

Orgenesis Inc.  
Form 10-K  
February 15, 2013

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended: **November 30, 2012**

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**

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code **+4165099832**

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

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

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

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

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

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]

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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

(Do not check if a smaller reporting company)

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 30, 2012, 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 \$20,274,031, based on the average bid and asked price for the registrant's common stock on the OTC Bulletin Board on May 30, 2012 of \$0.96 per share.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 49,617,903 shares of common stock as of January 31, 2013.

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## PART I

### ITEM 1. BUSINESS

#### Forward Looking Statements

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, should, expects, plans, anticipates, believes, estimates, predicts, potential negative of these terms or other comparable terminology. Forward-looking statements made in 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;
- \* our independent registered public accounting firm have expressed substantial doubt 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 subsidiary, Orgenesis Ltd., an Israeli corporation (the **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 one 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. 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 THM to license us all of the assets associated with Methods Of Inducing Regulated Pancreatic Hormone Production and Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues .

On October 11, 2011 we incorporated Orgenesis Ltd. as our wholly-owned 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 (Autologous Insulin Producing) cells.

Based on the licensed know how 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 (Autologus Insulin Producing) cells, and to provide the treatment process and protocols (the **Products** ). This licensed portfolio is based on the groundbreaking 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 shall commence 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:
  - \$50,000 on the date of initiation of phase I clinical trials in human subjects;
  - \$50,000 on the date of initiation of phase II clinical trials in human subjects;
  - \$150,000 on the date of initiation of phase III clinical trials in human subjects;
  - \$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
  - \$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 onetime 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 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 years 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.

Without derogating from THM's rights under any applicable law, THM shall be entitled to terminate this Agreement and/or the License hereunder 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:
  - granting of sublicenses;
  - confidentiality provisions;
  - perform payments to THM; and
  - 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 the License hereunder 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 - Medical Research, Infrastructure and Services Ltd. 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 Science 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 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 30, 2012, we and Fraunhofer Institute for Interfacial Engineering and Biotechnology ( **Fraunhofer IGB** ) entered into a service agreement 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.

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 progress in work be achieved within a significant period of time, then each contracting party shall be entitled to terminate the contract with one month notice.

#### *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 initial 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 enter 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 know-how.

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.

#### *Expanded distribution*

We intend to expand distribution of our products in foreign markets, likely through partnerships and licensing agreements with existing centers of Pancreatic Islet transplantations.

**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  $\beta$ -cells thus severely reducing  $\beta$ -cell mass. In T2DM, the pathogenesis involves insulin resistance, insulin deficiency and enhanced gluconeogenesis, while late progression stages eventually leads to  $\beta$ -cell failure and a significant reduction in  $\beta$ -cell function and mass. Thus, both T1DM and late-T2DM result in marked hypoinsulinemia, reduction in  $\beta$ -cell function and mass and lead to severe secondary complications, 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.

Diabetes afflicts nearly 180 million people worldwide and Frost and Sullivan in their Global Diabetes Market 2009 report predict that the DM epidemic that has been sweeping the globe for the past several years will continue at a rapid pace, while there are expected to be more than 380 million people around the world with DM by 2025. In the United States alone, 28 million people (8.2% of the population) have diabetes.

## **Competition**

Insulin therapy is used for **Insulin Depended 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 as 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, patients are sensitive to recurrent T1DM autoimmune attacks and there is also a shortage in tissues available for islet cells transplantation.

#### Human Embryonic Stem Cells (ESC)

The use of ESC is still in 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 attack 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 \$2,308,811 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 compliance, investor and public relations, and general administration. We also intend to engage experts in healthcare and in general business to advise us in various capacities. We currently have one full time employee located in Israel, three part time employees located in Israel and one full time employee located in Canada.

## Subsidiaries

On October 11, 2011, we incorporated our wholly owned subsidiary, Orgenesis Ltd., a company governed by the laws of Israel.

## 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	
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
Methods of Inducing Regulated Pancreatic Hormone Production	Italy	Granted	00935435.8	1180143	01-June-2000	09-May-2007



Title	Country	Status	Serial No.	Patent No.	Filing Date	Issue Date
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 United States Food and Drug Administration 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, which 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 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 approaches already used in man is autologous chondrocyte implantation.

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 United States Food and Drug Administration 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 EMA 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.

*Our independent registered public accounting firm have expressed 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 265,000, including general and administrative expenses, research and development but excluding acquisition costs. This amount could increase if we encounter difficulties that we cannot anticipate at this time. On January 31, 2013, we had cash and cash equivalents of approximately \$170,000. 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

*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 or unanticipated customer requirements.

*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 officer 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 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.*

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 an Israeli corporation to United States resident corporate parents are subject to provisions of the Convention for the Avoidance of Double Taxation between Israel and the United States, which 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 we do not cure such breach within one year of receiving the notice. If THM cancels the License Agreement, our business may be materially adversely affected. THM may also terminate the License Agreement if we breach an obligation contained in the License Agreement and do not cure it within 180 days of receiving notice of the breach.

*If we are unable to successfully acquire, develop or commercialize new products, our operating results will suffer.*

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize 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; 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 new products;
- 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 products;
- experiencing delays as a result of limited resources at FDA or other regulatory agencies; and
- changing review and approval policies and standards at 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 products will be recouped, even if we are successful in commercializing those 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 products 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 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 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 shareholders.*

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 shareholders. Further, such issuance may result in a change of control of our corporation.

*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 (known as **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 shares.

*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 shareholders 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 executive and head office is located at 21 Sparrow Circle, White Plains, NY 10605.

We are using the facilities and the equipment and personnel of the Chaim Sheba Medical Center of Israel at Tel Aviv, Tel Hashomer, 52621, Israel pursuant to an agreement between Tel Hashomer - Medical Research, Infrastructure and Services Ltd. and our Israeli subsidiary. We will pay Tel Hashomer the amount of New Israeli Shekel 279,000 (approximately US \$74,231.40) per year.

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 subsidiary is a party or of which any of our properties, or the properties of our subsidiary, 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 subsidiary or has a material interest adverse to our company or our subsidiary.

**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, 2012	\$0.93	\$0.47
August 31, 2012	\$0.85	\$0.40
May 31, 2012	\$1.64	\$0.71
February 29, 2012	\$0.81	\$0.30
November 30, 2011 <sup>(1)</sup>	\$0.30	\$0.01
August 31, 2011 <sup>(1)</sup>	\$6.00	\$0.55
May 31, 2011 <sup>(1)</sup>	\$1.25	\$1.25
February 28, 2011 <sup>(1)</sup>	\$0.56	\$0.17

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, TX 75034.

**Holders of Common Stock**

As of January 31, 2013, there were 8 holders of record of our common stock. As of such date, 49,617,903 shares were issued and outstanding.

**Dividends**

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

## Recent Sales of Unregistered Securities

### *Stock Options*

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.

On February 2, 2012, 2,781,905 options were granted to Mr Jacob BenArie, the Chief Executive Officer of our subsidiary, 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, 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 five equal annual instalments from the date of grant and expire on April 14, 2022.

