Orgenesis Inc. Form S-1/A March 07, 2014

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM S-1/A

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933** 

# **ORGENESIS INC.**

(Exact name of registrant as specified in its charter)

#### <u>Nevada</u>

(State or other jurisdiction of incorporation or organization)

2834 (Primary Standard Industrial Classification Code Number)

> <u>98-0583166</u> (I.R.S. Employer Identification Number)

#### 21 Sparrow Circle, White Plains, New York 10605 Tel: 426-509-9832

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Dov Weinberg Chief Financial Officer 21 Sparrow Circle, White Plains, New York 10605 <u>Tel: 9149490631</u>

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy of Communications To: Clark Wilson LLP Suite 900 - 885 West Georgia Street Vancouver, British Columbia V6C 3H1, Canada <u>Telephone: (604) 687-5700</u>

From time to time after the effective date of this registration statement. (Approximate date of commencement of proposed sale to the public)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

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

Large accelerated filer	[]	Accelerated filer	[ ]
Non-accelerated filer	[]	Smaller reporting company	[X]
(Do not check if a smaller repo	orting company)		
<b>Calculation of Registration H</b>	ee		

Title of Each Class of Securities to be Registered	Amount to be Registered <sup>(1)</sup>	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price <sup>(2)</sup>	Amount of Registration Fee
Common Stock	10,603,436 <sup>(3)</sup>	\$0.505	\$5,354,735.18	\$689.69 <sup>(4)</sup>

#### <u>Notes</u>

- (1) An indeterminate number of additional shares of common stock shall be issuable pursuant to Rule 416 under the Securities Act of 1933 to prevent dilution resulting from stock splits, stock dividends or similar transactions and in such an event the number of shares registered shall automatically be increased to cover the additional shares in accordance with Rule 416.
- (2) Estimated in accordance with Rule 457(o) under the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee. Based on the average of the high and low prices per share (\$0.57 high; \$0.44 low) for the registrant's common stock on March 6, 2014, as reported by Financial Industry Regulatory Authority's OTC Bulletin Board.
- (3) Consists of (i) up to 250,000 shares of common stock issued or to be issued to Kodiak Capital Group, LLC (Kodiak) as commitment shares pursuant to an Investment Agreement dated December 13, 2013 (the Investment Agreement) and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the Investment Agreement (ii) 1,526,718 shares of common stock issued to ATMI BVBA; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to ATMI BVBA.
- (4) A fee of \$942.58 was previously paid in connection with the Registration Statement on Form S-1 filed on January 7, 2014.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

ii

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any State where the offer or sale is not permitted.

Subject to Completion, Dated \_\_\_\_\_, 2014

### **Preliminary Prospectus**

### Orgenesis Inc. 10,603,436 shares of common stock

The selling stockholders identified in this prospectus may offer and sell up to 10,603,436 shares of our common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak Capital Group, LLC (**Kodiak**) as commitment shares pursuant to an Investment Agreement dated December 13, 2013 (the **Investment Agreement**) and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the Investment Agreement; (ii) 1,526,718 shares of common stock issued to ATMI BVBA; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to ATMI BVBA. The 7,550,000 shares of common stock as of March5, 2014.

The selling stockholders may sell all or a portion of the shares being offered pursuant to this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders. We will pay for expenses of this offering, except that the selling stockholders will pay any broker discounts or commissions or equivalent expenses applicable to the sale of their shares.

Kodiak is an underwriter within the meaning of the Securities Act of 1933 and other selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act of 1933 in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act of 1933.

Our common stock is quoted on Financial Industry Regulatory Authority s OTC Bulletin Board under the symbol ORGS . On March 5, 2014, the closing sale price for our common stock as reported by the OTC Bulletin Board was \$0.56 per share.

OUR BUSINESS IS SUBJECT TO MANY RISKS AND AN INVESTMENT IN OUR COMMON STOCK OFFERED THROUGH THIS PROSPECTUS WILL ALSO INVOLVE A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY READ AND CONSIDER THE SECTION OF THIS PROSPECTUS ENTITLED RISK FACTORS BEGINNING ON PAGE 6 OF THIS PROSPECTUS BEFORE BUYING ANY SHARES OF OUR COMMON STOCK. YOU SHOULD NOT INVEST UNLESS YOU CAN AFFORD TO LOSE YOUR ENTIRE INVESTMENT.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is \_\_\_\_\_, 2014.

# TABLE OF CONTENTS

PROSPECTUS SUMMARY	<u>3</u>
RISK FACTORS	<u>6</u>
FORWARD-LOOKING STATEMENTS	<u>12</u>
USE OF PROCEEDS	<u>13</u>
SELLING STOCKHOLDERS	<u>13</u>
PLAN OF DISTRIBUTION	<u>15</u>
DESCRIPTION OF SECURITIES	<u>17</u>
INTEREST OF NAMED EXPERTS AND COUNSEL	<u>21</u>
INFORMATION WITH RESPECT TO OUR COMPANY	<u>21</u>
DESCRIPTION OF BUSINESS	<u>21</u>
DESCRIPTION OF PROPERTY	<u>31</u>
LEGAL PROCEEDINGS	<u>31</u>
<u>MARKET PRICE OF AND DIVIDENDS ON OUR COMMON EQUITY AND RELATED</u> <u>STOCKHOLDER MATTERS</u>	<u>31</u>
MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	<u>33</u>
FINANCIAL STATEMENTS	<u>38</u>
<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND</u> <u>FINANCIAL DISCLOSURE</u>	<u>29</u>
DIRECTORS AND EXECUTIVE OFFICERS	<u>29</u>
EXECUTIVE COMPENSATION	<u>35</u>
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	<u>41</u>
TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS AND CORPORATE GOVERNANCE	<u>43</u>
WHERE YOU CAN FIND ADDITIONAL INFORMATION	<u>44</u>
DEALER PROSPECTUS DELIVERY OBLIGATION	<u>45</u>

In this prospectus, unless otherwise specified, all references to common shares refer to the shares of our common stock and the terms we, us, our, and Orgenesis mean Orgenesis Inc., a Nevada corporation, and our wholly ow subsidiaries, Orgenesis Ltd. (the **Subsidiary**), Orgenesis SPRL (the **Belgium Subsidiary**) and Orgenesis Maryland Inc. (the **US Subsidiary**).

### **PROSPECTUS SUMMARY**

### **Corporate Overview**

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

Effective August 31, 2011, we completed a merger with our subsidiary, Orgenesis Inc., a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we changed our name from Business Outsourcing Services, Inc. to Orgenesis Inc.

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

#### **Our Current Business**

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

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license patents and knowhow related to the development of autologous insulin producing (AIP) cells.

Based on the licensed knowhow and patents, our intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using a therapeutic agent (i.e., PDX-1, or additional pancreatic transcription factors in adenovirus-vector) that efficiently converts a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. The development of AIP cells is based on the licensed patents and knowhow. We believe that our major competitive advantage is in our cell transformation technology.

This technology was licensed based on the published work of Prof. Ferber. Prof. Ferber has developed this technology, as a researcher in Tel Hashomer, and has established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells in liver and convert them into pancreatic beta cell like cells. Furthermore, those cells were found to be resistant to the autoimmune attack.

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

# **Directors and Executive Officers**

As of March 5, 2014, our directors and executive officers are as follows:

Name	Position Held with our Company
Vered Caplan	Interim President ,Chief Executive Officer and Chairperson of the board of directors
Jacob BenArie	Chief Executive Officer of the Israeli Subsidiary
Dov Weinberg	Chief Financial Officer, Treasurer and Secretary
Sarah Ferber	Chief Scientific Officer
Guy Yachin	Director
Etti Hanochi	Director
Yaron Adler	Director
Dr. David Sidransky	Director

See Directors and Executive Officers on page 29.

# **Share Capital**

We are authorized to issue 1,750,000,000 common shares with a par value of \$0.0001 per share. As of March 5, 2014, there were 53,860,299common shares outstanding.

### Summary of the Offering

Shares being offered:	The selling stockholders identified in this prospectus may offer and sell up to 10,603,436 shares of our common stock, which will consists of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to the Investment Agreement and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the Investment Agreement; (ii) 1,526,718 shares of common stock issued to ATMI BVBA; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to ATMI BVBA. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of our issued and outstanding shares of common stock as of March 5, 2014.
Offering Price per share:	The selling stockholders may sell all or a portion of the shares being offered pursuant to this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.
Use of Proceeds:	We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders. We will pay for expenses of this offering, except that the selling stockholders will pay any broker discounts or commissions or equivalent expenses applicable to the sale of their shares.
Risk Factors:	See Risk Factors beginning on page 6 and the other information in this prospectus for a discussion of the factors you should consider before deciding to invest in shares of our common stock.
Summary of Financial Da	ta

The following information represents selected audited financial information for Orgenesis and its Subsidiaries for the years ended November 30, 2012 and 2013. The summarized financial information presented below is derived from and should be read in conjunction with our audited financial statements, including the notes to those financial statements, which are included elsewhere in this prospectus along with the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations beginning on page 33 of this prospectus.

Edgar Filing	: Orgenesis Inc.	- Form S-1/A
--------------	------------------	--------------

Statements of Operations Data	For the Year Ended November 30, 2013	For the Year Ended November 30, 2012
Operating Loss	\$5,460,502	\$4,988,559
Net Loss	\$5,539,159	\$4,998,143
Basic and Diluted Loss Per common stock	\$0.11	\$0.09

We have not generated any revenue since inception.

Balance Sheet Data	alance Sheet Data As of November 30, 2013	
Cash and Cash Equivalents	\$50,827	\$347
Working Capital Deficit	(\$888,672)	(\$288,572)
Total Assets	\$114,221	\$48,167
Total Liabilities	\$2,148,635	\$328,723
Accumulated Deficit	(\$10,674,975)	(\$5,135,816)

Please read this prospectus carefully. You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information provided by this prospectus is accurate as of any date other than the date on the front of this prospectus.

An investment in our common stock involves a number of very significant risks. You should carefully consider the information set out under Risk Factors and other information in this prospectus before purchasing shares of our common stock. The risks we face include the following:

- general economic and business conditions;
- substantial doubt about our ability to continue as a going concern;
- we may need to raise additional funds in the future which may not be available on acceptable terms or at all;
- if we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operations;
- we may not be able to successfully implement our business plan;
- conditions in Israel and the surrounding Middle East may materially adversely affect our subsidiary s operations and personnel;
- the ability of our subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by our subsidiary may be subject to taxes;
- THM may cancel the License Agreement;
- if we are unable to successfully acquire, develop or commercialize new products, our operating results will suffer;
- our expenditures may not result in commercially successful products;

- third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products; and
- extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

### **RISK FACTORS**

### **Risks Related to Our Company**

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

Since 2008, there has been a downturn in general worldwide economic conditions due to many factors, including the effects of the subprime lending and general credit market crises, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions, increased unemployment and liquidity concerns. In addition, these economic effects, including the resulting recession in various countries and slowing of the global economy, will likely result in fewer business opportunities as companies face increased financial hardship. Tightening credit and liquidity issues will also result in increased difficulties for our company to raise capital for our continued operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable. If we cannot raise the funds that we need or find a suitable product or business to acquire, we will go out of business. If we go out of business, investors will lose their entire investment in our company.

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

We have not generated any revenue from operations since our incorporation. We expect that our operating expenses will increase over the next 12 months. We estimate our average monthly expenses over the next 12 months to be approximately \$320,000, including general and administrative expenses, research and development. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As of February 28, 2014, we had cash and cash equivalents of approximately \$236253. As we cannot assure a lender that we will be able to successfully develop our pharmaceutical assets, we will almost certainly find it difficult to raise debt financing from traditional lending sources. If we cannot raise the money that we need in order to continue to operate our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail.

If we are unable to meet our debt service obligations and other financial obligations, we could be forced to restructure or refinance, seek additional equity capital or sell our assets. We might then be unable to obtain such financing or capital or sell our assets on satisfactory terms.

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

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

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

We are an early-stage company with only a limited operating history upon which to base an evaluation of our current business and future prospects. As a result, the revenue and income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business.

Errors may be made in predicting and reacting to relevant business trends and we will be subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our business, results of operations and financial condition to suffer.

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

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

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

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

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

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

# **Risks Relating to our Operations in Israel**

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

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

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

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

7

# **Risks Relating to the Pharmaceutical Business**

### THM may cancel the License Agreement.

Pursuant to the terms of the License Agreement, we are required to submit to THM the Development Plan within 18 months from the date of the License Agreement. We must develop, manufacture, sell and market the Products pursuant to the milestones and time schedule specified in the Development Plan. In the event we fail to fulfill the terms of the Development Plan, THM shall be entitled to terminate the License Agreement by providing us with written notice of such a breach and we do not cure such breach within one year of receiving the notice. If THM cancels the License Agreement, our business may be materially adversely affected. THM may also terminate the License Agreement if we breach an obligation contained in the License Agreement and do not cure it within 180 days of receiving notice of the breach.

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

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize new products and businesses in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- there are still major developmental steps required to bring the product to a clinical testing stage and clinical testing may not be positive;
- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;
- failure to receive requisite regulatory approvals for such products in a timely manner or at all;
- developing and commercializing a new product is time consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development and commercialization of our product;
- incomplete, unconvincing or equivocal clinical trials data;
- experiencing delays or unanticipated costs;
- significant and unpredictable changes in the payer landscape, coverage and reimbursement for our future products;
- experiencing delays as a result of limited resources at the U.S. Food and Drug Administration ( **FDA** ) or other regulatory agencies; and
- changing review and approval policies and standards at the FDA and other regulatory agencies.

As a result of these and other difficulties, products in development by us may or may not receive timely regulatory approvals, or approvals at all, necessary for marketing by us or other third-party partners. If any of our future products are not approved in a timely fashion or, when acquired or developed and approved, cannot be successfully manufactured, commercialized or reimbursed, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

#### Our expenditures may not result in commercially successful products.

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

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

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

# Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies are subject to extensive, complex, costly and evolving government regulation. For the U.S., this is principally administered by the FDA and to a lesser extent by the Drug Enforcement Administration (**DEA**) and state government agencies, as well as by varying regulatory agencies in foreign countries where products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations, and similar foreign statutes and regulations, govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our future products.

Under these regulations, we may become subject to periodic inspection of our facilities, procedures and operations and/or the testing of our future products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with current good manufacturing practice ( **cGMP** ) and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or warning letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a warning letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We may also be required to report adverse events associated with our future products to FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in labeling changes, recalls, market withdrawals or other regulatory actions.

The range of possible sanctions includes, among others, FDA issuance of adverse publicity, product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA s review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition and cash flows. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. If internal compliance programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business.

