIS INC.
(A development stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 14 - SUBSEQUENT EVENTS

1. During December 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 Company have agreed to file a registration statement with the U.S. Securities & Exchange Commission (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, the Company has the right at its sole discretion over a period of one year to sell up to \$3,000,000 million of common stock under the terms set forth in the agreement. Proceeds from this transaction will be used to fund research and development and working capital. In December 2013, the Company issued to Kodiak 250,000 commitment shares.
2. On December 6, 2013, the Company 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 Debenture) in the aggregate principal amount of \$100,000. Interest is calculated semi-annually and is payable, along with the principal on or before December 6, 2014. According to the agreement, in the event the Company completes an equity financing prior to the Maturity Date for gross proceeds of \$350,000 or more comprising Common Shares and/or warrants to purchase additional Common Shares, Mediapark will convert the Companies' Indebtedness into Common Shares and/or warrants on the same terms as the New Equity Financing. See also note 4 and note 14(4).
3. On December 23, 2013, the President and Chief Executive Officer, Sav DiPasquale, resigned. On the same date, the Company appointed the Chairperson of the Board as Interim President and Chief Executive Officer of the Company until a replacement is named. As a result of his resignation all options that were not vested are forfeited. All vested options expire 90 days after the date of cessation of employment.
4. In December 2013, the Company entered into a private placement agreement with new investors for up to \$1,000,000 in value of units (Units) each consisting of one Common share (Share) and one share purchase warrant. Each warrant provides the investors the right to purchase one common share of the Company (a Warrant Share) for \$0.52 for a term of three years. As of February 19, \$445,000 was raised in connection with this agreement.

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 Securities and Exchange Commission'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 cost-benefit 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 *Sarbanes-Oxley Act*, 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) (1992). 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.

Our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the design and operation of our internal control over financial reporting as of November 30, 2013 based on the criteria set forth in Internal Control – Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation 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, 2013. 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: (1) inadequate segregation of duties consistent with control objectives; and (2) 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 on Form 10-K, 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, 2014: (i) appoint additional qualified personnel to address inadequate segregation of duties and ineffective risk management; and (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 decision-making 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, 2013 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, 2013, our directors and executive officers, their age, positions held, and duration of such, are as follows:

Name	Position Held with our Company	Age	Date First Elected or Appointed
Vered Caplan	Interim President and Chief Executive Officer Chairperson of the board of directors	45	December 23, 2013 February 2, 2012
Jacob BenArie ⁽¹⁾	Chief Executive Officer of Subsidiary	45	December 17, 2012
Dov Weinberg	Chief Financial Officer, Treasurer and Secretary	61	February 2, 2012
Sarah Ferber	Chief Scientific Officer	59	February 2, 2012
Guy Yachin	Director	46	April 2, 2012
Etti Hanochi	Director	40	April 6, 2012
David Sidransky	Director	53	July 18, 2013
Yaron Adler	Director	43	April 17, 2012

Note

- ⁽¹⁾ Mr. BenArie resigned as President and Chief Executive Officer of our company on December 17, 2012. Mr. BenArie was appointed President and Chief Executive Officer of our company 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, Interim President and Chief Executive Officer and Chairperson of the Board of Directors

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 self-propelled disposable colonoscopies; Nehora Photonics Ltd., a company involved with non-invasive 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 bio-medical engineering from Tel-Aviv University specialized in signal processing; management for engineers from Tel-Aviv University specialized in business development; and a B.Sc. in mechanical engineering from the Technion specialized in software and cad systems.

We believe Ms. Caplan 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.

Dov Weinberg CPA, MBA, Chief Financial Officer, Secretary, and Treasurer

Mr. Dov Weinberg has more than 12 years of experience in the medical device and Biotech area. He is an owner and president of Weinberg Dalyo Inc., a U.S corporation which renders business development and financial services to companies in the life science industry. Mr. Weinberg currently serves as CFO of QRS systems Inc., Innovate Inc., and NaNaMed LLC and was previously the Chief Financial Officer of Impulse Dynamics from December 2000 until the beginning of 2009. Prior to that, Mr. Weinberg served for more than 15 years as the CFO of a large industrial multinational public corporation in charge of finance, information systems, and taxation of the company and its worldwide subsidiaries.