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 February 2, 2012 and expire on February 2, 2022.

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 instalments from the date of grant and expire on June 4, 2022.

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 instalments from the date of grant and expire on July 8, 2022.

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 instalments from the date of grant and expire on July 8, 2022.

On July 10, 2012, 3,338,285 options were granted to Ms. Vered Kaplan, the Company's Chairperson of the Board at an exercise price of \$0.001 per share, the options vest in two equal annual instalments from February 2, 2012 and expire on February 2, 2022.

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 instalments from the date of grant and expire on November 21, 2022.

### *Private Placements*

On February 2, 2012, we entered into a subscription agreement with Derby Management LLC ( **Derby** ) for the sale of 500,000 shares of our common stock at a purchase price of \$1.00 per share, for total consideration of \$500,000. Under the agreement Derby committed to purchase an additional 1,000,000 shares of our common stock at a purchase price of \$1.00 per share (the **February 2012 Warrants** ). Derby must exercise half of the February 2012 Warrants upon the earlier of: (i) us or our subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of the placement of shares. Derby must exercise the other half upon the feasibility of enhancement of cell propagation capability if achieve during three years from closing the February 2, 2012 subscription. The February 2012 Warrants were cancelled on July 31, 2012.

In April 2012, we entered into a subscription agreement with Derby for the sale of 100,000 shares of our common stock at a purchase price of \$1.00 per share for total consideration of \$100,000. Under the agreement, Derby committed to purchase an additional 100,000 shares of our common stock at a price of \$1.00 per share under the same terms as the February 2012 Warrants (the **April 2012 Warrants** ). On November 30, 2012, we amended the terms of the April 2012 Warrants to eliminate the requirement that they be exercised upon the achievement of milestones.

On July 31, 2012, we entered into a subscription agreement with Derby for the sale of 500,000 units of our company at a price of \$1.00 per unit for gross proceeds of \$500,000. Each unit is comprised of one share of our common stock and one share purchase warrant (the **July 2012 Warrants** ). Each July 2012 Warrant is exercisable into one share of our common stock at an exercise price of \$1.00 per share until one year from the date of the issuance. The July 2012 Warrants are not required to be exercised upon the achievement of milestones.

On December 3, 2012, we entered into a subscription agreement with Derby to issue an aggregate of 500,000 units of our company at a price of \$1.00 per unit for gross proceeds of \$500,000. Each unit is comprised of one share of our common stock and two share purchase warrants (the **December 2012 Warrants** ). Each December 2012 Warrant is exercisable into one share of our common stock at an exercise price of \$0.50 per share within two years from the date of the issuance of the December 2012 Warrant. In connection with this issuance, the July 2012 Warrants were cancelled, such that, as of February 14th, 2013, Derby holds 1,100,00 warrants in total, comprised of the April 2012 Warrants, as amended, and the December 2012 Warrants.

All securities issued to Derby were issued under the exemptions from the Securities Act of 1933 contained in Regulation S, as Derby represented that they are an offshore investor.

On February 2, 2012, we entered into a fee services agreement with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. ( **Mintz, Levin** ), whereby upon closing of the Private Placement, we agreed to pay Mintz, Levin \$80,000 and issue to Mintz Levin 1,390,952 common shares, being 2.5% of our fully diluted capitalization, which are subject to escrow for a period of two years. Mintz, Levin has undertaken work with regards to certain of our patents. We also agreed to pay Mintz, Levin an additional \$50,000 upon the consummation of the earlier of:

(i) the purchase of all of our outstanding common shares and/or amalgamation of our company or our wholly-owned Israeli subsidiary into or with another corporation;

(ii) our sublicensing the technology to a non-affiliate of our company; or

(iii) \$20,000 upon each of the following milestones (but in any event no more than \$50,000 in total):

(A) initiation by us of phase I clinical trials for the Product in human subjects,

(B) initiation by us of phase II clinical trials for the Product in human subjects, and

(C) initiation by us of phase III clinical trials for the Product in human subjects,

provided that if any payments are made under subsection (iii) above and thereafter an event described in subsection (i) or subsection (ii) occur, then we shall only pay an amount equal to the difference between \$50,000 and the amounts paid under subsection (iii) above.

## **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 prospectus and registration statement.

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, 2012.

Our operating results for the year ended November 30, 2012 are summarized as follows in comparison to our operating results for the same year ended November 30, 2011:

	<b>Year ended November 30,</b>	
	<b>2012</b>	<b>2011</b>
Research and Development Expenses	\$ 2,308,811	\$ -
General and Administrative Expenses	2,679,748	72,352
Operating Loss	\$ 4,988,559	\$ 72,352
Financial Expense, Net	9,584	-
Net Loss For The Period	\$ 4,998,143	\$ 72,352

### *Revenue*

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

### *General and Administrative Expenses*

	<b>Year ended November 30,</b>	
	<b>2012</b>	<b>2011</b>
Salaries & related expenses	\$ 192,973	\$ -
Stock-based compensation	1,889,326	-
Accounting and Legal	176,446	\$ 67,363
Professional fees	203,288	-
Business development	140,944	-
Transfer agent and filing fees	14,551	4,219
Other	62,220	770
Total	\$ 2,679,748	\$ 72,352

The increase in our expenses compare to the same period last year is because of the changing of our operations due to signing the License Agreement on February 2, 2012.. Most of the increase is due to stock based compensation and salary expenses.

### *Research and Development Expenses*

	<b>Year ended November 30,</b>	
	<b>2012</b>	<b>2011</b>
Patents registrations	\$ 619,288	\$ -
Salaries & related expenses	166,108	-
Stock-based compensation	1,329,651	-
Professional fees and consulting services	102,863	-
Others	90,901	-
Total	\$ 2,308,811	\$ -



The increase in our expenses compare to the same period last year is because of the changing of our operations due to signing the License Agreement on February 2, 2012. Most of the increase is due to stock based compensation and patent registration.

## Liquidity and Financial Condition

### Working Capital

	November 30 2012	November 30 2011	Percentage Increase / (Decrease)
Current Assets	\$ 38,598	\$ 2,340	1549.5%
Current Liabilities	\$ 327,170	\$ 85,013	284.8%
<b>Working Capital (Deficiency)</b>	<b>\$ (288,572)</b>	<b>\$ (82,673)</b>	<b>249%</b>

The increase of 249% in our working capital deficiency compared to the same period last year is because of the changing in our operation due to signing the License Agreement on February 2, 2012. The increase in our working capital deficiency is due to liabilities incurred in the ordinary course of operations in 2012.

### Cash Flows

	Year ended November 30,	
	2012	2011
Total net cash used in operating activities	(1,051,612)	(35,189)
Total net cash used in investing activities	(20,977)	-
Net cash provided by financing activities	1,071,661	35,000
Increase (Decrease) in Cash and Cash Equivalents	(928)	(189)

The increase in our cash used in operating activities compare to the same period last year is because of the changing of our operations due to signing the License Agreement on February 2, 2012. The increase in cash provided by financing activities compare to the same period last year is due to the financing described below.