For Europe, the European Medicines Agency ( **EMEA** ) will regulate our future products. Regulatory approval by the EMEA will be subject to the evaluation of data relating to the quality, efficacy and safety of our future products for its proposed use. The time taken to obtain regulatory approval varies between countries. Different regulators may impose

their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

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

9

# The pharmaceutical industry is highly competitive.

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

# **Risks Relating to Our Common Stock**

# If we issue additional shares in the future, it will result in the dilution of our existing stockholders.

Our articles of incorporation authorize the issuance of up to 1,750,000,000 shares of our common stock with a par value of \$0.0001 per share. Our board of directors may choose to issue some or all of such shares to acquire one or more companies or products and to fund our overhead and general operating requirements. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change of control of our company.

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

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

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

In addition to the penny stock rules described above, the Financial Industry Regulatory Authority (**FINRA**) has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our stock.

10

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

Although our common stock is currently listed for quotation on the OTC Bulletin Board, there is no market for our common stock. Even when a market is established and trading begins, trading through the OTC Bulletin Board is frequently thin and highly volatile. There is no assurance that a sufficient market will develop in our stock, in which case it could be difficult for stockholders to sell their stock. The market price of our common stock could fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of our competitors, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. In addition, the stock market is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

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

We have never paid any cash dividends and currently do not intend to pay any dividends for the foreseeable future. Because we do not intend to declare dividends, any gain on an investment in our company will need to come through an increase in the stock s price. This may never happen and investors may lose all of their investment in our company.

# **Risks Related to the Offering**

The selling stockholders are offering for resale of a maximum of 10,603,436 shares of our common stock, 7,550,000 shares of our common stock of which have been issued or may be issued to Kodiak under the equity line or as commitment shares. The resale of such shares by Kodiak or ATMI could depress the market price of our common stock.

The selling stockholders are offering for the resale of a maximum of 10,603,436 shares of our common stock under this prospectus. The sale of these shares into the public market by Kodiak or ATMI could depress the market price of our common shares. As of March 5, 2014, there were 53,860,299 shares of our common stock issued and outstanding. In total, we may issue up to \$3,000,000 of shares of our common stock to Kodiak pursuant to the equity line, meaning that we are obligated to file one or more registration statements covering the remaining common shares not covered by the registration statement of which this prospectus forms a part. The sale of those additional common shares into the public market by Kodiak or ATMI could further depress the market price of our common stock.

# Existing stockholders could experience substantial dilution upon the issuance of common stock pursuant to the equity line.

Our equity line with Kodiak contemplates our issuance of up to \$3,000,000 of shares of our common stock to Kodiak subject to certain restrictions and obligations. If the terms and conditions of the equity line are satisfied, and we choose to exercise our put rights to the fullest extent permitted and sell \$3,000,000 of shares of our common stock to Kodiak, our existing stockholders' ownership will be diluted by such sales.

# Kodiak will pay less than the then-prevailing market price for our common stock under the equity line.

The common stock to be issued to Kodiak pursuant to the equity line will be purchased at a 20% discount to the lowest daily volume weighted average price of our common shares. Therefore, Kodiak has a financial incentive to sell our common stock upon receiving the shares to realize the profit equal to the difference between the discounted price and the market price. If Kodiak sells the shares, the price of our common stock could decrease.

#### We may not be able to access sufficient funds under the equity line when needed.

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

# FORWARD-LOOKING STATEMENTS

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

- our anticipated use of proceeds;
- our plans to identify and acquire products that we believe will be prospective for acquisition and development;
- our intention to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- our belief that our treatment seems to be safer than other options;
- our belief that our major competitive advantage is in our cell transformation technology;
- our marketing plan;
- our plans to hire industry experts and expand our management team;
- our belief that Diabetes Mellitus will be one of the most challenging health problems in the 21st century and will have staggering health, societal and economic impact;
- our beliefs regarding the future of our competitors;
- our expectation that the demand for our products will eventually increase; and
- our expectation that we will be able to raise capital when we need it.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled Risk Factors and the risks set out below, any of which may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation:

- general economic and business conditions;
- substantial doubt about our ability to continue as a going concern;
- we may need to raise additional funds in the future which may not be available on acceptable terms or at all;
- if we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operation;



- we may not be able to successfully implement our business plan;
- conditions in Israel and the surrounding Middle East may materially adversely affect our subsidiary s operations and personnel;
- the ability of our subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by our subsidiary may be subject to taxes;
- THM may cancel the License Agreement;
- if we are unable to successfully acquire, develop or commercialize new products, our operating results will suffer;
- our expenditures may not result in commercially successful products;
- third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products;
- extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities; and
- other factors discussed under the section entitled Risk Factors .

These risks may cause our company s or our industry s actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

# **USE OF PROCEEDS**

We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders. All proceeds from the sale of such shares will be for the account of the selling stockholders. We will pay for expenses of this offering, except that the selling stockholders will pay any broker discounts or commissions or equivalent expenses applicable to the sale of their shares.

# SELLING STOCKHOLDERS

The selling stockholders identified in this prospectus may offer and sell up to 10,603,436 shares of our common stock, which will consists of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to the Investment Agreement and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the Investment Agreement; (ii) 1,526,718 shares of common stock issued to ATMI BVBA; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to ATMI BVBA. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of our issued and outstanding shares of common stock as of March 5, 2014.

None of the selling stockholders had or have any position or office, or other material relationship with us or any of our affiliates over the past three years.

We may require the selling stockholders to suspend the sales of the shares of our common stock being offered pursuant to this prospectus upon the occurrence of any event that makes any statement in this prospectus or the related registration statement untrue in any material respect or that requires the changing of statements in those documents in order to make statements in those documents not misleading.

The following table sets forth certain information regarding the beneficial ownership of shares of common stock by the selling stockholders as of March 5, 2014 and the number of shares of our common stock being offered pursuant to this prospectus. Except as otherwise described below, we believe that the selling stockholders have sole voting and investment powers over their shares.

	Shares Owned by the Selling		Number of Shar by Selling Stock Offering and P Issued and Outst	holder After the ercent of Total
Name of Selling Stockholder	Stockholder before the Offering <sup>(1)</sup>	Total Shares Offered in the Offering	# of Shares <sup>(2)</sup>	% of Class <sup>(2)</sup>
Kodiak Capital Group, LLC <sup>(3)</sup>	250,000	7,550,000 <sup>(4)</sup>	-	-
ATMI BVBA <sup>(5)</sup>	1,526,718	3,053,436 <sup>(6)</sup>	-	-
Totals	1,776,718	10,603,436	-	-

# <u>Notes</u>

- (1) Beneficial ownership is determined in accordance with Securities and Exchange Commission rules and generally includes voting or investment power with respect to shares of common stock. Shares of common stock subject to options, warrants and convertible debentures currently exercisable or convertible, or exercisable or convertible within 60 days, are counted as outstanding. The actual number of shares of common stock issuable upon the conversion of the convertible debentures is subject to adjustment depending on, among other factors, the future market price of our common stock, and could be materially less or more than the number estimated in the table.
- (2) Because the selling stockholders may offer and sell all or only some portion of the 10,603,436 shares of our common stock being offered pursuant to this prospectus and may acquire additional shares of our common stock in the future, we cannot provide an estimate of the number and percentage of shares of our common stock that any of the selling stockholders will hold upon termination of the offering.
- <sup>(3)</sup> Ryan Hodson of 260 Newport Center Drive Newport Beach, CA 92660 exercises voting and dispositive power with respect to the shares of our common stock that are beneficially owned by Kodiak Capital Group, LLC.
- <sup>(4)</sup> Consists of up to 250,000 shares of common stock issued to Kodiak as commitment shares pursuant to the Investment Agreement and up to 7,550,000 shares of common stock to be sold by Kodiak pursuant to the Investment Agreement.
- <sup>(5)</sup> We have been unable to obtain the information regarding the voting and dispositive powers with respect to the shares of our common stock that are beneficially owned by ATMI BVBA.
- (6) Consists of 1,526,718 shares of common stock issued to ATMI BVBA and 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to ATMI BVBA. THE OFFERING

On December 13, 2013, we entered into an investment agreement (the Investment Agreement ) with Kodiak. Although we are not mandated to sell shares under the Investment Agreement, the Investment Agreement gives us the option to sell to Kodiak, up to \$3,000,000 worth of our common stock over a 12 month period. The \$3,000,000 was stated as the total amount of available funding in the Investment Agreement because this was the maximum amount that

Kodiak agreed to offer us in funding. There is no assurance that the market price of our common stock will remain at its current price or increase substantially in the future. The number of common shares that remains issuable may not be sufficient, dependent upon the share price, to allow us to access the full amount contemplated under the Investment Agreement. Therefore, we may not have access to the remaining commitment under Investment Agreement unless the market price of our common stock remains at its current price or increases from its current level. Based on our stock price as of March 5, 2014, the registration statement covers the offer and possible sale of more than \$3,000,000 worth of our shares. We have registered additional shares in the event that our share price decreases.

The purchase price of the common stock shall be set at eighty percent (80%) of the lowest daily volume weighted average price (VWAP) of the common stock during the pricing period. The pricing period shall be the five (5) consecutive trading days immediately after we provide Kodiak with notice of a draw down (the Put Notice). Kodiak is not required to purchase any shares if it would exceed 9.99% of the number of shares outstanding on the closing date.

14

On any Closing Date, we shall deliver to Kodiak the number of shares of the Common Stock registered in the name of Kodiak as specified in the Put Notice. In addition, we must deliver the other required documents, instruments and writings required. Kodiak is not required to purchase the shares unless, among other things:

- Our registration statement with respect to the resale of the shares of common stock delivered in connection with the applicable put shall have been declared effective.
- We shall have obtained all material permits and qualifications required by any applicable state for the offer and sale of the Registrable Securities.
- We shall have filed with the SEC in a timely manner all reports, notices and other documents required.

We are aware that if we fail to perform our obligations and we fail to deliver to Kodiak on the Put Date the shares of common stock corresponding to the applicable put, Kodiak shall suffer financial hardship and therefore we acknowledge that we will be liable for any and all losses, commission, fees, interest, legal fees or any other financial hardships caused to Kodiak. Fees and penalties for such losses (liquidated damages) to Kodiak shall be paid by the Company in accordance with the following schedule:

LATE PAYMENT FOR EACH NO. OF DAYS LATE	\$100,000 WORTH OF COMMON STOCK
1	\$100
2	\$200
3	\$300
4	\$400
5	\$500
6	\$600
7	\$700
8	\$800
9	\$900
10	\$1,000
Over 10	\$1,000 + \$200 for each
	Business Day late beyond 10 days

As we draw down on the equity line of credit, shares of our common stock will be sold into the market by Kodiak. The sale of these additional shares could cause our stock price to decline. In turn, if the stock price declines and we issue more puts, more shares will come into the market, which could cause a further drop in the stock price. You should be aware that there is an inverse relationship between the market price of our common stock and the number of shares to be issued under the equity line of credit. If our stock price declines, we will be required to issue a greater number of shares under the equity line of credit. We have no obligation to utilize the full amount available under the equity line of credit.

# PLAN OF DISTRIBUTION

Each of the selling stockholders named above and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on FINRA s OTC Bulletin Board or any other stock exchange, market or trading facility on which the shares of our common stock are traded or in private transactions. These sales may be at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated

prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- privately negotiated transactions;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

ATMI BVBA may also sell shares under Rule 144 under the Securities Act of 1933, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

Kodiak is an underwriter within the meaning of the Securities Act of 1933 and other selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act of 1933 in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act of 1933. The selling stockholders have informed us that they do not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock of our company. Pursuant to a requirement by FINRA, the maximum commission or discount to be received by any FINRA member or independent broker-dealer may not be greater than 8% of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 promulgated under the Securities Act of 1933.

Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling stockholders. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act of 1933.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares covered by this prospectus. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act of 1933. We estimate that the expenses of the offering to be borne by us will be approximately \$68,000.We will not receive any proceeds from the resale of any of the shares of our common stock by the selling stockholders. We may, however, receive proceeds from the sale of our common stock under the Investment Agreement with Kodiak or exercise of warrants by the selling stockholders. Neither the Investment with Kodiak nor any rights of the parties under the Investment Agreement with Kodiak may be assigned or delegated to any other person.

Because Kodiak is, and other selling stockholders may be, an underwriter within the meaning of the Securities Act of 1933, they will be subject to the prospectus delivery requirements of the Securities Act of 1933 including Rule 172 thereunder. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We have entered into an agreement with Kodiak to keep this prospectus effective until the earlier to occur of the date on which (A) Kodiak shall have sold all of its common shares; (B) Kodiak has no right to acquire any additional shares of common stock under the Investment Agreement; or (C) Kodiak may sell the shares without volume limitations under Rule 144 (hereinafter referred to as the Registration Period ).

The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Securities Exchange Act of 1934 and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

# **DESCRIPTION OF SECURITIES**

#### **Common Shares**

We are authorized to issue 1,750,000,000 common shares with a par value of \$0.0001 per share. As of March 5, 2014 there were 53,860,299 common shares outstanding.

#### Voting Rights

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the stockholders including the election of directors. Except as otherwise required by law the holders of our common stock possess all voting power. According to our bylaws, in general, each director is to be elected by a majority of the votes cast with respect to the directors at any meeting of our stockholders for the election of directors at which a quorum is present. According to our bylaws, in general, the affirmative vote of a majority of the shares represented at the meeting and entitled to vote on any matter (which shares voting affirmatively also constitute at least a majority of the required quorum), except for the election of directors, is to be the act of our stockholders. Our bylaws provide that stockholders holding at least 33.3% of the shares entitled to vote, represented in person or by proxy, constitute a quorum at the meeting of our stockholders may be taken without a meeting and without prior notice if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding shares having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Our articles of incorporation and bylaws do not provide for cumulative voting in the election of directors. Because the holders of our common stock do not have cumulative voting rights and directors are generally to be elected by a majority of the votes casts with respect to the directors at any meeting of our stockholders for the election of directors, holders of more than fifty percent, and in some cases less than 50%, of the issued and outstanding shares of our common stock can elect all of our directors.

#### Dividend Rights

The holders of our common stock are entitled to receive such dividends as may be declared by our board of directors out of funds legally available for dividends. 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. We do not anticipate that dividends will be paid in the foreseeable future.

# Miscellaneous Rights and Provisions

In the event of our liquidation or dissolution, whether voluntary or involuntary, each share of our common stock is entitled to share ratably in any assets available for distribution to holders of our common stock after satisfaction of all liabilities.

Our common stock is not convertible or redeemable and has no preemptive, subscription or conversion rights. There are no conversions, redemption, sinking fund or similar provisions regarding our common stock.

Our common stock, after the fixed consideration thereof has been paid or performed, are not subject to assessment, and the holders of our common stock are not individually liable for the debts and liabilities of our company.

