

Edgar Filing: Orgenesis Inc. - Form 8-K

Orgenesis Inc.
Form 8-K
February 08, 2012

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) February 2, 2012

ORGENESIS INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation)

000-54329

(Commission File Number)

98-0583166

(IRS Employer Identification No.)

70 Denya St. Haifa Israel, 34980

(Address of principal executive offices and Zip Code)

+972.4.8242051

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

FORWARD-LOOKING STATEMENTS

This current report on Form 8-K 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" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements made in this Form 8-K 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

Edgar Filing: Orgenesis Inc. - Form 8-K

- 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 ability to identify attractive products and negotiate their acquisition or licensing;
- * our ability to effectively develop and market products that we acquire or license;
- * volatility in prices for our products;
- * risks inherent in the pharmaceutical industry;
- * competition for, among other things, capital, pharmaceutical products and skilled personnel; 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 8-K and unless otherwise indicated, the terms "we", "us" and "our" refer to Orgenesis Corp. and our wholly owned subsidiary, Orgenesis Ltd., an Israeli corporation (the "SUBSIDIARY"). Unless otherwise specified, all dollar amounts are expressed in United States dollars.

ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

Please see Item 2.01 of this current report on Form 8-K.

2

ITEM 2.01 COMPLETION OF LICENSING 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

Edgar Filing: Orgenesis Inc. - Form 8-K

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;
 - * \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time (the "SALES MILESTONE").

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

- * a one time payment, based, as applicable, on the value of either 5,563,809 shares of our common stock at the time of the Exit (these 5,563,809 shares of common stock being equivalent to 10% of our outstanding share capital on a fully diluted basis immediately following the closing of the Private Placement, as defined below); or
- * or the value of 1,000 common shares of our Subsidiary at the time of Exit (these 1,000 common shares constitute, at the date of the License Agreement, 10% of our Subsidiary's outstanding share capital on a fully diluted basis.

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

Edgar Filing: Orgenesis Inc. - Form 8-K

3

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 (as defined below) 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. THM is also entitled to terminate the License Agreement in the event that:

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

Edgar Filing: Orgenesis Inc. - Form 8-K

any country for reasons not dependant upon us;

4

- * 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 dependant 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.

In connection with the closing of the License Agreement, on February 2, 2012, we completed a private placement of units (each, a "UNIT"). Each Unit is comprised of one common share in our capital and two non-transferrable share purchase warrants (each, a "WARRANT"). Each Warrant is exercisable into one additional common share and shall expire after three years. The holders of such Unit must exercise half of their Warrants, at a price of \$1.00 per warrant share, for additional equity of \$500,000, upon the earlier of: (i) our company or our Subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of such placement of Units, and the other half, at a price of \$1.00 per warrant share, for additional equity of \$500,000, upon the feasibility of enhancement of cell propogation capability for three years from closing at a price of \$1.00 per warrant share. Each Unit was priced at \$1.00 for total gross proceeds of \$500,000. The Units were issued to offshore investors under the exemptions from the Securities Act of 1933 contained in Regulation S.

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 and this fee services agreement settles its fees for those services. 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.

Also, our former directors, Guilbert Cuison and Jerome Golez, have cancelled 33,873,049 of our common shares held by them. Also, Messrs. Cuison and Golez have granted to Oded Shvartz a conditional option to acquire 10,840,970 (each as to 5,420,485 shares) common shares of our company at a price of \$0.0003571 per share. The option is exercisable if we issue shares or grants options or warrants to purchase shares, or 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 1 option share for every 4 New Securities issued. The option is exercisable for a period of up to four

Edgar Filing: Orgenesis Inc. - Form 8-K

years after February 2, 2012. Should the option be exercised in full, Oded Shvartz would own up to 21,967,951 common shares in the capital of our company, which may result in a change of control.

BUSINESS

Corporate Overview

We were incorporated in the state of Nevada on June 5, 2008, under the name Business Outsourcing Services, Inc.

5

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 have 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 \$0.001 to 1,750,000,000 shares of common stock with a par value of \$0.001. Unless otherwise noted, all references in this report on Form 8-K to number of shares, price per share or weighted average number of shares outstanding have been adjusted to reflect these stock split on a retroactive basis.

