Orgenesis Inc.
Form 10-Q
October 15, 2013

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 10-Q

[X] Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended **August 31, 2013**

[ ] Transition Report pursuant to 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period _____ to _____

Commission File Number: **000-54329**

# ORGENESIS INC.

(Exact name of registrant as specified in its charter)

| **NEVADA** | **98-0583166** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS Employer Identification No.) |

**21 Sparrow Circle, White Plains, NY, 10605**

(Address of principal executive offices)

**845.591.3144**

(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
[**X**] Yes [ ] No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
[**X**] Yes [ ] No

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

| | |
|---|---|
| Large accelerated filer [ ] | Accelerated filer [ ] |
| Non-accelerated filer [ ] | Smaller reporting company [X] |

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
[ ] Yes [**X**] No

State the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date:
**As of October 14, 2013 there were 51,144,621 shares of common stock, par value $0.0001 outstanding.**

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## PART I - FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the SEC instructions to Form 10-Q. In the opinion of management, all adjustments considered necessary for a fair statement have been included. Operating results for the interim period ended August 31, 2013 are not necessarily indicative of the results that can be expected for the full year.

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

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AUGUST 31, 2013

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

**(A development stage company)**

CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars

| | August 31, 2013 Unaudited | November 30, 2012 Audited |
|---|---|---|
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 516,434 | $ 347 |
| Short term deposits | 10,002 | 10,002 |
| Prepaid expenses and Accounts receivable | 56,626 | 28,249 |
| Total current assets | $ 583,062 | $ 38,598 |
| **FUNDS IN RESPECT OF RETIREMENT BENEFIT OBLIGATIONS** | $ 2,857 | $ 1,296 |
| **PROPERTY AND EQUIPMENT, NET** | $ 13,708 | $ 8,273 |
| Total assets | $ 599,627 | $ 48,167 |
| **Liabilities and stockholders' deficiency** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable | $ 151,343 | $ 135,791 |
| Accrued expenses | 167,027 | 73,138 |
| Employees and related payables | 121,314 | 75,879 |
| Related parties | 42,362 | 42,362 |
| Loan (Note 3b5) | 258,333 | - |
| Total current liabilities | $ 740,379 | $ 327,170 |
| **LONG-TERM LIABILITIES** | | |
| Warrants (Note 5) | $ 1,161,956 | $ - |
| Retirement benefit obligations | 3,475 | 1,553 |
| Total long term liabilities | $ 1,165,431 | $ 1,553 |
| **Commitments** (Note 2) | | |
| Total liabilities | $ 1,905,810 | $ 328,723 |
| **STOCKHOLDERS' DEFICIENCY:** | | |
| Common stock of $0.0001 par value - authorized: 1,750,000,000 shares at August 31, 2013 and November 30, 2012; issued and outstanding: 51,144,621 and 49,117,903 shares at August 31, 2013 and November 30, 2012, respectively | 5,114 | 4,912 |
| Additional paid-in capital | 7,648,402 | 4,850,348 |
| Deficit accumulated during the development stage | (8,959,699) | (5,135,816) |
| Total Stockholders' deficiency | (1,306,183) | (280,556) |
| Total liabilities net of Stockholders' deficiency | $ 599,627 | $ 48,167 |

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

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

**(A development stage company)**

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)
U.S. dollars

| | Nine months ended | | Three months ended | | Period from June 5, 2008 (inception) through |
|---|---|---|---|---|---|
| | August 31, 2013 | August 31, 2012 | August 31, 2013 | August 31, 2012 | August 31, 2013 |
| **RESEARCH AND DEVELOPMENT EXPENSES** | 930,487 | 1,740,697 | 226,935 | 542,267 | 3,239,298 |
| **GENERAL AND ADMINISTRATIVE EXPENSES** | 2,844,350 | 1,876,966 | 935,228 | 1,346,807 | 5,661,771 |
| **OPERATING LOSS** | 3,774,837 | 3,617,663 | 1,162,163 | 1,889,074 | 8,901,069 |
| **FINANCIAL EXPENSE (INCOME), NET** | 49,046 | (13,731) | (224,723) | (13,820) | 58,630 |
| **NET LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD** | 3,823,883 | 3,603,932 | 937, 440 | 1,875,254 | 8,959,699 |
| | | | | | |
| **BASIC AND DILUTED LOSS PER COMMON STOCK** | 0.08 | 0.06 | 0.02 | 0.04 | |
| | | | | | |
| **WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER COMMON STOCK:** | 50,264,348 | 56,063,918 | 51,144,621 | 48,786,381 | |

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

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

**(A development stage company)**

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' CAPITAL DEFICIENCY
(UNAUDITED)
U.S. dollars

| | Common Stock Shares | $ | Additional paid-in capital | Deficit accumulated during the development stage | Total stockholders' Equity |
|---|---|---|---|---|---|
| **Balance at June 5, 2008** (inception) | - | $ - | $ - | $ - | $ - |
| **Changes during the period from June 5, 2008 through November 30, 2010** | | | | | |
| Shares issued to founder on June 5, 2008 $0.000357 Per Share | 56,000,000 | $ 5,600 | 14,400 | - | 20,000 |
| Private Placement at 0.00143$ Per Share | 24,500,000 | 2,450 | 32,550 | - | 35,000 |
| Net Loss for the period- Comprehensive loss | - | - | - | (65,321) | (65,321) |
| **Balance as of November 30, 2010** | 80,500,000 | 8,050 | 46,950 | (65,321) | (10,321) |
| | | | | | |
| Net Loss for the year- Comprehensive loss | - | - | - | (72,352) | (72,352) |
| | | | | | |
| **Balance as of November 30, 2011** | 80,500,000 | 8,050 | 46,950 | (137,673) | (82,673) |
| Shares cancelled | (33,873,049) | (3,387) | 3,387 | - | - |
| Warrants and shares issued for cash, net of issuance expenses | 1,100,000 | 110 | 1,071,551 | - | 1,071,661 |
| Stock-based compensation expenses related to options granted to employees | - | - | 2,976,922 | - | 2,976,922 |
| Stock-based compensation expenses related to options granted to consultant | - | - | 242,055 | - | 242,055 |
| Shares issued for services | 1,390,952 | 139 | 509,483 | - | 509,622 |
| Net loss for the year- Comprehensive loss | - | - | - | (4,998,143) | (4,998,143) |
| | | | | | |
| **Balance as of November 30, 2012** | 49,117,903 | $ 4,912 | $ 4,850,348 | $ (5,135,816) | $ (280,556) |
| | | | | | |
| **Changes during the nine month period ended August 31, 2013** (Unaudited) | | | | | |
| | | | | | |
| Shares issued for cash | 2,026,718 | 202 | 666,988 | - | 667,190 |
| | | | | | |
| Stock based compensation related to options granted to employees | - | - | 1,882,761 | - | 1,882,761 |
| | - | - | 242,161 | - | 242,161 |

| | | | | | |
|---|---|---|---|---|---|
| Stock-based compensation related to options granted to consultants | | | | | |
| Receipts on account of Shares | - | - | 6,144 | - | 6,144 |
| Net loss for the period- Comprehensive loss | - | - | - | (3,823,883) | (3,823,883) |
| **Balance as of August 31, 2013** | 51,144,621 | 5,114 | 7,648,402 | (8,959,699) | (1,306,183) |

