

Orgenesis Inc.  
Form S-1  
January 07, 2014

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

**FORM S-1**  
**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**Orgenesis Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of incorporation or organization)

**2834**

(Primary Standard Industrial Classification Code Number)

**98-0583166**

(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**

**Tel: 426-509-9832**

(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**

**Telephone: (604) 687-5700**

**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]

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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. [ ☐ ]

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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 ☒

(Do not check if a smaller reporting company)

## Calculation of Registration Fee

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	11,803,436	\$0.62	\$7,318,130	\$942.58

## Notes

- (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 (\$0.62 high; \$0.62 low) for the registrant's common stock on January 3, 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 8,500,000 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 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.**

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.**  
**11,803,436 shares of common stock**

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The selling stockholders identified in this prospectus may offer and sell up to 11,803,436 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 8,500,000 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 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 January 3, 2014, the closing sale price for our common stock as reported by the OTC Bulletin Board was \$0.62 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.

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## TABLE OF CONTENTS

<u>PROSPECTUS SUMMARY</u>	<u>3</u>
<u>RISK FACTORS</u>	<u>6</u>
<u>FORWARD-LOOKING STATEMENTS</u>	<u>12</u>
<u>USE OF PROCEEDS</u>	<u>13</u>
<u>SELLING STOCKHOLDERS</u>	<u>13</u>
<u>PLAN OF DISTRIBUTION</u>	<u>15</u>
<u>DESCRIPTION OF SECURITIES</u>	<u>17</u>
<u>INTEREST OF NAMED EXPERTS AND COUNSEL</u>	<u>20</u>
<u>INFORMATION WITH RESPECT TO OUR COMPANY</u>	<u>21</u>
<u>DESCRIPTION OF BUSINESS</u>	<u>21</u>
<u>DESCRIPTION OF PROPERTY</u>	<u>31</u>
<u>LEGAL PROCEEDINGS</u>	<u>31</u>
<u>MARKET PRICE OF AND DIVIDENDS ON OUR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	<u>31</u>
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>32</u>
<u>FINANCIAL STATEMENTS</u>	<u>41</u>
<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>87</u>
<u>DIRECTORS AND EXECUTIVE OFFICERS</u>	<u>87</u>
<u>EXECUTIVE COMPENSATION</u>	<u>93</u>
<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT</u>	<u>98</u>
<u>TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS AND CORPORATE GOVERNANCE</u>	<u>100</u>
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	<u>101</u>
<u>DEALER PROSPECTUS DELIVERY OBLIGATION</u>	<u>103</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 owned 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 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 Hormone Production In Non-Pancreatic Islet Tissues.

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license patents and knowhow related to the development of 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 December 31, 2013, our directors and executive officers are as follows:

3

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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 87.

### Share Capital

We are authorized to issue 1,750,000,000 common shares with a par value of \$0.0001 per share. As of December 31, 2013, there were 51,394,621 common shares outstanding.

### Summary of the Offering

**Shares being offered:** The selling stockholders identified in this prospectus may offer and sell up to 11,803,436 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 8,500,000 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.

**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 Data

The following information represents selected audited financial information for Orgenesis and its Subsidiaries for the years ended November 30, 2011 and 2012 and unaudited financial information for the nine month period ended August 31, 2013 and 2012. The summarized financial information presented below is derived from and should be read in conjunction with our audited financial statements and unaudited 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 32 of this prospectus.

<b>Statements of Operations Data</b>	<b>For the Year Ended November 30, 2012 (audited)</b>	<b>For the Year Ended November 30, 2011 (audited)</b>
Expenses	\$4,998,143	\$72,352
Net Loss	\$4,998,143	\$72,352
Basic and Diluted Loss Per common stock	\$0.09	\$0.00
<b>Statements of Operations Data</b>	<b>For the nine Months Ended August 31, 2013 (unaudited)</b>	<b>For the nine Months Ended August 31, 2012 (unaudited)</b>
Expenses	\$3,823,883	\$3,603,932
Net Loss	\$3,823,883	\$3,603,932
Basic and Diluted Loss Per common stock	\$0.08	\$0.06

We have not generated any revenue since inception.

<b>Balance Sheet Data</b>	<b>As At August 31, 2013 (unaudited)</b>	<b>As At November 30, 2012 (audited)</b>	<b>As At November 30, 2011 (audited)</b>
Cash and Cash Equivalents	\$516,434	\$347	\$1,275
Working Capital Deficit	(\$157,318)	(\$288,572)	(\$82,673)
Total Assets	\$599,627	\$48,167	\$2,340
Total Liabilities	\$1,905,810	\$328,723	\$85,013
Accumulated Deficit	(\$8,959,699)	(\$5,135,816)	(\$137,673)

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 \$265,000, including general and administrative expenses, research and development. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As of December 31, 2013, we had cash and cash equivalents of approximately \$400,402. As we cannot assure a lender that we will be able to successfully develop our pharmaceutical assets, we will almost certainly find it difficult to raise debt financing from traditional lending sources. If we cannot raise the money that we need in order to continue to operate our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our subsidiary has significant operations in Israel, including research and development. Since the establishment of the State of Israel in 1948, a number of armed conflicts and terrorist acts have taken place, which in the past, and may in the future, lead to security and economic problems for Israel. In addition, certain countries in the Middle East adjacent to Israel, including Egypt and Syria, recently experienced and some continue to experience political unrest and instability marked by civil demonstrations and violence, which in some cases resulted in the replacement of governments and regimes. Current and future conflicts and political, economic and/or military conditions in Israel and the Middle East region may affect our operations in Israel. The exacerbation of violence within Israel or the outbreak of violent conflicts involving Israel may impede our subsidiary's ability to engage in research and development, or otherwise adversely affect its business or operations. In addition, our subsidiary's employees in Israel may be required

to perform annual mandatory military service and are subject to being called to active duty at any time under emergency circumstances. The absence of these employees may have an adverse effect on our subsidiary's operations. Hostilities involving Israel may also result in the interruption or curtailment of trade between Israel and its trading partners, which could materially adversely affect our results of operations.