We have suffered recurring losses from operations. The continuation of our company is dependent in the short term upon raising additional capital as needed but there can be no assurance that we will be able to raise any further financing.

### Financings

In connection with various financings, we have issued warrants to Derby. For additional information, please see the discussion under Item 5 :: *Recent Sales of Unregistered Securities Private Placements* .

## 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, 2012, 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.

## Cash Requirements

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;
- collaborate with clinical center, specifically those performing Pancreatic Islet transplantations, in order to carry out clinical studies;
- locate suitable centers and sign a collaboration agreement;
- identify optional technologies for scale up of the cells production process (this activity will be carried out at subcontracted facilities of Sheba Medical Center); and
- 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 and working capital requirements for the next 12 months to be as follows:

<b>Expense</b>	<b>Amount</b>
Product development	\$ 1,670,516
Employee compensation	\$ 768,316
General and administration	\$ 320,000
Regulation and compliance	\$ 243,000
Business development	\$ 181,500
<b>Total</b>	<b>\$ 3,183,332</b>

If we are not able to obtain the additional financing on a timely basis, if and when it is needed, we may be forced to cease the operation of our business.

### **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.

### **Off Balance Sheet Arrangements**

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

### **Application Of Critical Accounting Estimates**

The preparation of financial statements in conformity with United States generally accepted accounting principles 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 date of the financial statements and the reported amounts of expenses during the year.

The more significant areas requiring the use of estimates include stock-based compensation and future income tax amounts. Management bases its estimates on assumptions considered to be reasonable under the circumstances. However, actual results may differ from the estimates.

### *Accounting Basis*

These financial statements are prepared on the accrual basis of accounting in conformity with accounting principles generally accepted in the United States of America.

The preparation of financial statements in conformity with generally accepted accounting principles of the United States 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 date of the financial statements and the reported amounts of expenses during the year.

The more significant areas requiring the use of estimates include stock-based compensation and future income tax amounts. Management bases its estimates on assumptions considered to be reasonable under the circumstances. However, actual results may differ from the estimates.

*Loss Per Share*

Net loss per common share is computed based on the weighted average number of common shares outstanding and common stock equivalents, if not anti-dilutive. We have not issued any potentially dilutive common shares.

Basic loss per share is calculated using the weighted average number of common shares outstanding and the treasury stock method is used to calculate diluted earnings per share. For the years presented, this calculation proved to be anti-dilutive.

*Income Taxes*

We provide for income taxes using an asset and liability approach.

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. No provision for income taxes is included in the statement due to its immaterial amount, net of the allowance account, based on the likelihood of the Company to utilize the loss carry-forward.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not Applicable.

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

**ORGENESIS INC.  
(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC.)**

**(A development stage company)**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF NOVEMBER 30, 2012**

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**ORGENESIS INC.**  
**(FORMERLY - BUSINESS OUTSOURCING SERVICES, INC.)**

(A development stage company)

CONSOLIDATED BALANCE SHEETS  
U.S. dollars

	November 30, 2012	November 30, 2011
<b>A s s e t s</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 347	\$ 1,275
Short term deposits	10,002	-
Prepaid expenses and Accounts receivable (Note 5)	28,249	1,065
Total current assets	\$ 38,598	\$ 2,340
<b>FUNDS IN RESPECT OF RETIREMENT BENEFIT OBLIGATIONS</b>	\$ 1,296	\$ -
<b>PROPERTY AND EQUIPMENT, NET</b> (Note 6)	\$ 8,273	-
Total assets	\$ 48,167	\$ 2,340
<b>Liabilities net of Stockholders' deficiency</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 135,791	\$ 44,513
Accrued expenses	73,138	5,000
Employees and related payables	75,879	-
Related parties (Note 10)	42,362	35,500
Total current liabilities	\$ 327,170	\$ 85,013
<b>RETIREMENT BENEFIT OBLIGATIONS</b>	\$ 1,553	-
<b>Commitments</b> (Note 2)		
Total liabilities	328,723\$	85,013\$
<b>STOCKHOLDERS' DEFICIENCY:</b>		
Common stock of \$0.0001 par value - authorized: 1,750,000,000 shares at November 30, 2012 and 2011; issued and outstanding: 49,117,903 and 80,500,000 shares at November 30, 2012 and 2011, respectively	4,912	8,050
Additional paid-in capital	4,850,348	46,950
Deficit accumulated during the development stage	(5,135,816)	(137,673)
Total Stockholders' deficiency	(280,556)	(82,673)
Total liabilities net of Stockholders' deficiency	\$ 48,167	\$ 2,340
<b>The accompanying notes are an integral part of these consolidated financial statements.</b>		



**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, 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, 2012
	2012	2011	
<b>RESEARCH AND DEVELOPMENT EXPENSES</b> (Note 7)	\$ 2,308,811	\$ -	\$ 2,308,811
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b> (Note 8)	2,679,748	72,352	2,817,421
<b>OPERATING LOSS</b>	\$ 4,988,559	\$ 72,352	\$ 5,126,232
<b>FINANCIAL EXPENSES, NET</b>	9,584	-	9,584
<b>NET LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD</b>	\$ 4,998,143	\$ 72,352	\$ 5,135,816
<b>BASIC AND DILUTED LOSS PER COMMON STOCK</b>	\$ 0.09	\$ 0	
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER STOCK:</b>	54,265,224	80,500,000	

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

**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC.)**

(A development stage company)

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

	Common Stock		Additional	Deficit	Total
	Shares	\$	paid-in	accumulated	stockholders'
			capital	during the	equity (capital
				development	Deficit)
				stage	
<b>Balance at June 5, 2008</b> (inception)	-	\$ -	\$ -	\$ -	\$ -
<b>Changes during the period</b> <b>from June 5, 2008 through</b> <b>November 30, 2010</b>					
Shares issued to founder on June 5, 2008 \$0.000357 Per Share	56,000,000	\$ 5,600	14,400	-	20,000
Private Placement at 0.00143\$ Per Share	24,500,000	2,450	32,550	-	35,000
Net Loss for the period- Comprehensive loss	-	-	-	(65,321)	(65,321)
<b>Balance as of November</b> <b>30, 2010</b>	80,500,000	8,050	46,950	(65,321)	(10,321)
Net Loss for the year- Comprehensive loss	-	-	-	(72,352)	(72,352)
<b>Balance as of November</b> <b>30, 2011</b>	80,500,000	8,050	46,950	(137,673)	(82,673)
<b>Changes during the year</b> <b>ended November 30, 2012</b>					
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	-	1,071,661
Stock-based compensation expenses related to options granted to employees	-	-	2,976,922	-	2,976,922
Stock-based compensation expenses related to options granted to consultant	-	-	242,055	-	242,055
Shares issued for services	1,390,952	139	509,483	-	509,622
Net loss for the year- Comprehensive loss				(4,998,143)	(4,998,143)
<b>Balance as of November</b> <b>30, 2012</b>	49,117,903	\$ 4,912	\$ 4,850,348	\$ (5,135,816)	\$ (280,556)

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



**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC.)**

(A development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS  
U.S. dollars