OUR CURRENT BUSINESS

We were previously engaged in the business of providing online accounting and bookkeeping services to small and medium sized companies who seek to save money by outsourcing these services.

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 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 Orgeneis 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.

Edgar Filing: Orgenesis Inc. - Form 8-K

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.

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.

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.

6

In the short term, we aim to take advantage of our clinical study centers in order to initiate sales in the Asian market. Once we obtain CE Mark for the AIP cell therapy, we anticipate initiating sales in the European market as well. 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 Pharmaccutical, Eli Lilly, GlaxoSmithKline, 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
- * 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

Edgar Filing: Orgenesis Inc. - Form 8-K

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, 21 million people (6.2% of the population) have diabetes.

The Global DM drug treatment market was valued at \$15 billion in 2005 and increased to \$21 billion in 2006. Due to the high prevalence of diabetes and lifestyle changes, we believe that the market will keep expanding. Oral anti-diabetics were the leading category of drugs - \$8.19 billion - and showed a growth rate of 6.3% from the total global sales in 2004. The total sales for

7

insulin products are \$6.83 billion in 2004. The annual direct cost of DM in the US is \$43 billion.

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 in 2005 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. The diabetes market landscape is quite dynamic and has changed significantly with a host of new participants.

Takeda Pharmaceutical Company Limited's Actos featured as one of the top selling diabetes drugs with global sales of \$4.20 billion in 2008. Although faced with tough competition from other novel oral antidiabetic drugs such as DPP-4 inhibitors and GLP-1 analogues, Takeda Pharmaceutical Company Limited is likely to maintain its market position because of its strong pipeline comprising of a

Edgar Filing: Orgenesis Inc. - Form 8-K

novel DPP-4 inhibitor Algolipitin.

MERCK & CO., INC's Januvia has been gaining market share and it had global sales of \$1.40 billion in 2008. However, strong competition is expected from a 'me-too' drug Onglyza, from AstraZeneca and Bristol-Myers Squibb Company.

Novo Nordisk A/S's insulin analogue Lantus witnessed good sales with global revenues of \$3.30 billion. Novo Nordisk A/S is banking on its once-a-day injection Victoza (Liraglutide), which is under FDA review. Though there were concerns on its safety profile (as it has caused thyroid tumors in a few people and rats), it is likely to get an approval soon. Once approved, this drug is expected to largely increase the market share of Novo Nordisk A/S. If the FDA fails to approve this drug, the impact is likely to pass on to companies such as Glaxo-SmithKline Pharmaceuticals Limited and F. Hoffman-La Roche Ltd that are currently pursuing research on similar drug compounds.

Eli Lilly and Company lost its market shares to Sanofi-aventis and Takeda Pharmaceutical Limited. However, Eli Lilly and Company, Amylin Pharmaceutical, Inc and Alkermes, Inc. have a novel version of Byetta once-a-week injection in the late stage pipeline. The results for this drug are quite positive as the efficacy is much more than the current Byetta. If this drug is approved, it is likely to pose serious threat to Novo Nordisk A/S's liraglutide--Victoza.

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.

8

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

Edgar Filing: Orgenesis Inc. - Form 8-K

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

9

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.

Edgar Filing: Orgenesis Inc. - Form 8-K

* 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.

We intend to dedicate most of our capital to research and development with no expectation of revenue from product sales in the foreseeable future.

RESEARCH AND DEVELOPMENT EXPENDITURES

We did not incur expenditures in research and development activities over the last two fiscal years.

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 and one part time employee located in Israel.