Our bylaws provide that our board of directors may amend our bylaws by a majority vote of our board of directors including any bylaws adopted by our stockholders, but our stockholders may from time to time specify particular provisions of these bylaws, which must not be amended by our board of directors. Our current bylaws were adopted by our board of directors. Therefore, our board of directors can amend our bylaws to make changes to the provisions relating to the quorum requirement and votes requirements to the extent permitted by the Nevada Revised Statutes.

# Anti-Takeover Provisions

Some features of the Nevada Revised Statutes, which are further described below, 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.

# Acquisition of Controlling Interest

The Nevada Revised Statutes contain provisions governing the acquisition of a controlling interest of certain Nevada corporations. These provisions provide generally that any person or entity that acquires in excess of a specified percentage of the outstanding voting shares of a Nevada corporation may be denied voting rights with respect to the acquired shares, unless the holders of a majority of the voting power of the corporation, excluding shares of which such acquiring person or entity, an officer or a director of the corporation, and an employee of the corporation exercises voting rights, elect to restore such voting rights in whole or in part. These provisions apply whenever a person or entity acquires shares that, but for the operation of these provisions, would bring voting power of such person or entity in the election of directors within any of the following three ranges:

- 1. 20% or more but less than 33 1/3%;
- 2.  $33 \frac{1}{3}\%$  or more but less than or equal to 50%; or
- 3. more than 50%.

The stockholders or board of directors of a corporation may elect to exempt the stock of the corporation from these provisions through adoption of a provision to that effect in the articles of incorporation or bylaws of the corporation. Our articles of incorporation and bylaws do not exempt our common stock from these provisions.

These provisions are applicable only to a Nevada corporation, which:

- 1. has 200 or more stockholders of record, at least 100 of whom have addresses in Nevada appearing on the stock ledger of the corporation; and
- 2. does business in Nevada directly or through an affiliated corporation.

At this time, we do not have 100 stockholders of record who have addresses in Nevada appearing on the stock ledger of our company nor do we conduct any business in Nevada, either directly or through an affiliated corporation. Therefore, we believe that these provisions do not apply to acquisitions of our shares and will not until such time as these requirements have been met. At such time as they may apply to us, these provisions may discourage companies or persons interested in acquiring a significant interest in or control of our company, regardless of whether such acquisition may be in the interest of our stockholders.

# Combination with Interested Stockholder

The Nevada Revised Statutes contain provisions governing the combination of any Nevada corporation that has 200 or more stockholders of record with an interested stockholder. As of March 5, 2014, we had approximately 12 stockholders of record. Therefore, we believe that these provisions do not apply to us and will not until such time as

these requirements have been met. At such time as they may apply to us, these provisions may also have the effect of delaying or making it more difficult to effect a change in control of our company.

A corporation affected by these provisions may not engage in a combination within three years after the interested stockholder acquires his, her or its shares unless the combination or purchase is approved by the board of directors before the interested stockholder acquired such shares. Generally, if approval is not obtained, then after the expiration of the three-year period, the business combination may be consummated with the approval of the board of directors before the person became an interested stockholder or a majority of the voting power held by disinterested stockholders, or if the consideration to be received per share by disinterested stockholders is at least equal to the highest of:

- 1. the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or within three years immediately before, or in, the transaction in which he, she or it became an interested stockholder, whichever is higher;
- 2. the market value per share on the date of announcement of the combination or the date the person became an interested stockholder, whichever is higher; or
- 3. if higher for the holders of preferred stock, the highest liquidation value of the preferred stock, if any.

Generally, these provisions define an interested stockholder as a person who is the beneficial owner, directly or indirectly of 10% or more of the voting power of the outstanding voting shares of a corporation. Generally, these provisions define combination to include any merger or consolidation with an interested stockholder, or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an interested stockholder of assets of the corporation having:

- 1. an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation;
- 2. an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation; or
- 3. representing 10% or more of the earning power or net income of the corporation.

#### **Transfer Agent**

The shares of our common stock are issued in registered form. The transfer agent and registrar for our common stock is Securities Transfer Corporation located at 2591 Dallas Parkway, Suite 102, Frisco, TX 75034.

### Warrants

As of March 5, 2014, we had a total of 4,768,590 warrants, which consisted of the following:

In April 2012, we issued 100,000 non-transferable warrants, which can be exercised into shares at an exercise price of \$1.00 per share until April 30, 2015.

In December 2012, we issued 1,000,000 non-transferable warrants, which can be exercised into shares at an exercise price of \$0.50 per share until November 30, 2014. In the event we issue any shares of our common stock or securities convertible into shares of our common stock at a price less than the purchase price of these warrants, the price shall be reduced to the new issuance price.

In March 2013, we issued 100,000 warrants in connection with agreements with Mediapark A.G. ( **Mediapark** ). Each warrant can be exercised into one share at an exercise price of \$0.50 per share until March 22, 2015. In the event we issue any shares of our common stock or securities convertible into shares of our common stock at a price less than the purchase price of these warrants, the price shall be reduced to the new issuance price.

In May 2013, we issued 1,526,718 warrants, which can be exercised into shares at an exercise price of \$1.00 per share until May 6, 2015. In the event we issue any shares of common stock or securities convertible into shares of our common stock at a price less than \$0.8515, the exercise price shall be reduced to the new issuance price. On March 4, 2014, we issued 1,128,849 units in a non-brokered private placement. Each unit consisted of one share of our common

stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years. As of March 4, 2014, the warrants issued in May 2013 have an exercise price \$0.52 per share.

On June 30, 2013, we exercised our discretion to extend the maturity date of a loan to Mediapark to September 30, 2013. In return for extending the maturity date, we issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of \$0.50 per share until June 30, 2015.

On September 30, 2013, we exercised our discretion to extend the maturity date of a loan to Mediapark to December 31, 2013. In return for extending the maturity date, we issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of \$0.50 per share until September 30, 2015.

On March 4, 2014, we issued 713,023 warrants to Mediapark in connection with the conversion of their convertible debenture, as described below under the heading Convertible Securities .

### Options

On May 23, 2012 our board of directors adopted the global share incentive plan (2012) ( **Global Share Incentive Plan** (2012) ). Under the Global Share Incentive Plan (2012), 12,000,000 shares of our common stock have been reserved for the grant of options, which may be issued at the discretion of our board of directors from time to time. Under this plan, each option is exercisable into one share of our common stock. As of March 5, 2014, we have issued 9,162,014 options under the Global Share Incentive Plan (2012) and 2,781,905 options outside of our Global Share Incentive Plan (2012).

On February 25, 2014, Sav DiPasquale exercised 623,806 options at a price of \$0.001 per share.

The options may be exercised after vesting and in accordance with the vesting schedule which will be determined by our board of directors for each grant. The maximum contractual life term of the options is 10 years. The fair value of each stock option grant is estimated at the date of grant using the Black and Scholes option pricing model. The expected term is equal to the contractual life, based on management estimation for the expected dates of exercising of the options.

# **Convertible Securities**

In March 2013, we entered into a loan and warrant subscription agreement with Mediapark. We received a loan (the **Loan**) in the total amount of \$250,000. We also issued 100,000 warrants in consideration of the Loan (please see the discussion above under the heading Warrants). The Loan bears interest at an annual rate of 8%, which is calculated quarterly. The Loan currently matures on December 31, 2013. If we have not paid the Loan in full at the maturity date or, if extended, the extended maturity date, Mediapark has the right of conversion in respect of the total outstanding amount of the Loan including accrued interest as of the conversion date into common shares, at a price per common share equal to the lower of: (1) \$0.75 and (2) the value of weighted average price for the five trading days prior to the date of conversion. On June 30, 2013 and September 30, 2013, we exercised our discretion to extend the maturity date of the loan to September 30, 2013 and December 31,2013. In return for extending the maturity date, we issued to Mediapark additional 200,000 Warrants at an exercise price of \$0.50 per warrant.

On December 6, 2013, we entered into a convertible loan agreement with Mediapark pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the **Debenture**) in the aggregate principal amount of \$100,000. Interest is calculated semi-annually and is payable, along with the principal on or before December 6, 2014.

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

On March 4, 2014, we issued 1,128,849 units in a non-brokered private placement. Each unit consisted of one share of our common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years. As a result, we had \$370,772 including principle and interest outstanding as at March 3, 2014 due to Mediapark and have issued to Mediapark 713,023 shares of common stock at a price of \$0.52 and 713,023 warrants to acquire additional shares of our common stock at a price of \$0.52 per share for a period of our indebtedness.

## **Change in Control**

There are no provisions in our certificate of incorporation or 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 subsidiary, such as merger, reorganization, tender offer, sale or transfer of substantially all of our assets, or liquidation.

### INTEREST OF NAMED EXPERTS AND COUNSEL

The financial statements as of November 30, 2013 and November 30, 2012 and for the years ended included in this Prospectus have been so included in reliance on the report of Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, which contains an explanatory paragraph relating to our company's ability to continue as a going concern as described in Note 1a to the financial statements, given on the authority of said firm as experts in auditing and accounting.

Clark Wilson LLP, of Suite 900 885 West Georgia Street, Vancouver, British Columbia, Canada has provided an opinion on the validity of the shares of our common stock being offered pursuant to this prospectus.

No expert named in the registration statement of which this prospectus forms a part as having prepared or certified any part thereof (or is named as having prepared or certified a report or valuation for use in connection with such registration statement) or counsel named in this prospectus as having given an opinion upon the validity of the securities being offered pursuant to this prospectus or upon other legal matters in connection with the registration or offering such securities was employed for such purpose on a contingency basis. Also at the time of such preparation, certification or opinion or at any time thereafter, through the date of effectiveness of such registration statement or that part of such registration statement to which such preparation, certification or opinion relates, no such person had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in our company or any of its parents or subsidiaries. Nor was any such person connected with our company or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer or employee.

# INFORMATION WITH RESPECT TO OUR COMPANY

### **DESCRIPTION OF BUSINESS**

### **Corporate History**

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

Effective August 31, 2011, we completed a merger with our subsidiary, Orgenesis Inc., a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we changed our name from Business Outsourcing Services, Inc. to Orgenesis Inc.

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

#### **Our Current Business**

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

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license patents and knowhow related to the development of AIP cells.

Based on the licensed knowhow and patents, our intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using a therapeutic agent (i.e., PDX-1, or additional pancreatic transcription factors in adenovirus-vector) that efficiently converts a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. The development of AIP cells is based on the licensed patents and knowhow. We believe that our major competitive advantage is in our cell transformation technology.

This technology was licensed based on the published work of Prof. Ferber. Prof. Ferber has developed this technology, as a researcher in Tel Hashomer, and has established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells in liver and convert them into pancreatic beta cell like cells. Furthermore, those cells were found to be resistant to the autoimmune attack.

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

## The License Agreement

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

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

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

16% of all sublicensing fees.

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

Milestone payments as follows:

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

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

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

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

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

If, THM chooses not to receive any consideration as a result of an Exit, THM shall be entitled to continue to receive all the rights and consideration it is entitled to pursuant to the License Agreement (including, without limitation, the exercise of the rights pursuant to future Exit events), and any agreement relating to an Exit event shall be subject to the surviving entity s and/or the purchaser s undertaking towards THM to perform all of our obligations pursuant to the License Agreement. If THM chooses to receive the consideration as a result of an Exit, the Royalty payments will cease.

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

We agreed to submit to THM a commercially reasonable plan which shall include all research and development activities as required for the development and manufacture of the Products, including preclinical and clinical activities until an FDA or any other equivalent regulatory authority s approval for marketing and including all regulatory procedures required to obtain such approval for each Product (a **Development Plan**), within 18 months from the date of the License Agreement. We must develop, manufacture, sell and market the Products pursuant to the milestones and time schedule specified in the Development Plan. In the event we fail to fulfill the terms of the Development Plan, THM shall be entitled to terminate the License Agreement with a one year prior written notice, provided that during such year we do not cure the breach of the Development Plan. We anticipate that we will submit the Development Plan in March 2014.

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

We materially change our business.

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

- o granting of sublicenses;
- o confidentiality provisions;
- o perform payments to THM; and
- o indemnity and insurance.

We have challenged, challenge, or cause any third party to challenge, the intellectual property rights or other rights of THM to the Licensed Information anywhere in the world.

We may terminate the License Agreement and return the Licensed Information to THM only in the following events:

the development and/or manufacture of the Licensed Information is not successful according to the scientific criteria acceptable in the relevant field of the invention;

if the registration and/or defense of a patent is not successful, in any country for reasons not dependent upon us;

the development and/or manufacture of the Licensed Information is not approved by the proper regulation procedures as mandated under the relevant laws for reasons not dependent upon us; or

an external specialist in the field of the Product(s) determined in a reasoned and explained written opinion that there is insufficient market demand for the Products and such written opinion was provided to THM. *Development* 

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

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

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

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

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

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

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

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

## Marketing

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

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

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

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

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

### Future Products

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

### Market

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

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

## Competition

Insulin therapy is used for Insulin Dependent Diabetes Mellitus (IDDM) patients who are not controlled with oral medications, but this therapy has some disadvantages. Weight gain is a common side effect of insulin therapy, which is a risk factor for cardiovascular disease. Injection of insulin causes pain and inconvenience for patients. Patient compliance and inconvenience of self-administering multiple daily insulin injections is also considered a disadvantage of this therapy. The most serious adverse effect of insulin therapy is hypoglycemia.

The global diabetes market comprising the insulin, insulin analogues and other antidiabetic drugs has been evolving rapidly. A look at the diabetes market reveals that it was dominated by a handful of participants such as Novo Nordisk A/S, Eli Lilly and Company, Sanofi-Aventis, Takeda Pharmaceutical Company Limited, Pfizer Inc., Merck KgaA, and Bayer AG.

### Threats from pancreas islet transplantation and cell therapies

#### Transplant procedure

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

Transplants are often performed by a radiologist, who uses x-rays and ultrasound to guide placement of a catheter a small plastic tube through the upper abdomen and into the portal vein of the liver. The islets are then infused slowly through the catheter into the liver. The patient receives a local anesthetic and a sedative. In some cases, a surgeon may perform the transplant through a small incision, using general anesthesia.

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

#### Studies and reports

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

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

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

In a 2006 report of the Immune Tolerance Network s international islet transplantation study, researchers emphasized the value of transplantation in reversing a condition known as hypoglycemia unawareness. People with hypoglycemia unawareness are vulnerable to dangerous episodes of severe hypoglycemia because they are not able to recognize that their blood glucose levels are too low. The study showed that even partial islet function after transplant can eliminate

hypoglycemia unawareness.

Pancreatic islet transplantation (cadaver donors) is an allogeneic transplant, and as in all allogeneic transplantations there is a risk for graft rejection and patients must receive lifelong immune suppressants. Though this technology has shown good results clinically there are several setbacks, such as patients being sensitive to recurrent T1DM autoimmune attacks and a shortage in tissues available for islet cells transplantation.

