

Orgenesis Inc.
Form 10-Q
October 15, 2014

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

FORM 10-Q

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

For the Quarterly Period Ended **August 31, 2014**

or

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

For the Transition Period from _____ to _____

Commission file number: **000-54329**

ORGENESIS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or
organization)

98-0583166

(I.R.S. Employer Identification No.)

21 Sparrow Circle White Plains, NY, 10605

(Address of principal executive offices) (zip code)

(480) 659-6404

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes☒ No ☐

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

Large Accelerated
accelerated filer filer ☐ ☐

☐ ☐
Non-accelerated Smaller
filer ☐ reporting
company
☒

(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 ☒ No

As of October 13, 2014, there were 55,172,617 shares of registrant's common stock outstanding.

ORGENESIS, INC.
FORM 10-Q
FOR THE QUARTER ENDED AUGUST 31, 2014

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PART I UNAUDITED FINANCIAL INFORMATION**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

ORGENESIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
In U.S. Dollars

| | As of August 31, 2014 (Unaudited) | As of the Year Ended November 30, 2013 (Audited) |
|---|---|--|
| <u>ASSETS</u> | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 1,533,147 | \$ 50,827 |
| Short-term bank deposit | 10,002 | 10,002 |
| Prepaid expenses and other account receivable | 96,385 | 36,908 |
| Total current assets | 1,639,534 | 97,737 |
| FUNDS IN RESPECT OF RETIREMENT BENEFITS OBLIGATION | | |
| | 4,842 | 3,630 |
| PROPERTY AND EQUIPMENT, NET | 15,729 | 12,854 |
| Total assets | \$ 1,660,105 | \$ 114,221 |
| <u>Liabilities net of Stockholders deficiency</u> | | |
| CURRENT LIABILITIES: | | |
| Short-term bank credit | \$ 13,896 | \$ - |
| Accounts payable | 236,963 | 138,775 |
| Accrued expenses | 811,012 | 386,122 |
| Related parties | 42,362 | 42,362 |
| Employees and related payables | 488,290 | 155,100 |
| Advance payment on account of grant | 110,678 | - |
| Convertible loans and accrued interest | 2,614,770 | 264,050 |
| Total current liabilities | 4,317,971 | 986,409 |
| LONG-TERM LIABILITIES: | | |
| Warrants liability | 1,435,000 | 1,157,954 |
| Retirement benefits obligation | 5,421 | 4,272 |
| Total long-term liabilities | 1,440,421 | 1,162,226 |
| COMMITMENTS AND CONTINGENCIES (Note 3) | | |
| Total liabilities | \$ 5,758,392 | \$ 2,148,635 |
| STOCKHOLDER'S EQUITY (DEFICIT): | | |

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Common stock, \$0.0001 par value, 1,750,000 shares authorized,
55,172,617 (unaudited) and 51,144,621 shares issued and outstanding
as of August 31, 2014 (unaudited) and November 30, 2013,
respectively

| | | |
|-------------------------------|--------------|--------------|
| | 5,517 | 5,114 |
| Additional paid-in capital | 12,568,738 | 8,635,447 |
| Accumulated deficit | (16,672,542) | (10,674,975) |
| Total stockholders' (deficit) | (4,098,287) | (2,034,414) |

Total Liabilities net of Stockholders deficiency \$ 1,660,105 \$ 114,221

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

ORGENESIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
In U.S. Dollars

| | For the Three Months Ended | | For the Nine Months Ended | |
|--|----------------------------|-----------------|---------------------------|-----------------|
| | August 31, 2014 | August 31, 2013 | August 31, 2014 | August 31, 2013 |
| | (Unaudited) | (Unaudited) | (Unaudited) | (Unaudited) |
| REVENUE | \$ - | \$ - | \$ - | \$ - |
| OPERATING EXPENSES: | | | | |
| Research and development | 845,599 | 226,935 | 1,936,079 | 930,487 |
| General and administrative | 440,058 | 935,228 | 2,032,073 | 2,844,350 |
| Total operating expenses | 1,285,657 | 1,162,163 | 3,968,152 | 3,774,837 |
| OPERATING LOSS | (1,285,657) | (1,162,163) | (3,968,152) | (3,774,837) |
| Financial expenses (income), net | (2,206,588) | 224,723 | (2,029,415) | (49,046) |
| Total other expense | (2,206,588) | 224,723 | (2,029,415) | (49,046) |
| NET LOSS | \$ (3,492,245) | \$ (937,440) | \$ (5,997,567) | \$ (3,823,883) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | | | | |
| - Basic and diluted | 54,916,980 | 51,144,621 | 53,672,820 | 50,264,348 |
| NET LOSS PER SHARE - Basic and diluted | \$ (0.06) | \$ (0.02) | \$ (0.11) | \$ (0.08) |

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

ORGENESIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' CAPITAL
DEFICIENCY
In U.S. Dollars

| | Common Stock Number | Par Value | Additional Paid-in Capital | Accumulated Deficit | Total |
|--|------------------------|-----------|-------------------------------|------------------------|----------------|
| Balance at November 30, 2013 | 51,144,621 | \$ 5,114 | \$ 8,635,447 | \$ (10,674,975) | \$ (2,034,414) |
| Stock-based compensation related to options granted to employees and | - | - | 1,076,428 | - | 1,076,428 |
| Stock-based compensation related to options granted to consultants | - | - | 901,733 | - | 901,733 |
| Issuances of shares and warrants | 2,095,013 | 210 | 1,094,196 | - | 1,094,406 |
| Conversions of convertible loans into shares and warrants | 713,023 | 71 | 630,432 | - | 630,503 |
| Issuance of shares along with convertible loan | 500,000 | 50 | 179,950 | - | 180,000 |
| Exercise of stock options into shares | 623,806 | 62 | 562 | - | 624 |
| Exercise of warrants into shares and warrants | 96,154 | 10 | 49,990 | - | 50,000 |
| Net loss | - | - | - | (5,997,567) | (5,997,567) |
| Balance at August 31, 2014 (unaudited) | 55,172,617 | \$ 5,517 | \$ 12,568,738 | \$ (16,672,542) | \$ (4,098,287) |

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

ORGENESIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
In U.S. Dollars

| | For the Nine Months Ended | |
|--|---------------------------|-------------------|
| | August 31, 2014 | August 31, 2013 |
| | (Unaudited) | (Unaudited) |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income (loss) | \$ (5,997,567) | \$ (3,823,883) |
| Adjustments to reconcile net income to net cash used in operating activities: | | |
| Stock-based compensation related to options granted to employees | 1,076,428 | 1,882,761 |
| Stock-based compensation related to options granted to consultants | 901,733 | 242,161 |
| Receipt on account of shares to be issued to consultant on account of services | - | 6,144 |
| Increase in accrued severance pay | 1,149 | 1,922 |
| Depreciation expense | 2,589 | 2,404 |
| Change in fair value of warrants and embedded derivative | 1,291,046 | (51,802) |
| Financial expense on convertible loans and funding fees | 682,223 | 73,525 |
| Changes in operating assets and liabilities: | | |
| Increase in prepaid expenses and other accounts receivable | (59,477) | (12,621) |
| Increase in accounts payable | 135,594 | 15,552 |
| Increase in accrued expenses | 424,890 | 93,889 |
| Increase in employee and related party payables | 333,190 | 45,435 |
| Increase in advance payment on account of grant | 110,678 | - |
| | - | - |
| Net cash used in operating activities | (1,097,524) | (1,524,513) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of property and equipment | (5,464) | (7,839) |
| Amounts funded in respect of retirement benefits obligation | (1,212) | (1,561) |
| Other | - | - |
| Net cash used in investing activities | (6,676) | (9,400) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Short-term bank credit | 13,896 | - |
| Proceeds from issuance of shares and warrant | 922,000 | 1,800,000 |
| Proceeds from exercise of stock options | 624 | - |
| Proceeds from exercise of warrants into shares and warrants | 50,000 | - |
| Proceeds from loan received | 100,000 | 250,000 |
| Proceeds from issuance of convertible loan together with shares | 1,500,000 | - |
| Net cash provided by financing activities | 2,586,520 | 2,050,000 |
| NET CHANGE IN CASH | 1,482,320 | 516,087 |
| CASH AT BEGINNING OF PERIOD | 50,827 | 347 |
| CASH AT END OF PERIOD | \$ 1,533,147 | \$ 516,434 |

SUPPLEMENTAL INFORMATION:

Cash paid during the period for:

| | | | | |
|--------------|----|---|----|---|
| Interest | \$ | - | \$ | - |
| Income taxes | \$ | - | \$ | - |

Non-cash investing and financing activities:

| | | | | |
|--|----|---------|----|---|
| Common stock issued for rendered services | \$ | 37,406 | \$ | - |
| Common stock issued for conversion of loans and accrued interest | \$ | 370,772 | \$ | - |

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

ORGENESIS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 GENERAL AND BASIS OF PRESENTATION

Orgenesis, Inc. (the Company), incorporated in the State of Nevada on June 5, 2008, is engaged, together with its subsidiaries, in the research and development of a new technology for regeneration of functional insulin-producing cells, thus, enabling normal glucose regulated insulin secretion, via cell therapy.