Mr. Weinberg has been a Certified Public Accountant since 1979 and received an MBA from Bar-Ilan University in 1984 and a B.A. in Economics & Accounting from Tel Aviv University in 1977.

Prof. Sarah Ferber Ph.D., Chief Scientific Officer

Prof. Sarah 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 post-doctoral fellowship at the Joslin Diabetes Lab at Harvard Medical School. Prof. Ferber's breakthrough discovery suggested that humans carry their own stem-cells 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 D-Cure.

Guy Yachin, Director

Guy 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

Dr. Sidransky is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine's Department of Otolaryngology and Professor of Oncology, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at the John Hopkins University School of Medicine. Dr. Sidransky is one of the most highly cited researchers in clinical and medical journals in the world in the field of oncology during the past decade, with over 460 peer-reviewed publications. Dr. Sidransky is a founder of a number of biotechnology companies and holds numerous biotechnology patents.

Dr. Sidransky has served as Vice Chairman of the Board of Directors, and was, until the merger with Eli Lilly, a director of ImClone Systems, Inc., a global biopharmaceutical company committed to advancing oncology care. He is serving, or has served on, the scientific advisory boards of MedImmune, 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 (2005-2008) 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.) 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 high-tech 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 Hi-Tech public and private companies.

She holds a B.A in Accounting and a Management degree from the Management College, an MBA from Tel-Aviv University, a Master's degree in Law from Bar-Ilan 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

In 1999 Mr. Adler co-founded IncrediMail Ltd. (NasdaqGM: MAIL) and served as its Chief Executive Officer until 2008 and President until 2009. In 1999, prior to founding IncrediMail, Mr. Adler consulted Israeli start-up companies regarding Internet products, services and technologies. Mr. Adler served as a Product Manager from 1997 to 1999, and as a software engineer from 1994 to 1997, at Tecnomatix Technologies Ltd., a software company that develops and markets production-engineering solutions to complex automated manufacturing lines that fill the gap between product design and production, and which was acquired by UGS Corp. in April 2005. In 1993, Mr. Adler held a software engineer position at Intel Israel. He has a B.A. in computer sciences and economics from Tel-Aviv University.

We believe Mr. Adler is qualified to serve on our board of directors because of his education and business experiences as described above.

Jacob Benarie MBA, B.Sc., Chief Executive Officer and President of Orgenesis Ltd.

Jacob BenArie served as our Chief Executive Officer and President from February to December 2012. For the last five years he served as the CEO of Beta-Stim Ltd., a private held company that developed a therapy for the treatment of Type 2 Diabetes. Mr. BenArie also co-founded Beta-Stim, Slender Medical and the Medical Device Design & Manufacture Israel conference. Mr. BenArie has over 15 years of experience in different management and R&D positions in life science start-up companies. Mr. BenArie holds a B.Sc. in electronic engineering and MBA, both from the Technion - Israel Institute of Technology.

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 part-time 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 in-person meetings and \$200 for attending meetings via conference call. We will also grant 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 out-of-pocket 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, lipid-lowering compounds, and reproductive indications. He led reviews of landmark approvals including those of the first statin, insulin analog, metformin, PPAR-agonist, and growth hormone for non-GH 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 1992-93.

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 in-person meetings and \$200 for attending meetings via conference call. We will also grant 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 out-of-pocket 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 NIH-funded 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 in-person meetings and meetings via conference call. We will also grant 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 out-of-pocket 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 Vice-President 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 co-editor of numerous books, monographs, chapters and articles. Dr. Skyler was founding Editor-in-Chief 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 have 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 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 directors' 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 10A-3 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.

The board of directors 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. 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 include 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 Bar-Ilan 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 directors. 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 incentive-compensation and equity-based 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 re-election or re-appointment. 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 OTC Markets 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-

and-desist 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 self-regulatory 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.