#### Human Embryonic Stem Cells (ESC)

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

#### **Our** Advantages

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

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

We are aware of no other company focused exclusively on development of AIP cells. The pharmaceutical industry is fragmented and it is a competitive market. We compete with many pharmaceutical companies, both large and small and there may be technologies in development of which we are not aware.

### **Research and Development Expenditures**

We incurred \$1,452,456 in research and development expenditures in the last fiscal year. We intend to dedicate most of our capital to research and development with no expectation of revenue from product sales in the foreseeable future.

#### Employees

We intend to hire additional staff and to engage consultants in general administration. We also intend to engage experts in healthcare and in general business to advise us in various capacities. As of November 30, 2013, we had two full time employees and four part time employees located in Israel.

#### Subsidiaries

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

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

On October 11, 2013, Orgenesis Ltd. incorporated a wholly-owned subsidiary in Belgium, Orgenesis SPRL. We established a subsidiary in Belgium in order to coordinate the process development and manufacturing activities

together with the clinical studies in Europe, and later on to be our center for our activities in Europe.

The incorporation of Orgenesis SPRL followed a strategic decision in May 2013 to work with ATMI disposable bioreactors as the major component in our product manufacturing. Also, we made another strategic decision in September 2013 to work with Masthercell SPRL, a Belgium company, as our CMO (Contract Manufacturing Organization) in order to develop a manufacturing process and to manufacture our product. Both companies are located in Belgium. In addition, we are already conducting some portion of our process development with Fraunhofer IGB in Germany and all those activities will be coordinated through Orgenesis SPRL.

### **Intellectual Property**

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

Title	Country	Status	Serial No.	Patent No.	Filing Date	Issue Date
Methods of Inducing Regulated Pancreatic Hormone Production	Australia	Granted	50974/00	779619	01-June-2000	09-June-2005
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Australia	Granted	2004236573	2004236573	12-May-2004	04-Feb-2010
Methods of Inducing Regulated Pancreatic Hormone Production	Canada	Pending	2371995		01-June-2000	
Methods of Inducing Regulated Pancreatic Hormone Production	European Patent Convention	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	European Patent Convention	Published	04732369.6		12-May-2004	
Methods of Inducing Regulated Pancreatic Hormone Production	France	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production	Germany	Granted	00935435.8	60034781.8-08	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production	Italy	Granted	00935435.8	1180143	01-June-2000	09-May-2007
Methods of Inducing Regulated Pancreatic Hormone Production in	Japan	Published	2010-261850		12-May-2004	

Edgar Filing: Orgenesis Inc. - Form S-1/A

Non-Pancreatic Islet Tissues						
Methods of Inducing Regulated Pancreatic Hormone Production in Non-Pancreatic Islet Tissues	Japan	Published	2010-288937		01-June-2000	
Methods of Inducing Regulated Pancreatic Hormone Production	United Kingdom	Granted	00935435.8	1180143	01-June-2000	09-May-2007

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

**Government Regulations** 

We have not sought approval from the FDA for the AIP cells.

Among all forms of cell therapy modalities, we believe that autologous cell replacement therapy seems to be of the highest benefit. We believe that it seems to be safer than other options as it does not alter the host genome but only alters the set of expressed genetic information which seems to be highly specific to the reprogramming protocol. It provides an abundant source of therapeutic tissue, which is not rejected by the patient and does not have to be treated by immune suppressants. It is highly ethical since no human organ donations or embryo derived cells are needed. The proposed therapeutic approach does not need cells bio-banking at birth, which is both expensive and cannot be used for patients born prior to 2000.

Within the last decade, many studies published in leading scientific journals confirmed the capacity of reprogramming adult cells from many of our mature organs to either alternate organs or to stem like cells. The most widely used autologous cell replacement protocol is the one used for autologous implantation of bone marrow stem cells. This protocol is widely used in patients undergoing a massive chemotherapy session which destroys their bone marrow cells. However, the cell therapy protocol for cancer patients delineated above does not require extensive cell culture, in vitro. An additional autologous cell therapy approach already used in man is autologous chondrocyte implantation (ACI).

In the United States, Genzyme Corporation provides the only FDA approved ACI treatment: Carticel. The Carticel treatment is designated for young, healthy patients with medium to large sized damage to cartilage. During an initial

procedure, the patient s own chondrocytes are removed arthroscopically from a non-load-bearing area from either the intercondylar notch or the superior ridge of the medial or lateral femoral condyles.

To aid us in our efforts to achieve the highest level of compliance with FDA requirements, we have looked to hire experts in the field of pharmaceutical compliance.

#### Regulatory Process in the United States

Our product is subject to regulation as biological products under the Public Health Service Act and the Food, Drug and Cosmetic Act. The FDA generally requires the following steps for pre-market approval or licensure of a new biological product:

- Pre-clinical laboratory and animal tests conducted in compliance with the Good Laboratory Practice, or GLP, requirements to assess a drug s biological activity and to identify potential safety problems, and to characterize and document the product s chemistry, manufacturing controls, formulation, and stability;
- Submission to the FDA of an Investigational New Drug, or IND application, which must become effective before clinical testing in humans can begin;
- Obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials;
- Conducting adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with Good Clinical Practice, or GCP requirements;
- Compliance with current Good Manufacturing Practices, or cGMP regulations and standards;
- Submission to the FDA of a Biologics License Application, or BLA, for marketing that includes adequate results of pre -clinical testing and clinical trials;
- FDA reviews the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses; and
- Obtaining FDA approval of the BLA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent. The FDA may also require post marketing testing and surveillance of approved products, or place other conditions on the approvals.

# Regulatory Process in Europe

The European Union ( EU ) has approved a regulation specific to cell and tissue therapy product, the Advanced Therapy Medicinal Product (ATMP) regulation. For products such as our AIP that are regulated as an ATMP, the EU Directive requires:

- Compliance with current Good Manufacturing Practices, or cGMP regulations and standards, pre-clinical laboratory and animal testing;
- Filing a Clinical Trial Application (CTA) with the various member states or a centralized procedure; Voluntary Harmonization Procedure (VHP), a procedure which makes it possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries;
- Obtaining approval of Ethic Committees of research institutions or other clinical sites to introduce the AIP into humans in clinical trials;
- Adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; and
- Submission to EMEA for a Marketing Authorization (MA); Review and approval of the MAA (Marketing Authorization Application).

# Clinical trials

Typically, both in the U.S. and the European Union, clinical testing involves a three-phase process although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers or patients and are designed to provide information about product safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. Phase III clinical trials are generally large-scale, multi-center, comparative trials conducted with patients afflicted with a target disease in order to provide statistically valid proof of efficacy, as well as safety and potency. In some circumstances, the FDA or EMA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market. During all phases of clinical development, regulatory agencies require extensive

monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Monitoring all aspects of the study to minimize risks is a continuing process. All adverse events must be reported to the FDA or EMA.

### **DESCRIPTION OF PROPERTY**

#### **Principal Offices**

Our principal offices are located at 21 Sparrow Circle, White Plains, New York, 10605. We are presently benefitting from free rental space until such time as our operations ramp up. Once we attain the necessary funding and increase our employee base, we will look for more spacious facilities to meet our growing needs. We believe that this arrangement will be suitable for the next 12 months.

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

#### LEGAL PROCEEDINGS

We know of no material pending legal proceedings to which our company or our subsidiaries is a party or of which any of our properties, or the properties of our subsidiaries, is the subject. In addition, we do not know of any such proceedings contemplated by any governmental authorities.

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

### MARKET PRICE OF AND DIVIDENDS ON OUR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Market information

Our common stock is quoted on FINRA s OTC Bulletin Board under the symbol ORGS .

Set forth below are the range of high and low bid quotations for the period indicated as reported by the OTC Markets. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

Quarter Ended	Bid High	Bid Low
November 30, 2013	\$0.70	\$0.70
August 31, 2013	\$0.95	\$ 0.56
May 31, 2013	\$1.20	\$0.63
February 28, 2013	\$0.80	\$0.35
November 30, 2012	\$1.01	\$0.47
August 31, 2012	\$1.05	\$0.31
May 31, 2012	\$1.66	\$0.69
February 29, 2012	\$0.70	\$0.13
November 30, 2011 <sup>(1)</sup>	\$0.30	\$0.01
	31	

Quarter Ended	Bid High	Bid Low	
August 31, 2011 <sup>(1)</sup>	\$6.00	\$0.55	
May 31, 2011 <sup>(1)</sup>	\$1.25	\$1.25	
February 28, 2011 <sup>(1)</sup>	\$0.56	\$0.17	

<u>Note</u>

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

## **Transfer Agent**

The shares of our common stock are issued in registered form. The transfer agent and registrar for our common stock is Securities Transfer Corporation located at 2591 Dallas Parkway, Suite 102, Frisco, TX 75034.

# Holders of Common Stock

As of March 5, 2014, there were 25 holders of record of our common stock. As of such date, 53,860,299 shares were issued and outstanding.

# **Registration Rights**

On May 6, 2013, we entered into a subscription agreement with ATMI, pursuant to which ATMI purchased 1,526,718 units of our securities at a price of \$0.8515 per unit for total consideration of \$1,300,000. Each unit consists of one share of our common stock and one common share purchase warrant. Each warrant may be exercised pursuant to the terms of the warrant certificate for a period of two years from issuance at an exercise price of \$1.00, subject to adjustments as set out in the warrant certificate. On March 4, 2014, we issued 1,128,849 units in a non-brokered private placement. Each unit consisted of one share of our common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years. As of March 4, 2014, the warrants issued in May 2013 have an exercise price \$0.52 per share. In connection with the subscription agreement, we also entered into a registration rights agreement dated May 6, 2013, whereby we agree to provide notice to ATMI that we will register their shares if we file a registration statement with the Securities and Exchange. We are registering these securities in this registration statement.

# Dividends

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

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

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

• we would not be able to pay our debts as they become due in the usual course of business; or

• our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

### MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Our management s discussion and analysis of financial condition and results of operations provides a narrative about our financial performance and condition that should be read in conjunction with the audited financial statements of Orgenesis and its Subsidiaries for the period ended November 30, 2013 and related notes thereto included in this prospectus. This discussion contains forward looking statements reflecting our current expectations and estimates and assumptions about events and trends that may affect our future operating results or financial position. Our actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements due to a number of factors, including, but not limited to, those set forth in the sections of this prospectus titled Risk Factors beginning at page 6 above and Forward-Looking Statements beginning at page 12 above.

#### **Results of Operations**

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

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

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

#### Revenue

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

### Research and Development Expenses

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

The decrease in total research and development expenses is mainly due to the decrease in stock-based compensation expenses and patents registration. The decrease in patent registration expenses is due to one-time non-cash compensation granted to our patents lawyers on February 2, 2012 in the amount of \$509,622. The decrease in

stock-based compensation expenses is due to options that was granted to an employee in the prior period and was fully vested in February 2013. The increase in professional and consulting is mainly due to development services in Europe.

#### General and Administrative Expenses

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

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

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

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

#### Financial Expenses

#### Year ended November 30,

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

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

### Liquidity and Financial Condition

#### Working Capital

	November 30, 2013	November 30, 2012	Percentage Increase
Current Assets	\$ 97,737	\$ 38,598	153 %
<b>Current Liabilities</b>	\$ 986,409	\$ 327,170	201 %
Working Capital			
(Deficiency)	\$ (888,672)	\$ (288,572)	208 %

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

Cash Flows

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

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

# **Recent Financings**

# Agreements with Kodiak Capital Group, LLC

We have entered into a \$3 million common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beach-based institutional investor (**Kodiak**). This registration statement registers up to7,300,000 of the shares that may be issued to Kodiak under the terms of the common stock purchase agreement. After the SEC has declared the registration statement related to the transaction effective, we have the right at our sole discretion over a period of one year to sell up to \$3 million of common stock under the terms set forth in the agreement. Proceeds from this transaction will be used to fund our research and development and for working capital. In connection with the entering of the stock purchase agreement, we have paid a commitment fee by issuing 250,000 shares in restricted common shares of our company to Kodiak.

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

# Loan Agreement with Mediapark A.G.

On December 6, 2013, we entered into a convertible loan agreement with Mediapark A.G., a Marshall Islands company ( **Mediapark** ), pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the **Debenture** ) in the aggregate principal amount of US \$100,000. Interest is calculated semi-annually and is payable, along with the principal on or before December 6, 2014.

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

We currently have outstanding another 8% unsecured convertible loan with Mediapark in the amount of US \$250,000.

On March 4, 2014, we issued 1,128,849 units in a non-brokered private placement. Each unit consisted of one share of our common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years. As a result, we had \$370,772 including principle and interest outstanding as at March 3, 2014 due to Mediapark and have issued to Mediapark 713,023 shares of common stock at a price of \$0.52 and 713,023 warrants to acquire additional shares of

our common stock at a price of \$0.52 per share for a period of three years in full payment of our indebtedness.

### **Going Concern**

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

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

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

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

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

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

### **Future Financing**

We will require additional funds to implement our growth strategy for our new business. These funds may be raised through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of our shares.

There can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. If we are not able to obtain the additional financing on a timely basis should it be required, or generate significant material revenues from operations, we will not be able to meet our other obligations as they become due and we will be forced to scale down or perhaps even cease our operations.

### **Off-Balance Sheet Arrangements**

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

### **Significant Accounting Policies**

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

## Income Taxes

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

## Stock-Based Compensation

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

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

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

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

### Warrants classified as liabilities

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

The fair value of the warrants is determining by using a Monte Carlo type model based on a risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issue dates, then for each path to use the Black-Scholes model to estimate the value of the warrants on the last issue date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant delay in this input would result a higher fair value measurement.