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

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

**(A development stage company)**

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
U.S. dollars

| | Nine months ended | | Period from June 5, 2008 (inception date) through |
|---|---|---|---|
| | August 31, 2013 | August 31, 2012 | August 31, 2013 |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | | |
| Net loss | (3,823,883) | (3,603,932) | (8,959,699) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | | |
| Write-off of website development costs | - | - | 15,000 |
| Stock based compensation related to options granted to employees | 1,882,761 | 2,139,260 | 4,859,683 |
| Stock-based compensation related to options granted to consultants | 242,161 | 122,513 | 484,216 |
| Depreciation | 2,404 | 856 | 3,809 |
| Change in fair value of warrants liabilities | (51,802) | - | (51,802) |
| Interest expenses due to loan | 73,525 | - | 73,525 |
| Increase in accrued severance pay, net | 1,922 | 922 | 3,475 |
| Receipt on account of Shares due to services rendered | 6,144 | 509,622 | 515,766 |
| Changes in operating assets and liabilities: | | | |
| Increase in prepaid expenses and accounts receivable | (12,621) | (25,722) | (40,870) |
| Increase in accounts payable | 15,552 | 51,222 | 151,343 |
| Increase in accrued expenses | 93,889 | - | 167,027 |
| Increase in related parties | - | 6,862 | 42,362 |
| Increase in employees and related payables | 45,435 | 49,395 | 121,314 |
| | | | |
| Net cash used in operating activities | (1,524,513) | (749,002) | (2,614,851) |
| | | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | | |
| Purchase of fixed assets | (7,839) | (9,678) | (17,517) |
| Website development costs | - | - | (15,000) |
| Investment in short term deposits | - | - | (10,002) |
| Amounts funded in respect of retirement benefits obligations | (1,561) | (677) | (2,857) |
| Net cash used in investing activities | (9,400) | (10,355) | (45,376) |
| | | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | | |
| Proceeds from Warrants and shares issued for cash | 1,800,000 | 1,071,661 | 2,926,661 |
| Proceeds from loan received and warrants issued for cash | 250,000 | - | 250,000 |
| | | | |
| Net cash provided by financing activities | 2,050,000 | 1,071,661 | 3,176,661 |
| **INCREASE IN CASH AND CASH EQUIVALENTS** | 516,087 | 312,304 | 516,434 |

| | | | |
|---|---|---|---|
| **CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD** | 347 | 1,275 | - |
| **CASH AND CASH EQUIVALENTS AT END OF PERIOD** | 516,434 | 313,579 | 516,434 |

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**ORGENESIS INC.**
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**
**(A development stage company)**
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

## NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

### a. General:

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

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

On October 11, 2011, the Company incorporated a wholly-owned subsidiary in Israel, Orgenesis Ltd. (the Israeli Subsidiary ), which is engaged in research and development. On July 31, 2013, the Company incorporated a wholly-owned subsidiary in Maryland Orgenesis Inc. (the US Subsidiary ), which will be engaged in research and development. The US subsidiary has not commenced its operation yet.

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

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

The Group is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with ASC Topic 915 Development Stage Entities .

### b. Basis Of Presentation

The accompanying unaudited interim condensed consolidated financial statements as of August 31, 2013 have been prepared in accordance with accounting principles generally accepted in the United States. Accordingly, they do not include all the information and footnotes required for annual financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair statement have been included. The accounting principles applied in the preparation of the interim statements are consistent with those applied in the preparation of the annual financial statements; however, the interim statements do not include all the information and explanations required for the annual financial statements. The condensed consolidated balance sheet data as of November 30, 2012 was derived from the Company s audited financial statements, but does not include all disclosures required by generally accepted accounting principles. For additional information, including the Company s significant accounting policies, refer to the consolidated financial statements and related footnotes in the Company s fiscal 2012 Annual Report on Form 10-K. Operating results for the nine months ended August 31, 2013, are not necessarily indicative of the results that be expected for the year ending November 30, 2013.

**ORGENESIS INC.**
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**
**(A development stage company)**
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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

**c. Going concern considerations**

The accompanying unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has stock holders' deficiency in a total amount of $1,306,183and net losses for the period from inception (June 5, 2008) through August 31, 2013, of $8,959,699 as well as a negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following August 31, 2013. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that the Company will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

**d. Warrants issued as part of capital raisings that are classified as a liability**

Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the statement of financial position. The liability is measured both initially and in subsequent periods at fair value, with changes in fair value charged to finance expenses, net. See note 5.

**e. Fair value measurement:**

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

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

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

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

**ORGENESIS INC.**
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**
**(A development stage company)**
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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

As of August 31, 2013 the assets or liabilities measured at Level 3 fair value comprise of warrants. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent.

**f. Newly issued and recently adopted Accounting Pronouncements**

1. In June 2011, the Financial Accounting Standards Board (the FASB ) issued Accounting Standards Update (ASU) 2011-05, an update to ASC No. 220, Presentation of Comprehensive Income, which eliminates the option to present other comprehensive income and its components in the statement of shareholders equity. The Company can elect to present the items of net income and other comprehensive income in a single continuous statement of comprehensive income or in two separate, but consecutive, statements. Under either method the statement would need to be presented with equal prominence as the other primary financial statements. The amended guidance, which must be applied retroactively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with earlier adoption permitted. In December 2011, the FASB issued another update on the topic, which deferred the effective date pertaining only to the presentation of reclassification adjustments on the face of the financial statements. The Company adopted the pronouncement in the annual financial statements as of November 30, 2012.