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

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

## **Risks Relating to the Pharmaceutical Business**

*THM may cancel the License Agreement.*

Pursuant to the terms of the License Agreement, we are required to submit to THM the Development Plan within 18 months from the date of the License Agreement. We must develop, manufacture, sell and market the Products pursuant to the milestones and time schedule specified in the Development Plan. In the event we fail to fulfill the terms of the Development Plan, THM shall be entitled to terminate the License Agreement by providing us with written notice of such a breach and 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 ( **EMA** ) will regulate our future products. Regulatory approval by the EMA will be subject to the evaluation of data relating to the quality, efficacy and safety of our future products for its proposed use. The time taken to obtain regulatory approval varies between countries. Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

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

*The pharmaceutical industry is highly competitive.*

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

### **Risks Relating to Our Common Stock**

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

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

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

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

reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock.

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

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

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

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

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

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

### **Risks Related to the Offering**

*The selling stockholders are offering for resale of a maximum of 11,803,436 shares of our common stock, 8,750,000 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 could depress the market price of our common stock.*

The selling stockholders are offering for the resale of a maximum of 11,803,436 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 December 31, 2013, there were 51,394,621 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 exist 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 11,803,436 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 8,500,000 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.

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 December 31, 2013 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.

Name of Selling Stockholder	Shares Owned by the Selling Stockholder before the Offering <sup>(1)</sup>	Total Shares Offered in the Offering	Number of Shares to Be Owned by Selling Stockholder After the Offering and Percent of Total <sup>(1)</sup> Issued and Outstanding Shares	
			# of Shares <sup>(2)</sup>	% of Class <sup>(2)</sup>
Kodiak Capital Group, LLC	250,000	8,750,000 <sup>(3)</sup>	-	-
ATMI BVBA	1,526,718	3,053,436 <sup>(4)</sup>	-	-
<b>Totals</b>	<b>1,776,718</b>	<b>11,803,436</b>	-	-

#### Notes

- (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 11,803,436 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.
- (3) Consists of up to 250,000 shares of common stock issued to Kodiak as commitment shares pursuant to the Investment Agreement and up to 8,500,000 shares of common stock to be sold by Kodiak pursuant to the Investment Agreement.
- (4) 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 January 3, 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.

## Edgar Filing: Orgenesis Inc. - Form S-1

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.

The selling stockholders 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 \$52,000. 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 Agreement 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 (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 December 31, 2013 there were 51,394,621 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. Our bylaws also provide that any action which may be taken at any annual or special 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 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 December 31 2013, we had approximately 11 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 December 31, 2013, we had a total of 2,926,718 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 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.

## 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 December 31, 2013, we have issued 9,417,427 options under the Global Share Incentive Plan (2012) and 2,781,905 options outside of our Global Share Incentive Plan (2012).

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 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.

## 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, 2012 and for the year 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.

The financial statements as of November 30, 2011 and for the year ended included in this Prospectus have been so included in reliance on the report of Silberstein Ungar, PLLC 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 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 with a par value of \$0.0001. Unless otherwise noted, all references in this annual report to number of shares, price per share or weighted average number of shares outstanding have been adjusted to reflect the stock split on a retroactive basis.

#### Our Current Business

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

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

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

licensed patents and knowhow. We believe that our major competitive advantage is in our cell transformation technology.

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

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

### *The License Agreement*

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

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

- A royalty (the **Royalty** ) of 3.5% of net sales.
- 16% of all sublicensing fees.
- An annual fee (the **Annual Fee** ) of \$15,000, which shall commence on January 1, 2012 and shall be paid once every year thereafter. The Annual Fee is non-refundable, but it shall be credited each year due, against the Royalty, to the extent that such are payable, during that year.
- Milestone payments as follows:
  - ◆ \$50,000 on the date of initiation of phase I clinical trials in human subjects;
  - ◆ \$50,000 on the date of initiation of phase II clinical trials in human subjects;
  - ◆ \$150,000 on the date of initiation of phase III clinical trials in human subjects;
  - ◆ \$750,000 on the date of initiation of issuance of an approval for marketing of the first Product by the FDA or any other equivalent authority; and
  - ◆ \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time (the **Sales Milestone** ).

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

- a 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 January 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:
  - ◆ granting of sublicenses;
  - ◆ confidentiality provisions;
  - ◆ perform payments to THM; and
  - ◆ indemnity and insurance.
- We breach any of our obligations thereunder other than material breaches, and such breach remains uncured for 200 days after written notice from THM.
- We become insolvent; file a petition or have a petition filed against us, under any laws relating to insolvency; enter into any voluntary arrangement for the benefit of our creditors; or appoint or have appointed on our behalf a receiver, liquidator or trustee of any of our property or assets, under any laws relating to insolvency; and such petition, arrangement or appointment is not dismissed or vacated within 90 days.
- We have ceased to carry on our business for a period of more than 60 days.
- We have challenged, challenge, or cause any third party to challenge, the intellectual property rights or other rights of THM to the Licensed Information anywhere in the world.

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