## FINANCIAL STATEMENTS ORGENESIS INC. (A development stage Company)

# CONSOLIDATED FINANCIAL STATEMENTS

# AS OF NOVEMBER 30, 2013

## TABLE OF CONTENTS

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

27

Page

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM To the Shareholders of ORGENESIS INC. (A Development Stage Company)

We have audited the accompanying consolidated balance sheet of Orgenesis Inc. (A Development Stage Company) and its subsidiaries (the Company ) as of November 30, 2013 and 2012, and the related consolidated statements of comprehensive loss, changes in stockholders deficiency and cash flows for the years then ended and cumulatively, for the period from June 5, 2008 (inception date) to November 30, 2013. These financial statements are the responsibility of the Company's board of directors and management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, based upon our audit, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of November 30, 2013 and 2012, and the consolidated results of its operations and its cash flows for the years then ended and cumulatively, for the period from June 5, 2008 (inception date) to November 30, 2013, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1a to the financial statements, the Company has recurring losses for the period from inception through November 30, 2013 and presently the Company does not have sufficient cash and other resources to meet its requirements in the following twelve months. These factors raise substantial doubt as to the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1a. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

	<u>/s/ Kesselman &amp; Kesselman</u>
Tel-Aviv, Israel	Kesselman & Kesselman
February 19, 2014	Certified Public Accountants (Isr.)
	A member firm of PricewaterhouseCoopers International Limited

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

F-1

# ORGENESIS INC. (A development stage Company)

# CONSOLIDATED BALANCE SHEETS U.S. dollars

		November 30, 2013		November 30, 2012
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	\$	50,827	\$	347
Short term deposits		10,002		10,002
Prepaid expenses and other accounts receivable (Note 6)		36,908		28,249
Total current assets	\$	97,737	\$	38,598
FUNDS IN RESPECT OF RETIREMENT BENEFIT				
OBLIGATION	\$	3,630	\$	1,296
	\$	12,854	\$	8,273
PROPERTY AND EQUIPMENT, NET (Note 7)				
Total assets	\$	114,221	\$	48,167
Liabilities net of Stockholders' deficiency				
CURRENT LIABILITIES:				
A	¢	120 775	¢	125 701
Accounts payable	\$	138,775	\$	135,791
Accrued expenses		386,122		73,138
Employees and related payables		155,100 42,362		75,879
Related parties Loan (Note 4)		42,302 264,050		42,362
Total current liabilities	\$	986,409	\$	327,170
Total current naointies	φ	960,409	φ	527,170
LONG-TERM LIABILITIES				
Warrants (Note 8)	\$	1,157,954	\$	_
Retirement benefit obligations	Ψ	4,272	ψ	1,553
Total long-term liabilities	\$	1,162,226	\$	1,553
Commitments (Note 2)	Ψ	1,102,220	Ψ	1,555
Total liabilities	\$	2,148,635	\$	328,723
	Ŷ	2,1 10,000	Ŷ	020,120
STOCKHOLDERS' DEFICIENCY:				
Common stock of \$0.0001 par value - authorized: 1,750,000,00	00			
shares at				
November 30, 2013 and 2012; issued and outstanding:				
51,144,621 and				
49,117,903 shares at November 30, 2013 and 2012,				
respectively		5,114		4,912
Additional paid-in capital		8,635,447		4,850,348
Deficit accumulated during the development stage		(10,674,975)		(5,135,816)

Total Stockholders' deficiency		(2,034,414)	(280,556)
Total liabilities net of Stockholders' deficiency	\$	114,221 \$	48,167
The accompanying notes are an integral part of the	nese consoli	dated financial statem	ents.

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS U.S. dollars

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

F-3

# **ORGENESIS INC.**

(A development stage Company)

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

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

F-4

# ORGENESIS INC. (A development stage Company)

## CONSOLIDATED STATEMENTS OF CASH FLOWS U.S. dollars

	Year e Novem 2013		Period from June 5, 2008 (inception date) through November 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(5,539,159)\$	(4,998,143)\$	(10,674,975)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Write-off of website development costs	-	_	15,000
Stock-based compensation expenses related to options granted to employees	2,795,655	2,976,922	5,772,577
Stock-based compensation expenses related to options granted to consultants	316,312	242,055	558,367
Increase in accrued severance pay, Net	2,719	1,553	4,272
Shares issued for services rendered	6,144	509,622	515,766
Depreciation	3,257	1,406	4,663
Depresation	5,257	1,400	7,005
Change in fair value of warrants liabilities	(133,316)	-	(133,316)
Interest expenses due to loan	172,510	-	172,510
Changes in operating assets and liabilities:	, 0		;= - = = =
Increase in prepaid expenses and accounts receivable	(8,659)	(27,184)	(36,908)
Increase in accounts payable	2,984	91,278	138,775
Increase in accrued expenses	312,984	68,138	386,122
Increase in related parties	- ,	6,862	42,362
Increase in employees and related payables	79,221	75,879	155,100
I J I I I I I I I I I I I I I I I I I I	,	· - ) - · -	,
Net cash used in operating activities	(1,989,348)	(1,051,612)	(3,079,685)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(7,838)	(9,679)	(17,517)
Website development costs	(7,050)	(9,079)	(17,517) (15,000)
Investment in short term deposits		(10,002)	(10,002)
Amounts funded in respect of retirement benefits obligations	(2,334)	(10,002) (1,296)	(3,630)
Net cash used in investing activities	(10,172)	(20,977)	(46,149)
	(10,172)	(20,777)	(+0,1+2)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from Warrants and shares issued for cash	1,800,000	1,071,661	2,926,661
Proceeds from loan received and warrants issued for cash	250,000	-	250,000
Net cash provided by financing activities	2,050,000	1,071,661	3,176,661
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	50,480	(928)	50,827
HIGHLIGE (DECKERGE) III CASH AND CASH EQUIVALENIS	50,700	(720)	50,027

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		347	1,275	-	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$	50,827 \$	347 \$	50,827	
The accompanying notes are an integral part of these consolidated financial statements.					

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1 SIGNIFICANT ACCOUNTING POLICIES:

#### **a.** General:

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

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

On February 2, 2012, the Subsidiary entered into an agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the Licensor ). The Subsidiary was granted a worldwide royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

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

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

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

The Group is engaged in research and development in the biotechnology field and is considered a development stage Company in accordance with ASC Topic 915 Development Stage Entities . The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (June 5, 2008) through November 30, 2013, of \$10,674,975 as well as a negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following November 30, 2013. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that the Company will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders, including via future exercise of 2,926,718 warrants for a total amount of \$1,543,893 as mentioned in note 3(b). During December 2013, the company raised capital of \$445,000. See note 14(4)

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability. If the Company is unsuccessful in raising additional financing, it may need to curtail, discontinue or cease operations.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

### b. Basis Of Presentation

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

## c. Use of estimates in the preparation of financial statements

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the financial statements date and the reported expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the valuation of stock based compensation and warrants issued.

## d. Research and development

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, stock-based compensation expenses, payroll taxes and other employees' benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

## e. Principles of consolidation

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

## f. Functional currency

The currency of the primary economic environment in which the operations of the Company and its subsidiaries are conducted is the US dollar (\$ or dollar). The Belgium Subsidiary has only commenced immaterial operations.

Most of the Group's expenses are incurred in dollars and source of the Group's financing has been provided in dollars. Thus, the functional currency of the Company and its subsidiaries is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions exchange rates at transaction dates or average rates and (2) for other items (derived from non-monetary balance sheet items such as depreciation) historical exchange rates. The resulting transaction gains or losses are carried to financial income or expenses, as appropriate.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

## g. Income Taxes

1. Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. It is the Company s policy to classify interest and penalties on income taxes as interest expense or penalties expense. The Company has provided a full valuation allowance with respect to its deferred tax assets.

2. Uncertainty in income tax

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

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

## h. Stock-Based Compensation

The Company accounts for employee stock-based compensation in accordance with the guidance of ASC Topic 718, Compensation which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their grant date fair values. The fair value of the equity instrument is charged to compensation expense and credited to additional paid-in capital over the period during which services are rendered.

The Company follows ASC Topic 505-50, formerly EITF 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services, for stock options and warrants issued to consultants and other non- employees. In accordance with ASC Topic 505-50, these stock options issued as compensation for services provided to the Company are accounted for based upon the fair value of the options. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

## i. Warrants issued as part of capital raisings that are classified as a liability

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

### j. Fair value measurement:

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

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

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

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

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

## k. Property and equipment

Property and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the assets.

Annual rates of depreciation are as follows:

Computers	33%
Lab equipment	15%
Office furniture	6%

## **l.** Loss per common stock

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

## m. Concentration of credit risk

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (continued):

## n. Newly issued and recently adopted Accounting Pronouncements

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

# NOTE 2 COMMITMENTS

1. On February 2, 2012 the Subsidiary entered into a licensing agreement with the Licensor. According to the agreement, the Subsidiary was granted a worldwide royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

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

- a. A royalty of 3.5% of net sales.
- b. 16% of all sublicensing fees received.
- c. An annual license fee of \$15,000, which commenced on January 1, 2012 and shall be paid once every year thereafter (the "Annual Fee"). The Annual Fee is non-refundable, but it shall be credited each year due, against the royalty noted above, to the extent that such are payable, during that year.
- d. Milestone payments as follows:
  - 1. \$50,000 on the date of initiation of phase I clinical trials in human subjects;
  - 2. \$50,000 on the date of initiation of phase II clinical trials in human subjects;
  - 3. \$150,000 on the date of initiation of phase III clinical trials in human subjects;
  - 4. \$750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA.
  - 5. \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time, (The "Sales Milestone").

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

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Subsidiary of the Company and/or consolidation of the Subsidiary or the Company into or with another corporation ("Exit"), the

Licensor shall be entitled to choose whether to receive from the Company a one-time payment based, as applicable, on the value of either 5,563,809 shares of Common Stock of the Company at the time of the Exit or the value of 1,000 shares of common stock of the Subsidiary at the time of the Exit.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## **NOTE 2 COMMITMENTS** (continued):

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

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

- 3. On February 2, 2012, the Company entered into a consultancy agreement with Weinberg Dalyo Inc., for financial consulting services for a consideration of \$3,000 per month. During the period of this agreement, if the consultant locates an investor, which the Company enters into a binding investment agreement, the consultant is entitled to a bonus of 1.5% from the total investment in cash. During 2013 the fee has been updated to \$12,500 per month.
- 4. On February 2, 2012, the Subsidiary entered into an employment agreement (the Ferber Employment Agreement ) with Prof. Sarah Ferber. Pursuant to the Ferber Employment Agreement, Prof. Ferber agrees to serve as our Chief Scientific Officer. Prof. Ferber will be paid a gross salary of NIS (Israeli shekel) 36,000 per month, which is approximately \$10,217 based on an exchange rate of 1 NIS equals \$0.2838 as of November 30, 2013. In the event the Company completes a financing of at least \$1,000,000 (in addition to the \$1.5 million private placement in February 2012), Prof. Ferber s salary will double. On May 6 2013, the Company completed a financing of over \$1,000,000, therefore. Prof. Ferber will be paid a gross salary of NIS (Israeli shekel) 72,000 per month, which is approximately \$20,433 based on an exchange rate of 1 NIS equals \$0.2838 as of November 30, 2013.
- 5. On February 2, 2012, the Subsidiary entered into a compensation agreement (the Caplan Compensation Agreement ) with Ms. Caplan. Pursuant to the Caplan Compensation Agreement, Ms. Caplan agrees to serve as a director of our Company. Ms. Caplan will be paid a gross salary of NIS (Israeli shekel) 10,000 per month, which is approximately \$2,838 based on an exchange rate of 1 NIS equals \$0.2838 as of November 30, 2013. In the event the Company completes a financing of at

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

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

F-11

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## **NOTE 2 COMMITMENTS:** (continued):

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

On October 23, 2013, 255,413 performance options were granted to Mr. Dipasquale based on his agreement. See also note 5(9) and note 14(3).

- 11. On March 27, 2013, the Company signed an agreement with Mintz Levin, its patent attorneys, in which 16% of its fees will be converted to shares of the Company at market price. A total of \$6,144 will be converted into common shares. As of November 30, 2013 the issuance of shares has not yet occurred.
- 12. On May 6, 2013 the Subsidiary entered into a Process Development Agreement with ATMI BVBA, a Belgium Company which is a wholly owned subsidiary of Advanced Technology Materials, Inc. ( ATMI ), a US publicly traded company. According to the agreement ATMI will provide services in cell research. The Company will use ATMI's unique technology while the Company will provide to ATMI the required materials for purpose of the study. According to the agreement the Company will pay per achieved phase, as defined in the agreement, with total consideration of Euro 606,500 for all

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 3 STOCKHOLDERS' DEFICIENCY:

#### a. Share capital:

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

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

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

## b. Financing:

- 1. In 2012, the Company completed a private placement with Derby Management LLC for total consideration of \$1,100,000 for 1,100,000 shares of common stock and 1,100,000 common stock warrants at purchase price of \$1.00 per share.
- 2. In December 2012, the Company entered into a subscription agreement with Derby for the issuance of 500,000 units for a total consideration of \$500,000. Each unit is comprised of one share of the Company's Common Stock and two non-transferable Common Stock warrants. Each Common Stock warrant ("December Warrants") can be exercised into one share at a purchase price of \$0.50 per warrant and is exercisable until November 30, 2014. See also Note 8.

In connection with this agreement, the 1,000,000 Warrants issued in July 2012 were cancelled. F-13

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## **NOTE 3 STOCKHOLDERS' EQUITY (continued):**

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

# NOTE 4 LOAN

 In March 2013, the Company entered into a loan and warrant subscription agreement with Mediapark A.G., a Marshall Islands Company (Mediapark). The Company received a loan (the Loan) in the total amount of \$250,000 and issued to the investor 100,000 warrants (March Warrant). Each Common Stock warrant can be exercised into one share at a purchase price of \$0.50 per warrant and is exercisable until March 22, 2015. See also Note 8.

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

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

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

- 2. On June 30, 2013 the Company exercised its discretion to extend the maturity date of the loan to September 30, 2013, In return for extending the maturity date, the Company issued to Mediapark additional Warrants at an exercise price of \$0.50 per warrant. The fair value of the warrants was \$48,800 based on Monte Carlo pricing-model. See also Note 8.
- 3. On September 30, 2013, the Company extended the maturity date of a loan from Mediapark to December 31, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of \$0.50 per share until September 30, 2015. The fair value of the warrants was \$46,000 based on Monte Carlo pricing-model. See also Note 8 and Note 14.2.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 5 STOCK BASED COMPENSATION

## 1. Global Share Incentive Plan:

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

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

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

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

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

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

F-15

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 5 STOCK BASED COMPENSATION (continued):

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

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

The fair value of each option grant is estimated on the date of grant using the Black Scholes option-pricing model with the following assumptions:

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

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

	201	3	201	2	
	Number Of Options	Weighted Average exercise price \$	Number of options	Weighted Average exercise price \$	
Options outstanding at the					
beginning of the year	10,315,815	0.297	-	-	
Changes during the year:					
Granted	1,978,950	0.96	10,315,815	0.297	
Expired	-	-	-	-	
Options outstanding at end of the year	12,294,765	0.265	10,315,815	0.297	
Options exercisable at end of the year	6,611,982	0.20	2,781,905	0.17	
-	F-16				

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 5 STOCK BASED COMPENSATION (continued):

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

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

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

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

Exercise prices	Number of exercisable options	Total Exercise value
\$		\$
0.0001	2,781,905	278
0.001	1,924,556	1,925
0.69	1,622,778	1,119,717
0.79	188,504	148,918
0.85	94,240	80,104
	6,611,982	1,350,942
	F-17	1

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 5 STOCK BASED COMPENSATION (continued):

### **Options granted to non-employees:**

- 1. On April 14, 2012, 471,200 options were granted to Dr. G. Alexander (Zan) Fleming, the Company's advisor, at an exercise price of \$1.40 per share. The options vest in five equal annual installments from the date of grant and expire on April 14, 2022. The fair value of these options as of the date of grant is \$564,907 using the Black and Scholes option-pricing model.
- 2. On June 4, 2012, 706,904 options were granted to Mr. Dov Weinberg, the Company's CFO, at an exercise price of \$0.69 per share. The options vest in four equal semi annual installments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant is \$500,678 using the Black and Scholes option-pricing model.
- 3. On November 21, 2012, 100,000 options were granted to Camillo Ricordi, a consultant for the Company, at an exercise price of \$0.61 per share. The options vest in five equal annual installments from the date of grant and expire on November 21, 2022. The fair value of these options as of the date of grant is \$64,513 using the Black and Scholes option-pricing model.
- 4. On August 2, 2013, 100,000 options were granted to Prof. Skyler, one of the Company's board advisors, at an exercise price of \$0.96 per share. The options vest in five equal annual installments from the date of grant and expire on April 4, 2023. The fair value of these options as of the date of grant was \$65,620 using the Black and Scholes option-pricing model.