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:

Docket Number -----	Title -----	Country -----	Status -----	Appln No. ---	Publication No. ---	Patent N -----
21415-501/	Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	United States of America	Granted	09/584216		6,774,12
21415-501 CIP	Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	United States of America	Published	10/843801	2005-0090465	
21415-501 DIV/	Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	United Slates of America	Allowed	10/852994		
21415-501 PRO/023	Methods Of Inducing Regulated Pancreatic Hormone Production	United Kingdom	Granted	00935435.8	1180143	1180143

Edgar Filing: Orgenesis Inc. - Form 8-K

10

Docket Number -----	Title -----	Country -----	Status -----	Appln No. ---	Publication No. ---	Patent N -----
21415-501 PRO/061	Methods Of Inducing Regulated Pancreatic Hormone Production	Patent Cooperation Treaty	National	IB00/00824	WO00/72885	
21415- 501/D01	Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	Japan	Published	2010-261850	2011-68660	
21415- 501/D02	Methods or Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	Japan	Published	2010-288937	2011-57716	
21415-501 PRO/032	Methods Of Inducing Regulated Pancreatic Hormone Production	Japan	Published	2000-620991	500457	
21415-501 PRO/031	Methods Of Inducing Regulated Pancreatic Hormone Production	Italy	Granted	00935435.8	1180143	118014
21415-501 PRO/016	Methods Of Inducing Regulated Pancreatic Hormone Production	Germany	Granted	00935435.8	1180143	60034781.8
21415-501 PRO/022	Methods Of Inducing Regulated Pancreatic Hormone Production	France	Granted	00935435.8	1180143	118014
21415-501 PRO B/019	Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissue	European Patent Convention	Published	04732369.6	1624898	
21415-501 PRO/008	Methods Of Inducing Regulated Pancreatic Hormone Production	Canada	Pending	2371995		
21415-501 PRO/004	Methods Of Inducing Regulated Pancreatic Hormone Production	Australia	Granted	50974/00	779619	
21415-501 PRO B/004	Methods Of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues	Australia	Granted	2004236573	2004236573	

GOVERNMENT REGULATIONS

Edgar Filing: Orgenesis Inc. - Form 8-K

We have not sought approval from the United States Food and Drug Administration for the AIP cells.

11

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;

Edgar Filing: Orgenesis Inc. - Form 8-K

- * 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.

12

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

Edgar Filing: Orgenesis Inc. - Form 8-K

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.

13

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 AUDITORS 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 as we ramp-up our business. We estimate our average monthly expenses over the next 12 months to be approximately \$100,000, including general and administrative expenses but excluding acquisition costs and the cost of any development activities. On February 2, 2012, we had cash and cash equivalents & commitments of approximately \$1,500,000. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As we cannot assure a lender that we will be able to successfully acquire and develop 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. As of February 2, 2012, we had total debt of approximately \$200,000.

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.

Edgar Filing: Orgenesis Inc. - Form 8-K

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.

14

BECAUSE OUR DIRECTORS AND OFFICERS ARE NOT ALL RESIDENTS OF THE UNITED STATES, INVESTORS MAY FIND IT DIFFICULT TO ENFORCE, WITHIN THE UNITED STATES, ANY JUDGMENTS OBTAINED AGAINST OUR SOLE DIRECTOR AND OFFICER.

Our directors and officer are not all 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 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.

Edgar Filing: Orgenesis Inc. - Form 8-K

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.

15

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.

Edgar Filing: Orgenesis Inc. - Form 8-K

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 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 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 COMMERCIALY 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.

16

THIRD PARTIES MAY CLAIM THAT WE INFRINGE THEIR PROPRIETARY RIGHTS AND MAY PREVENT US FROM MANUFACTURING AND SELLING SOME OF OUR 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

Edgar Filing: Orgenesis Inc. - Form 8-K

or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our 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 products.

Under these regulations, we may become subject to periodic inspection of our facilities, procedures and operations and/or the testing of our 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 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 products. Regulatory approval by the EMA will be subject to the evaluation of data relating to the quality, efficacy and safety of our 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.

Edgar Filing: Orgenesis Inc. - Form 8-K

17

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 noncompetitive 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 common stock with a par value of \$0.001 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

Edgar Filing: Orgenesis Inc. - Form 8-K

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.

18

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

Edgar Filing: Orgenesis Inc. - Form 8-K

of their investment in our company.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

Our audited financial statements for the years ended November 30, 2010 and 2009 and related management's discussion and analysis of financial condition and results of operations are available in our annual report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2011. Our unaudited financial statements for the nine month periods ended August 31, 2011 and 2010 and related management's discussion and analysis of financial condition and results of operations are available in our quarterly report on Form 10-Q filed with the Securities and Exchange Commission on October 17, 2011.