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

**ORGENESIS INC.**
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**
**(A development stage company)**
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

**NOTE 2 - COMMITMENTS:**

**1.** On February 2, 2012 the Subsidiary entered into a licensing agreement with the Licensor. According to the agreement, the Subsidiary was granted a worldwide royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.
As consideration for the Licensed Information (as defined), the Subsidiary will pay the following to the Licensor:

a. A royalty of 3.5% of net sales.
b. 16% of all sublicensing fees received.
c. An annual license fee of $15,000, which commenced on January 1, 2012 and shall be paid once every year thereafter (the Annual Fee ). The Annual Fee is non-refundable, but it shall be credited each year due, against the royalty noted above, to the extent that such are payable, during that year.
d. Milestone payments as follows:

1. $50,000 on the date of initiation of phase I clinical trials in human subjects;
2. $50,000 on the date of initiation of phase II clinical trials in human subjects;
3. $150,000 on the date of initiation of phase III clinical trials in human subjects;
4. $750,000 on the date of initiation of issuance of an approval for marketing of the first Product by the FDA.
5. $2,000,000, when worldwide net sales of Products have reached the amount of $150,000,000 for the first time, (The Sales Milestone ).

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Subsidiary of the Company and/or consolidation of the Subsidiary or the Company into or with another corporation ( Exit ), the Licensor shall be entitled to choose whether to receive from the Company a one-time payment based, as applicable, on the value of either 5,563,809 shares of Common Stock of the Company at the time of the Exit or the value of 1,000 shares of common stock of the Subsidiary at the time of the Exit.

**ORGENESIS INC.**
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**
**(A development stage company)**
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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

**2.** On February 2, 2012 the Company entered into an agreement with Mintz, Levin, Ferris, Glovsky and Popeo, P.c. ( Mintz, Levin ) for professional services related to the patent registration. In addition to an amount of $80,000 paid to this service provider, the Company issued 1,390,952 shares of common stock that will be held in escrow for two years. As a result of the escrow, the fair value of these shares issued for services were $509,622 based on a 34.57% discount calculated, on the price per share on February 2, 2012. The Company will pay an additional $50,000 upon consummation of the earlier of:

1. The purchase of all the Company's common shares and/or amalgamation of the company or the Subsidiary into or with another Corporation.

2. The Company sublicensing the technology to a non-affiliate of the Company.

3. $20,000 upon each of the following milestones (but in any event no more than $50,000 in total):

    1. Initiation by the Company of phase I clinical trials for the Company's product in human subjects.
    2. Initiation by the Company of phase II clinical trials in human subjects.
    3. Initiation by the Company of phase III clinical trials in human subjects.

**3.** On February 2, 2012, the Company entered into a consultancy agreement with Weinberg Dalyo Inc, for financial consulting services for a consideration of $3,000 per month. During the period of this agreement, if the consultant locates an investor, which the Company enters into a binding investment agreement, the consultant is entitled to a bonus of 1.5% from the total investment in cash.

**4.** On February 2, 2012, the Subsidiary entered into an employment agreement (the Ferber Employment Agreement ) with Prof. Sarah Ferber. Pursuant to the Ferber Employment Agreement, Prof. Ferber agrees to serve as our Chief Scientific Officer. Prof. Ferber will be paid a gross salary of NIS (Israeli shekel) 36,000 per month, which is approximately $9,961 based on an exchange rate of 1 NIS equals $0.2767 as of August 31, 2013. In the event we complete a financing of at least $1,000,000 (in addition to the $1.5 million private placement in February 2012), Prof. Ferber s salary will double. On May 6 2013, the Company has completed the financing of over $1,000,000, therefore.

Prof. Ferber will be paid a gross salary of NIS (Israeli shekel) 72,000 per month, which is approximately $19,923 based on an exchange rate of 1 NIS equals $0.2767 as of August 31, 2013.

**5.** On February 2, 2012, the Subsidiary entered into a compensation agreement (the Caplan Compensation Agreement ) with Ms. Caplan. Pursuant to the Caplan Compensation Agreement, Ms. Caplan agrees to serve as a director of our company. Ms. Caplan will be paid a gross salary of NIS (Israeli shekel) 10,000 per month, which is approximately $2,767 based on an exchange rate of 1

NIS equals $0.2767 as of August 31, 2013.

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

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

**ORGENESIS INC.**
**(FORMERLY BUSINESS OUTSOURCING SERVICES, INC)**
**(A development stage company)**
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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

**7.** On April 17, 2012 the Company entered into an agreement with Yaron Adler to serve as a director in the Company's board of directors for a consideration for every board meeting on an hourly basis. In the event the Company receives an aggregate financing of at least $3,000,000 he will be entitled to a one-time payment in the amount of $15,000. See also note 4(5).

**8.** On April 24, 2012 the Company entered into an agreement with Granzer Regulatory Consulting &services (Granzer) to provide services with regard to regulatory and development aspects in connection with pharmaceutical products in the area of chemistry and pharmacy , clinical and regulatory. The company shall pay for services of Granzer range of 125-300 Euro per hour or 2,400 Euro per day.

**9.** On October 18, 2012 the Company entered into an agreement with Fraunhofer IGB to perform experiment and studies on transplants of liver cells in order to develop the manufacturing process in standards that will enable Orgenesis to use it in clinical trials. According to the agreement the company should pay per achieved phase which are defined in the agreement a total consideration of 260,000 Euro for all services. Under the terms of the agreement it's the company's discretion whether to conclude all the phases or only part of them.

**10.** On January 7, 2013 the Company appointed a new CEO to the Company, whose compensation will consist of an annual gross salary of $180,000 and the eligibility to receive stock options, performance shares and an annual bonus at the discretion of our board of directors upon the performance as follow:

a. 982,358 Performance Shares (2%) will be issued upon the completion of a fundraising.

b. 1,473,537 Performance Shares (3%) will be issued as to 25% on each of the first, second, third and fourth anniversaries of the date of the employment agreement.

As of August 31, 2013 the performance conditions describe above were not met.

**11.** On March 27, 2013, the Company signed an agreement with Mintz Levin, our patent attorneys, in which 16% of the fees will be converted to shares of the Company at market price. A total of $6,144 will be converted into common shares. As of August 31, 2013 the issuance of shares has not yet occurred.

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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

**OTE 3 STOCKHOLDERS' EQUITY:**

**a. Share capital**

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

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

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

**b. Financing:**

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

2. In April 2012, the Company completed a private placement of $100,000 with Derby for 100,000 shares of common stock and 100,000 common stock warrants at a purchase price of $1.00 per share (the April Warrants ).

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

4. In December 2012, the Company entered into a subscription agreement with Derby for the issuance of 500,000 units for a total consideration of $500,000. Each unit is comprised of one share of the Company's Common Stock and two non-transferable Common Stock warrants. Each Common Stock warrant ( December Warrants ) can be exercised into one share at a purchase price of $ 0.50 per warrant and is exercisable until November 30, 2014. See also Note 5.

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

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

5. In March 2013, the Company entered into a loan and warrant subscription agreement with Mediapark A.G., a Marshall Islands company ( Mediapark ). The Company received a loan (the Loan ) in the total amount of $250,000 and issued to the investor 100,000 warrants ( March Warrant ). Each Common Stock warrant can be exercised into one share at a purchase price of $0.50 per warrant and is exercisable until March 22, 2015. See also Note 5.