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, 2013, 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 OTC Markets 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 particulars of compensation paid to the following persons:

- our principal executive officer and principal financial officer;
- our most highly compensated executive officers other than the CEO and CFO who were serving as executive officers at the end of the last completed fiscal year; and
- who we will collectively refer to as the named executive officers, for our fiscal years ended November 30, 2013 are set out in the following summary compensation table:

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 (\$)
Jacob BenArie <i>Former CEO & President</i> ¹	2013	204,891	Nil	Nil	474,174	Nil	24,552	Nil	703,617
	2012	141,200	Nil	Nil	381,545	Nil	23,375	Nil	546,120
Dov Weinberg	2013	126,600	Nil	Nil	231,936	Nil	Nil	Nil	357,936
	2012	47,000	Nil	Nil	201,203	Nil	Nil	Nil	248,203

Edgar Filing: Orgenesis Inc. - Form 10-K

<i>CFO, Treasurer & Secretary</i> ²									
Sarah Ferber <i>Chief Scientific Officer</i> ³	2013 2012	200,604 123,654	Nil Nil	Nil Nil	268,861 1,288,798	Nil Nil	34,706 26,120	Nil Nil	504,171 1,438,572

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 (\$)
Sav DiPasquale President & CEO ⁴	2013	184,669	Nil	Nil	369,506	Nil	Nil	Nil	554,175
	2012	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Notes

- (1) 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.
 - (2) Mr. Weinberg was appointed Treasurer, CFO and Secretary on February 2, 2012.
 - (3) Prof. Ferber was appointed Chief Scientific Officer on February 2, 2012.
 - (4) Mr. DiPasquale was appointed President and CEO on December 17, 2012 and resigned on December 23, 2013.
- 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 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 have 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.

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 agrees 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 agrees 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 out-of-pocket expenses; and the grant of 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 one-time 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 operating subsidiary, Orgenesis Ltd.

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. The consideration for acting as our President and Chief Executive Officer, and working toward equity fundraising efforts is:

1. a base salary of US \$180,000;
2. grant of options pursuant to our stock option plan;
3. issuance of up to 2,455,895 options to be issued over time by fulfilling certain performance criteria while he remains as President and CEO; the options are exercisable at a price of \$0.001 per share;
4. a bonus which is subject to the discretion of our board of directors; and
5. reimbursement of any pre-approved expenses incurred while performing his duties as our President and Chief Executive Officer.

We granted 255,413 options to Mr. DiPasquale on October 23, 2013, which expires 10 years from the date of grant. Mr. DiPasquale resigned as our President and Chief Executive Officer on December 23, 2013.

On January 2, 2014 our board approved a grant of 368,393 options at an exercise price of \$0.001 per share. The grant is based on Sav DiPasquale's signed employment agreement from December 23, 2012. According to Mr. DiPasquale's employment agreement, all vested options expire 90 days after the date of cessation of employment.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of November 30, 2013.

	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 (#)
Jacob BenArie	1,622,778	1,159,127		0.69	02/02/2022	Nil	Nil	Nil

	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 (#)
Dov Weinberg	530,178	176,726		0.69	02/02/2022	Nil	Nil	Nil
Sarah Ferber	2,781,905	Nil		0.0001	02/02/2022	Nil	Nil	Nil
Sav DiPasquale	255,413	1,473,537	Nil	0.001	23/03/2014 ⁽¹⁾	Nil	Nil	Nil

(1) These options expire 90 days after the date that Mr. DiPasquale resigned.

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, 2013.

	Fees earned or paid in cash (\$)	Stock awards (\$)	Option awards (\$)	Non-equity incentive plan compensation (\$)	Change in pension value and nonqualified deferred compensation earnings (\$)	All other compensation (\$)	Total (\$)
Vered Caplan	140,037	Nil	1,467,748	Nil	6,641	Nil	1,614,426
Guy Yachin	30,336	Nil	71,025	Nil	Nil	Nil	101,361
Etti Hanochi	9,112	Nil	33,319	Nil	Nil	Nil	42,431
Yaron Adler	Nil	Nil	98,824	Nil	Nil	Nil	98,824
Dr. David Sidransky	Nil	Nil	12,577	Nil	Nil	Nil	12,577
Jay Skyler	400	Nil	9,011	Nil	Nil	Nil	9,411
Dr. Zan Fleming	400	Nil	66,800	Nil	Nil	Nil	67,200
Camilo Recordi	400	Nil	8,564	Nil	Nil	Nil	8,964

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 (the **Caplan Compensation Agreement**) with Ms. Vered Caplan. Pursuant to the Caplan Compensation Agreement, Ms. Caplan agrees to serve as a director of our company. Ms. Caplan will be paid a gross salary of NIS (Israeli shekel) 10,000 per month, which is approximately \$2,689 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 \$2,000,000, Ms. Caplan will be paid a one-time bonus of \$100,000. 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 one-time 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.