RECENT FINANCING ACTIVITIES

On February 2, 2012, we completed a private placement (the "PRIVATE PLACEMENT") of units (each, a "UNIT"). Each Unit is comprised of one common share in our capital and two non-transferrable share purchase warrants (each, a "WARRANT"). Each Warrant is exercisable into one additional common share and shall expire after three years. The holders of such Unit must exercise half of their Warrants, at a price of \$1.00 per warrant share, for additional equity of \$500,000, upon the earlier of: (i) our company or our Subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of such placement of Units, and the other half, at a price of \$1.00 per warrant share, for additional equity of \$500,000, upon the feasibility of enhancement of cell propagation capability for three years from closing at a price of \$1.00 per warrant share. Each Unit was priced at \$1.00 for total gross proceeds of \$500,000. The Units were issued to offshore investors under the exemptions from the Securities Act of 1933 contained in Regulation S.

19

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 and this fee services agreement settles its fees for those services. 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 Products 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.

CASH REQUIREMENTS

Our primary objectives for the next twelve month period are to further develop

Edgar Filing: Orgenesis Inc. - Form 8-K

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:

Expense	Amount
-----	-----
Product development	\$ 323,500
Employee compensation	484,184
General and administration	38,552
Professional services fees	334,868
Regulation and compliance	109,500
Business development	174,000

TOTAL:	\$1,464,604
	=====

20

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 financing to fund our planned operations, including further development, clinical testing, regulatory requirements, commercializing our existing assets. We currently do not have committed sources of additional financing and may not be able to obtain additional financing, particularly, if the volatile conditions in the stock and financial markets, and more particularly the market for early development stage pharmaceutical company stocks persist.

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, if and when it is needed, we will be forced to delay or scale down some or all of our development activities or perhaps even cease the operation of our business.

Since inception we have funded our operations primarily through equity and debt financings and we expect that we will continue to fund our operations through the equity and debt financing. If we raise additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. Obtaining commercial loans, assuming those loans would be available, will increase our liabilities and future cash commitments.

Edgar Filing: Orgenesis Inc. - Form 8-K

There is no assurance that we will be able to maintain operations at a level sufficient for an investor to obtain a return on his, her, or its investment in our common stock. Further, we may continue to be unprofitable.

PROPERTIES

EXECUTIVE OFFICES AND REGISTERED AGENT

Our executive and head office is located at 70 Denya St. Haifa Israel, 3498. We pay approximately \$1,300 per month for rent. We believe that this arrangement will be suitable for the next 12 months.

INTELLECTUAL PROPERTY

The description of our intellectual property rights is under the section entitled "Business - Intellectual Property".

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following tables set forth, as of February 2, 2012, 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, 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.

21

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL HOLDERS

Title of Class -----	Name and Address of Beneficial Owner -----	Amount and Nature of Beneficial Ownership(1) -----	Percent of Class -----
----------------------------	--	--	------------------------------

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL HOLDERS

Common Stock	Oded Shvartz 130 Biruintei Bvd., Pantelimon, Ilfov, Romania	11,126,951(2) Direct	23.6%
Common Stock	Guilbert Cuison 1001 SW 5th Avenue, Suite 1100 Portland, OR 97204	5,500,015(2) Direct	11.7%
Common Stock	Jerome Golez 1001 SW 5th Avenue, Suite 1100 Portland, OR 97204	5,500,015(2) Direct	11.7%

SECURITY OWNERSHIP OF MANAGEMENT

Edgar Filing: Orgenesis Inc. - Form 8-K

Common Stock	Vered Caplan 6 Sharabi street, Neve tzedek, Tel-Aviv 65147, Israel	nil(3)	Direct	nil
Common Stock	Jacob BenArie 70 Denya st. Haifa, Israel 34980	nil	Direct	nil
Common Stock	Dov Weinberg 21 Sparrow Circle White Plains, New York 10605	nil	Direct	nil
Common Stock	Prof. Sarah Ferber Shderot Hahaskala 17b, Tel-Aviv 67890, Israel	2,781,905(4)	Direct	5.9%
Common Stock	Directors & Executive Officers as a group (4 persons)	2,781,905	Direct	5.9%