   The warrants issued are detachable from the loan and classified as a liability due to down-round protection (through ratchet and anti-dilution provisions), therefore the Company allocated the proceeds from Mediapark, first to the warrants based upon the fair value of the warrants, and the residual amount of proceeds was allocated to the Loan. As of the issuance day, the fair value of the warrants was $65,192 based on Monte Carlo pricing-model. See also Note 5.

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

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

   On June 30, 2013 the Company exercised its discretion to extend the maturity date of the loan to September 30, 2013. In return for extending the maturity date, the Company issued to Mediapark additional Warrants at an exercise price of $0.50 per warrant. On September 30, 2013 the Company extended the maturity date of the loan to December 31, 2013. See also note 7(1).

6. In May 2013, the Company entered into a subscription agreement with ATMI, pursuant to which ATMI purchased 1,526,718 units at a price of $0.8515 per unit for total consideration of $1,300,000. Each Unit consists of one share of the Company's Common Stock and one Common Stock warrant. Each Common Stock warrant ( May Warrants ) can be exercised into one share at a purchase price of $1 per warrant and is exercisable until May 6, 2015. See also Note 5.

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**NOTE 4 STOCK BASED COMPENSATION**

1. Global Share Incentive Plan:

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

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

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

2. On February 2, 2012 2,781,905 options were granted to Prof. Sara Ferber, the Company's Chief Scientific Officer, at an exercise price of $0.0001 per share. The options vest in twelve equal monthly installments from the date of grant and expire on February 2, 2022 .The fair value of these options on the date of grant was $1,557,867 using the Black and Scholes option-pricing model.

3. On February 2, 2012, 2,781,905 options were granted to Mr Jacob BenArie, the CEO of Orgenesis Ltd, at an exercise price of $0.69 per share, the options vest in twelve equal quarterly installments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant was $1,404,819 using the Black and Scholes option-pricing model.

4. On June 4, 2012, 471,200 options were granted to Mr. Guy Yachin, the Company's member of the board of directors, at an exercise price of $0.85 per share, the options vest in five equal annual instalments from the date of grant and expire on June 4, 2022. The fair value of these options as of the date of grant was $363,478 using the Black and Scholes option-pricing model.

5. On July 8, 2012, 706,890 options were granted to Mr. Yaron Eldar, the Company's member of the board of directors, at an exercise price of $0.79 per share, the options vest in five equal annual instalments from the date of grant and expire on July 8, 2022. The fair value of these options as of the date of grant was $506,635 using the Black and Scholes option-pricing model.

6.

On July 10, 2012, 3,338,285 options were granted to Ms. Caplan, the Company's Chairperson of the Board at an exercise price of $0.001 per share, the options vest in two equal annual instalments from the date of grant and expire on February 2, 2022. The fair value of these options as of the date of grant was $2,935,496 using the Black and Scholes option-pricing model.

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

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

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

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

| | For options granted until August 30, 2013 |
|---|---|
| Expected option life (years) | 10.0 |
| Expected stock price volatility (%) | 98-105 |
| Risk free interest rate (%) | 1.53-1.86 |
| Expected dividend yield (%) | 0.0 |

A summary of the Company's stock option granted to employees and directors as of August 31, 2013 and changes for the nine months ended August 31, 2012 is presented below:

| | **Nine months ended** | | | |
|---|---|---|---|---|
| | **August 31, 2013** | | **August 31, 2012** | |
| | **Number Of Options** | **Weighted average exercise price $** | **Number of options** | **Weighted average exercise price $** |
| Options outstanding at the beginning of the year | 10,315,815 | 0.297 | - | - |
| Changes during the period: | | | | |
| Granted - at market price | 250,000 | 0.75 | 10,315,815 | 0.186 |
| Expired | - | - | - | - |

| | | | | |
|---|---|---|---|---|
| Options outstanding at end of the period | 10,565,815 | 0.313 | 10,315,815 | 0.186 |
| Options exercisable at end of the period | 4,455,602 | 0.27 | 1,854,603 | 0.172 |

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

Costs incurred in respect of stock based compensation for employees and directors, for the nine months ended August 31, 2013 and August 31, 2012 were $1,882,761 and $2,139,260, respectively. The weighted average period of the remaining unearned compensation of $ 2,247,380 at August 31, 2013 will be recorded over 2.3 years.

The following table presents summary information concerning the options granted to employees outstanding as of August 31, 2013:

| Exercise price $ | Number of outstanding options | Weighted average remaining contractual Life Years | Weighted average Exercise price $ | Aggregate intrinsic value $ |
|---|---|---|---|---|
| 0.0001 | 2,781,905 | 8.42 | 0.0001 | 2,086,151 |
| 0.001 | 3,338,285 | 8.42 | 0.001 | 2,500,375 |
| 0.69 | 2,781,905 | 8.42 | 0.69 | 166,914 |
| 0.75 | 250,000 | 9.87 | 0.75 | - |
| 0.79 | 942,520 | 8.85 | 0.79 | - |
| 0.85 | 471,200 | 8.76 | 0.85 | - |
| | 10,565,815 | 8.51 | 0.31 | 4,753,440 |

The following table presents summary of information concerning the options exercisable as of August 31, 2013:

| Exercise price $ | Number of Exercisable options | Weighted Average Exercise price $ |
|---|---|---|
| 0.0001 | 2,781,905 | 278 |
| 0.69 | 1,390,953 | 959,757 |
| 0.79 | 188,504 | 148,918 |
| 0.85 | 94,240 | 80,104 |
| | 4,455,602 | 1,189,058 |

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

**Options granted to non-employees:**

1. On April 14, 2012, 471,200 options were granted to Dr. G. Alexander (Zan) Fleming, the Company's advisor, at an exercise price of $1.40 per share, the options vest five equal annual instalments from the date of grant and expire on April 14, 2022. The fair value of these options as of the date of grant is $564,907 using the Black and Scholes option-pricing model.

2. On June 4, 2012, 706,904 options were granted to Mr. Dov Weinberg, the Company's CFO, at an exercise price of $0.69 per share, the options vest in four equal semi - annual installments from February 2, 2012 and expire on February 2, 2022. The fair value of these options as of the date of grant is $500,678 using the Black and Scholes option-pricing model.

3. On November 21, 2012, 100,000 options were granted to Camillo Ricordi, a consultant for the Company, at an exercise price of $0.61 per share, the options vest in five equal annual installments from the date of grant and expire on November 21, 2022. The fair value of these options as of the date of grant is $64,513 using the Black and Scholes option-pricing model.