	2012	Year ended November 30, 2011	Period from June 5, 2008 (inception date) through November 30, 2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (4,998,143)	\$ (72,352)	\$ (5,135,816)
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	2,976,922	-	2,976,922
Stock-based compensation expenses related to options granted to consultant	242,055	-	242,055
Changes in retirement benefit obligations	1,553		1,553
Shares issued for services rendered	509,622		509,622
Depreciation	1,406	-	1,406
Changes in operating assets and liabilities:			
Increase in prepaid expenses and accounts receivable	(27,184)	(912)	(28,249)
Increase in accounts payable	91,278	37,675	135,791
Increase in employees and related payables	75,879	-	75,879
Increase in accrued expenses	68,138	400	73,138
Related parties	6,862	35,000	42,362
Net cash used in operating activities	(1,051,612)	(189)	(1,090,337)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of fixed assets	(9,679)	-	(9,679)
Amounts funded in respect of retirement benefit obligations	(1,296)		(1,296)
Website development costs	-	-	(15,000)
Investment in short term deposits	(10,002)		(10,002)
Net cash used in investing activities	(20,977)	-	(35,977)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from warrants and shares issued for cash, net of issuance expenses	1,071,661	-	1,126,661
Net cash provided by financing activities	1,071,661	-	1,126,661



<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(928)		(189)		347
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	1,275		1,464		-
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	347	\$	1,275	\$	347

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

**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC.)**  
**(A development stage company)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:**

**a. General:**

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

On August 31, 2011, the Company changed its name from Business Outsourcing Services, Inc. to Orgenesis Inc. , by way of merger with its wholly-owned subsidiary Orgenesis Inc., which was formed solely for the change of name.

On October 11, 2011, the Company incorporated a wholly-owned subsidiary in Israel, Orgenesis Ltd. (the "Subsidiary"), which is engaged in research and development. Unless the context indicates otherwise, the term Group refers to Orgenesis Inc. and its Israeli subsidiary, Orgenesis Ltd. (the Subsidiary ).

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.

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, 2012, of \$5,135,816 as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following November 30, 2012. 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 1,100,000 warrants for a total amount of \$600,000 as mentioned in note 3(2).

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.

**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC)**  
**(A development stage company)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continue):

**b. Accounting principles**

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 stock based compensation and valuation of tax exposures.

**d. Functional currency**

The currency of the primary economic environment in which the operations of the Company and Subsidiary are conducted is the US dollar ( \$ or dollar ).

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 the Subsidiary 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.

**e. Principles of consolidation**

The consolidated financial statements include the accounts of the Company and its wholly-owned Subsidiary. All inter-company transactions and balances have been eliminated in consolidation.

**f. Cash and cash equivalents**

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

**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC)**  
**(A development stage company)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continue):

**g. 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%
Office furniture and equipment	6%

**h. Income taxes**

1. 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.

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 Subsidiary have not been taken into account in computing the deferred income taxes, as it is the Company's intent and ability to hold this investment.

**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC)**  
**(A development stage company)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continue):

**j. Loss per common stock**

Basic and diluted net loss per common stock are 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 was 7,883,198 for the year ended November 30, 2012 (0 for the year ended November 30, 2011).

**k. 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.

**l. 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 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.

**ORGENESIS INC.**  
**(FORMERLY- BUSINESS OUTSOURCING SERVICES, INC)**  
**(A development stage company)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continue):

**m. Fair value measurement**

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The fair value of the financial instruments included in the working capital of the Company is usually identical or close to their carrying value.

The three levels of inputs that may be used to measure fair value are 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.

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

**n. Reclassifications**

Certain figures in respect of prior years have been reclassified to conform to the current year presentation.

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**ORGENESIS INC.**  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**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").

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.

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):
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 2 COMMITMENTS** (continued):

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.
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.
4. 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 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.
5. 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. Vered 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 as of February 2, 2012. In the event we complete a financing of at least \$ 2,000,000, Ms. Vered will be paid a onetime bonus 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.
7. On April 2, 2012 the Company entered into an agreement with Guy Yachin to serve as a director in the Company's board of directors for a consideration of \$2,500 per month and an additional payment for every board meeting on an hourly basis. See also note 4 (4).
8. On April 6, 2012 the Company entered into an agreement with Ettie Hanochi to serve as a director in the Company's board of directors for a consideration of \$300 the first hour of attendance in at Board meetings, and \$200 per each additional hour. See also note 4(7).
9. 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. See also note 4(5).
10. 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 of Granzer range of 125-300 Euro per hour or 2,400 Euro per day.

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- 11.** On October 18, 2012 the company entered into an agreement with Fraunhofer IGB to perform experiment 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 should pay per achieved phases which are defined in the agreement for a total consideration of 260,000 Euro for all services. Under the terms of the agreement its the company's discretions whether to conclude all the phases or only part of them.
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**(A development stage company)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 3 STOCKHOLDERS' DEFICIENCY:**

**1. Share capital:**

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

The share capital is composed of common stock of \$0.0001 par value each: 1,750,000,000 shares authorized at November 30, 2012 and November 30, 2011; 49,117,903 and 80,500,000 shares issued and outstanding at November 30, 2012 and November 30, 2011, respectively.

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 have 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.

**2. Financing:**

In February 2012, the Company entered into a subscription agreement with Derby Management LLC ("Derby") for the sale of 500,000 shares of the Company's common stock at a purchase price of \$1.00 per share, for total consideration of \$500,000. Under the agreement the subscribers committed to purchase additional 1,000,000 shares of the Company's common stock at a purchase price of \$1.00 per share (the February Warrants). Under the terms of the warrants 500,000 shares will be issued for an additional consideration of \$500,000, upon the earlier of: (i) the Company or its Subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of the placement of shares. The remaining 500,000 shares will be issued for an additional consideration of \$500,000 upon the feasibility of enhancement of cell propagation capability if achieved prior to February 2, 2015.

In April 2012, the Company completed a private placement of \$100,000 with Derby for 100,000 shares of common stock and 100,000 common stock warrants at a purchase price of \$1.00 per share (the April Warrants). The fair value of the April Warrants as of the date of grant was \$35,315 using the Black and Scholes option-pricing model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 104%; risk free interest of 1.26%, and an expected life of 2 years.

In July 2012, the Company entered into a subscription agreement with Derby for an additional 500,000 common stock and 500,000 common stock warrants at a purchase price of \$1.00 per share (the July Warrants) for total consideration of \$1.00. In connection with this agreement, the February Warrants were cancelled.

For further information see Note 11(1).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 4 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 instalments 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 instalments 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 Chairperson of the Board at an exercise price of \$0.001 per share, the options vest in two equal annual instalments from February 2, 2012 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 instalments 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.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2012
Expected option life (years)	10.0
Expected stock price volatility (%)	104- 105
Risk free interest rate (%)	1.53-1.86
Expected dividend yield (%)	0.0

A summary of the Company's stock option granted to employees and directors as of November 30, 2012 is presented below:

	<b>2012</b>	<b>Weighted Average exercise price</b>
	<b>Number of options</b>	
		<b>\$</b>
Options outstanding at the beginning of the year	-	-
Changes during the year:		
Granted - at market price	10,315,815	0.297
Expired	-	-
Options outstanding at end of the year	10,315,815	0.297
Options exercisable at end of the year	2,781,905	0.17

\*The company did not granted stock based compensation during the year 2011.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 4 STOCK BASED COMPENSATION** (continued):

Costs incurred in respect of stock based compensation for employees and directors, for the year ended November 30, 2012 was \$ 2,976,922. The weighted average period of the remaining unearned compensation of \$4,012,375 at November 30, 2012 will be recorded over 2.2 years.