-
- (1) Percentage of ownership is based on 47,126,951 shares of our common stock issued and outstanding as of February 2, 2012. 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 11,126,951 common shares representing 20% of our share capital on a fully diluted basis. Guilbert Cuison and Jerome Golez (each as to 5,420,485 shares) have granted to Oded Shvartz a conditional option to acquire 10,840,970 common shares of our company at a price of \$0.0003571 per share. The option is exercisable only if we issue shares or grants options or warrants to purchase shares, or 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 1 option share for every 4 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 21,967,951 common shares in the capital of our company.
- (3) We have agreed to grant Ms. Caplan options to acquire up to 3,338,285 of our common shares for a price per share equal to \$0.001. We have not yet granted these options.
- (4) Prof Ferber currently holds 5% of our share capital on a fully diluted basis. On February 2, 2012, we granted Prof. Ferber stock options to acquire up to 2,781,905 of our common shares for a price per share equal to \$0.001 for a period of ten years. Any stocks issued to Prof. Ferber will be held in escrow for a period of two years from the date the License Agreement closed.

22

CHANGES IN CONTROL

We are not aware of any arrangement that may result in a change in control of our company.

Edgar Filing: Orgenesis Inc. - Form 8-K

DIRECTORS AND EXECUTIVE OFFICERS

The following individuals serve as the director and executive officers of our company.

Name	Position	Age	Date First Elected or Appointed
----	-----	---	-----
Vered Caplan	Director	43	February 2, 2012
Jacob BenArie	Chief Executive Officer and President	43	February 2, 2012
Dov Weinberg	Chief Financial Officer, Secretary, and Treasurer	59	February 2, 2012
Dr. Sarah Ferber	Chief Scientist Officer	57	February 2, 2012

BUSINESS EXPERIENCE

The following is a brief account of the education and business experience of director and executive officers during at least 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.

JACOB BENARIE MBA, B.SC., CHIEF EXECUTIVE OFFICER AND PRESIDENT

Prior his joining to Orgenesis, Jacob BenArie served for the last 5 years as the CEO of Beta-Stim Ltd, a private held company that developed a therapy for the treatment of type 2 diabetics. 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.

DOV WEINBERG CPA, MBA, CHIEF FINANCIAL OFFICER, SECRETARY, AND TREASURER

Mr. Dov Weinberg has more than 11 years of experience in the medical device area. He is an owner and president of Weinberg Dalyo Inc a U.S corporation which

Edgar Filing: Orgenesis Inc. - Form 8-K

renders business development and financial services to companies in the life

23

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. Dr. 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 JDRE, the Israel Academy of Science foundation (ISF) and D-Cure.

TERM OF OFFICE

Each director of our company is to serve for a term of one year 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 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

Edgar Filing: Orgenesis Inc. - Form 8-K

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

24

- (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.

EXECUTIVE COMPENSATION

SUMMARY COMPENSATION

The particulars of compensation paid to the following persons:

- (a) our principal executive officer;
- (b) each of our two most highly compensated executive officers who were serving as executive officers at the end of the year ended November 30, 2011; and
- (c) up to two additional individuals for whom disclosure would have been provided under (b) but for the fact that the individual was not serving as our executive officer at the end of the most recently completed financial year,

who we will collectively refer to as the named executive officers, for our years ended November 30, 2011 and 2010, are set out in the following summary compensation table:

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	NonEquity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation
-----	----	---	---	---	---	---	---	
Gilbert Cuison Former President, Secretary, and Director	2011 2010	Nil Nil	Nil Nil	Nil Nil	Nil Nil	Nil Nil	Nil Nil	
Jerome Golez Former Treasurer	2011 2010	Nil Nil	Nil Nil	Nil Nil	Nil Nil	Nil Nil	Nil Nil	

Edgar Filing: Orgenesis Inc. - Form 8-K

and Director

EMPLOYMENT OR CONSULTING AGREEMENTS

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, 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 \$0.001.