4. On August 2, 2013 100,000 options were granted to Prof. Skyler , one of the Company's advisory board, at an exercise price of $0.96 per share, the options vest in five equal annual installments from the date of grant and expire on April 4, 2023. The fair value of these options as of the date of grant was $ 65,620 using the Black and Scholes option-pricing model.

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

| | For options granted until August 31, 2013 |
|---|---|
| Expected option life (years) | 10.0 |
| Expected stock price volatility (%) | 98-110 |
| Risk free interest rate (%) | 1.53-2.78 |
| Expected dividend yield (%) | 0.0 |

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

A summary of the status of the stock options granted to non-employees as of August 31, 2013 and August 31, 2012 and changes for the nine months ended is presented below:

| | Nine months ended | | | |
|---|---|---|---|---|
| | August 31, 2013 | | August 31, 2012 | |
| | Number Of Options | Weighted average exercise price $ | Number of options | Weighted average exercise price $ |
| Options outstanding at beginning of year | 1,278,104 | 0.95 | - | - |
| Changes during the year: | | | | |
| Granted - at market price | 100,000 | 0.96 | 1,178,104 | 0.97 |
| Expired | | | - | - |
| Options outstanding at end of the period | 1,378,104 | 0.94 | 1,178,104 | 0.97 |
| Options exercisable at end of the period | 624,418 | 0.8 | 176,726 | 0.69 |

Costs incurred in respect of stock based compensation for consultants, for the nine months ended August 31, 2013 and August 31, 2012 were $242,161 and $122,513 respectively. The weighted average period of the remaining unearned compensation of $ 423,417 as of August 31, 2013 will be recorded over 3.11 years. The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2013:

| Exercise prices $ | Number of Outstanding options | Weighted average Remaining Contractual Life Years | Weighted Average Exercise Price | Aggregate intrinsic value $ |
|---|---|---|---|---|
| 0.61 | 100,000 | 9.22 | 0.61 | 14,000 |
| 0.69 | 706,904 | 8.42 | 0.69 | 42,414 |
| 0.96 | 100,000 | 9.59 | 0.96 | - |
| 1.4 | 471,200 | 8.62 | 1.4 | - |
| | 1,378,104 | 8.63 | 0.942 | 56,414 |

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

The following table presents summary of information concerning the options exercisable as of August 31, 2013:

| Exercise prices | Number of Exercisable options | Total Exercise price $ |
|---|---|---|
| 0.69 | 530,178 | 365,822 |
| 1.4 | 94,240 | 131,936 |
| | 624,418 | 497,758 |

**NOTE 5- WARRANTS**

As part of the Company's private placements as described in note 3 the Company issued to the investors warrants, as follows:

1. In December 2012, the Company issued 1,000,000 non-transferable Common Stock warrants. Each Common Stock warrant ( December Warrants ) can be exercised into one share at an exercise price of $ 0.50 per warrant and is exercisable until November 30, 2014. In the event the Company will issue any Common Stock or securities convertible into the Common Stock at a price less than the purchase price of the Warrants, the price shall be reduced to the new issuance price.

   As of February 28, 2013, the December Warrants were presented within stockholders equity. After further review, the Company has determined that these instruments should have been classified as liabilities. Changes in the fair value of these Warrants require adjustments to the amount of the liabilities recorded on the Company's balance sheet, and the corresponding gain or loss is required to be recorded in the Company's statement of comprehensive loss.

   In March 2013 the Company issued 100,000 warrants ( March Warrant ) in connection with the agreements with Mediapark. Each Common Stock warrant can be exercised into one share at an exercise price of $0.50 per warrant and is exercisable until March 22, 2015. In the event the Company will issue any Common Stock or securities convertible into the Common Stock at a price less than the purchase price of the Warrants, the price shall be reduced to the new issuance price.

2. In May 2013, the Company issued 1,526,718 warrants ( May Warrants ). Each Common Stock warrant can be exercised into one share at an exercise price of $1 per warrant and is exercisable until May 6, 2015. In the event the Company will issue any Common Stock or securities convertible into the Common Stock at a price less than $0.8515, the price shall be reduced to the new issuance price.

3. On June 30, 2013 the company exercised its discretion to extend the maturity date of the Mediapark Loan to September 30, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 additional Warrants at an exercise price of $0.5. For additional information see Note 3b5.

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**NOTE 5- WARRANTS (continued):**

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

Financial liabilities carried at fair value as of August 31, 2013 are classified in the tables below in one of the three fair value categories:

| | Fair value measurements at reporting date using | |
|---|---|---|
| | **Level 3** | **Total** |
| **Warrants -** | | |
| August 31, 2013 | $ 1,161,956 | $ 1,161,956 |

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

| | **During the nine months ended August 31, 2013** | **During the three months ended August 31, 2013** |
|---|---|---|
| Carrying value at the beginning of the period | $ - | $ 1,402,530 |
| Additions | $ 1,245,270 | 47,268 |
| Changes in fair value of warrant liabilities | (83,314) | (287,842) |
| Carrying value at the end of the period | | |
| | $ 1,161,956 | $ 1,161,956 |

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**NOTE 6 TAXES ON INCOME**

**1. Corporate taxation in the U.S.**

The applicable corporate tax rate for the Company is 34%.

**2. Corporate taxation in Israel:**

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

**3. Deferred income taxes:**

| | As of August 31, 2013 | As of November 30, 2012 |
|---|---|---|
| In respect of: | | |
| Net operating loss carry forward | $ 749,424 | $ 344,307 |
| R&D expenses | 123,584 | 57,344 |
| Holiday and recreation pay | 10,806 | 3,968 |
| Severance pay accruals | 869 | 402 |
| Less Valuation allowance | (884,683) | (406,021) |
| Net deferred tax assets | $ - | $ - |

Realization of deferred tax assets is dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income. As the achievement of required future taxable income is uncertain, the Company recorded a full valuation allowance.

**NOTE 7 - SUBSEQUENT EVENTS**

1. On September 30, 2013 the Company extended the maturity date of the loan to December 31, 2013 in return for extending the maturity date the Company issued to Mediapark 100,000 Additional Warrants. See also note 3b5.

2. On October 11, 2013 Orgenesis Ltd. established a wholly-owned subsidiary in Belgium, Orgenesis SPRL, which will be engaged in development and manufacturing activities together with the clinical studies in Europe.

**ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

***Forward-Looking Statements***

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may , should , expects , plans , anticipates , believes , estimates , predicts , potential negative of these terms or other comparable terminology. Forward-looking statements made in a quarterly report on Form 10-Q includes statements about:

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

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

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

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

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

As used in this quarterly report on Form 10-Q and unless otherwise indicated, the terms we , us , our , or the Compa refer to Orgenesis Inc. and our wholly owned subsidiaries, Orgenesis Ltd.,(the Israeli Subsidiary ) and Orgenesis Inc. (the US Subsidiary ) . Unless otherwise specified, all dollar amounts are expressed in United States dollars.