The following table presents summary information concerning the options granted to employees and directors outstanding as of November 30, 2012:

Exercise prices \$	Number of outstanding options	Weighted average remaining contractual Life Years	Weighted average Exercise price \$	Aggregate intrinsic value \$
0.0001	2,781,905	9.17	0.0001	1,947,055
0.001	3,338,285	9.17	0.001	2,333,461
0.69	2,781,905	9.17	0.69	27,819
0.79	235,630	9.68	0.79	-
0.79	706,890	9.60	0.79	-
0.85	471,200	9.51	0.85	-
	10,315,815	9.23	0.297	4,308,335

The following table presents summary of information concerning the options exercisable as of November 30, 2012:

Exercise prices \$	Number of Exercisable options	Total Exercise value \$
0.0001	2,086,429	209
0.69	695,476	479,879
	2,781,905	480,088

Options granted to non employees:

- 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 five equal annual instalments 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 4 STOCK BASED COMPENSATION (continued):**

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 February 2, 2012 and expire on February 2, 2022. The fair value of these options as of the date of grant is \$5500,678 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 instalments 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.

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, 2012
Expected option life (years)	10.0
Expected stock price volatility (%)	104- 110
Risk free interest rate (%)	1.51-1.62
Expected dividend yield (%)	0.0

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 4 STOCK BASED COMPENSATION** (continued):

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

	2012	Weighted Average exercise price \$
	Number of options	
Options outstanding at the beginning of the year	-	-
Changes during the year:		
Granted - at market price	1,278,104	0.95
Expired	-	-
Options outstanding at end of the year	1,278,104	0.95
Options exercisable at end of the year	176,726	0.69

\*The company did not granted stock based compensation during 2011.

Costs incurred in respect of stock based compensation for consultants, for the twelve months ended November 30 2012 was \$242,055. The weighted average period of the remaining unearned compensation of \$583,680 at November 30, 2012 will be recorded over 2.98 years.

The following table presents summary information concerning the options granted to non employees outstanding as of November 30, 2012:

Exercise prices \$	Number of outstanding options	Weighted average remaining contractual Life Years	Weighted average Exercise price	Aggregate intrinsic value \$
1.4	471,200	9.37	1.4	-
0.69	706,904	9.17	0.69	7,069
0.61	100,000	9.98	0.61	9,000
	1,278,104	9.31	0.95	16,069

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 4 STOCK BASED COMPENSATION** (continued):

The following table presents summary of information concerning the options exercisable as of November 30, 2012:

Exercise prices \$	Number of exercisable options	Total Exercise price \$
0.69	176,726	121,941
	176,726	121,941

**NOTE 5 PREPAID EXPENSES AND ACCOUNTS RECEIVABLE**

	Year ended November 30,	
	2012	2011
VAT	\$ 15,441	\$ -
Prepaid expenses	12,808	1,065
	\$ 28,249	\$ 1,065

**NOTE 6 PROPERTY AND EQUIPMENT, NET**

	Year ended November 30,	
	2012	2011
Cost:		
Office Furniture	\$ 2,841	\$ -
Computers	6,838	-
	9,679	-
Less accumulated depreciation	1,406	-
	\$ 8,273	\$ -

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 7 RESEARCH AND DEVELOPMENT EXPENSES**

	Year ended November 30,	
	2012	2011
Patents registrations	\$ 619,288	\$ -
Salaries & related expenses	166,108	-
Stock-based compensation	1,329,651	-
Professional fees and consulting services	102,863	-
Other	90,901	-
Total	\$ 2,308,811	\$ -

**NOTE 8 GENERAL AND ADMINISTRATIVE EXPENSES**

	Year ended November 30,	
	2012	2011
Salaries & related expenses	\$ 192,973	\$ -
Stock-based compensation	1,889,326	-
Accounting and Legal	176,446	\$ 67,363
Professional fees	203,288	-
Business development	140,944	-
Transfer agent and filing fees	14,551	4,219
Other	62,220	770
Total	\$ 2,679,748	\$ 72,352

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 9 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 the 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 2012 is 25%.

**c. Tax losses carried forward to future years**

**1. The Company**

As of November 30, 2012, the Company had net operating loss (NOL) carry-forwards equal to \$600,641 that are 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, 2012, the Subsidiary had approximately \$560,355 of NOL carry-forwards that are available to reduce future taxable income with no limited period of use.

**d. Deferred income taxes:**

	<b>November 30</b>	
	<b>2012</b>	<b>2011</b>
In respect of:		
Net operating loss carry forward	\$ 344,307	\$ 46,810
R&D expenses	57,344	\$ 0
Holiday and recreation pay	3,968	\$ 0
Severance pay accruals	402	\$ 0
Less - Valuation allowance	\$ 406,021	\$ 46,810
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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 9 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, 2012 the Company has not received final tax assessment

**2. The Subsidiary**

As of November 30, 2012 the Subsidiary has not received final tax assessment.

**g.** As of November 30, 2012 the Company has not accrued a provision for uncertain tax positions.

**NOTE 10 RELATED PARTIES**

	Year ended November	
	2012	30, 2011
a. Management and consulting fees to the Chairman of the Board. See also Note 10d.	\$ 22,679	\$ -
b. Compensation to the non- executive directors (except the Chairman of the Board)	\$ 27,344	\$ -

c. With respect to options granted to the Company's Chief Executive Officer, see Note 4(3).

d. With respect to options granted to the Company's board members. See Note 4.

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 the gross proceeds to the company of at least \$3,000,000.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 11 - SUBSEQUENT EVENTS**

1. In December 2012, the Company entered into a subscription agreement with Derby for the issuance of 500,000 units for a total consideration of \$500,000. Each unit is comprised of one share of the Company's common stock and two non-transferable common stock warrants. Each common stock warrant ("December Warrants") can be exercised at a purchase price of \$ 0.50 per warrant and is exercisable until December 2, 2014.

In connection with this agreement, the July Warrants were cancelled.

As of December 3, 2012, following this transaction, Derby 1,100,000 warranty exercisable into the company's common stock shares, comprised of the December Warrants and the April Warrants.

2. On January 7, 2013 the Company appointed a new CEO 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 our board of directors upon the performance of certain milestones.
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## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

### **(a) Resignation of Independent Accountant.**

On March 21, 2012, Silberstein Ungar, PLLC was released as our independent accountant. On March 21, 2012, we engaged Kesselman and Kesselman, a member firm of PricewaterhouseCoopers International Limited ("PricewaterhouseCoopers Israel") as our principal independent accountant. In March, 2012, the board of our company approved the dismissal of Silberstein Ungar, PLLC and the engagement of PricewaterhouseCoopers Israel as its independent auditor.