These unaudited condensed consolidated financial statements of the Company and its wholly-owned subsidiaries have been prepared in accordance with U.S. GAAP and pursuant to the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial statements. Accordingly, they do not contain all information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, the unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of August 31, 2014, the consolidated results of operations and comprehensive loss for the three and nine-month periods ended August 31, 2014 and 2013, and the consolidated cash flows for the nine-month periods ended August 31, 2014 and 2013.

The financial data and other information disclosed in the notes to the condensed consolidated financial statements related to these periods are unaudited. The results for the three and nine-month periods ended August 31, 2014 are not necessarily indicative of the results to be expected for the year ending November 30, 2014.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended November 30, 2013. The condensed consolidated balance sheet data as of November 30, 2013 was derived from the audited consolidated financial statements for the year ended November 30, 2013, but does not include all disclosures required by U.S. GAAP.

In June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, Development Stage Entities (Topic 915), Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (ASU 2014-10). The amendments in ASU 2014-10 remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from accounting principles generally accepted in the United States of America (U.S. GAAP). In addition, the amendments eliminate the requirements for development stage entities to: (i) present inception-to-date information in the statements of income, cash flows, and shareholder equity; (ii) label the financial statements as those of a development stage entity; (iii) disclose a description of the development stage activities in which the entity is engaged; and (iv) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The presentation and disclosure requirements in Accounting Standard Codification (ASC) Topic 915, Development Stage Entities are no longer required for interim and annual reporting periods beginning after December 15, 2014. The revised consolidation standards will take effect in annual periods beginning after December 15, 2015. However, early adoption is permitted. The Company has elected to early adopt the provisions of ASU 2014-10 for these unaudited condensed consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Currently, there is no guidance under U.S. GAAP about

management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in this Update provide that guidance. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). For the period ended August 31, 2014, management evaluated the Company's ability to continue as a going concern and concluded that substantial doubt has not been alleviated about the Company's ability to continue as a going concern. While the Company continues to explore further significant sources of financing, management's assessment was based on the uncertainty related to the amount and nature of such financing over the next twelve months.

Going Concern

These unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has accumulated losses since inception of \$16,672,542, as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following August 31, 2014. 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 in either the public or private equity markets. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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. However, there is no assurance that the Company will be successful with those initiatives.

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

NOTE 2 - FAIR VALUE PRESENTATION

The fair value measurement guidance clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in the valuation of an asset or liability. It establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under the fair value measurement guidance are described below:

Level 1 - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2 - Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3 - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

As of August 31, 2014, the Company's assets and liabilities that are measured at fair value and classified as level 3 fair value are as follows:

| | August 31, 2014 | |
|----------------------|-----------------|--------------|
| | <u>Level 3</u> | <u>Total</u> |
| Warrants | \$ 1,435,000 | \$ 1,435,000 |
| Embedded derivative* | \$ 1,588,000 | \$ 1,588,000 |

| | November 30, 2013 | |
|----------|-------------------|--------------|
| | <u>Level 3</u> | <u>Total</u> |
| Warrants | \$ 1,157,954 | \$ 1,157,954 |

* The embedded derivative is presented in the Company's balance sheets on a combined basis with the related host contract (the convertible loans).

The fair value of each of the warrants described in Note 6a is determined by using a Monte Carlo type valuation 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 issuance dates. Then for each path to use the Black-Scholes valuation model to estimate the value of the warrants on the last issuance 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 issuance dates.

The fair value of the embedded derivative described in Note 5b is determined by using the Black-Scholes valuation model. Notwithstanding the anti-dilution provision as described in Note 5b the Black Scholes formula produces a value that is substantially the same to the value under more flexible option valuation models such as the Monte Carlo simulation model due to an ineffectiveness of this protection feature over the relatively short term of the embedded derivative.

The following table presents the assumptions that were used for the models as of August 31, 2014:

| | Warrants | Embedded Derivative |
|--------------------------------------|-----------|---------------------|
| Fair value of shares of common stock | \$ 0.90 | \$ 0.90 |
| Expected volatility | 90% | 86% |
| | 0.03% - | |
| Risk free interest rate | 0.12% | 0.04% |
| Expected term (years) | 0.25 1.08 | 0.33 |
| Expected dividend yield | 0% | 0% |

The table below sets forth a summary of the changes in the fair value of the Company's financial liabilities classified as Level 3 for the nine months ended August 31, 2014:

| | Warrants | Embedded Derivative |
|---|--------------|---------------------|
| Balance at beginning of period | \$ 1,157,954 | \$ - |
| Additions | - | 574,000 |
| Changes in fair value during the period | 277,046 | 1,014,000 |
| Balance at end of period | \$ 1,435,000 | \$ 1,588,000 |

NOTE 3 COMMITMENTS AND CONTINGENT LIABILITIES

a. Tel Hashomer - Medical Research, Infrastructure and Services Ltd.

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

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

- 1) A royalty of 3.5% of net sales;

- 2) 16% of all sublicensing fees received;
- 3) 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; and
- 4) Milestone payments as follows:
 - a) \$50,000 on the date of initiation of phase I clinical trials in human subjects;
 - b) \$50,000 on the date of initiation of phase II clinical trials in human subjects;
 - c) \$150,000 on the date of initiation of phase III clinical trials in human subjects; and
 - d) \$750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA.
 - e) \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time, (The Sales Milestone).

As of August 31, 2014 the Company has not reached any of these milestones.

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Israeli Subsidiary and/or consolidation of the Israeli 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 Israeli Subsidiary at the time of the Exit.

On March 22, 2012, the Israeli 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 consideration of approximately \$74,000 for a year. On May 1, 2013, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately \$92,000, and on May 4, 2014, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately \$114,000.

b. Mintz, Levin, Ferris, Glovsky and Popeo, P.C.

On February 2, 2012, the Company entered into an agreement with its patent attorneys, Mintz, Levin, Ferris, Glovsky and Popeo, P.C. (Mintz Levin) for professional services related to patent registration. In addition to an amount of \$80,000 paid to Mintz Levin, 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 additional \$50,000 upon consummation of the earlier of:

- 1) The purchase of all the Company's common stock and/or amalgamation of the Company or its 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):
 - a) Initiation by the Company of phase I clinical trials for the Company's product in human subjects.
 - b) Initiation by the Company of phase II clinical trials in human subjects.
 - c) Initiation by the Company of phase III clinical trials in human subjects.

As of August 31, 2014, the Company has not reached any of these milestones.

On March 27, 2013, the Company signed an agreement with Mintz Levin in which 16% of its fees will be converted to shares of common stock of the Company at market price. On July 14, 2014, \$13,395 of fees incurred were converted into 25,759 shares of common stock.

c. Pall Life Science Belgium BVBA

On May 6, 2013, the Israeli Subsidiary entered into a Process Development Agreement with Pall Life Science Belgium BVBA (formerly ATMI BVBA), a Belgian Company which is a wholly-owned subsidiary of Pall Corporation (Pall), a U.S. publicly traded company. According to the agreement, Pall will provide services in cell research. The Company will use Pall s unique technology while the Company will provide to Pall 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 a total consideration of Euro 606,500 for all services. As of August 31, 2014, the Company received services in total value of Euro 360,315.

d. Aspen Agency Limited

On April 3, 2014, the Company entered into a consulting agreement with Aspen Agency Limited, a Hong Kong corporation (Aspen), pursuant to which Aspen has agreed to provide investment banking, investor relations and business development services to the Company. In consideration for Aspen's services, the Company has agreed to issue to Aspen 3,000,000 stock options to acquire shares of the Company's common stock at an exercise price of \$0.52 per share, for a period of three years. The options will be subject to vesting provisions as follows:

- 1) 1,000,000 options (the First Tranche) will vest as of the date of execution of the agreement; and
- 2) In the event Aspen exercises all 1,000,000 vested First Tranche options during the first 12 months of the agreement, the Second Tranche of 2,000,000 options will vest.

The term of the consulting agreement is from April 3, 2014 and will run for an indefinite period unless terminated by either party providing 30 days written notice.