25

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

We have not awarded any shares of stock, options or other equity securities to our directors or executive officers from our inception on June 5, 2008 to November 30, 2011.

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.

COMPENSATION OF DIRECTORS

Our directors have not received any compensation for the fiscal year ended November 30, 2011. 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 one time 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.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

TRANSACTIONS WITH RELATED PERSONS, PROMOTERS, AND CERTAIN CONTROL PERSONS

Edgar Filing: Orgenesis Inc. - Form 8-K

Except as set out below and discussed under the heading "Employment or Consulting Agreements" above, since our inception on June 5, 2008, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of the following persons had or will have a direct or indirect material interest:

- (a) any director or executive officer of our company;
- (b) any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our outstanding shares of common stock;
- (c) and of our promoters and control persons; and
- (d) any member of the immediate family (including spouse, parents, children, siblings and in-laws) of any of the foregoing persons.

On June 5, 2008, we sold 1,600,000 shares of our common stock to Guilbert Cuison and Jerome Golez, our directors at the time, for cash payment to us of \$20,000.

26

On June 5, 2008 Guilbert Cuison, one of our directors at the time, provided us with a working capital loan in the amount of \$500. The amount has increased to \$15,500 due to further advances. The loan is non-interest bearing, unsecured, and has no specific terms of repayment.

DIRECTOR INDEPENDENCE

Our board of directors consists of Vered Caplan. Our securities are quoted on the OTC Bulletin Board 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 Ms. Caplan is an independent director.

LEGAL PROCEEDINGS

We know of no material pending legal proceedings to which our company or subsidiary is a party or of which any of their property 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 director, officer or affiliate of our company, or any registered or beneficial stockholder of our company, or any associate of any such director, officer, affiliate, or stockholder is a party adverse to our company or subsidiary or has a material interest adverse to our company or subsidiary.

MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

MARKET INFORMATION

Our common stock is quoted on the OTC Bulletin Board of the Financial Industry Regulatory Authority under the symbol "BOUUD". There were no trades of our shares of common stock made through the facilities of the OTC Bulletin Board during our fiscal years ended November 30, 2010 and 2009 and six month period ended May 31, 2011.

Set forth below are the range of high and low bid quotations for the period indicated as reported by the OTC Bulletin Board. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may

Edgar Filing: Orgenesis Inc. - Form 8-K

not necessarily represent actual transactions.

Quarter Ended	Bid High	Bid Low
-----	-----	-----
November 30, 2011	Nil	Nil
May 31, 2011	Nil	Nil
February 28, 2011	Nil	Nil
November 30, 2010	\$0.20	\$0.11
August 31, 2010	Nil	Nil
May 31, 2010	Nil	Nil
February 28, 2010	Nil	Nil
November 30, 2009	Nil	Nil

TRANSFER AGENT

Our shares of common stock are issued in registered form. The transfer agent and registrar for our common stock is Routh Stock Transfer, Inc., at 6860 North Dallas Parkway, Suite 200, Plano, Texas 75024.

27

HOLDERS OF COMMON STOCK

As of February 2, 2012, there were 8 holders of record of our common stock. As of such date, 47,126,951 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.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

We did not have any equity compensation plans in place at November 30, 2011.

RECENT SALES OF UNREGISTERED SECURITIES

On February 2, 2012, we completed a private placement of 500,000 units (each, a "UNIT"). Each Unit is comprised of one common share in our capital and two non-transferrable share purchase warrants (each, a "WARRANT"). Each Warrant is exercisable into one additional common share and shall expire after three years. The holders of such Unit must exercise half of their Warrants, at a price of \$1.00 per warrant share, for additional equity of \$500,000, upon the earlier of: (i) our company or our Subsidiary signing an agreement with a clinical center, and (ii) 6 months following the closing of such placement of Units, and the other half, at a price of \$1.00 per warrant share, for additional equity of \$500,000, upon the feasibility of enhancement of cell propagation capability for three years from closing at a price of \$1.00 per warrant share. Each Unit was priced at \$1.00 for total gross proceeds of \$500,000. The units were issued to offshore investors under the exemptions from the Securities Act of 1933 contained in Regulation S.