The report of Silberstein Ungar, PLLC regarding our financial statements for the fiscal years ended November 30, 2011 and 2010 did not contain any adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles, except that such report on our financial statements for the years ended November 30, 2011 and 2010 contained an explanatory paragraph in respect to uncertainty as to our ability to continue as a going concern. During the years ended November 30, 2011 and 2010 and during the period from the end of the most recently completed fiscal year through March 21, 2012, the date of dismissal, there were no disagreements with Silberstein Ungar, PLLC on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Silberstein Ungar, PLLC would have caused it to make reference to such disagreements in its reports.

### **(b) Engagement of Independent Accountant.**

Concurrent with the dismissal of Silberstein Ungar, PLLC, we engaged PricewaterhouseCoopers Israel, as our independent accountant. Prior to engaging PricewaterhouseCoopers Israel, we did not consult with PricewaterhouseCoopers Israel regarding the application of accounting principles to a specific completed or contemplated transaction or regarding the type of audit opinion that might be rendered by PricewaterhouseCoopers Israel on our financial statements, and PricewaterhouseCoopers Israel did not provide any written or oral advice that was an important factor considered by our company in reaching a decision as to any such accounting, auditing or financial reporting issue. The engagement of PricewaterhouseCoopers Israel was approved by our board of directors.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures.**

Our management, under the supervision and with the participation of our Principal Executive Officer and our Principal Financial Officer and Principal Accounting Officer, have evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15 or 15d-15(f), promulgated under the *Securities Exchange Act of 1934, as amended*, as of the end of the period covered by this Annual Report. Based on such evaluation, our Principal Executive Officer and our Principal Financial Officer and Principal Accounting Officer have concluded that as of the end of the period covered by this annual report, our disclosure controls and procedures were not effective to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC, and that material information relating to our company is made known to management, including the Principal Executive Officer, our Principal Financial Officer and Principal Accounting Officer, during the period when our periodic reports are being prepared to allow timely decisions regarding required disclosure.

### **Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities



Exchange Act of 1934 as a process designed by, or under the supervision of, the Principal Executive Officer, our Principal Financial Officer and Principal Accounting Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of our company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of our company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

As of November 30, 2012 management assessed the effectiveness of our internal control over financial reporting based on the criteria for effective internal control over financial reporting established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( **COSO** ) and SEC guidance on conducting such assessments. Based on that evaluation, they concluded that, during the period covered by this report, such internal controls and procedures were not effective to detect the inappropriate application of US GAAP rules as more fully described below. This was due to deficiencies that existed in the design or operation of our internal controls over financial reporting that adversely affected our internal controls and that may be considered to be material weaknesses.

The matters involving internal controls and procedures that our management considered to be material weaknesses under the standards of the Public Company Accounting Oversight Board were: (1) lack of a functioning audit committee; (2) inadequate segregation of duties consistent with control objectives; and (3) ineffective controls over period end financial disclosure and reporting processes.

Management believes that the material weaknesses set forth in items (1) and (2) above did not have an effect on our financial results. Management has remedied the material weakness set forth in item (1) after November 30, 2012, as discussed below.

#### *Management's Remediation Initiatives*

In an effort to remediate the identified material weaknesses and other deficiencies and enhance our internal controls, we have initiated the following series of measures:

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:

- the appointment, remuneration and termination of our auditors;



- reviewing and discussing with management our audited financial statements and reviewing with management and our auditors our financial statements;
- reviewing the performance of and fees paid to the auditors; and
- 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.

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.

#### *Changes in internal control over financial reporting*

There were no changes in our internal control over financial reporting during the fiscal year ended November 30, 2012 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 at February 14th, 2013, our directors and executive officers, their age, positions held, and duration of such, are as follows:

<b>Name</b>	<b>Position Held with our Company</b>	<b>Age</b>	<b>Date First Elected or Appointed</b>
Vered Caplan	Chair of the board	44	February 2, 2012
Jacob BenArie <sup>(1)</sup>	Chief Executive Officer of Subsidiary	44	December 17, 2012
Dov Weinberg	Chief Financial Officer, Treasurer and Secretary	60	February 2, 2012
Sarah Ferber	Chief Scientific Officer	58	February 2, 2012
Guy Yachin	Director	45	April 2, 2012
Etti Hanochi	Director	39	April 6, 2012
	Director	42	April 17, 2012

Yaron Adler			
Sav DiPasquale	President and Chief Executive Officer	51	December 17, 2012

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.

**Certain Significant Employees**

We do not have other significant employees.

### *Business Experience*

The following is a brief account of the education and business experience of our director 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, Director

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. Serves currently as CFO of QRS systems Inc. Innovate Inc. and NaNaMED LLC and *was* 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 Account 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 Scientist 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 USA 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 USA, 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 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.

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 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 his 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.

Sav DiPasquale, President and Chief Executive Officer

Mr. DiPasquale worked with GlaxoSmithKline Inc. (NYSE:GSK), a research-based pharmaceutical company in Canada, for over 16 years serving in various technology and marketing capacities including his most recent role as Vice President, Business Development and Corporate Planning. Mr. DiPasquale holds a B.Sc. in computer science from the University of Toronto and has completed the Executive Program at the Schulich School of Business.

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.



*Term of Office*

Each director of our company is to serve for a term ending on the date of subsequent annual meeting of stockholders following the annual meeting at which such director was elected. Notwithstanding the foregoing, each director is to serve until his successor is elected and qualified or until his death, resignation or removal. Our board of directors is to elect our officers and each officer is to serve until his successor is elected and qualified or until his or her death, resignation or removal.

*Family Relationships*

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

**Involvement in Certain Legal Proceedings**

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

- (a) 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;
- (b) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- (c) 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;
- (d) 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;
- (e) 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
- (f) 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, 2012, the filing requirements applicable to its officers, directors and greater than 10% beneficial owners were complied with other than the following:

Name	Number of Late Reports	Number of Transactions that were not Reported on a Timely Basis	Failure to File
Vered Caplan	2 <sup>1</sup>	2 <sup>1</sup>	1 <sup>1</sup>
Jacob BenArie	2 <sup>2</sup>	2 <sup>2</sup>	1 <sup>2</sup>
Dov Weinberg	2 <sup>3</sup>	2 <sup>3</sup>	2 <sup>3</sup>
Sarah Ferber	1 <sup>4</sup>	1 <sup>4</sup>	N/A
Guy Yachin	2 <sup>5</sup>	2 <sup>5</sup>	1 <sup>5</sup>
Etti Hanochi	2 <sup>6</sup>	2 <sup>6</sup>	2 <sup>6</sup>
Yaron Adler	1 <sup>7</sup>	1 <sup>7</sup>	1 <sup>7</sup>
Sav DiPasquale	1 <sup>8</sup>	1 <sup>8</sup>	N/A
Gilbert Cuison	1 <sup>9</sup>	1 <sup>9</sup>	1 <sup>9</sup>
Jerome Golez	1 <sup>10</sup>	1 <sup>10</sup>	1 <sup>10</sup>
Oded Shvartz	1 <sup>11</sup>	1 <sup>11</sup>	1 <sup>11</sup>