The fair value of the First Tranche of the options was determined by using a Monte Carlo model. The fair value of the Second Tranche of the options was determined by using the Black-Scholes valuation model based on the projected values of the Company's shares of common stock generated by the Monte Carlo simulation model with the following assumptions:

| | | |
|---|----|--------|
| Fair value of the Company's shares of common stock: | \$ | 0.51 |
| Expected life (years): | | 1 - 3 |
| Expected stock price volatility: | | 100% |
| | | 0.11 - |
| Risk free interest rate: | | 0.95% |
| Expected dividend yield: | | 0.0% |

The fair value of \$744,000 was recorded on April 3, 2014 as additional paid-in-capital in the balance sheet with a corresponding expense in general and administrative expenses.

e. MaSTherCell SA

On July 3, 2014, the Company's Belgian subsidiary, Orgenesis SPRL (the Belgian Subsidiary) entered into a service agreement with MaSTherCell SA, a company incorporated in Belgium (MaSTherCell), pursuant to which MaSTherCell will conduct certain clinical tests related to diabetes treatment research. The Belgian Subsidiary will pay MaSTherCell for its services Euro 962,500 with 30% payable upon the date of approval of the DGO6 grant (as defined in Note 5b) with the balance being invoiced monthly. Services will commence upon approval of the DG06.

The term of the service agreement will run until all work is completed or by either party providing 30 days written notice of termination.

f. Maryland Technology Development Corporation

On June 30, 2014, the Company's subsidiary, Orgenesis Maryland, Inc., entered into a grant agreement with Maryland Technology Development Corporation (TEDCO). TEDCO was created by the Maryland State Legislature in 1998 to facilitate the transfer and commercialization of technology from Maryland's research universities and federal labs into the marketplace and to assist in the creation and growth of technology-based businesses in all regions of the State. TEDCO is an independent organization that strives to be Maryland's lead source for entrepreneurial business assistance and seed funding for the development of startup companies in Maryland's innovation economy. TEDCO administers the Maryland Stem Cell Research Fund to promote State-funded stem cell research and cures through financial assistance to public and private entities within the State. Under the agreement, TEDCO has agreed to give the subsidiary an amount not to exceed \$406,431 (the Grant).

The Grant will be used solely to finance the costs to conduct the research project entitled Autologous Insulin Producing (AIP) Cells for Diabetes during a period of two years. On July 22, 2014, the subsidiary received an advance payment of \$203,215 on account of the grant. Through August 31, 2014, an amount of \$92,537 out of the \$203,215 was spent. The amount of grant that was spent through August 31, 2014 was recorded as a deduction of research and development expenses in the statement of operations. The remaining \$110,678 is presented on the balance sheet as of August 31, 2014 among current liabilities.

NOTE 4 STOCKHOLDERS CAPITAL DEFICIENCY

a. Share Capital

The Company's common shares are traded on the OTC Market Group's OTCQB under the symbol ORGS.

b. Financings

- 1) In April and July 2012, the Company completed a private placement with Derby Management, LLC (Derby) for a total consideration of \$1,100,000 for 1,100,000 shares of common stock and 1,100,000 warrants.
- 2) In December 2012, the Company entered into a subscription agreement with Derby for the issuance of 500,000 units for a total consideration of \$500,000. Each unit is comprised of one share of the Company's common stock and two non-transferrable warrants (See also Note 6). In connection with this agreement, the 1,000,000 warrants issued to Derby were cancelled in July 2013.
- 3) In May 2013, the Company entered into a subscription agreement with Pall, pursuant to which Pall purchased 1,526,718 units at a price of \$0.8515 per unit for total consideration of \$1,300,000. Each unit consisted of one share of the Company's common stock and one warrant (See also Note 6). On March 28, 2014, on June 11, 2014 and on July 31, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC, covering the shares under the subscription agreement, which allows Pall to sell the shares (including shares that will be issued to Pall as a result of the exercise of the warrants).
- 4) On December 13, 2013, the Company entered into a \$3,000,000 common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beach-based institutional investor (Kodiak). The purchase agreement is conditioned, among other things, by filing a registration statement with the SEC covering the shares that may be issued to Kodiak under the terms of the common stock purchase agreement. After the SEC has declared the registration statement related to the transaction effective (March 18, 2014; See below), the Company has the right at its sole discretion over a period of one year to sell shares of common stock under the terms set forth in the agreement in the total amount of up to \$3,000,000. Proceeds from this transaction will be used to fund research and development and working capital. Pursuant to the common stock purchase agreement, the Company issued to Kodiak 250,000 shares of common stock of the Company at no consideration. The Company valued the shares at their fair value of \$135,000 and recorded the charge as financing cost. The Company's ability to put shares to Kodiak and obtain funds under the equity line is limited by the terms and conditions in the common stock purchase agreement, including restrictions on when the Company may exercise its put rights, restrictions on the amount the Company may put to Kodiak at any one time, which is determined in part by the trading volume of the Company's common stock, and a limitation on its ability to put shares to Kodiak.
- 5) During the first quarter of 2014, the Company issued 1,128,849 units in a non-brokered private placement for total consideration of \$587,001. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of

three years. The fair value of these warrants as of the date of issuance was \$393,411 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 117%; risk free interest of 0.68%, and an expected life of three years.

- 6) On April 24, 2014, the Company issued 384,615 units at a purchase price of \$0.52 to one investor in a non-brokered private placement for a total consideration of \$200,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was \$117,047 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 102%; risk free interest of 0.91%, and an expected life of three years.

- 7) On June 30, 2014, the Company entered into a debt settlement agreement with one creditor, whereby it settled a debt in the amount of \$24,011 by the issuance of 46,175 share of its common stock at a price per share of \$0.52. On July 14, 2014, the Company entered into a debt settlement agreement with another creditor, whereby it settled a debt in the amount of \$13,395 by the issuance of 25,759 shares of its common stock at a price per share of \$0.52.
- 8) In July 2014, one of the investors mentioned in Note 4b(5) above exercised warrants to purchase 96,154 shares of the Company's common stock at an exercise price of \$0.52 for a total consideration of \$50,000. As an inducement to the investor to exercise the warrants, the Company issued the investor twice the number of warrants exercised, or 192,308 new warrants, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was \$60,023 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 103%; risk free interest of 0.98%, and an expected life of three years.
- 9) In July 2014, the Company issued 144,230 units at a purchase price of \$0.52 per unit to one investor in a non-brokered private placement for total consideration of \$75,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was \$45,172 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 103%; risk free interest of 0.95%, and an expected life of three years.
- 10) In August 2014, the Company issued 115,385 units at a purchase price of \$0.52 per unit to one investor in a non-brokered private placement for total consideration of \$60,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was \$43,300 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 102%; risk free interest of 0.93%, and an expected life of three years.

On March 28, 2014 and on June 11, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 (See Note 4b(4) above) and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

c. Stock-Based Compensation

During the three months ended August 31, 2014, the Company granted an aggregate of 3,137,300 options to its employees and consultants.

Options Granted to Employees

- 1) On August 1, 2014, the Company granted an aggregate of 200,000 stock options to an employee that are exercisable at \$0.50 per share, with 50,000 vesting quarterly over one year. The fair value of these options as of the date of grant was \$80,531 using the Black and Scholes option-valuation model. In addition, the Company granted an aggregate of 200,000 stock options to an employee that are exercisable at \$0.50 per share, with 25,000 vesting quarterly over two years. The fair value of these options as of the date of grant was \$96,058 using the Black and Scholes option-valuation model.
- 2) On August 22, 2014, the Company granted an aggregate of 2,762,250 stock options to the Company's Chief Executive Officer that are exercisable at \$0.0001 per share. Out of the total granted, 414,304 options vested immediately with a fair value as of the date of grant of \$260,981 using the Black and Scholes option-valuation model, 1,242,996 options will vest quarterly over 4 years, with a fair value as of the date of grant of \$782,997 using the Black and Scholes option-valuation model, and 1,104,950 options will vest based on certain performance criteria.

The fair value of the options on the date of grant was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are mainly as follows:

| | Three Months Ended <u>August 31, 2014</u> |
|---------------------------------|---|
| Value of one common share | \$ 0.53 - 0.63 |
| Dividend yield | 0% |
| Expected stock price volatility | 101% |
| Risk free interest rate | 1.67 - 2.52% |
| Expected term (years) | 5 - 10 |

Options Granted to Consultants

On August 1, 2014, the Company granted an aggregate of 1,080,000 stock options to a consultant that are exercisable at \$0.50, with 216,000 vesting immediately and 216,000 for each of the next four years. The fair value of these options as of the date of grant was \$403,614 using the Black and Scholes option-valuation model. The underlying data used for computing the fair value of the options are mainly as follows:

| | Three Months Ended <u>August 31, 2014</u> |
|---------------------------------|---|
| Value of one common share | \$ 0.53 |
| Dividend yield | 0% |
| Expected stock price volatility | 101% |
| Risk free interest rate | 1.31% |
| Expected term (years) | 4 |

NOTE 5 CONVERTIBLE LOAN AGREEMENTS

a. Mediapark A.G.