On February 2, 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:

Edgar Filing: Orgenesis Inc. - Form 8-K

- (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.

On June 5, 2008, we sold 28,000,000 (800,000 pre-split) shares of our common stock to each of Guilbert Cuison, our then President and director, and Jerome Golez, our then Treasurer and director at a purchase price of \$0.0125 per pre-split share, for aggregate proceeds of \$20,000. We believe this issuance was exempt under Section 4(2) and/or Regulation S of the Securities Act of 1933. No advertising or general solicitation was employed in offering the securities. The

28

offering and sale were made only to Mr. Cuison and Mr. Gomez who are non-U.S. citizens, and transfers were restricted by us in accordance with the requirements of the Securities Act of 1933.

During the period between July 2008 and October 2008, we sold an aggregate of 24,500,000 (700,000 pre-split) shares of our common stock to our shareholders at \$0.05 per pre-split share for aggregate proceeds of \$35,000. We believe that the issuances of these securities were exempt from registration as an offering completed under Regulation S of the Securities Act of 1933. We believe that this exemption from registration was available because each purchaser represented to us, among other things, that he, she or it was a non-U.S. person as defined in Regulation S and was not acquiring the shares for the account or benefit of, directly or indirectly, any U.S. person. Further, we did not otherwise engage in distribution of these shares in the U.S.

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 1,750,000,000 shares of common stock, with a par value of \$0.001 per share.

VOTING RIGHTS

With respect to all matters upon which our stockholders are entitled to vote or to which our stockholders are entitled to give consent, the holders of the outstanding shares of our common stock are entitled to cast thereon one vote in person or by proxy for each share of our common stock standing in his, her or its name. Our bylaws provide that when a quorum is present or represented at any meeting, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy will be sufficient to elect members of our board of directors or to decide any question brought before such meeting, unless the question is one upon which by express provision of the statutes or of our articles of incorporation, a different vote is required in which case such express provision will govern and control the decision of such question. Our bylaws provide that the holders of at least one third (33.3%) of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, will constitute a quorum at all meetings of the

Edgar Filing: Orgenesis Inc. - Form 8-K

stockholders for the transaction of business except as otherwise provided by statute or by our articles of incorporation. In addition, our bylaws provide that any action which may be taken by the vote of the stockholders at a meeting may be taken without a meeting if authorized by the written consent of stockholders holding at least a majority of the voting power, unless the provisions of the statutes or of our articles of incorporation require a greater proportion of voting power to authorize such action in which case such greater proportion of written consents will be required. Our articles of incorporation provide that our board of directors is expressly authorized to make, alter and repeal our bylaws, subject to the power of our stockholders to change or repeal the bylaws. In addition, our bylaws provide that our board of directors, by a majority vote of our board of directors at any meeting may amend our bylaws, including bylaws adopted by the stockholders, but the stockholders may from time to time specify particular provisions of the bylaws, which will not be amended by our board of directors.

DIVIDEND RIGHTS

Holders of our common stock are entitled to receive such cash dividends as may be declared thereon by our board of directors from time to time out of assets of funds of our company legally available therefore. Our board of directors is not obligated to declare a dividend. Any future dividends will be subject to the discretion of our board of directors and will depend upon, among other things, future earnings, the operating and financial condition of our company, its capital requirements, general business conditions and other pertinent factors. It is not anticipated that dividends will be paid in the foreseeable future.

OTHER RIGHTS

No stockholder of our company has any preemptive or other right to subscribe for any additional un-issued or treasury shares of stock or for other securities of any class, or for rights, warrants or options to purchase stock, or for scrip, or for securities of any kind convertible into stock or carrying stock purchase warrants or privileges unless so authorized by our company.

29

Except as otherwise required by the Nevada Revised Statutes and as may otherwise be provided in our articles of incorporation, each share of our common stock has identical powers, preferences and rights, including rights in liquidation.

ANTI-TAKEOVER PROVISIONS

Some features of the Nevada Revised Statutes, may have the effect of deterring third parties from making takeover bids for control of our company or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of common stock as a result of a takeover bid. We have amended our bylaws and articles such that these provisions are not applicable to our company.