***Corporate Overview***

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

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

Effective August 31, 2011 we affected a 35 to one forward stock split of our authorized and issued and outstanding common stock. As a result, our authorized capital has increased from 50,000,000 shares of common stock with a par value of $0.001 to 1,750,000,000 shares of common stock with a par value of $0.0001. Unless otherwise noted, all references in this quarterly 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 Medical Research, Infrastructure and Services Ltd. (the Licensor ) 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 (the **License Agreement** ) to license patents and knowhow related to the development of AIP (Autologous Insulin Producing) cells. On July 31, 2013, we incorporated a wholly-owned subsidiary in Maryland named Orgenesis Inc. On October 11, 2013, Orgenesis Ltd. incorporated a wholly-owned subsidiary in. Belgium, Orgenesis SPRL.

Based on the licensed know how and patents, our intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using a therapeutic agent (i.e., PDX-1, and 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.

***Recent Corporate Developments***

Since the commencement of our third quarter ended August 31, 2013 we experienced the following corporate developments:

Agreement with Professor Jay Skyler

On April 9, 2013, we executed a consulting agreement with Professor Jay Skyler. Prof. Skyler has agreed to be appointed to our Board of Advisors committee, and we will pay Prof. Skyler an hourly fee for attending in person meetings and meetings via conference call. In July, 2013 we granted Prof. Skyler 100,000 stock options exercisable into one share at an exercise price of $ 0.96. The options vest in five equal annual installments from the date of grant. Prof. Skyler will also be reimbursed for out of pocket expenses incurred for carrying out consulting business.

*Agreement with Dr. David Sidransky*

On July 16, 2013 we entered into an agreement with Dr. David Sidransky. Under the terms of the agreement, we have appointed Dr. Sidransky to our board of directors.

In consideration of Dr. Sidransky s services we will pay for his attendance at Board meetings at the rate of $300 for the first hour of attendance and $200 for each additional hour or portion of an hour. We issued to Dr. Sidransky 250,000 stock options subject to the terms of our stock option plan, at an exercise price of $0.75 per option share. We will also reimburse any pre-approved business expenses incurred by Dr. Sidransky.

Dr. Sidransky is an oncologist and research scientist who works with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine and Professor of Oncology, Otolaryngology, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at John Hopkins University and Hospital.

Dr. Sidransky has served as ViceChairman of the Board of Directors, and was, until the merger with Eli Lilly, a director of ImClone Systems Inc., a global biopharmaceutical company. He has served on scientific advisory boards of MedImmune, LLC, Roche Holding Ltd., Amgen Inc. and Veridex, LLC (a Johnson & Johnson diagnostic company), and is currently on the board of KV Pharmaceutical Company, Rosetta Genomics Ltd. and Champions Oncology, Inc. Dr. Sidransky served as Director (2005-2008) of the American Association for Cancer Research (AACR). He was the chairperson of AACR International Conferences (2006 and 2007) on Molecular Diagnostics in Cancer Therapeutic Development: Maximizing Opportunities for Personalized Treatment.

Dr. Sidransky obtained his MD from Baylor College of Medicine in Houston, Texas.

*Mediapark*

On March 22, 2013, we entered into a subscription agreement with Mediapark A.G., a Marshall Islands company, pursuant to which Mediapark purchased an 8% unsecured convertible Loan (the Loan ) in the aggregate principal amount of US $250,000 and we issued to Mediapark 100,000 warrants (the Warrant ). Each Warrant carries the right to purchase one share of common stock at a price of $0.50 per share for a period of 24 months from issuance of the Warrant, on terms set out in the Warrant Certificate. In the event we issue any common shares or securities convertible into common shares at a price less than $0.50 while any of these warrants remain unexercised, the exercise price shall be reduced for any unexercised warrants to the price the new securities were issued.

The Loan matures is on June 30, 2013. Interest is calculated on a quarterly basis. We have the right to extend the maturity date for an additional period of up to 90 days provided we issue an equal number of Warrants to the number issued to the investor on initial closing.

On June 30, 2013, we exercised our discretion to extend the maturity date of the Loan to September 30, 2013. In return for extending the maturity date, we issued to Mediapark 100,000 additional Warrants. On September 30, 2013, we extended the maturity date of the Loan to December 31, 2013, in exchange for issuing 100,000 additional Warrants.

If the Loan is not repaid at the maturity date, or, if extended, at the end of the extended period the holder may convert the loan and any accrued and unpaid interest into shares of our common stock at the lower of $0.75 per share and the 5 day Volume Weighted Average Price ( VWAP ) of our common shares trading price prior to conversion. The investor is under no obligation to convert and may take a realization process to recover funds, interest and expenses of collection.

*Renewal of Agreement*

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

*Belgium Subsidiary*

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

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

*Maryland Subsidiary.*

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

***Results of Operations***

The following summary of our results of operations should be read in conjunction with our condensed financial statements for the three and nine months ended August 31, 2013.

*Revenue*

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

*Expenses*

Our expenses for the three and nine months ended August 31, 2013 are summarized as follows in comparison to our expenses for the three and nine months ended August 31, 2012:

| | Nine Months Ended | |
|---|---|---|
| | August 31, 2013 | August 31, 2012 |
| Research and development expenses | $ 930,487 | $ 1,740,697 |
| Business development expenses | $ 1,354,324 | $ 1,052,794 |
| General and administration expenses[1] | $ 1,490,026 | $ 824,172 |
| Net loss including financial expenses | $ 3,823,883 | $ 3,603,932 |

| | Three Months Ended | |
|---|---|---|
| | August 31 2013 | August 31 2012 |
| Research and development expenses | $ 226,935 | $ 542,267 |
| Business development expenses | $ 442,046 | $ 1,003,924 |
| General and administration expenses[1] | $ 493,182 | $ 342,883 |
| Net loss including financial expenses | $ 937,440 | $ 1,889,074 |

[1] This classification is not the same as the classification in the financial statements.