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 "Mediapark Loan") in the total amount of \$250,000 and issued to Mediapark 100,000 warrants. Each warrant can be exercised into one share of common stock at a purchase price of \$0.50 per share and is exercisable until March 22, 2015. See also Note 6. The warrants issued are detachable from the Mediapark Loan and classified as a liability due to down-round protection (ratchet and anti-dilution provisions). Therefore the Company allocated the proceeds from Mediapark, first to the warrants based upon their fair value and the residual amount was allocated to the Mediapark Loan. As of the issuance day of the warrants, the fair value of the warrants was \$65,192 based on Monte Carlo valuation-model. See also Note 6.

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

If the Company has not paid the Mediapark Loan in full at the maturity date or, if extended, at the extended maturity date, Mediapark has the right of conversion in respect of the total outstanding amount of the principal balance including accrued interest as of the conversion date into shares of common stock, at a price per share equal to the lower of: (i) \$0.75, and (ii) the value of the weighted average price of the share during 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 Mediapark 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 share. The fair value of the warrants was \$48,800 based on Monte Carlo valuation-model. See also Note 6.

On September 30, 2013, the Company extended again the maturity date of Mediapark Loan to December 31, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 warrants, which can be exercised into shares at an exercise price of \$0.50 per share until September 30, 2015. The fair value of the warrants was \$46,000 based on Monte Carlo valuation-model. See also Note 6.

On December 6, 2013, the Company entered into an amendment of the Mediapark Loan, pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the Mediapark Convertible Loan) in the aggregate principal amount of \$100,000. Interest is calculated semi-annually and is payable, along with the principal, on or before December 6, 2014. According to the agreement, in the event that the Company completes an equity financing prior to the maturity date for gross proceeds of \$350,000 or more, Mediapark will convert the Company's indebtedness under the Mediapark Loan and the Mediapark Convertible loan into shares of common stock and/or warrants on the same terms as the new equity financing.

As a result of the issuance of 1,128,849 units described in Note 4b(5), the Mediapark Loan and the Convertible Loan described above in the aggregate amount of \$370,772 (including principal and interest) outstanding as of March 3, 2014 were converted on that date to 713,023 shares of common stock of the Company at a conversion rate of \$0.52 per share and to 713,023 warrants to acquire additional shares of the Company's common stock at an exercise price of \$0.52 per share for a period of three years. The fair value of these warrants as of the date of issuance was \$259,731 using the Black-Scholes valuation model based on the following assumptions: dividend yield of 0% for all years; expected volatility of 117%; risk free interest of 0.66%, and an expected life of three years.

b. Nine Investments Limited

On May 29, 2014, the Company entered into a convertible loan agreement with Nine Investments Limited, a Hong Kong company (Nine Investments), pursuant to which Nine Investments loaned the Company \$1,500,000 which the Company subsequently transferred to its Belgian subsidiary, Orgenesis SPRL, to fund a research project to develop new medical technologies and cell therapies for the treatment of diabetes. The Company received the funds on June 4, 2014 (the Closing Date). Interest is calculated at 8% semi-annually and is payable, along with the principal on or before December 31, 2014 subject to acceleration for specific events including: (i) if a grant of money to Orgenesis SPRL is not approved by Department De La Gestion Financiere Direction De L analyse Financiere (DGO6) within 90 days after the loan proceeds are advanced; and (ii) if the Company raises, in the aggregate, gross proceeds of more than \$400,000 between the date of the loan and the maturity date, but only to the extent of gross proceeds so raised that are in excess of \$400,000.

Nine Investments may provide the Company with written notice to convert all or part of the loan into shares of its common stock at \$0.40 per share. The conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment in the event and in the manner following: (i) if and whenever

the Company's common shares at any time outstanding shall be subdivided into a greater or consolidated into a lesser number of common shares, or in case of any capital reorganization or of any reclassification of the capital of the Company or in case of the consolidation, merger or amalgamation of the Company with or into any other company or of the sale of the assets of the Company as or substantially as an entirety or of any other company, the conversion price shall be decreased or increased proportionately; and (ii) in the event the Company issues any shares of common stock or securities convertible into shares at a price less than the conversion price, the conversion price shall be reduced for any unpaid or unconverted loan amount to the new issuance price.

As consideration for entering into the loan agreement, on June 5, 2014, the Company issued to Nine Investments 500,000 shares of its common stock.

The Company allocated the proceeds from Nine Investments between the shares and the convertible loan based on the relative fair value. In addition, the conversion right is detachable from the loan and classified as a derivative due to down-round protection (full ratchet and anti-dilution provisions). Therefore, the Company attributed, to the conversion right derivative, out of the proceeds allocated to the convertible loan based on its fair value. The allocation of conversion right and bonus shares represents a discount to the loan and will be accreted until the maturity date of the loan (December 31, 2014).

The table below presents the fair value of the instruments issued as of the Closing Date and the allocation of the proceeds:

| | Total Fair Value | Allocation of Proceeds |
|-------------------------------|-----------------------------|-----------------------------------|
| Loan component | \$ 1,262,000 | \$ 746,000 |
| Bonus shares component | 250,000 | 180,000 |
| Embedded derivative component | 574,000 | 574,000 |
| Total | \$ 2,086,000 | \$ 1,500,000 |

The bonus shares component was recorded as additional paid-in-capital and the fair value of the embedded derivative component is classified as a financial liability because the conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment and will be measured in subsequent periods at fair value with changes in fair value charged to financial expenses or income, net. Due to the difference between the amounts actually owed to the lender and the presentation of the loan in the financial statement, the loan was measured, subsequent to its initial recognition, at amortized cost on the basis of the effective interest method over the loan period.

NOTE 6 WARRANTS

As part of the Company's private placements and loan received as described in Notes 4 and 5, the Company issued warrants, as follows:

a. Warrants Which are Subject to Exercise Price Adjustments

- 1) In December 2012, the Company issued 1,000,000 non-transferable warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$0.50 per share and is exercisable until November 30, 2014. In the event the Company will issue any shares of common stock or securities convertible into shares of common stock at a price less than \$0.50, the exercise price shall be reduced to the new issuance price.
- 2) In March 2013, the Company issued 100,000 warrants in connection with the loan and warrant subscription agreement with Mediapark (see Note 5a). Each warrant can be exercised into one share of common stock at an exercise price of \$0.50 per share and is exercisable until March 22, 2015. In the event the Company issues any shares of common stock or securities convertible into shares of common stock at a price less than \$0.50, the exercise price shall be reduced to the new issuance price.
- 3) In May 2013, the Company issued 1,526,718 warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$1.00 per share and is exercisable until May 6, 2015. In the event the Company issues any shares of common stock or securities convertible into shares of common stock at a price less than \$0.8515, the exercise price shall be reduced to the new issuance price. As a result of the issuance of 1,128,849 warrants during the second quarter of 2014, the exercise price of those warrants was

reduced to \$0.52 per share.

- 4) On June 30, 2013, the Company exercised its discretion to extend the maturity date of the Mediapark Loan from September 30, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 additional warrants at an exercise price of \$0.50 per share until June 30, 2015. In the event the Company issues any shares of common stock or securities convertible into shares of common stock at a price less than \$0.50, the exercise price shall be reduced to the new issuance price (See also Note 5).
- 5) On September 30, 2013, the Company exercised its discretion to extend the maturity date of the Mediapark loan from December 31, 2013. In return for extending the maturity date, the Company issued to Mediapark 100,000 additional warrants, which can be exercised into shares at an exercise price of \$0.50 per share until September 30, 2015. In the event the Company issues any shares of common stock or securities convertible into shares of common stock at a price less than \$0.50, the exercise price shall be reduced to the new issuance price (See also Note 5).

b. Warrants Which are Not Subject to Exercise Price Adjustments

- 1) In April 2012, the Company issued 100,000 non-transferable warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$1.00 per share and is exercisable until November 30, 2014.
- 2) In March 2014, the Company issued 1,128,849 warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$0.52 per share and is exercisable until March 2017. In July 2014, 96,154 warrants were exercised (See Note 4b8).
- 3) On March 3, 2014, as a result of the conversion of the Mediapark loans, the Company issued to Mediapark 713,023 warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$0.52 per share and is exercisable until March 3, 2017 (See also Note 5).
- 4) On April 24, 2014, the Company issued 384,615 warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$0.52 per share and is exercisable until April 24, 2017.
- 5) In July 2014, the Company issued 336,538 warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$0.52 per share and is exercisable until July 2017.
- 6) In August 2014, the Company issued 115,385 warrants. Each warrant can be exercised into one share of common stock at an exercise price of \$0.52 per share and is exercisable until August 2017.