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 will issue to Mr. Yachin stock options subject to the terms of our stock option plan, at an exercise price set at the time of the grant. We will also reimburse Mr. Yachin's pre-approved business expenses.

On April 6, 2012, we entered into an agreement with Ettie Hanochi to serve as a member of our board of directors for a consideration of \$300 for the first hour of attendance at Board meetings, and \$200 per each additional hour. We will issue 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. We will also reimburse any pre-approved 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 one-time 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 will issue 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. We will also reimburse any pre-approved business expenses incurred by Mr. Adler.

On July 17, 2013 we entered into an agreement with Dr. David Sidransky dated for reference July 17, 2013. Under the terms of the agreement, we have appointed Dr. Sidransky to our board of directors. In consideration of 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 will issue to Dr. Sidransky 250,000 stock options subject to the terms of our stock option plan, at an exercise price of \$0.85 per option share. We will also reimburse any pre-approved business expenses incurred by Dr. Sidransky.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the outstanding equity awards held by each of our directors as of November 30, 2013.

Name	Option awards					Stock awards		
	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 (#)
Vered Caplan	1,669,143	1,669,143	253,337	0.001	02/02/2022	Nil	Nil	Nil
Guy Yachin	94,240	376,960	255,132	0.85	04/06/2022	Nil	Nil	Nil
Etti Hanochi	47,126	188,504	126,177	0.79	07/08/2022	Nil	Nil	Nil
Yaron Adler	141,378	565,512	365,055	0.79	08/07/2022	Nil	Nil	Nil
Dr. David Sidransky	Nil	250,000	154,973	0.75	16/07/2023	Nil	Nil	Nil

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

The following tables set forth, as of February 19, 2014, 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 13d-3 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 Ilfov, Romania	11,126,920 Direct ⁽²⁾	21.8%
Common Stock	Gilbert A Cuison Block 616 Bedok Reservoir Rd #03-1108 Singapore 470616	5,420,485 Direct ⁽²⁾	10.6%
Common Stock	Jerome P Golez Block 117 Bihan St #20-29 Singapore 570117	5,500,015 Direct ⁽²⁾	10.8%
	Total Beneficial Holders as a Group	22,047,420 Direct	43.1%

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, Tel-Aviv 65147, Israel	3,338,285 Direct ⁽³⁾	6.5%
Common Stock	Jacob BenArie 70 Denya st. Haifa, Israel 34980	1,854,603 Direct ⁽⁴⁾	3.6%
Common Stock	Dov Weinberg 21 Sparrow Circle White Plains, New York 10605	706,904 Direct ⁽⁵⁾	1.4%
Common Stock	Prof. Sarah Ferber Shderot Hahaskala 17b Tel-Aviv Israel 67890	2,781,905 Direct ⁽⁶⁾	5.4%
Common Stock	Guy Yachin 7 Orchard Way N Potomac MD 20854	94,240 Direct ⁽⁷⁾	0.2%

Title of class	Name and address of beneficial owner	Amount and nature of beneficial ownership⁽¹⁾	Percent of class
Common Stock	Etti Hanochi 18 Aharonovitch Sh Kfar Saba, L3	47,126 Direct ⁽⁸⁾	0.1%
Common Stock	Yaron Adler 19 Chelouche Street Tel-Aviv Israel 65154	141,378 Direct ⁽⁹⁾	0.3%
Common Stock	Sav DiPasquale 506 Vaughan Mills Road Vaughan, ON L4H 1G9	255,413 Direct ⁽¹⁰⁾	0.5%
Common Stock	Dr. G. Alexander (Zan) Fleming	94,240 Direct ⁽¹¹⁾	0.2%
Common Stock	Prof. Camilio Ricordi 1450 NW 10 th Avenue Miami Florida 33136	20,000 Direct ⁽¹²⁾	0%
Common Stock	Directors & Executive Officers as a group (8 persons)	9,334,094 Direct	18.3%