Research and development expenses

| | Nine Months Ended | |
|---|---|---|
| | August 31 2013 | August 31 2012 |
| Patent registration | $ 55,983 | $ 589,622 |
| Salaries & related expenses | 493,735 | 1,016,030 |
| Professional fees and consulting services | 204,965 | 65,669 |
| Other research expenses | $ 175,804 | $ 69,376 |
| Total | $ 930,487 | $ 1,740,697 |

The decrease in patents registration is due to one-time non-cash compensation (in 2012) of $509,622 to our patents attorneys .The decrease in salaries and related expenses is due to stock-based compensation expenses to an employee in prior period, those options were fully vested in February 2013.

| | Three Months Ended | |
|---|---|---|
| | August 31 2013 | August 31 2012 |
| Patent registration | $ 4,177 | $ - |
| Salaries & related expenses | 96,918 | 438,917 |
| Professional fees and consulting services | 65,993 | 56,452 |
| Other research expenses | $ 59,847 | $ 46,898 |
| Total | $ 226,935 | $ 542,267 |

The decrease in salaries and related expenses is due to a non-cash item regarding options to an employee, which were fully vested in February 2013. Accordingly, no expense was recorded for this item in the quarter ended August 31, 2013.

Business development expenses

| | Nine Months Ended | |
|---|---|---|
| | August 31, 2013 | August 31, 2012 |
| Salaries & related expenses | 1,134,968 | 949,996 |
| Other | $ 219,356 | $ 102,798 |
| Total | $ 1,354,324 | $ 1,052,794 |

The increase in salaries & related expenses in the nine months ended August 31, 2013 as compared to the same period previous year is related to one-time bonus expenses and stock based compensation due to an employee.

| | Three Months Ended | |
|---|---|---|
| | August 31, 2013 | August 31, 2012 |
| Salaries & related expenses | 384,227 | 943,967 |
| Other | $ 57,819 | $ 59,958 |
| Total | $ 442,046 | $ 1,003,924 |

The decrease in salaries & related expenses in the three months ended August 31, 2013 as compared to the three months ended August 31, 2012 is due to stock based compensation to an employee which was recorded in Q3 2012.

General and Administrative Expenses

| | Nine Months Ended | |
|---|---|---|
| | August 31 2013 | August 31 2012 |
| Salaries & related expenses | $ 833,169 | $ 399,152 |
| Accounting & legal | 183,186 | 215,139 |
| Transfer agent & filing fees | 6,530 | 14,317 |
| Other general & administrative | $ 467,140 | $ 195,564 |
| Total | $ 1,490,025 | $ 824,172 |

| | Three Months Ended | |
|---|---|---|
| | August 31 2013 | August 31 2012 |
| Salaries & related expenses | $ 280,704 | $ 191,051 |
| Accounting & legal | 54,187 | 48,210 |
| Transfer agent & filing fees | 3,075 | 8,657 |
| Other general & administrative | $ 155,216 | $ 94,965 |
| Total | $ 493,182 | $ 342,883 |

The increase in salaries and related expenses is due to the appointment of our new Chief Executive Officer, who was recruited in December 2012 and to vesting of options which was recorded in 2013. The increase in other general and administrative expenses is related to consulting and professional services including stock based compensation in return to services provided.

***Liquidity and Financial Condition***

*Working Deficiency*

| | As of August 31, 2013 | As of November 30, 2012 |
|---|---|---|
| Current Assets | $ 583,062 | $ 38,598 |
| Current Liabilities | $ 740,380 | $ 327,170 |
| Working Deficiency | $ (157,318) | $ (288,572) |

The increase in our current assets at August 31, 2013, as compared to November 30, 2012, is due to a fund raising completed on May 6, 2013.The increase in current liabilities is mainlyrelated to a $250,000 loan that we received on March 22, 2013

*Cash Flows*

| | Nine Months Ended | |
|---|---|---|
| | August 31 2013 | August 31 2012 |
| Net cash used in operations | $ (1,524,513) | $ (749,002) |
| Net cash used in investing activities | $ (9,400) | $ (10,355) |
| Net cash provided by financing activities | $ 2,050,000 | $ 1,071,661 |
| Increase in cash during the period | $ 516,087 | $ 312,304 |

The increase in cash is mainly due to the 2,050,000 fund raising by the company during the nine months ended on August 31, 2013 compared to the amount of 1,071,661 in the same period previous year. The increase in operation expenses is related to our expanded operations this year in comparison to previous year.

***Going Concern***

The accompanying unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. We have net losses for the period from inception (June 5, 2008) through August 31, 2013, of $8,959,699 as well as a negative cash flow from operating activities. Presently, we do not have sufficient cash resources to meet our plans in the 12 months following August 31, 2013. These factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives, as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that we will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability.

***Cash Requirements***

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

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

- initiate regulatory activities in Asia, Europe and USA;

- locate suitable centers and sign a collaboration agreement;

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

We estimate our operating expenses and working capital requirements for the next 12 months to be as follows:

| **Expense** | | **Amount** |
|---|---|---|
| Product development | $ | 1,561,956 |
| General and administration | | 963,183 |
| Manufacturing | | 1017,859 |
| Business development | | 300,781 |
| **Total** | $ | 3,843,779 |

***Future Financing***

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

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

***Off Balance Sheet Arrangements***

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

***Significant Accounting Policies***

Our significant accounting policies are more fully described in the notes to our condensed consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended November 30, 2012. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

*Income Taxes*

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

*Stock-Based Compensation*

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

We account for share-based compensation granted to employees in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based compensation is recognized as an expense over the requisite service period, net of estimated forfeitures.

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

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

*Warrants classified as liabilities*

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

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

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not Applicable

**ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our president and chief executive officer (who is our principal executive officer) and our chief financial officer, treasurer, and secretary (who is our principal financial officer and principal accounting officer) to allow for timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the foregoing, we concluded that our disclosure controls and procedures were ineffective as of the end of the period covered by this quarterly report due to the following material weaknesses: (1) inadequate segregation of duties consistent with control objectives; and (2) ineffective controls over period end financial disclosure and reporting processes.

*Management s Remediation Initiatives*

To remediate such weaknesses, we believe we would need to implement the following changes: (i) appoint additional qualified personnel to address inadequate segregation of duties and ineffective risk management; and (ii) adopt sufficient written policies and procedures for accounting and financial reporting. The remediation efforts set out in (i)

and (ii) are largely dependent upon our securing additional financing to cover the costs of implementing the changes required. If we are unsuccessful in securing such funds, remediation efforts may not be undertaken. Until we have the required funds, we do not anticipate implementing these remediation steps.

*Changes in internal control over financial reporting*

There were no changes in our internal control over financial reporting during the three months ended August 31, 2013 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

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

### ITEM 1A. RISK FACTORS

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our company and its business before purchasing shares of our company s common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. You could lose all or part of your investment due to any of these risks.