NOTE 7 SUBSEQUENT EVENTS

On September 1, 2014, the Company entered into a convertible loan agreement for \$50,000. The loan bears an annual interest rate of 6% and matures on February 28, 2015, unless converted earlier. The lender shall have the right to convert all or any portion of the outstanding principal amount and all accrued but unpaid interest thereon into shares of common stock of the Company at a conversion price of \$0.40 per share.

On September 1, 2014, the Company granted 650,000 stock options to an employee that are exercisable at \$0.50 per share and vest quarterly over 4 years.

On September 15, 2014, the Company entered into a convertible loan agreement for \$100,000. The loan bears an annual interest rate of 6% and matures on March 15, 2015, unless converted earlier. The lender shall have the right to convert all or any portion of the outstanding principal amount and all accrued but unpaid interest thereon into shares of common stock of the Company at a conversion price of \$0.40 per share.

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* set forth in our Annual Report on Form 10-K for the year ended November 30, 2013, any of which may cause our company's 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;
- our needs to raise additional funds in the future which may not be available on acceptable terms or at all;
- our inability to successfully recruit and retain qualified personnel in order to continue our operations;
- our ability to successfully implement our business plan;
- conditions in Israel and the surrounding Middle East which may materially adversely affect our subsidiary's operations and personnel;
- the ability of our Israeli 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;
- any probability that Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (**THM**) may cancel the License Agreement;
- if we are unable to successfully acquire, develop or commercialize new products;
- our expenditures not resulting in commercially successful products;
- third parties claiming that we may be infringing their proprietary rights that may prevent us from manufacturing and selling some of our products;
- the impact of extensive industry regulation, and how that 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* set forth in our Annual Report on Form 10-K for the year ended November 30, 2013.

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 *Company* refer to Orgenesis, Inc. and our wholly-owned subsidiaries, Orgenesis Ltd. (the *Israeli Subsidiary*), Orgenesis SPRL (the *Belgian Subsidiary*), and Orgenesis Maryland, Inc. (the *U.S. Subsidiary*). Unless otherwise specified, all dollar amounts are expressed in United States dollars.

Corporate Overview

We were incorporated in the state of Nevada on June 5, 2008 under the name Business Outsourcing Services, Inc. Effective August 31, 2011, we completed a merger with our subsidiary, Orgenesis, Inc., a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we changed our name from Business Outsourcing Services, Inc. to Orgenesis, Inc.

Effective August 31, 2011, we effected a 35 to 1 forward stock split of our authorized and issued and outstanding common stock. As a result, our authorized capital has increased from 50,000,000 shares of common stock with a par value of \$0.0001 to 1,750,000,000 shares of common stock with a par value of \$0.0001. On February 27, 2012, we filed a Certificate of Correction with the Secretary of State of the State of Nevada, correcting the par value of 1,750,000,000 shares of common stock which was incorrectly stated as \$0.001 to 1,750,000,000 shares of common stock with a par value of \$0.0001. Unless otherwise noted, all references in this 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 THM to license us all of the assets associated with *Methods Of Inducing Regulated Pancreatic Hormone Production* and *Methods of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues*.

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license patents and knowhow related to the development of autologous insulin producing (*AIP*) cells. Based on the licensed knowhow and patents, our intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using a therapeutic agent (i.e., *PDX-1*, or additional pancreatic transcription factors in adenovirus-vector) that efficiently converts a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. The development of *AIP* cells is based on the licensed patents and knowhow. We believe that our major competitive advantage is in our cell transformation technology.

This technology was licensed based on the published work of Prof. Ferber who has developed this technology, as a researcher in THM, 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 the year through our third quarter ended August 31, 2014 we experienced the following corporate developments:

Private Placement

During the first quarter of 2014, the Company issued 1,128,849 units in a non-brokered private placement for total consideration of \$587,001. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

Convertible Loans with Mediapark A.G.

On December 6, 2013, we entered into a convertible loan agreement with Mediapark A.G., a Marshall Islands company (Mediapark), pursuant to which Mediapark purchased an 8% unsecured convertible debenture (the Convertible Loan) in the aggregate principal amount of \$100,000. On March 22, 2013, we entered into a similar convertible loan agreement with Mediapark in the aggregate principal amount of \$250,000. The agreement states that if we complete an equity financing prior to the maturity date of the loan in an amount greater than \$350,000, Mediapark would convert all of our outstanding indebtedness into equity securities on the same terms as the current financing. As a result, on March 3, 2014, both loans in the aggregate amount of \$370,772 (principle and interest) outstanding as of that date were converted into 713,023 shares of common stock at a price of \$0.52 and 713,023 warrants to acquire additional shares of our common stock at a price of \$0.52 per share for a period of three years in full payment of our indebtedness.

Chief Executive Officer

On August 14, 2014, our Board of Directors confirmed that Ms. Vered Caplan, who has served as our President and Chief Executive Officer on an interim basis since December 23, 2013, has been appointed as our President and Chief Executive Officer. On August 22, 2014, our wholly-owned Israeli subsidiary, Orgenesis Ltd., entered into a Personal Employment Agreement with Ms. Caplan on the following key terms:

- (a) a base salary of NIS 49,585 (as of August 22, 2014, equates to approximately \$14,100) per month, retroactive to January 1, 2014;
- (b) a monthly contribution based on Ms. Caplan's previous month's salary equal to either:
 - (i) 13.33% to a Managers Insurance policy; or
 - (ii) 14.33% to a comprehensive pension plan;
- (c) a performance bonus payable at the discretion of our Compensation Committee; and
- (d) the grant of stock options to be granted by our company, as follows:
 - (i) Options to purchase 1,657,300 shares of our company's common stock (representing approximately three percent (3%) of our company's issued and outstanding shares of common stock, which will vest as follows:
 - (i) options to purchase 414,304 shares of common stock shall vest immediately on the date of grant and
 - (ii) options to purchase the balance of 1,242,996 shares of common stock shall vest on a quarterly basis over a period of four years from the date of grant (i.e., initially, 77,687 of the options shall vest three months following the grant date).

- (ii) Options to purchase 1,104,950 shares of our company's common stock, representing approximately two percent (2%) of our company's issued and outstanding common stock, which will vest pursuant to performance milestones to be determined by our Compensation Committee no later than December 31, 2014.

- (iii) All of the options are to have an exercise price equal to the par value per share of our common stock and all of them will expire on the 10th anniversary of the grant date. The employment agreement, which replaces a previous employment agreement with Ms. Caplan dated April 1, 2012, contains other customary terms, covering matters such as non-competition; confidentiality; indemnity and insurance; use of leased car; and vacation, health and other benefits.

Chief Financial Officer

Effective August 1, 2014, Joseph Tenne resigned as our Chief Financial Officer, Treasurer and Secretary. Mr. Tenne's resignation was not as a result of any disagreement with our company operations, policies or practices. Mr. Tenne will remain as Chief Financial Officer of our Israeli subsidiary, Orgenesis Ltd. Subsequent to the quarter ended August 31, 2014, the Company entered into an agreement with Dorit Kreiner who replaced Mr. Tenne as Chief Financial Officer of Orgenesis Ltd. Mr. Tenne remains as a director of Orgenesis Ltd.

On August 1, 2014, we appointed Neil Reithinger as our Chief Financial Officer, Treasurer and Secretary with the following terms:

- (a) payment of a monthly salary of \$1,500;
- (b) payment of an annual bonus as determined by our company in its sole discretion;
- (c) participation in our company's pension plan;
- (d) a grant of 200,000 stock options exercisable at the market price of \$0.50 for a period of 5 years and which are subject to vesting provisions; and
- (e) Reimbursement of expenses.

In addition, on August 1, 2014, we entered into a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, (Eventus) pursuant to which Eventus has agreed to provide financial consulting and shareholder communication services to our company. In consideration for Eventus' services, we have agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement is for a period of one year from August 1, 2014 and shall automatically renew for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Neil Reithinger.

Chief Executive Officer of our Subsidiary, Orgenesis Maryland, Inc.