Notes

- (1) Percentage of ownership is based on 51,144,621 shares of our common stock issued and outstanding as of February 19, 2014. 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 21.7% 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 3,338,285 stock options exercisable either immediately or within the next 60 days.
- (4) Consists of 1,854,603 stock options exercisable either immediately or within the next 60 days.
- (5) Consists of 706,904 stock options exercisable either immediately or within the next 60 days.
- (6) Consists of 2,781,905 stock options exercisable either immediately or within the next 60 days.

Edgar Filing: Orgenesis Inc. - Form 10-K

- (7) Consists of 94,240 stock options exercisable either immediately or within the next 60 days.
- (8) Consists of 47,126 stock options exercisable either immediately or within the next 60 days.
- (9) Consists of 141,378 stock options exercisable either immediately or within the next 60 days.
- (10) Consists of 255,413 stock options exercisable either immediately or within the next 60 days.

(11) Consists of 94,240 stock options exercisable either immediately or within the next 60 days.

(12) Consists of 20,000 stock options exercisable either immediately or within the next 60 days.

Changes in Control

As of December 31, 2013, 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 and discussed under the heading "Compensation Discussion and Analysis" or the "The License Agreement" above, since December 1, 2010, 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:

(a) any director or executive officer of our company;

(b) 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;

(c) and of our promoters and control persons; and

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

On June 2, 2012, we signed a promissory note with Guilbert Cuison, one of our shareholders, in the principal amount of \$42,363. According to the note, we will return the loan granted by the shareholder within thirty days from the date we completes on equity financing resulting in gross proceeds to us of at least \$3,000,000.

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 and Yaron Adler. Our securities are quoted on the OTC Markets 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 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 PricewaterhouseCoopers Israel, for the year ended November 30, 2013 and November 30, 2012:

Services	2013	2012
Audit fees	\$ 73,220	70,000
Audit related fees	nil	nil
Tax fees	10,000	10,000
All other fees	nil	nil
Total fees	\$ 83,220	\$ 80,000

Audit Fees

The audit fees were paid for the Audit services of our Annual and Quarterly reports and for review of S1.

Tax Fees

The tax fees were paid for reviewing tax positions taken by us.

Pre-Approval Policies and Procedures

Our board of directors pre-approves 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 PricewaterhouseCoopers Israel and believes that the provision of services for activities unrelated to the audit is compatible with maintaining their respective independence.

PART IV**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Exhibits required by Regulation S-K

No.	Description
3.1	Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S-1 filed on April 2, 2009)
3.2	Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.3	Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.4	Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.5	Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.6	Certificate of Correction dated February 27, 2012 (incorporated by reference to an exhibit to a current report on Form 8-K/A filed on March 16, 2012)
10.1	Form of Private Placement Subscription Agreement (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.2	

Edgar Filing: Orgenesis Inc. - Form 10-K

	Licensing Agreement dated February 2, 2012 with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.3	Employment Agreement dated February 2, 2012 between our company and Prof. Sarah Ferber (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.4	Stock Option Agreement dated February 2, 2012 between our company, Prof. Sarah Ferber and Clark Wilson LLP (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.5	Fee Service Agreement dated February 2, 2012 between our company and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)