***Risks Related to Our Company***

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

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

*Substantial doubt about our ability to continue as a going concern.*

We have not generated any revenue from operations since our incorporation. We expect that our operating expenses will increase over the next 12 months as we ramp-up our business. We have net losses for the period from inception (June 5, 2008) through August 31, 2013, of $8,959,699 as well as negative cash flow from operating activities. Presently, we do not have sufficient cash resources to meet our requirements in the 12 months following August 31, 2013. This amount could increase if we encounter difficulties that we cannot anticipate at this time. As we cannot assure a lender that we will be able to successfully acquire and develop pharmaceutical assets, we will almost

certainly find it difficult to raise debt financing from traditional lending sources. If we cannot raise the money that we need in order to continue to operate our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail.

*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 on satisfactory terms.*

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

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

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

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

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

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

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

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

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

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

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

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

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

The ability of our subsidiary to pay dividends is governed by Israeli law, which provides that dividends may be paid by an Israeli corporation only out of its earnings as defined in accordance with the Israeli Companies Law of 1999, provided that there is no reasonable concern that such payment will cause such subsidiary to fail to meet its current and expected liabilities as they come due. Cash dividends paid by an Israeli corporation to United States resident corporate parents are subject to provisions of the Convention for the Avoidance of Double Taxation between Israel and the United States, which may result in our subsidiary having to pay taxes on any dividends it declares.

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

*THM may cancel the License Agreement.*

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

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

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

- there are still major developmental steps required to bring the product to a clinical testing stage; clinical testing may not be positive;
- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;

- failure to receive requisite regulatory approvals for such products in a timely manner or at all;
- developing and commercializing a new product is time consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development

and commercialization of new products;

- incomplete, unconvincing or equivocal clinical trials data;
- experiencing delays or unanticipated costs;
- significant and unpredictable changes in the payer landscape, coverage and reimbursement for our products;
- experiencing delays as a result of limited resources at FDA or other regulatory agencies; and
- changing review and approval policies and standards at FDA and other regulatory agencies.

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

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

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

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

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

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

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

Under these regulations, we may become subject to periodic inspection of our facilities, procedures and operations and/or the testing of our future products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our

systems and processes are in compliance with cGMP and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or warning letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a warning letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We may also be required to report adverse events associated with our future products to FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in labeling changes, recalls, market withdrawals or other regulatory actions.

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

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

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

*The pharmaceutical industry is highly competitive.*

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

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

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

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

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

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

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

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

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

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

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

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

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

| No. | Description |
|---|---|
| 3.1 | Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S-1 filed on April 2, 2009) |
| 3.2 | Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011) |
| 3.3 | Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011) |
| 3.4 | Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011) |
| 3.5 | Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011) |
| 3.6 | Certificate of Correction dated February 27, 2012 (incorporated by reference to an exhibit to a current report on Form 8-K/A filed on March 16, 2012) |
| 10.1 | Form of Private Placement Subscription Agreement (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012) |
| 10.2 | Licensing Agreement dated February 2, 2012 with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012) |
| 10.3 | Employment Agreement dated February 2, 2012 between our company and Prof. Sarah Ferber (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012) |
| 10.4 | Stock Option Agreement dated February 2, 2012 between our company, Prof. Sarah Ferber and Clark Wilson LLP (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012) |
| 10.5 | Fee Service Agreement dated February 2, 2012 between our company and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012) |
| 10.6 | Compensation Letter dated February 2, 2012 between our company and Vered Caplan (incorporated by reference to an exhibit to a current report on Form 8-K filed on February 8, 2012) |
| 10.7 | Personal Employment Agreement with Jacob Ben Arie dated February 2, 2012 (incorporated by reference to our current report on Form 8-K filed on March 15, 2012) |
| 10.8 | Consultancy Agreement dated March 2, 2012 with Weinberg Dalyo Inc. (incorporated by reference to our current report on Form 8-K filed on March 15, 2012) |
| 10.9 | Investor Relations Agreement dated March 15, 2012 with Crescendo Communications, LLC (incorporated by reference to our current report on Form 8-K filed on March 15, 2012) |
| 10.10 | Research Services Agreement dated March 22, 2012 with Tel Hashomer Medical Research, Infrastructure and Services Ltd. (incorporated by reference to our current report on Form 8-K filed on April 13, 2012) |
| 10.11 | Director Agreement with Guy Yachin dated April 2, 2012 (incorporated by reference to our current report on Form 8-K filed on April 5, 2012) |
| 10.12 | |

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|---|---|
| | Director Agreement with Yaron Adler dated April 6, 2012 (incorporated by reference to our current report on Form 8-K filed on April 23, 2012) |
| 10.13 | Director Agreement with Etti Hanochi dated April 6, 2012 (incorporated by reference to our current report on Form 8-K filed on April 25, 2012) |
| 10.14 | Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on May 2, 2012) |
| 10.15 | Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on May 2, 2012) |
| 10.16 | Board of Advisors Consulting Agreement April 14, 2012 (incorporated by reference to our current report on Form 8-K filed on May 31, 2012) |
| 10.17 | Global Share Incentive Plan (2012) (incorporated by reference to our current report on Form 8-K filed on May 31, 2012) |
| 10.18 | Appendix Israeli Taxpayers Global Share Incentive Plan (incorporated by reference to our current report on Form 8-K filed on May 31, 2012) |

| No. | Description |
|---|---|
| 10.19 | Letter agreement with the Investor Relations Group Inc. dated May 2, 2012 (incorporated by reference to our current report on Form 8-K filed on May 31, 2012) |
| 10.20 | Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on August 3, 2012) |
| 10.21 | Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on August 3, 2012) |
| 10.22 | Cancellation and Amendment of Warrants Agreement (incorporated by reference to our current report on Form 8-K filed on December 10, 2012) |
| 10.23 | Employment Term Sheet with Mr. Sav DiPasquale dated December 17, 2012 (incorporated by reference to our current report on Form 8-K filed on January 7, 2013) |
| 10.24 | Form of subscription agreement and loan agreement (incorporated by reference to our current report on Form 8-K filed on March 25, 2013) |
| 10.25 | Form of warrant certificate (incorporated by reference to our current report on Form 8-K filed on March 25, 2013) |
| 10.26 | Board of Advisors Consulting Agreement with Professor Jay Sklyer (incorporated by reference to our current report on Form 8-K filed on April 9, 2013) |
| 10.27 | May 6, 2013 Process Development Agreement with ATI BVBA |
| 10.28 | Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on May 9, 2013) |
| 10.29 | Form of warrant (incorporated by reference to our current report on Form 8-K filed on May 9, 2013) |
| 10.30 | Registration Rights Agreement (incorporated by reference to our current report on Form 8-K filed on May 9, 2013) |
| 31.1* | Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2* | Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1* | Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2* | Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101* | Interactive Data Files pursuant to Rule 405 of Regulation S-T. |

*Filed herewith

**SIGNATURES**

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

ORGENESIS INC.

By:

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

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