On August 4, 2014, our subsidiary, Orgenesis Maryland, Inc. entered into an employment agreement with Scott Carmer, to be effective July 1, 2014. In consideration for acting as our subsidiary's Chief Executive Officer, we will pay Mr. Carmer the following compensation:

- (a) an annual salary of \$250,000;
- (b) an annual bonus of up to \$100,000 subject to the discretion of our board of directors and a further bonus as determined by meeting certain milestones; and
- (c) a grant of shares or options.

Kodiak Capital Group, LLC

On December 13, 2013, the Company entered into a \$3,000,000 common stock purchase agreement with Kodiak Capital Group, LLC, a Newport Beach-based institutional investor (Kodiak). The purchase agreement is conditioned, among other things, by filing a registration statement with the SEC covering the shares that may be issued to Kodiak under the terms of the common stock purchase agreement. After the SEC has declared the registration statement related to the transaction effective (March 18, 2014), the Company has the right at its sole discretion over a period of one year to sell shares of common stock under the terms set forth in the agreement in the total amount of up to \$3,000,000. Proceeds from this transaction will be used to fund research and development and working capital. Pursuant to the common stock purchase agreement, the Company issued to Kodiak 250,000 shares of common stock of the Company at no consideration. The Company's ability to put shares to Kodiak and obtain funds under the equity

line is limited by the terms and conditions in the common stock purchase agreement, including restrictions on when the Company may exercise its put rights, restrictions on the amount the Company may put to Kodiak at any one time, which is determined in part by the trading volume of the Company's common stock, and a limitation on its ability to put shares to Kodiak.

Prospectuses

The Company filed prospectuses dated March 28, 2014, June 11, 2014 and July 31, 2014 pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

Consulting Agreement with Aspen Agency Limited

On April 3, 2014, the Company entered into a consulting agreement with Aspen Agency Limited, a Hong Kong corporation (Aspen), pursuant to which Aspen has agreed to provide investment banking, investor relations and business development services to the Company. In consideration for Aspen's services, the Company has agreed to issue to Aspen 3,000,000 stock options to acquire shares of the Company's common stock at an exercise price of \$0.52 per share, for a period of three years. The options will be subject to vesting provisions as follows:

- 1) 1,000,000 options (the First Tranche) will vest as of the date of execution of the agreement; and
- 2) In the event Aspen exercises all 1,000,000 vested First Tranche options during the first 12 months of the agreement, the Second Tranche of 2,000,000 options will vest.

The term of the consulting agreement is from April 3, 2014 and will run for an indefinite period unless terminated by either party providing 30 days written notice.

Private Placement with Mediapark A.G.

On April 24, 2014, we issued 384,615 units to one investor in a non-brokered private placement, at a purchase price of \$0.52 per unit for proceeds of \$200,000. Each unit consists of one share of our common stock and one nontransferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years.

Convertible Loans with Nine Investments Ltd.

On May 29, 2014, we entered into a convertible loan agreement with Nine Investments Limited, a Hong Kong company (Nine Investments), pursuant to which Nine Investments loaned us \$1,500,000 which we subsequently transferred to our Belgian subsidiary, Orgenesis SPRL, to fund a research project to develop new medical technologies and cell therapies for the treatment of diabetes. We received the funds on June 4, 2014 (the Closing Date). Interest is calculated at 8% semi-annually and is payable, along with the principal on or before December 31, 2014 subject to acceleration for specific events including: (i) if a grant of money to Orgenesis SPRL is not approved by Department De La Gestion Financiere Direction De L'analyse Financiere (DGO6) within 90 days after the loan proceeds are advanced; and (ii) if the Company raises, in the aggregate, gross proceeds of more than \$400,000 between the date of the loan and the maturity date, but only to the extent of gross proceeds so raised that are in excess of \$400,000.

Nine Investments may provide the Company with written notice to convert all or part of the loan into shares of its common stock at \$0.40 per share. The conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment in the event and in the manner following: (i) if and whenever

the Company's common shares at any time outstanding shall be subdivided into a greater or consolidated into a lesser number of common shares, or in case of any capital reorganization or of any reclassification of the capital of the Company or in case of the consolidation, merger or amalgamation of the Company with or into any other company or of the sale of the assets of the Company as or substantially as an entirety or of any other company, the conversion price shall be decreased or increased proportionately; and (ii) in the event the Company issues any shares of common stock or securities convertible into shares at a price less than the conversion price, the conversion price shall be reduced for any unpaid or unconverted loan amount to the new issuance price.

As consideration for entering into the loan agreement, on June 5, 2014, the Company issued to Nine Investments 500,000 shares of its common stock.

Service Agreement with MaSTherCell SA

On July 3, 2014, the Company's Belgian subsidiary, Orgenesis SPRL (the "Belgian Subsidiary") entered into a service agreement with MaSTherCell SA, a company incorporated in Belgium ("MaSTherCell"), pursuant to which MaSTherCell will conduct certain clinical tests related to diabetes treatment research. The Belgian Subsidiary will pay MaSTherCell for its services Euro 962,500 with 30% payable upon the date of approval of the DGO6 grant with the balance being invoiced monthly. Services will commence upon approval of the DG06. The term of the service agreement will run until all work is completed or by either party providing 30 days' written notice of termination.

Exercise of warrants and issuance of new warrants

In July 2014, one of our investors exercised warrants to purchase 96,154 shares of our common stock at an exercise price of \$0.52 for a total consideration of \$50,000. The Company issued him 192,308 new warrants. Each warrant entitles the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

Private Placement with a Non-U.S. Investor

In July 2014, we issued 144,230 units to one investor in a non-brokered private placement, at a purchase price of \$0.52 per unit for proceeds of \$75,000. Each unit consists of one share of our common stock and one nontransferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of our common stock at a price of \$0.52 per share for a period of three years.

Debt settlement agreements

On June 30, 2014, we entered into a debt settlement agreement with one of our creditors, whereby we settled a debt in the amount of \$24,011 by the issuance of 46,175 shares of our common stock at a price per share of \$0.52.

On July 14, 2014, we entered into a debt settlement agreement with one of our creditors, whereby we settled a debt in the amount of \$13,395 by the issuance of 25,759 shares of our common stock at a price per share of \$0.52.

Research Grant from the State of Maryland

On June 30, 2014, the Company's subsidiary, Orgenesis Maryland, Inc., entered into a grant agreement with Maryland Technology Development Corporation ("TEDCO"). TEDCO was created by the Maryland State Legislature in 1998 to facilitate the transfer and commercialization of technology from Maryland's research universities and federal labs into the marketplace and to assist in the creation and growth of technology-based businesses in all regions of the State. TEDCO is an independent organization that strives to be Maryland's lead source for entrepreneurial business assistance and seed funding for the development of startup companies in Maryland's innovation economy. TEDCO administers the Maryland Stem Cell Research Fund to promote State-funded stem cell research and cures through financial assistance to public and private entities within the State. Under the agreement, TEDCO has agreed to give the subsidiary an amount not to exceed \$406,431 (the "Grant"). The Grant will be used solely to finance the costs to conduct the research project entitled "Autologous Insulin Producing (AIP) Cells for Diabetes" during a period of two years. On July 22, 2014, the subsidiary received an advance payment of \$203,215 on account of the grant.

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, 2014.

Comparison of the Three Months Ended August 31, 2014 and the Three 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 months ended August 31, 2014 are summarized as follows in comparison to our expenses for the three months ended August 31, 2013:

| | Three Months Ended August 31, | |
|-------------------------------------|--------------------------------------|-------------|
| | 2014 | 2013 |
| Research and development expenses | \$ 845,599 | \$ 226,935 |
| General and administration expenses | 440,058 | 935,228 |
| Financial expenses (income), net | 2,206,588 | (224,723) |
| Loss | \$ 3,492,245 | \$ 937,440 |

Research and Development Expenses

| | Three Months Ended August 31, | |
|---|--------------------------------------|-------------|
| | 2014 | 2013 |
| Salaries and related expenses | \$ 263,162 | \$ 96,918 |
| Stock-based compensation | 344,051 | - |
| Professional fees and consulting services | 284,143 | 65,993 |
| Other research and development expenses | 46,780 | 64,024 |
| Less - grant | (92,537) | - |
| Total | \$ 845,599 | \$ 226,935 |

The increase in stock-based compensation and professional fees and consulting services in the three months ended August 31, 2014, compared to the same quarter last year is mainly due to an additional research and development activities including stock-based compensation for employees.