Edgar Filing: Orgenesis Inc. - Form 10-K

No.	Description
10.6	Compensation Letter dated February 2, 2012 between our company and Vered Caplan (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012)
10.7	Personal Employment Agreement with Jacob Ben Arie dated February 2, 2012 (incorporated by reference to our current report on Form 8-K filed on March 15, 2012)
10.8	Consultancy Agreement dated March 2, 2012 with Weinberg Dalyo Inc. (incorporated by reference to our current report on Form 8-K filed on March 15, 2012)
10.9	Investor Relations Agreement dated March 15, 2012 with Crescendo Communications, LLC (incorporated by reference to our current report on Form 8-K filed on March 15, 2012)
10.10	Research Services Agreement dated March 22, 2012 with Tel Hashomer Medical Research, Infrastructure and Services Ltd. (incorporated by reference to our current report on Form 8-K filed on April 13, 2012)
10.11	Director Agreement with Guy Yachin dated April 2, 2012 (incorporated by reference to our current report on Form 8-K filed on April 5, 2012)
10.12	Director Agreement with Yaron Adler dated April 6, 2012 (incorporated by reference to our current report on Form 8-K filed on April 23, 2012)
10.13	Director Agreement with Etti Hanochi dated April 6, 2012 (incorporated by reference to our current report on Form 8-K filed on April 25, 2012)
10.14	Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on May 2, 2012)
10.15	Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on May 2, 2012)
10.16	Board of Advisors Consulting Agreement April 14, 2012 (incorporated by reference to our current report on Form 8-K filed on May 31, 2012)
10.17	Letter agreement with the Investor Relations Group Inc. dated May 2, 2012 (incorporated by reference to our current report on Form 8-K filed on May 31, 2012)
10.18	Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on August 3, 2012)
10.19	Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on August 3, 2012)
10.20	Service Agreement with Fraunhofer Institute for Interfacial Engineering and Biotechnology (incorporated by reference to our current report on Form 8-K filed on November 9, 2012)
10.21	Board of Advisors Consulting Agreement dated November 14, 2012 (incorporated by reference to our current report on Form 8-K filed on November 27, 2012)
10.22	Cancellation and Amendment of Warrants Agreement (incorporated by reference to our current report on Form 8-K filed on December 10, 2012)
10.23	Employment Term Sheet with Mr. Sav DiPasquale dated December 17, 2012 (incorporated by reference to our current report on Form 8-K filed on January 7, 2013)
10.24	Form of subscription agreement and loan agreement (incorporated by reference to our current report on Form 8-K filed on March 25, 2013)

Edgar Filing: Orgenesis Inc. - Form 10-K

10.25	Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on March 25, 2013)
10.26	Board of Advisors Consulting Agreement with Professor Jay Sklyer (incorporated by reference to our current report on Form 8-K filed on April 9, 2013)
10.27	May 6, 2013 Process Development Agreement with ATMI BVBA (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)
10.28	Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)
10.29	Form of warrant (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)

No.	Description
10.30	Registration Rights Agreement (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)
10.31	Employment Agreement with Sav DiPasquale dated February 17, 2013 (incorporated by reference to our current report on Form 8-K filed on October 23, 2013)
10.32	Letter Agreement with Sav DiPasquale dated May 29, 2013 (incorporated by reference to our current report on Form 8-K filed on October 23, 2013)
10.33	Term sheet with Mediapark Investments Limited
10.34	Convertible Loan Agreement dated December 6, 2013 with Mediapark Investments Limited (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
10.35	Investment Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
10.36	Registration Rights Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
<u>21.1*</u>	<u>Subsidiaries of our company</u>
<u>31.1*</u>	<u>Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>31.2*</u>	<u>Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>32.1*</u>	<u>Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
<u>32.2*</u>	<u>Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
99.1	Global Share Incentive Plan (2012) (incorporated by reference to our current report on Form 8-K filed on May 31, 2012)
99.2	Appendix Israeli Taxpayers Global Share Incentive Plan (incorporated by reference to our current report on Form 8-K filed on May 31, 2012)
99.3	Audit Committee Charter (incorporated by reference to our current report on Form 8-K filed on January 15, 2013)
99.4	Compensation Committee Charter (incorporated by reference to our current report on Form 8-K filed on January 15, 2013)
<u>99.5*</u>	<u>Report of Independent Registered Public Accounting Firm</u>
101*	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

*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, 2014

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.

/s/ Vered Caplan
Vered Caplan
President, Chief Executive Officer, and Chairperson of
the Board
(Principal Executive Officer)
Date: February 19, 2014

/s/ Dov Weinberg
Dov Weinberg
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting
Officer)
Date: February 19, 2014

/s/ David Sidransky
David Sidransky
Director
Date: February 19, 2014

/s/ Guy Yachin
Guy Yachin
Director
Date: February 19, 2014

/s/ Etti Hanochi
Etti Hanochi
Director
Date: February 19, 2014

/s/ Yaron Adler
Yaron Adler
Director
Date: February 19, 2014