The fair value of each option grant is estimated on the date of grant using the Black Scholes option-pricing model with the following assumptions:

	For options granted during the year ended November 30 2013	For options granted during the year ended November 30, 2012
Expected option life (years)	10.0	10.0
Expected stock price volatility (%)	97.1	104- 110
Risk free interest rate (%)	2.63	1.51-1.62
Expected dividend yield (%)	0.0	0.0
	F-18	

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 5 STOCK BASED COMPENSATION (continued):

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

	201	3	201	2
	Weighted Number Average of Exercise options Price		Number of options	Weighted Average exercise price \$
Options outstanding at the				
beginning of the year	1,278,104	0.95	-	-
Changes during the year:				
Granted - at market price	100,000	0.96	1,278,104	0.95
Expired	-	-	-	-
Options outstanding at end of				
the year	1,378,104	0.95	1,278,104	0.95
Options exercisable at end				
of the year	644,418	0.79	176,726	0.69

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

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

Exercise prices \$	Number of outstanding options	Weighted average remaining contractual Life Years	Weighted average Exercise price	Aggregate intrinsic value \$
0.61	100,000	8.98	0.61	9,000
0.69	706,904	8.17	0.69	7,069
0.9	100,000	9.34	0.96	-
1.4	471,200	8.37	1.4	-
	1,378,104	8.38	0.95	16,069
		F-19		

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# NOTE 5 STOCK BASED COMPENSATION (continued):

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

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

# NOTE 6 PREPAID EXPENSES AND ACCOUNT RECEIVABLE

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

	\$ 36,908	\$ 28,249
DODEDT	NIEW	

# NOTE 7 PROPERTY AND EQUIPMENT, NET

		Year ended November 30, 2013 2012		
Cost:				
Office Furniture	\$	3,761 \$	2,841	
Lab Equipment		5,901	-	
Computers		7,855	6,838	
		17,517	9,679	
Less accumulated depreciation		4,663	1,406	
-				
	\$	12,854 \$	8,273	
F-2	20			

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

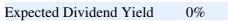
## **NOTE 8- WARRANTS:**

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

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

The fair value of each of the warrants described above is determined by using a Monte Carlo type model based on a risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issue dates, then for each path to use the Black-Scholes model to estimate the value of the warrants on the last issue date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant delay in this input would result a higher fair value measurement. As of November 30, 2013, these are the assumptions which were used for the model:

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



F-21

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

## NOTE 8- WARRANTS (continued):

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

	Fair value measurements at reporting date using					
		Level 3	T	'otal		
Warrants -						
November 30, 2013	\$	1,157,954	\$	1,157,954		

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

	November 30 2013
Carrying value at the beginning of the year	-
Additional warrant liabilities issued	1,291,270
Changes in fair value of warrant liabilities	(133,316)
Carrying value at the end of the year	\$ 1,157,954
F-22	

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# NOTE 9 RESEARCH AND DEVELOPMENT EXPENSES

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

## NOTE 10 GENERAL AND ADMINISTRATIVE EXPENSES

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

# NOTE 11 FINANCIAL EXPENSES, NET

		Year ended November 30,	
		2013	2012
Interest expenses due to loan	\$	172,510 \$	-
Changes in fair value of warran	its	(133,316)	-
Foreign exchange loss -net		33,761	7,069
Bank commissions - net		5,702	2,515
Total	\$	78,657 \$	9,584
	F-23		

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 12 TAXES ON INCOME

#### a. The Company

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

## b. The Subsidiary

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

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

## c. Tax losses carried forward to future years

#### 1. The Company

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

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

## 2. The Subsidiary

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

#### d. Deferred income taxes:

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

## Net deferred tax assets

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forwards losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not more likely than not achievable, the Company recorded a full valuation allowance.

\_

F-24

## ORGENESIS INC. (A development stage Company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### NOTE 12 TAXES ON INCOME (continued)

#### e. Reconciliation of the theoretical tax expense to actual tax expense

The main reconciling item between the statutory tax rate of the Company and the effective rate is the provision for full valuation allowance in respect of tax benefits from carry forward tax losses due to the uncertainty of the realization of such tax benefits (see above).

## f. Tax assessments

#### 1. The Company

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

#### 2. The Subsidiary

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

g. As of November 30, 2013 the Company has not accrued a provision for uncertain tax positions.NOTE 13 RELATED PARTIES

	Year ended	Novem	ıber 30,
	2013		2012
a. Management and consulting fees to the			
Chairman of the Board.	\$ 140,037	\$	22,679
b. Compensation to the non- executive directors			
(except the Chairman of the Board)	\$ 40,648	\$	27,344

c. With respect to options granted and salary paid to the Company s Chief Executive Officer, see Note 5(3).

- d. With respect to options granted to the Company s board members. See Note 5.
- e. On June 2, 2012 the Company signed a promissory note with Guilbert Cuison, one of the Company's shareholders. According to the note, the Company will return the loan granted by the shareholder within thirty days from the date the Company completes on equity financing resulting in gross proceeds to the Company of at least \$3,000,000.

F-25

# **ORGENESIS INC.** (A development stage Company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **NOTE 14 - SUBSEQUENT EVENTS**

- 1. During December 2013, the Company entered into a \$3,000,000 common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beach-based institutional investor (Kodiak). The Company have agreed to file a registration statement with the U.S. Securities & Exchange Commission (SEC) covering the shares that may be issued to Kodiak under the terms of the common stock purchase agreement. After the SEC has declared the registration statement related to the transaction effective, the Company has the right at its sole discretion over a period of one year to sell up to \$3,000,000 million of common stock under the terms set forth in the agreement. Proceeds from this transaction will be used to fund research and development and working capital. In December 2013, the Company issued to Kodiak 250,000 commitment shares.
- 2. On December 6, 2013, the Company entered into a convertible loan agreement with Mediapark A.G., a Marshall Islands Company (Mediapark), pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the Debenture) in the aggregate principal amount of \$100,000. Interest is calculated semi-annually and is payable, along with the principal on or before December 6, 2014. According to the agreement, in the event the Company completes an equity financing prior to the Maturity Date for gross proceeds of \$350,000 or more comprising Common Shares and/or warrants to purchase additional Common Shares, Mediapark will convert the Companies' Indebtedness into Common Shares and/or warrants on the same terms as the New Equity Financing. See also note 4 and note 14(4).
- 3. On December 23, 2013, the President and Chief Executive Officer, Sav DiPasquale, resigned. On the same date, the Company appointed the Chairperson of the Board as Interim President and Chief Executive Officer of the Company until a replacement is named. As a result of his resignation all options that were not vested are forfeited. All vested options expire 90 days after the date of cessation of employment.
- 4. In December 2013, the Company entered into a private placement agreement with new investors for up to \$1,000,000 in value of units (Units) each consisting of one Common share (Share) and one share purchase warrant. Each warrant provides the investors the right to purchase one common share of the Company (a Warrant Share) for \$0.52 for a term of three years. As of February 19, \$445,000 was raised in connection with this agreement.

F-26

## CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

#### **Resignation of Independent Accountant.**

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

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

#### **Engagement of Independent Accountant.**

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

## DIRECTORS AND EXECUTIVE OFFICERS

#### **Directors and Executive Officers, Promoters and Control Persons**

As at March 5, 2014, our directors and executive officers, their age, positions held, and duration of such, are as follows:

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

Yaron Adler	Director	43	April 17, 2012
<u>Note</u>			

(1) Mr. BenArie resigned as President and Chief Executive Officer of our company on December 17, 2012. Mr. BenArie was appointed President and Chief Executive Officer of our company on February 2, 2012.

### **Business Experience**

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

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

Since 2008, Ms. Caplan has been Chief Executive Officer of Kamedis, a company focused on utilizing plant extracts for dermatology purposes. From 2004 to 2007, Ms. Caplan was Chief Executive Officer of GammaCan, a company focused on the use of immunoglobulins for treatment of cancer. During the previous five years, Ms. Caplan has been a director of the following companies: Opticul Ltd., a company involved with optic based bacteria classification; Inmotion Ltd., a company involved with self-propelled disposable colonoscopies; Nehora Photonics Ltd., a company involved with non-invasive blood monitoring; Ocure Ltd., a company involved with wound management; Eve Medical Ltd., a company involved with hormone therapy for Menopause and PMS; and Biotech Investment Corp., a company involved with prostate cancer diagnostics. Ms. Caplan has a M.Sc. in bio-medical engineering from Tel-Aviv University specialized in signal processing; management for engineers from Tel-Aviv University specialized in software and cad systems.

We believe Ms. Caplan is qualified to serve on our board of directors because of her education and business experiences, including her experience as a director of similar companies, as described above.

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

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

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

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

Prof. Sarah Ferber studied biochemistry at the Technion under the supervision of Professor Avram Hershko and Professor Aharon Ciechanover, winners of the Nobel Prize in Chemistry in 2004. She completed a post-doctoral fellowship at the Joslin Diabetes Lab at Harvard Medical School. Prof. Ferber s breakthrough discovery suggested that humans carry their own stem-cells throughout adulthood, thus obviating the need for embryonic stem cells for generating an organ in need. Most of the research was conducted in Prof. Ferber s lab, in the Endocrine Research Lab at the Sheba Medical Center, and currently employs 11 scientists. Prof. Sarah Ferber received TEVA, LINDNER, RUBIN and WOLFSON awards for this research. Prof. Ferber s research work has been funded over the past 10 years by the JDRF, the Israel Academy of Science foundation (ISF) and D-Cure.

#### Guy Yachin, Director

Guy Yachin is the CEO of NasVax Ltd., a company focused on the development of improved immunotherapeutics and vaccines. Prior to joining NasVax, Guy served as CEO of MGVS, a cell therapy company focused on blood

vessels disorders, leading the company through clinical studies in the US and Israel, financial rounds, and a keystone strategic agreement with Teva Pharmaceuticals. He was CEO and founder of Chiasma Inc., a biotechnology company focused on the oral delivery of macromolecule drugs, where he built the company s presence in Israel and the US, concluded numerous financial rounds, and guided the company s strategy and operation for over six years. Earlier he was CEO of Naiot Technological Center, and provided seed funding and guidance to more than a dozen biomedical startups such as Remon Medical Technologies, Enzymotec and NanoPass. He holds a BSc. in Industrial Engineering and Management and an MBA from the Technion Israel Institute of Technology.

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

## David Sidransky, Director

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

Dr. Sidransky has served as Vice Chairman of the Board of Directors, and was, until the merger with Eli Lilly, a director of ImClone Systems, Inc., a global biopharmaceutical company committed to advancing oncology care. He is serving or has served on the scientific advisory boards of MedImmune, Roche, Amgen and Veridex, LLC (a Johnson & Johnson diagnostic company), among others, and is currently on the board of KV Pharmaceutical, Rosetta Genomics and Champions Oncology, Inc. Dr. Sidransky served as Director (2005-2008) of the American Association for Cancer Research (AACR). He was the chairperson of AACR International Conferences (2006 and 2007) on Molecular Diagnostics in Cancer Therapeutic Development: Maximizing Opportunities for Personalized Treatment. Dr. Sidransky is the recipient of a number of awards and honors, including the 1997 Sarstedt International Prize from the German Society of Clinical Chemistry, the 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians, and the 2004 Richard and Hinda Rosenthal Award from the American Association of Cancer Research.

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

## Etti Hanochi, Director

Etti Hanochi (CPA Isr.) joined Nextage Ltd. as a Partner in 2010. Ms. Hanochi has extensive experience in mergers and acquisition transactions, accounting and tax consultations. Ms. Hanochi has broad experience in implementing internal procedures and controls and specializes in US GAAP. Under the role of Chief Financial Officer at Nextage, Ms. Hanochi has acted as VP Finance and CFO of several high-tech companies, including Intucell (acquired by Cisco in January 2013) and XtremIO (acquired by EMC in May 2012). Prior to joining Nextage Ltd., Ms. Hanochi worked as a Senior Manager at Ernst & Young for almost 11 years for many Hi-Tech public and private companies.

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

We believe Ms. Hanochi is qualified to serve on our board of directors because of her education and business experiences, including her experience as a director of similar companies, as described above.

## Yaron Adler, Director

In 1999 Mr. Adler co-founded IncrediMail Ltd. (NasdaqGM: MAIL) and served as its Chief Executive Officer until 2008 and President until 2009. In 1999, prior to founding IncrediMail, Mr. Adler consulted Israeli start-up companies regarding Internet products, services and technologies. Mr. Adler served as a Product Manager from 1997 to 1999, and as a software engineer from 1994 to 1997, at Tecnomatix Technologies Ltd., a software company that develops and markets production-engineering solutions to complex automated manufacturing lines that fill the gap between

product design and production, and which was acquired by UGS Corp. in April 2005. In 1993, Mr. Adler held a software engineer position at Intel Israel. He has a B.A. in computer sciences and economics from Tel-Aviv University.

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

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

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

### **Family Relationships**

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

#### **Significant Employees**

We do not have other significant employees.

#### **Committees of Board of Directors**

#### Board of Advisors

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

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

#### Dr. Fleming

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

Dr. Fleming is a board certified endocrinologist with medical and research training at Emory, Vanderbilt, and National Institutes of Health. He served as reviewer and supervisory medical officer for 12 years at the FDA and brings extensive clinical experience and regulatory responsibility in the therapeutic area of diabetes and other general metabolic, bone, and endocrine disorders, growth and development, nutrition, lipid-lowering compounds, and reproductive indications. He led reviews of landmark approvals including those of the first statin, insulin analog, metformin, PPAR-agonist, and growth hormone for non-GH deficiency indications. He was responsible for the regulation of the earliest biotech products including human insulin and growth hormone. Dr. Fleming helped to shape a number of FDA policies and practices related to therapeutic review and regulatory communication and represented the FDA at the International Conference on Harmonisation (ICH) and the World Health Organization, where he was stationed in 1992-93.