General and Administrative Expenses

| | Three Months Ended August 31, | |
|---|--------------------------------------|-------------|
| | 2014 | 2013 |
| Salaries and related expenses | \$ 52,664 | \$ 120,230 |
| Stock-based compensation | 151,917 | 544,701 |
| Accounting and legal fees | 102,132 | 54,187 |
| Professional fees | 92,458 | 3,075 |
| Business development | 5,165 | 57,819 |
| Other general and administrative expenses | 35,722 | 155,216 |
| Total | \$ 440,058 | \$ 935,228 |

The decrease in stock-based compensation in the three months ended August 31, 2014, compared to the same quarter last year is due to the prior year having stock-based compensation for a number of employees whose options had fully vested and from a change in mix of employees from general and administrative to research and development activities. The increase in professional fees in the three months ended August 31, 2014, compared to the same quarter

last year is mainly due to accounting and legal expenses for fundraising and start of operations in Europe in 2014.

Financial Expenses (Income), Net

| | Three Months Ended August 31, | |
|---|--------------------------------------|--------------|
| | 2014 | 2013 |
| Non-cash financial expenses (income): | | |
| Increase (decrease) in fair value of warrants and embedded derivative | \$ 1,893,000 | \$ (240,576) |
| Interest expense on convertible loans | 280,770 | 5,255 |
| Cash financial expenses (income): | | |
| Foreign exchange loss, net | 31,221 | 9,021 |
| Bank commissions, net | 1,597 | 1,577 |
| Total | \$ 2,206,588 | \$ (224,723) |

The increase in the fair value of the warrants in the three months ended August 31, 2014, compared to the same quarter last year is mainly due to an increase in the price of our shares of common stock. The increase in interest expense in the three months ended August 31, 2014, compared to the same quarter last year is mainly attributable to additional warrants granted on convertible loans.

Comparison of the Nine Months Ended August 31, 2014 and the 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 nine months ended August 31, 2014 are summarized as follows in comparison to our expenses for the nine months ended August 31, 2013:

| | Nine Months Ended August 31, | |
|-------------------------------------|-------------------------------------|--------------|
| | 2014 | 2013 |
| Research and development expenses | \$ 1,936,079 | \$ 930,487 |
| General and administration expenses | 2,032,073 | 2,844,350 |
| Financial expenses (income), net | 2,029,415 | 49,046 |
| Loss | \$ 5,997,567 | \$ 3,823,883 |

Research and Development Expenses

| | Nine Months Ended August 31, | |
|---|-------------------------------------|-------------|
| | 2014 | 2013 |
| Salaries and related expenses | \$ 652,178 | \$ 224,879 |
| Stock-based compensation | 704,215 | 268,856 |
| Professional fees and consulting services | 567,767 | 204,965 |
| Other research and development expenses | 104,456 | 231,787 |
| Less grant | (92,537) | - |
| Total | \$ 1,936,079 | \$ 930,487 |

The increase in salaries and related expenses and in stock-based compensation in the nine months ended August 31, 2014, compared to the same period last year is mainly due to an additional research and development activities including stock-based compensation for current employees and an increase of the salary of our Chief Scientific Officer in the end of the second quarter of 2013. The increase in professional fees and other research and development expenses in the nine months ended August 31, 2014, compared to the same period last year is related to expansion of research and development operations in 2014, mainly in Europe.

General and Administrative Expenses

| | Nine Months Ended August 31, | |
|---|------------------------------|--------------|
| | 2014 | 2013 |
| Salaries and related expenses | \$ 179,044 | \$ 862,098 |
| Stock-based compensation | 317,863 | 1,106,040 |
| Accounting and legal fees | 253,798 | 183,186 |
| Professional fees | 1,062,708 | 6,530 |
| Business development | 113,647 | 219,356 |
| Other general and administrative expenses | 105,012 | 467,140 |
| Total | \$ 2,032,073 | \$ 2,844,350 |

The decrease in salaries and related expenses and in stock-based compensation in the nine months ended August 31, 2014, compared to the same period last year is due to the prior year having higher employee compensation cost and stock-based compensation for a number of employees whose options had fully vested. In addition, the decrease is resulting from a change in mix of employees from general and administrative to research and development activities. The increase in professional fees in the nine months ended August 31, 2014, compared to the same period last year is mainly due to accounting and legal expenses for fundraising and start of operation in Europe in 2014 and granting of stock options with a fair value of \$744,000 to Aspen in April 2014. The decrease in business development expenses in the nine months ended August 31, 2014, compared to the same period last year is mainly due to bonus which was recorded in the first half of 2013.

Financial Expenses (Income), Net

| | Nine Months Ended August 31, | |
|---|------------------------------|--------------|
| | 2014 | 2013 |
| Non-cash financial expenses (income): | | |
| Increase (decrease) in fair value of warrants and embedded derivative | \$ 1,291,046 | \$ (188,167) |
| Interest expense on convertible loans | 547,223 | 209,783 |
| Funding fees to Kodiak | 135,000 | - |
| Cash financial expenses (income): | | |
| Foreign exchange loss, net | 52,131 | 22,842 |
| Bank commissions, net | 4,015 | 4,588 |
| Total | \$ 2,029,415 | \$ 49,046 |

The increase in the fair value of the warrants in the nine months ended August 31, 2014, compared to the same period last year is mainly due to an increase in the price of our shares of common stock and an embedded derivative that was granted on June 2014. The increase in interest expense in the nine months ended August 31, 2014, compared to the same period last year is mainly attributable to additional warrants granted on convertible loans. The funding fees to Kodiak in the nine months ended August 31, 2014 represent the fair value of 250,000 shares of common stock issued to Kodiak as part of a stock purchase agreement with Kodiak.

Liquidity and Financial Condition

Working Capital Deficiency

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| | August 31, 2014 | November 30 2013 |
|----------------------------|--------------------|---------------------|
| Current assets | \$ 1,639,534 | \$ 97,737 |
| Current liabilities | 4,317,971 | 986,409 |
| Working capital deficiency | \$ (2,678,437) | \$ (888,672) |

The increase in current assets is mainly due to an increase in cash from the investment from Nine Investments Limited totaling \$1,500,000 during the nine months ended August 31, 2014. The increase in current liabilities was due to an increase in expenses which resulted in an increase of accounts payable, accrued expenses and employees and related payables of \$856,268 during the nine months ended August 31, 2014, in addition to an increase in convertible loans and accrued interest of \$2,350,720.

Cash Flows

| | Nine Months Ended August 31, | |
|---|------------------------------|----------------|
| | 2014 | 2013 |
| Net cash used in operating activities | \$ (1,097,524) | \$ (1,524,513) |
| Net cash used in investing activities | (6,676) | (9,400) |
| Net cash provided by financing activities | 2,586,520 | 2,050,000 |
| Increase in cash and cash equivalents | \$ 1,482,320 | \$ 516,087 |

The decrease in net cash used in operating activities in the nine months ended August 31, 2014, compared to the same period last year is mainly related to the increase in our current liabilities such as accounts payable, accrued expenses and employees and related payables of \$893,674 in the nine months ended August 31, 2014, compared to \$154,876 in the same period last year. This amount was offset by an increase in net loss (excluding stock based compensation expenses and changes in fair value of warrants) from \$1,750,763 in the nine months ended August 31, 2013 to \$2,681,668 in the nine months ended August 31, 2014, as a result of expanded operations in 2014. The increase in cash provided by financing activities in the nine months ended August 31, 2014 compared to the comparable period in 2013 is mainly due to an increase in convertible loans of \$1,500,000 which was offset by a decrease in capital received through sales of common stock.

Going Concern

The unaudited interim condensed consolidated financial statements contained in this quarterly report have been prepared assuming that the company will continue as a going concern. We have accumulated losses for the period from inception (June 5, 2008) through August 31, 2014, of \$16,672,542 as well as negative cash flow from operating activities. Presently, we do not have sufficient cash resources to meet our plans in the twelve months following August 31, 2014. 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.

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

initiate regulatory activities in Asia, Europe and the United states;
locate suitable centers and sign a collaboration agreement;

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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 the Sheba Medical Center);

initialize efforts to validate the manufacturing process (in certified labs); and

raise sufficient capital to perform initial clinical safety testing.

We estimate our operating expenses for the next 12 months as of August 31, 2014 to be as follows:

| | |
|----------------------------|--------------|
| Product development | \$ 4,200,000 |
| General and administrative | 1,150,000 |
| Business development | 350,000 |
| Total | \$ 5,700,000 |

Future Financing

We will require additional funds to implement our growth strategy for our business. These funds may be raised through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of our shares. There can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. If we are not able to obtain the additional financing on a timely basis should it be required, or generate significant material revenues from operations, we will not be able to meet our other obligations as they become due and we will be forced to scale down or perhaps even cease our operations.