ARTICLES OF INCORPORATION AND BYLAWS

There are no provisions in our articles of incorporation or our bylaws that would delay, defer or prevent a change in control of our company and that would operate only with respect to an extraordinary corporate transaction involving our company or any of our subsidiaries, such as merger, reorganization, tender offer, sale or transfer of substantially all of its assets, or liquidation.

INDEMNIFICATION OF DIRECTORS AND OFFICERS

Nevada Revised Statutes provide that:

Edgar Filing: Orgenesis Inc. - Form 8-K

- * a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with the action, suit or proceeding if he or she acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful;
- * a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him or her in connection with the defense or settlement of the action or suit if he or she acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation. Indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper; and
- * to the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding, or in defense of any claim, issue or matter therein, the corporation must indemnify him or her against expenses, including attorneys' fees, actually and reasonably incurred by him or her in connection with the defense.

30

Nevada Revised Statutes provide that we may make any discretionary indemnification only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances. The determination must be made:

- * by our stockholders;
- * by our board of directors by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding;
- * if a majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding so orders, by independent legal counsel in a written opinion;
- * if a quorum consisting of directors who were not parties to the action, suit or proceeding cannot be obtained, by independent legal counsel in a written opinion; or
- * by court order.

Nevada Revised Statutes provide that a corporation may purchase and maintain

Edgar Filing: Orgenesis Inc. - Form 8-K

insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee or agent, or arising out of his status as such, whether or not the corporation has the authority to indemnify him against such liability and expenses.

Our articles of incorporation also provide that we must indemnify to the fullest extent permitted by law any person made or threatened to be made to a party to any threatened, pending or completed action or proceeding by reason of the fact that he or she is or was a director of our company against judgments, fines, penalties, excise taxes, amounts paid in settlement and costs, charges and expenses that he or she incurs in connection with such action or proceeding. Our bylaws provide a similar right of indemnification for a person who is or was a director or officer of our company. In addition, our bylaws provide that our board of directors may cause our company to purchase and maintain insurance on behalf of any person who is or was a director or officer of our company against any liability asserted against such person and incurred in any such capacity or arising out of such status, whether or not our company would have the power to indemnify such person.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 3.02 UNREGISTERED SALES OF EQUITY SECURITIES.

Please see Item 2.01 of this current report on Form 8-K.

ITEM 5.01 CHANGE IN CONTROL OF REGISTRANT.

Please see Item 2.01 of this current report on Form 8-K.

ITEM 5.02 DEPARTURE OF DIRECTORS OR CERTAIN OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS; COMPENSATORY ARRANGEMENTS OF CERTAIN OFFICERS.

Please see Item 2.01 of this current report on Form 8-K.

ITEM 5.06 CHANGE IN SHELL COMPANY STATUS.

Management has determined that, as a result of the transaction described in Item 2.01 of this current report, our company has ceased to be a shell company as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934. Please refer to Item 2.01 of this current report on Form 8-K for a description of these transactions.

31

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

Not applicable

EXHIBITS

No.	Description
---	-----
3.1	Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S-1 filed on April 2, 2009)

Edgar Filing: Orgenesis Inc. - Form 8-K

- 3.2 Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
- 3.3 Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
- 3.4 Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
- 3.5 Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
- 10.1* Form of Private Placement Subscription Agreement
- 10.2* Licensing Agreement dated February 2, 2012 with Tel Hashomer - Medical Research, Infrastructure and Services Ltd.
- 10.3* Employment Agreement dated February 2, 2012 between our company and Prof. Sarah Ferber
- 10.4* Stock Option Agreement dated February 2, 2012 between our company, Prof. Sarah Ferber and Clark Wilson LLP
- 10.5* Fee Service Agreement dated February 2, 2012 between our company and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
- 10.6* Compensation Letter dated February 2, 2012 between our company and Vered Caplan
- 21.1 Orgenesis Ltd. our 100% wholly-owned subsidiary incorporated in Israel on October 11, 2011

* Filed herewith.

32

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ORGENESIS CORP.

Per: /s/ Vered Caplan

Authorized Signatory

Date: February 8, 2012

33