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

#### Prof. Ricordi

On November 14, 2012, we executed a consulting agreement with Professor Camillo Ricordi. Prof. Ricordi has agreed to be appointed to our Board of Advisors committee and we will pay Prof. Ricordi an hourly fee of \$300 for attending in person meetings and \$200 for attending meetings via conference call. We will also grant Prof. Ricordi 100,000 stock options. The options will be subject to our stock option plan and will have vesting provisions. Prof. Ricordi will also be reimbursed for out of pocket expenses incurred for carrying out consulting business.

The agreement is for an indefinite period unless terminated by either party with 30 days advance written notice to the other party.

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

#### Dr. Skyler

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

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

#### Nominating Committee

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

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

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

#### Audit Committee

On December 27, 2012, our company s board of directors formed an audit committee and adopted an Audit Committee Charter. According to its charter, the Audit Committee shall consist of at least one member, and a majority of members shall meet the independence requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended (the **1934 Act**). Also, one of the members shall qualify as an audit committee financial expert as defined by Rule 309 of the 1934 Act. The Audit Committee Charter describes the primary functions of the Audit Committee, including the following:

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

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

#### Audit Committee and Audit Committee Financial Expert

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

## Compensation Committee

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

- review and recommend to our board of directors the appropriate compensation level for our executive officers;
- oversee our compensation and benefit plans, policies and practices, including its executive compensation plans and incentive-compensation and equity-based plans;
- monitor and evaluate, at their sole discretion, matters relating to the compensation and benefits structure of our company; and
- take such other actions within the scope of the Compensation Committee s Charter as our board of directors may assign to the Compensation Committee from time to time or as the Compensation Committee deems necessary or appropriate.

#### **Potential Conflicts of Interest**

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

#### **Director Independence**

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

#### **Involvement in Certain Legal Proceedings**

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

- 1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- 2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- 3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- 4. being found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- 5. being the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of: (i) any federal or state securities or commodities law or regulation; or (ii) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or (iii) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- 6. being the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Securities Exchange Act of 1934), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

### **EXECUTIVE COMPENSATION**

#### **Summary Compensation**

The particulars of compensation paid to the following persons:

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

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Nonequity incentive plan compensation (\$)	Change in pension value and non- qualified deferred compensation earnings (\$)	All Other Compensation (\$)	Total (\$)
Jacob BenArie Former CEO & President <sup>1</sup>	2013 2012	204,891 141,200	Nil Nil	Nil Nil	474,174 381,545	Nil Nil	24,552 23,375	Nil Nil	703,617 546,120
Dov Weinberg <i>CFO</i> , <i>Treasurer</i> & <i>Secretary</i> <sup>2</sup>	2013 2012	126,600 47,000	Nil Nil	Nil Nil	231,936 201,203	Nil Nil	Nil Nil	Nil Nil	357,936 248,203
Sarah Ferber <i>Chief</i> <i>Scientific</i> <i>Officer</i> <sup>3</sup>	2013 2012	200,604 123,654	Nil Nil	Nil Nil	268,861 1,288,798	Nil Nil	34,706 26,120	Nil Nil	504,171 1,438,572
Sav DiPasquale Former President & CEO <sup>4</sup>	2013 2012	184,669 N/A	Nil N/A	Nil N/A	369,506 N/A	Nil N/A	Nil N/A	Nil N/A	554,175 N/A

#### <u>Notes</u>

(1) Mr. BenArie was appointed President and CEO on February 2, 2012 and resigned on December 17, 2012. On December 17, 2012, Mr. BenArie was appointed as President and CEO of our subsidiary.

(2) Mr. Weinberg was appointed Treasurer, CFO and Secretary on February 2, 2012.

(3) Prof. Ferber was appointed Chief Scientific Officer on February 2, 2012.

(4) Mr. DiPasquale was appointed President and CEO on December 17, 2012 and resigned on December 23, 2013. *Compensation Discussion and Analysis* 

On February 2, 2012, we entered into a consultancy agreement with Weinberg Dalyo Inc. for financial consulting services for a consideration of \$3,000 per month. Weinberg Dalyo Inc. is owned by our Chief Financial Officer, Mr. Weinberg. During the period of this agreement, if the consultant locates an investor, which we enter into a binding investment agreement, the consultant is entitled to a bonus of 2% from the total investment in cash. Due to additional work by Mr. Weinberg regarding the quarterly and annual filings of our company, due diligence with investors and financial work regarding fund raising, we have increased the compensation payable to Mr. Weinberg as follows: on

January 31, 2013, to \$9,000 per month, on April 30, 2013, to \$10,000 per month, on May 31, 2013, to \$11,000 per month, and on August 2013, to \$12,500 per month.

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

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

On December 17, 2012, Mr. Jacob BenArie resigned as President and Chief Executive Officer. There were no disagreements between Mr. BenArie and our company. Mr. BenArie retains his position as President and Chief Executive Officer of our operating subsidiary, Orgenesis Ltd.

On January 3, 2013, we executed an employment term sheet with Mr. Sav DiPasquale to act as our President and Chief Executive Officer to be effective December 17, 2012 in consideration for, among other things, an annual gross salary of US\$180,000. On February 17, 2013 we executed an employment agreement with Sav DiPasquale to act as our President and Chief Executive Officer, which formalized the term sheet dated December 17, 2012. The consideration for acting as our President and Chief Executive Officer, and working toward equity fundraising efforts is:

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

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

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

## Outstanding Equity Awards at Fiscal Year-End

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

	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options unexercisable (#)	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested (#)	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested (#)
Jacob BenArie	1,622,778	1,159,127	Nil	0.69	02/02/2022	Nil	Nil	Nil

	Ŭ	0 0			
		37	7		
		37			

	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options unexercisable (#)	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units or stock that have not vested (#)	E inc A aw nun sh un c righ ha ve
Dov Weinberg	530,178	176,726	Nil	0.69	02/02/2022	Nil	Nil	
Sarah Ferber	2,781,905	Nil	Nil	0.0001	02/02/2022	Nil	Nil	
Sav DiPasquale	255,413	1,473,537	Nil 38	0.001	23/03/2014 <sup>(1)</sup>	Nil	Nil	

<sup>(1)</sup> These options expire 90 days after the date that Mr. DiPasquale resigned. *Retirement or Similar Benefit Plans* 

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

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

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

## **Director Compensation**

The following table sets forth for each director certain information concerning his compensation for the year ended November 30, 2013.

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

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

On February 2, 2012, we entered into a compensation agreement (the **Caplan Compensation Agreement**) with Ms. Vered Caplan. Pursuant to the Caplan Compensation Agreement, Ms. Caplan agrees to serve as a director of our company. Ms. Caplan will be paid a gross salary of NIS (Israeli shekel) 10,000 per month, which is approximately \$2,689 based on an exchange rate of 1 NIS equals 0.2689 USD as of February 2, 2012. In the event we complete a financing of at least \$2,000,000, Ms. Caplan will be paid a one-time bonus of \$100,000. We also agreed to grant to Ms. Caplan stock options to purchase 3,338,285 shares of our common stock at a price per share equal to \$0.001. In the event we complete a financing of at least \$2,000,000, Ms. Caplan will be paid a one-time bonus of \$100,000. On May 6, 2013, we have completed a financing of over \$2,000,000 and recorded an expense of \$100,000.

On April 2, 2012, we entered into an agreement with Guy Yachin to serve as a member of our board of directors for a consideration of \$2,500 per month and an additional payment for every board meeting at the rate of \$300 for the first hour of attendance and \$200 for each additional hour or portion of an hour. In addition, we paid Mr. Yachin a signing bonus of \$5,000. We issued to Mr. Yachin stock options subject to the terms of our stock option plan, at an exercise price set at the time of the grant. We will also reimburse Mr. Yachin s pre-approved business expenses.

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

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

On July 17, 2013 we entered into an agreement with Dr. David Sidransky dated for reference July 17, 2013. Under the terms of the agreement, we have appointed Dr. Sidransky to our board of directors. In consideration of Dr. Sidransky s services we will pay for his attendance at Board meetings at the rate of \$300 for the first hour of attendance and \$200 for each additional hour or portion of an hour. We issued to Dr. Sidransky 250,000 stock options subject to the terms of our stock option plan, at an exercise price of \$0.85 per option share. We will also reimburse any pre-approved business expenses incurred by Dr. Sidransky.

## Outstanding Equity Awards at Fiscal Year-End

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

		C	Option awards				Stoc	k awards		
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested (#)	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested (#)		
Vered Caplan	1,669,143	1,669,143	Nil	0.001	02/02/2022	Nil	Nil	Nil		
Guy Yachin	94,240	376,960	Nil	0.85	04/06/2022	Nil	Nil	Nil		

		С	Option awards				Stoc	k awards
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested (#)	Equity incentiv plan awards number unearne shares, ur or other rights th have no vested (#)
Etti Hanochi	47,126	188,504	Nil	0.79	07/08/2022	Nil	Nil	Nil
Yaron Adler	141,378	565,512	Nil	0.79	08/07/2022	Nil	Nil	Nil
Dr. David Sidransky	Nil	250,000	Nil	0.75	16/07/2023	Nil	Nil	Nil

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following tables set forth, as of March 5, 2014, certain information with respect to the beneficial ownership of our common stock by each stockholder known by us to be the beneficial owner of more than 5% of our common stock and by each of our current directors and executive officers. Each person has sole voting and investment power with respect to the shares of common stock, except as otherwise indicated. Beneficial ownership consists of a direct interest in the shares of common stock, except as otherwise indicated.

In the following tables, we have determined the number and percentage of shares beneficially owned in accordance with Rule 13d-3 of the *Securities Exchange Act of 1934* based on information provided to us by our controlling stockholder, executive officers and directors, and this information does not necessarily indicate beneficial ownership for any other purpose. In determining the number of shares of our common stock beneficially owned by a person and the percentage ownership of that person, we include any shares as to which the person has sole or shared voting power or investment power, as well as any shares subject to warrants or options held by that person that are currently exercisable or exercisable within 60 days.

Title of class	Name and address of beneficial owner	Amount and nature of beneficial ownership $^{(1)}$	Percent of class
Common Stock	Oded Shvartz 130 Biruintei Blvd Pantelmon Ilfov, Romania	11,126,920 Direct <sup>(2)</sup>	20.6%

Security Ownership of Certain Beneficial Holders

	Gilbert A Cuison Block 616 Bedok Reservoir Rd #03-1108 Singapore 470616		5,420,485	Direct <sup>(2)</sup>	10.1%	
		/1				

Title of class	Name and address of beneficial owner	Amount and nature of beneficial ownership <sup>(1)</sup>	Percent of class
Common Stock	Jerome P Golez Block 117 Bihan St #20-29 Singapore 570117	5,500,015 Direct <sup>(2)</sup>	10.2%
	Total Beneficial Holders as a Group	22,047,420	40.1%

Security Ownership of Management

Title of class	Name and address of beneficial ownerVered Caplan 6 Sharabi street, Neve tzedek, Tel-Aviv 65147, Israel	Amount and nature of beneficial ownership <sup>(1)</sup>		Percent of class
Common Stock		3,338,285	Direct <sup>(3)</sup>	6.2%
Common Stock	Jacob BenArie 70 Denya st. Haifa, Israel 34980	1,854,603	Direct <sup>(4)</sup>	3.4%
Common Stock	Dov Weinberg 21 Sparrow Circle White Plains, New York 10605	706,904	Direct <sup>(5)</sup>	1.3%
Common Stock	Prof. Sarah Ferber Shderot Hahaskala 17b Tel-Aviv Israel 67890	2,781,905	Direct <sup>(6)</sup>	5.2%
Common Stock	Guy Yachin 7 Orchard Way N Potomac MD 20854	94,240	Direct <sup>(7)</sup>	0.2%
Common Stock	Etti Hanochi 18 Aharonovitch Sh Kfar Saba, L3	47,126	Direct <sup>(8)</sup>	0.1%
Common Stock	Yaron Adler 19 Chelouche Street Tel-Aviv Israel 65154	141,378	Direct <sup>(9)</sup>	0.3%
Common Stock	Dr. G. Alexander (Zan) Fleming Box 1260 East Ridge Street, Harpers Ferry, West Virginia 25425	94,240	Direct <sup>(11)</sup>	0.2%
Common Stock	Prof. Camilio Ricordi 1450 NW 10th Avenue Miami Florida 33136	20,000	Direct <sup>(12)</sup>	0.04%
	Directors & Executive Officers as a group (9 persons)	9,078,681		17.1%

## <u>Notes</u>

- (1) Percentage of ownership is based on 53,860,299 shares of our common stock issued and outstanding as of March 5, 2014. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants, but are not deemed outstanding for purposes of computing the percentage ownership of any other person.
- (2) Oded Shvartz currently holds 11,126,920 shares of common stock representing 21.4% of our share capital on a fully diluted basis. Guilbert Cuison and Jerome Golez have granted to Oded Shvartz a conditional option to acquire 10,840,970 shares of common stock at a price of \$0.0003571 per share. The option is exercisable only if we issue shares, grant options, or warrants to purchase shares, or any other security or right convertible into shares of our company (collectively, **New Securities**). In that event, Oded Shvartz shall have the right to exercise the option by purchasing one option share for every four New Securities issued. The option is exercised in full, Oded Shvartz would own up to 21,967,890 common shares in the capital of our company.
- <sup>(3)</sup> Consists of 3,338,285 stock options exercisable either immediately or within the next 60 days.
- <sup>(4)</sup> Consists of 1,854,603 stock options exercisable either immediately or within the next 60 days.
- <sup>(5)</sup> Consists of 706,904 stock options exercisable either immediately or within the next 60 days.
- <sup>(6</sup> Consists of 2,781,905 stock options exercisable either immediately or within the next 60 days.
- <sup>(7)</sup> Consists of 94,240 stock options exercisable either immediately or within the next 60 days.
- <sup>(8)</sup> Consists of 47,126 stock options exercisable either immediately or within the next 60 days.
- <sup>(9)</sup> Consists of 141,378 stock options exercisable either immediately or within the next 60 days.
- <sup>(10)</sup> Consists of 255,413 stock options exercisable either immediately or within the next 60 days.
- <sup>(11)</sup> Consists of 94,240 stock options exercisable either immediately or within the next 60 days.
- <sup>(12)</sup> Consists of 20,000 stock options exercisable either immediately or within the next 60 days. **Changes in Control**

As of March 5, 2014, we are not aware of any arrangement that may result in a change in control of our company.

# TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS AND CORPORATE GOVERNANCE

Other than as disclosed below, there has been no transaction, since our inception on June 5, 2008, or currently proposed transaction, in which we were or are to be a participant and the amount involved exceeds the lesser of \$120,000 or one percent of our total assets at year end for the last completed fiscal year, and in which any of the following persons had or will have a direct or indirect material interest:

- (i) Any director or executive officer of our company;
- (ii) 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;
- (iii) Any of our promoters and control persons; and
- (iv) Any member of the immediate family (including spouse, parents, children, siblings and in- laws) of any of the foregoing persons.

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

For information regarding compensation for our executive officers and directors, see Executive Compensation .

## **Director Independence**

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

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are not required to deliver an annual report to our stockholders unless our directors are elected at a meeting of our stockholders or by written consents of our stockholders. If our directors are not elected in such manner, we are not required to deliver an annual report to our stockholders and will not voluntarily send an annual report.

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. Such filings are available to the public over the internet at the Securities and Exchange Commission s website at http://www.sec.gov.

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act of 1933 with respect to the securities offered under this prospectus. This prospectus, which forms a part of that registration statement, does not contain all information included in the registration statement. Certain information is omitted and you should refer to the registration statement and its exhibits.

You may review a copy of the registration statement at the Securities and Exchange Commission s public reference room at 100 F Street, N.E. Washington, D.C. 20549 on official business days during the hours of 10 a.m. to 3 p.m. You may obtain information on the operation of the public reference room by calling the Securities and Exchange Commission at 1-800-SEC-0330. You may also read and copy any materials we file with the Securities and Exchange Commission at the Securities and Exchange Commission s public reference room. Our filings and the registration statement can also be reviewed by accessing the Securities and Exchange Commission s website at http://www.sec.gov.

No finder, dealer, sales person or other person has been authorized to give any information or to make any representation in connection with this offering other than those contained in this prospectus and, if given or made, such information or representation must not be relied upon as having been authorized by our company. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any of the securities offered hereby by anyone in any jurisdiction in which such offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to any person to whom it is unlawful to make such offer or solicitation. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of these securities. Our business, financial condition, results of operation and prospects may have changed after the date of this prospectus.

Common Shares Orgenesis Inc. Common Stock

# End of Prospectus

\_\_\_\_\_, 2014

## DEALER PROSPECTUS DELIVERY OBLIGATION

Until \_\_\_\_\_\_, all dealers that effect transactions in these securities whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

No finder, dealer, sales person or other person has been authorized to give any information or to make any representation in connection with this offering other than those contained in this prospectus and, if given or made, such information or representation must not be relied upon as having been authorized by our company. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any of the securities offered hereby by anyone in any jurisdiction in which such offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to any person to whom it is unlawful to make such offer or solicitation. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of these securities. Our business, financial condition, results of operation and prospects may have changed after the date of this prospectus.

## **INFORMATION NOT REQUIRED IN PROSPECTUS**

#### **Other Expenses of Issuance and Distribution**

The following table sets forth the expenses payable by us in connection with the issuance and distribution of the securities being registered hereunder. No such expenses will be borne by the selling stockholders. All of the amounts shown are estimates, except for the Securities and Exchange Commission registration fees.

Securities and Exchange Commission registration fees	\$	943	
Accounting fees and expenses	\$	12,000	
Accounting rees and expenses	Ψ	12,000	
Legal fees and expenses	\$	50,000	
Transfer agent and registrar fees	\$	1,000	
	Ψ	1,000	
Miscellaneous expenses	\$	4,000	
Total	\$	67,943	
	Indemnification of Directors and Officers		

Indemnification of Directors and Officers

Nevada Revised Statutes provide that:

- 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.

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 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 bylaws also require us to indemnify directors, officers and employees to the fullest extent allowed by law, provided, however, that it will be within the discretion of our board of directors whether to advance any funds in advance of disposition of any action, suit or proceeding.

### **Recent Sales of Unregistered Securities**

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 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.

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

- (i) the purchase of all of our outstanding common shares and/or amalgamation of our company or our wholly-owned Israeli subsidiary into or with another corporation;
- (ii) our sublicensing the technology to a non-affiliate of our company; or
- (iii) \$20,000 upon each of the following milestones (but in any event no more than \$50,000 in total):
  - (A) initiation by us of phase I clinical trials for the Product in human subjects,

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

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

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

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

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

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

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

On March 22, 2013, we entered into a subscription agreement with Mediapark A.G., a Marshall Islands company, pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the **Debenture**) in the aggregate principal amount of US \$250,000 and issued to the investor 100,000 warrants. Each warrant carries the right to purchase one share of common stock for a period of 24 months from issuance of the warrant.

The Debenture matures 90 days from the date of issuance of the Debenture, but the loan must be repaid earlier if we close a financing of \$1,000,000 or more. Interest is calculated on the basis of a 360-day year and accrues daily commencing on the date the Debenture is issued until payment in full of the principal amount, together with all accrued and unpaid interest. We may extend the maturity date for a period of up to 90 days provided we issue an equal number of Warrants to the number issued to the investor on initial closing.

If the Debenture is not repaid at the maturity date, the holder may convert the loan and any accrued and unpaid interest into shares of our common stock at the lower of \$0.75 per share and the 5 day VWAP of our common shares trading price for the 5 days prior to conversion. The investor is under no obligation to convert and may take realization proceedings to recover funds, interest and expenses of collection.

On June 30, 2013, we exercised our discretion to extend the maturity date of the Debenture to September 30, 2013. In return for extending the maturity date, we issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of \$0.50 per share until June 30, 2015.

On September 30, 2013, we exercised our discretion to extend the maturity date of the Debenture to December 31, 2013. In return for extending the maturity date, we issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of \$0.50 per share until September 30, 2015.

On May 6, 2013, we entered into a subscription agreement with ATMI, pursuant to which ATMI purchased 1,526,718 units of our securities at a price of \$0.8515 per unit for gross proceeds of \$1,300,000. Each unit consists of one share of our common stock and one common share purchase warrant. Each warrant may be exercised pursuant to the terms of the warrant certificate for a period of two years from issuance at an exercise price of \$1.00, subject to adjustments as set out in the warrant certificate. On March 4, 2014, we issued 1,128,849 units in a non-brokered private placement. Each unit consisted of one share of our common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years. As of March 4, 2014, the warrants issued in May 2013 have an exercise price \$0.52 per share. In connection with the subscription agreement, we also entered into a registration rights agreement dated May 6, 2013, whereby we agree to provide notice to ATMI that we will register their shares if we file a registration statement with the Securities and Exchange.

On December 6, 2013, we entered into a convertible loan agreement with Mediapark pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the Debenture ) in the aggregate principal amount of US \$100,000. Interest is calculated semi-annually and is payable, along with the principal on or before December 6, 2014.

If the Debenture is not repaid at the maturity date, the holder may convert the loan and any accrued and unpaid interest into shares of our common stock at a price per share of 80% of the VWAP for the five trading days prior to the date Mediapark provides us with written notice of conversion. The loan will be converted into the same terms as any shares and/or warrant financing of \$350,000 or more Orgenesis completes before maturity of the loan.On February 25, 2014, Sav DiPasquale exercised 623,806 options at a price of \$0.001 per share. 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.

On March 4, 2014, we issued 1,128,849 units to 13 investors in a non-brokered private placement, at a purchase price of \$0.52 per unit for gross proceeds of \$587,001. Each unit consisted of one share of our common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years.

We issued:

- (i) 1,032,695 of these units to 12 non-US persons (as that term is defined in Regulation S of the Securities Act of 1933, as amended) in an offshore transaction in which we relied on the exemptions from the registration requirements provided for in Regulation S and/or Section 4(2) of the Securities Act of 1933, as amended; and
- (ii) 96,152 of these units to one US person, who is an accredited investor (as that term is defined in Rule 501 of Regulation D under the Securities Act of 1933, as amended), and in issuing these units to this person we relied on the exemptions from the registration requirements provided for in Rule 506 Regulation D and/or Section 4(a)(2) of the Securities Act of 1933, as amended.

On December 6, 2013, we entered into a convertible loan agreement with Mediapark A.G., a Marshall Islands company, pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the Debenture ) in the aggregate principal amount of US \$100,000. On March 22, 2013, we entered a similar convertible loan agreement with Mediapark in the aggregate principal amount of \$250,000. Section 8 of the agreement states that if we complete an equity financing prior to the maturity date of the loan, in an amount greater than \$350,000 Mediapark would convert all our outstanding indebtedness into equity securities on the same terms as the current financing. As a result, we had \$370,772 including principle and interest outstanding as at March 3, 2014 due to Mediapark and have therefore issued to Mediapark 713,023 shares of common stock at a price of \$0.52 and 713,023 warrants to acquire

additional shares of our common stock at a price of \$0.52 per share for a period of three years in full payment of our indebtedness. We granted the securities to one non-U.S. person (as that term is defined in Regulation S of the United States Securities Act of 1933, as amended) in an offshore transaction in which we relied on the registration exemption provided for in Regulation S and/or Section 4(2) of the Securities Act of 1933.

### Exhibits

Exhibit Number Description

### (3) Articles of Incorporation and Bylaws

- 3.1 Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S-1 filed on April 2, 2009)
- 3.2 Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
- 3.3 Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
- 3.4 Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
- 3.5 Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8- K filed on September 21, 2011)
- 3.6 Certificate of Correction dated February 27, 2012 (incorporated by reference to an exhibit to a current report on Form 8-K/A filed on March 16, 2012)

### (5) Opinion regarding Legality

5.1<sup>\*</sup> Opinion of Clark Wilson LLP regarding the legality of the securities being registered

#### (10) Material Contracts

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

- 10.7 Personal Employment Agreement with Jacob BenArie dated February 2, 2012 (incorporated by reference to our current report on Form 8-K filed on March 15, 2012)
- 10.8 Consultancy Agreement dated March 2, 2012 with Weinberg Dalyo Inc. (incorporated by reference to our current report on Form 8-K filed on March 15, 2012)
- 10.9 Investor Relations Agreement dated March 15, 2012 with Crescendo Communications, LLC (incorporated by reference to our current report on Form 8-K filed on March 15, 2012)
- 10.10 Research Services Agreement dated March 22, 2012 with Tel Hashomer Medical Research, Infrastructure and Services Ltd. (incorporated by reference to our current report on Form 8-K filed on April 13, 2012)
- 10.11 Director Agreement with Guy Yachin dated April 2, 2012 (incorporated by reference to our current report on Form 8-K filed on April 5, 2012)

50

- 10.12 Director Agreement with Yaron Adler dated April 6, 2012 (incorporated by reference to our current report on Form 8-K filed on April 23, 2012)
- 10.13 Director Agreement with Etti Hanochi dated April 6, 2012 (incorporated by reference to our current report on Form 8-K filed on April 25, 2012)
- 10.14 Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on May 2, 2012)
- 10.15 Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on May 2, 2012)
- 10.16 Board of Advisors Consulting Agreement dated April 14, 2012 (incorporated by reference to our current report on Form 8-K filed on May 31, 2012)
- 10.17 Letter agreement with the Investor Relations Group Inc. dated May 2, 2012 (incorporated by reference to our current report on Form 8-K filed on May 31, 2012)
- 10.18 Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on August 3, 2012)
- 10.19 Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on August 3, 2012)
- 10.20 Service Agreement with Fraunhofer Institute for Interfacial Engineering and Biotechnology (incorporated by reference to our current report on Form 8-K filed on November 9, 2012)
- 10.21 Board of Advisors Consulting Agreement dated November 14, 2012 (incorporated by reference to our current report on Form 8-K filed on November 27, 2012)
- 10.22 Cancellation and Amendment of Warrants Agreement (incorporated by reference to our current report on Form 8-K filed on December 10, 2012)
- 10.23 Employment Term Sheet with Mr. Sav DiPasquale dated December 17, 2012 (incorporated by reference to our current report on Form 8-K filed on January 7, 2013)
- 10.24 Form of subscription agreement and loan agreement (incorporated by reference to our current report on Form 8-K filed on March 25, 2013)
- 10.25 Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on March 25, 2013)
- 10.26 Board of Advisors Consulting Agreement with Professor Jay Sklyer (incorporated by reference to our current report on Form 8-K filed on April 9, 2013)
- 10.27 May 6, 2013 Process Development Agreement with ATMI BVBA (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)
- 10.28 Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)

10.29	Form of warrant (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)
10.30	Registration Rights Agreement (incorporated by reference to our current report on Form 8-K filed on May 9, 2013)
10.31	Employment Agreement with Sav DiPasquale dated February 17, 2013 (incorporated by reference to our current report on Form 8-K filed on October 23, 2013)
10.32	Letter Agreement with Sav DiPasquale dated May 29, 2013 (incorporated by reference to our current report on Form 8-K filed on October 23, 2013)
10.33	Term sheet with Mediapark Investments Limited
10.34	Convertible Loan Agreement dated December 6, 2013 with Mediapark Investments Limited (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
10.35	Investment Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)
	51

10.36 Registration Rights Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013)

### (16) Letter Regarding Change in Certifying Accountant

16.1 Letter from Silberstein Ungar, PLLC regarding change in certifying accountant (incorporated by reference to our current report on Form 8-K filed on March 21, 2012)

### (21) Subsidiaries

21.1 Orgenesis Ltd. our wholly-owned Israeli corporation

## (23) Consents of Experts and Counsel

#### 23.1\* Consent of PricewaterhouseCoopers Israel

23.2\* Consent of Clark Wilson LLP (included in Exhibit 5.1)

\*Filed herewith.

52

## Undertakings

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering; and

4. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

For the purpose of determining liability of the undersigned registrant under the Securities Act of 1933 to any purchaser in the distribution of the securities, the undersigned registrant undertakes that in a primary offering of

securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

1. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

2. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

3. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned company or its securities provided by or on behalf of the undersigned registrant; and

4. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

54

#### Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned thereunto duly authorized in the city of Tel Aviv, Israel on March 7, 2014.

### **ORGENESIS INC.**

By:

/s/ Vered Caplan
Vered Caplan
President, Chief Executive Officer, and
Chairperson of the Board
(Principal Executive Officer)
Date: March 7, 2014
Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

/s/ Vered Caplan Vered Caplan President, Chief Executive Officer, and Chairperson of the Board (Principal Executive Officer)

Date: March 7, 2014

/s/ David Sidransky David Sidransky Director Date: March 7, 2014

/s/ Etti Hanochi Etti Hanochi Director Date: March 7, 2014 /s/ Dov Weinberg Dov Weinberg Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)

/s/ Guy Yachin Guy Yachin Director Date: March 7, 2014

Date: March 7, 2014

/s/ Yaron Adler Yaron Adler Director Date: March 7, 2014