- <sup>1</sup> Ms. Caplan filed her initial Form 3 past the 10-day event date and did not file a Form 4 with respect to the July 10, 2012 grant of stock options.
- <sup>2</sup> Mr. BenArie filed his initial Form 3 past the 10-day event date and did not file a Form 4 with respect to the February 2, 2012 grant of stock options.
- <sup>3</sup> Mr. Weinberg has not filed an initial Form 3 and did not file a Form 4 with respect to the June 4, 2012 grant of stock options.
- <sup>4</sup> Ms. Ferber filed her initial Form 3 past the 10-day event date.
- <sup>5</sup> Mr. Yachin filed his initial Form 3 past the 10 day event date and did not file a Form 4 with respect to the June 4, 2012 grant of stock options.
- <sup>6</sup> Ms. Hanochi has not filed an initial Form 3 and did not file a Form 4 with respect to the August 7, 2012 grant of stock options
- <sup>7</sup> Mr. Adler did not file a Form 4 with respect to the July 8, 2012 grant of options.
- <sup>8</sup> Mr. DiPasquale filed his initial Form 3 past the 10-day event date.

- <sup>9</sup> Mr. Cuison did not file a Form 4 with respect to the February 2, 2012 cancellation of shares of common stock.
- <sup>10</sup> Mr. Golez did not file a Form 4 with respect to the February 2, 2012 cancellation of shares of common stock.
- <sup>11</sup> Mr. Shvartz did not file an initial Form 3 with respect to his 22.4% ownership of common stock  
As of the date of filing this Form 10-K, we have filed all outstanding insider reports, except for the insider report of Ms. Etti Hanochi.

## **Code of Ethics**

We currently do not have a Code of Ethics.

## **Corporate Governance**

Our board of directors has concluded that three of members of our board of directors are independent as the term independent is defined by the rules of the New York Stock Exchange and Rule 10A-3 of the U.S. Securities Exchange Act of 1934, as amended. Vered Caplan is not considered to be independent as she is employed by our company.

## **Committees of the Board**

### *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 Advisor members may be compensated for their time in options to purchase our 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 Advisor 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 and Prof. Ricordi. Camilo

### Dr. Fleming

On April 14, 2012, we executed a consulting agreement with G. Alexander Fleming. Dr. Fleming has agreed to be appointed to our Board of Advisor s 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 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

#### *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 nominee. Our company does not have any defined policy or procedural requirements for shareholders 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 shareholder 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:

- the appointment, remuneration and termination of our auditors;
- reviewing and discussing with management our audited financial statements and reviewing with management and our auditors our financial statements;
- reviewing the performance of and fees paid to the auditors; and



- 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. Both members of the Compensation Committee are independent directors. The role of the Compensation Committee is to:

- review and recommend to our board of directors the appropriate compensation level for our executive officers;
- oversee our compensation and benefit plans, policies and practices, including its executive compensation plans and incentive-compensation and equity-based plans;
- monitor and evaluate, at their sole discretion, matters relating to the compensation and benefits structure of our company; and
- 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.

## **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, 2012 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 (\$)
Guilbert Cuison <i>Former President, Secretary and Director</i> <sup>1</sup>	2012	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Jerome Golez <i>Former Treasurer &amp; Director</i> <sup>2</sup>	2012	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Jacob BenArie <i>Former CEO &amp; President</i> <sup>3</sup>	2012	141,200	N/A	N/A	381,545	Nil	23,375	N/A	546,120
Dov Weinberg <i>CFO, Treasurer &amp; Secretary</i> <sup>4</sup>	2012	47,000	N/A	Nil	201,203	Nil	Nil	Nil	248,203
Sarah Ferber <i>Chief Scientific Officer</i> <sup>5</sup>	2012	123,654	N/A	Nil	1,288,798	Nil	26,120	Nil	1,438,572
Sav DiPasquale <i>President &amp; CEO</i> <sup>6</sup>	2012	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Mr. Cuison resigned as a director and officer on February 2, 2012.

<sup>2</sup> Mr. Golez resigned as a director and officer on February 2, 2012.

<sup>3</sup> 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.

<sup>4</sup> Mr. Weinberg was appointed Treasurer, CFO and Secretary on February 2, 2012

<sup>5</sup> Prof. Ferber was appointed Chief Scientific Officer on February 2, 2012.

<sup>6</sup> Mr. DiPasquale was appointed President and CEO on December 17, 2012.

We did not pay any compensation of any form to any officer or director of our company during the fiscal year ended November 30, 2011.

### *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. 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.

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.

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. Mr. DiPasquale is also eligible to receive stock options and an annual bonus at the discretion of our board of directors upon the performance of certain equity fundraising. Mr. DiPasquale may also earn performance shares over time and upon certain milestones. The options will be subject to our stock option plan and will have vesting provisions. The employment term sheet is for an indefinite period unless terminated by either party with 30 days advance written notice to the other party.

### *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, 2012.

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 options (#)	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested (#)	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: market payout value of unearned shares, units or other rights that have not vested (\$)

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						(#)			
Guilbert Cuison	Nil	Nil	Nil	N/A	N/A	N/A	N/A	N/A	N/A
Jerome Golez	Nil	Nil	Nil	N/A	N/A	N/A	N/A	N/A	N/A
Jacob BenArie	695,476	2,086,429	2,781,905	\$0.69	Feb 2-22	N/A	N/A	N/A	N/A
Dov Weinberg	176,726	530,178	706,904	\$0.69	Apr 4-22	N/A	N/A	N/A	N/A
Sarah Ferber	2,086,429	695,476	2,781,905	\$0.0001	Feb 2-22	N/A	N/A	N/A	N/A
Sav DiPasquale	Nil	Nil	Nil	N/A	N/A	N/A	N/A	N/A	N/A

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*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, 2012.

	<b>Fees earned or paid in cash (\$)</b>	<b>Stock awards (\$)</b>	<b>Option awards (\$)</b>	<b>Non-equity incentive plan compensation (\$)</b>	<b>Change in pension value and nonqualified deferred compensation earnings (\$)</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Vered Caplan	22,679	<	1,214,787	<	2,611	<	1,240,077
Guy Yachin	26,150	<	37,321	<	<	<	63,471
Etti Hanochi	nil	<	11,710	<	<	<	11,710
Yaron Adler	1,194	<	42,755	<	<	<	43,949

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. Vered 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. Vered will be paid a onetime bonus of \$100,000. We also agreed to grant to Ms. Vered stock options to purchase 3,338,285 shares of our common stock at a price per share equal to \$0.001.

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 the first hour of attendance in 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 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. 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.

*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, 2012.<>

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 (#)	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested (\$)
Vered Caplan	1,669,142	1,669,143	3,338,285	\$0.001	Feb 2-22	N/A	N/A	N/A	N/A
Guy Yachin	Nil	471,200	471,200	\$0.85	June 4-22	N/A	N/A	N/A	N/A
Etti Hanochi	Nil	235,630	235,630	\$0.79	July 8-22	N/A	N/A	N/A	N/A
Yaron Adler	Nil	706,890	706,890	\$0.79	July 8-22	N/A	N/A	N/A	N/A

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

**Securities Authorized for Issuance under Equity Compensation Plans**

*Equity Compensation Plan Information*

The following table provides a summary of the number of stock options granted under our stock option plan, the weighted average exercise price and the number of stock options remaining available for issuance under our stock

option plans as at November 30, 2012:

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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))
Equity compensation plans approved by security holders	Nil	N/A	N/A
Equity compensation plans not approved by security holders	8,812,014	\$0.485	3,187,986

On May 23, 2012 our board of directors adopted the global share incentive plan (2012). Under the Global Share Incentive Plan (2012) 12,000,000 shares have been reserved for the grant of options, which may be issued at the discretion of our board of directors from time to time. Under this plan, each option is exercisable into one share of common stock of our company.

The options may be exercised after vesting and in accordance with the vesting schedule which will be determined by our company's board of directors for each grant. The maximum contractual life term of the options is 10 years.

### Beneficial Ownership

The following tables set forth, as of January 31, 2013, 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 <sup>(1)</sup>	Percent of class
Common Stock	Oded Shvartz 130 Biruintei Blvd Pantelmon Ilfov, Romania	11,126,920	Direct <sup>(2)</sup> 22.4%
	Gilbert A Cuison	5,500,016	Direct <sup>(2)</sup> 11.2%

Common  
Stock

Block 616 Bedok Reservoir  
Rd  
#03-1108  
Singapore 470616

Common Stock	Jerome P Golez	5,500,015	Direct <sup>(2)</sup>	11.2%
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Block 117  
Bihan St #20-29  
Singapore 570117

<b>Title of class</b>	<b>Name and address of beneficial owner</b>	<b>Amount and nature of beneficial ownership<sup>(1)</sup></b>	<b>Percent of class</b>	
	<b>Total Beneficial Holders as a Group</b>	<b>22,126,951</b>	<b>44.80%</b>	
<i>Security Ownership of Management</i>				
<b>Title of class</b>	<b>Name and address of beneficial owner</b>	<b>Amount and nature of beneficial ownership<sup>(1)</sup></b>	<b>Percent of class</b>	
Common Stock	Vered Caplan 6 Sharabi street, Neve tzedek, Tel-Aviv 65147, Israel	1,669,142	Direct <sup>(3)</sup>	3.3%
Common Stock	Jacob BenArie 70 Denya st. Haifa, Israel 34980	927,302	Direct <sup>(4)</sup>	1.85%
Common Stock	Dov Weinberg 21 Sparrow Circle White Plains, New York 10605	353,452	Direct <sup>(5)</sup>	0.07%
Common Stock	Prof. Sarah Ferber Shderot Hahaskala 17b Tel-Aviv Israel 67890	2,781,905	Direct	5.6%%
Common Stock	Guy Yachin 7 Orchard Way N Potomac MD 20854	nil	n/a	n/a
Common Stock	Etti Hanochi ◇ ◇	nil	n/a	n/a
Common Stock	Yaron Adler 19 Chelouche Street Tel-Aviv Israel 65154	nil	n/a	n/a
Common Stock	Sav DiPasquale 506 Vaughan Mills Road Vaughan, ON L4H 1G9	nil	n/a	n/a
<b>Common Stock</b>	<b>Directors &amp; Executive Officers as a group (8 persons)</b>	<b>5,731,801</b>	<b>Direct</b>	<b>10.82%</b>

(1) Percentage of ownership is based on 49,617,903 shares of our common stock issued and outstanding as of January 31, 2013. 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 22.4% 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, 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 1,669,143 stock options exercisable within 60 days of November 30, 2012.
- (4) Consists of 927,302 stock options exercisable within 60 days of November 30, 2012.

(5) Consists of 176,726 stock options exercisable within 60 days of November 30, 2012.

### **Changes in Control**

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.

For the fiscal year ended November 30, 2012, we paid management and consulting fees of \$22,679 to Ms. Vered Caplan compared to nil for the fiscal year ended November 30, 2011.

For the fiscal year ended November 30, 2012, we paid compensation of \$26,150 to Mr Guy Yachin, compared to nil for the fiscal year ended November 30, 2011.

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

### **Corporate Governance**

#### *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, 2012 and November 30, 2011:

<b>Services</b>	<b>2012</b>	<b>2011</b>
Audit fees	\$ 70,000	nil
Audit related fees	nil	nil
Tax fees	10,000	nil
All other fees	nil	nil
<b>Total fees</b>	<b>\$ 80,000</b>	<b>\$ 0</b>

The following table sets forth the fees billed to the Company for professional services rendered by Silberstein Ungar, PLLC, for the year ended November 30, 2012 and November 30, 2011:

<b>Services</b>	<b>2012</b>	<b>2011</b>
Audit fees	\$ 5,000	\$ 7,625
Audit related fees	nil	nil
Tax fees	3,200	nil
All other fees	1,750	nil
<b>Total fees</b>	<b>\$ 9,950</b>	<b>\$ 7,625</b>

#### *Audit Fees*

This category includes the fees for the audit of our consolidated financial statements and the quarterly reviews of interim financial statements. This category also includes advice on audit and accounting matters that arose during or as a result of the audit or the review of interim financial statements and services in connection with SEC filings.

#### *Tax Fees*

Consisted of fees billed for professional services rendered by the principal accountant for tax compliance, preparation of tax returns, analysis of FIN 48..

#### *All Other Fees*

Consisted of fees relating to consulting with respect to the transfer of the file from Silberstein Ungar, PLLC to PricewaterhouseCoopers Israel.

## **PART IV**

### **ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Exhibits required by Regulation S-K

<b>No.</b>	<b>Description</b>
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	

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	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)



No.	Description
10.2	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)
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)
16.1	Letter from Silberstein Ungar, PLLC regarding change in certifying accountant (incorporated by reference to our current report on Form 8-K filed on March 21, 2012)

21.1 Orgenesis Ltd. our wholly-owned Israeli corporation

31.1\* Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

No.	Description
31.2*	<u>Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2*	<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)
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/ Sav DiPasquale*  
Sav DiPasquale  
President and Chief Executive Officer  
(Principal Executive Officer)  
Date: February 15, 2013

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/ Sav DiPasquale*  
Sav DiPasquale  
President and Chief Executive Officer  
(Principal Executive Officer)  
Date: February 15, 2013

*/s/ Dov Weinberg*  
Dov Weinberg  
Chief Financial Officer, Treasurer and Secretary  
(Principal Financial Officer and Principal  
Accounting Officer)  
Date: February 15, 2013

*/s/ Vered Caplan*  
Vered Caplan  
Director  
Date: February 15, 2013

*/s/ Guy Yachin*  
Guy Yachin  
Director  
Date: February 15, 2013

*/s/ Etti Hanochi*  
Etti Hanochi  
Director  
Date: February 15, 2013

*/s/ Yaron Adler*  
Yaron Adler  
Director  
Date: February 15, 2013