Off-Balance Sheet Arrangements

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

Significant Accounting Policies

A comprehensive discussion of our significant accounting policies is included in the Management's Discussion and Analysis of Financial Condition and Results of Operations section in our annual report on Form 10-K for the fiscal year ended November 30, 2013 filed with the SEC on February 19, 2014.

In addition, in June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, Development Stage Entities (Topic 915), Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (ASU 2014-10). The amendments in ASU 2014-10 remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from accounting principles generally accepted in the United States of America (U.S. GAAP). In addition, the amendments eliminate the requirements for development stage entities to: (i) present inception-to-date information in the statements of income, cash flows, and shareholder equity; (ii) label the financial statements as those of a development stage entity; (iii) disclose a description of the development stage activities in which the entity is engaged; and (iv) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The presentation and disclosure requirements in Accounting Standard Codification (ASC) Topic 915, Development Stage Entities are no longer required for interim and annual reporting periods beginning after December 15, 2014. The revised consolidation standards will take effect in annual periods beginning after December 15, 2015, however, early adoption is permitted. We have elected to early adopt the provisions of ASU No. 2014-10 for our unaudited condensed consolidated financial statements that are included in this quarterly report.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity’s liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Currently, there is no guidance under U.S. GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern or to provide related footnote disclosures. The amendments in this Update provide that guidance. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity’s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management’s plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). For the period ended August 31, 2014, management evaluated the Company’s ability to continue as a going concern and concluded that substantial doubt has not been alleviated about the Company’s ability to continue as a going concern. While the Company continues to explore further significant sources of financing, management’s assessment was based on the uncertainty related to the amount and nature of such financing over the next twelve months.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable

ITEM 4. CONTROLS AND PROCEDURES

Disclosure 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 SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our interim 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. The ineffectiveness of our disclosure controls and procedures was due to material weaknesses identified in our internal control over financial reporting, described below.

Management’s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting. In order to evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002. Our management, with the participation of our principal executive officer and principal financial officer has conducted an assessment, including testing, using the criteria in Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the

design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation. Based on this evaluation, our management concluded our internal control over financial reporting was not effective as of August 31, 2014. The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses which are indicative of many small companies with small staff:

- (i) inadequate segregation of duties consistent with control objectives; and
- (ii) ineffective controls over period end financial disclosure and reporting processes.

Our company plans to take steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this quarterly report on Form 10-Q, we have not been able to remediate the material weaknesses identified above. To remediate such weaknesses, we plan to implement the following changes during our fiscal year ending November 30, 2014:

- (i) appoint additional qualified personnel to address inadequate segregation of duties and ineffective risk management;
- (ii) adopt sufficient written policies and procedures for accounting and financial reporting.

The remediation efforts set out in (i) is largely dependent upon our company securing additional financing to cover the costs of implementing the changes required. If we are unsuccessful in securing such funds, remediation efforts may be adversely affected in a material manner. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake.

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, 2014 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 risk factors included in the Risk Factors section of our annual report on Form 10-K for the fiscal year ended November 30, 2013 filed with the SEC on February 19, 2014, in addition to other information contained in that annual report and in this quarterly 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 adversely affected due to any of those risks. You could lose all or part of your investment due to any of these risks.

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

During the first quarter of 2014, the Company issued 1,128,849 units in a non-brokered private placement for total consideration of \$587,001. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

On April 24, 2014, the Company issued 384,615 units at a purchase price of \$0.52 to one investor in a non-brokered private placement for a total consideration of \$200,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

On June 30, 2014, the Company entered into a debt settlement agreement with one creditor, whereby it settled a debt in the amount of \$24,011 by the issuance of 46,175 share of its common stock at a price per share of \$0.52.

In July 2014, one investor exercised warrants to purchase 96,154 shares of the Company's common stock at an exercise price of \$0.52 for a total consideration of \$50,000. As an inducement to the investor to exercise the warrants, the Company issued the investor twice the number of warrants exercised, or 192,308 new warrants, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

In July 2014, the Company issued 144,230 units at a purchase price of \$0.52 per unit to one investor in a non-brokered private placement for total consideration of \$75,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

On July 14, 2014, the Company entered into a debt settlement agreement with one creditor, whereby it settled a debt in the amount of \$13,395 by the issuance of 25,759 shares of its common stock at a price per share of \$0.52.

In August 2014, the Company issued 115,385 units at a purchase price of \$0.52 per unit to one investor in a non-brokered private placement for total consideration of \$60,000. Each unit consisted of one share of the Company's common stock and one non-transferable common share purchase warrant, with each warrant entitling the holder to acquire one additional share of the Company's common stock at an exercise price of \$0.52 per share for a period of three years.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

On March 28, 2014 and on June 11, 2014, the Company filed prospectuses pursuant to Rule 424(b)(3), which are part of a registration statement filed by the Company with the SEC. Under the prospectuses, the selling stockholders identified in the prospectuses may offer and sell up to 10,603,436 shares of the Company's common stock, which will consist of: (i) up to 250,000 shares of common stock issued or to be issued to Kodiak as commitment shares pursuant to common stock purchase agreement dated December 13, 2013 and up to 7,300,000 shares of common stock to be sold by Kodiak pursuant to the common stock purchase agreement; (ii) 1,526,718 shares of common stock issued to Pall ; and (iii) up to 1,526,718 shares of common stock that may be issued upon the exercise of warrants issued to Pall. The 7,550,000 shares of common stock registered for resale by Kodiak represents 14% of the Company's issued and outstanding shares of common stock as of March 5, 2014. The selling stockholders may sell all or a portion of the shares being offered pursuant to the prospectuses at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

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 | Term sheet with Mediapark Investments Limited (incorporated by reference to our current report on Form 8-K filed on December 16, 2013) |
| 10.2 | Convertible Loan Agreement dated December 6, 2013 with Mediapark Investments Limited (incorporated by reference to our current report on Form 8-K filed on December 16, 2013) |
| 10.3 | Investment Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013) |
| 10.4 | Registration Rights Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to our current report on Form 8-K filed on December 16, 2013) |
| 10.5 | Form of subscription agreement (incorporated by reference to our current report on Form 8-K filed on March 4, 2014) |
| 10.6 | Form of warrant (incorporated by reference to our current report on Form 8-K filed on March 4, 2014) |
| 10.7 | Consulting Agreement dated April 3, 2014 with Aspen Agency Limited (incorporated by reference to our current report on Form 8-K filed on April 7, 2014) |
| 10.8 | Stock Option Agreement dated April 3, 2014 with Aspen Agency Limited (incorporated by reference to our current report on Form 8-K filed on April 7, 2014) |
| 10.9 | Personal Employment Agreement dated April 16, 2014 by and between Orgenesis Ltd. and Joseph Tenne (incorporated by reference to our current report on Form 8-K filed on April 16, 2014) |
| 10.10 | Form of subscription agreement with form of warrant (incorporated by reference to our current report on Form 8-K filed on April 28, 2014) |
| 10.11 | Convertible Loan Agreement dated May 29, 2014 with Nine Investments Limited (incorporated by reference to our current report on Form 8-K filed on May 30, 2014) |
| 10.12 | Services Agreement between Orgenesis SPRL and MaSTherCell SA dated July 3, 2014 incorporated by reference to our current report on Form 8-K filed on July 7, 2014) |
| 10.13 | Financial Consulting Agreement dated August 1, 2014 with Eventus Consulting, P.C., (incorporated by reference to our current report on Form 8-K filed on August 5, 2014) |
| 10.14 | |

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|--------------|---|
| | Personal Employment Agreement dated August 1, 2014 by and between Orgenesis, Inc. and Neil Reithinger (incorporated by reference to our current report on Form 8-K filed on August 5, 2014) |
| 10.14 | Personal Employment Agreement dated as of July 23, 2014 by and between Orgenesis Maryland Inc. and Scott Carmer (incorporated by reference to our current report on Form 8-K filed on August 6, 2014) |
| 10.14 | Personal Employment Agreement dated August 22, 2014 by and between Orgenesis Ltd. and Vered Caplan (incorporated by reference to our current report on Form 8-K filed on August 25, 2014) |
| 21.1 | Orgenesis Ltd., a company governed by the laws of Israel and 100% wholly owned |
| 21.2 | Orgenesis SPRL, a company governed by the laws of Belgium and 100% wholly owned |
| 21.3 | Orgenesis Maryland Inc., a company governed by the laws of the state of Maryland and 100% wholly owned |
| <u>31.1*</u> | <u>Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u> |

| No. | Description |
|--------------|--|
| <u>31.2*</u> | <u>Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u> |
| <u>32.1*</u> | <u>Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u> |
| <u>32.2*</u> | <u>Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u> |
| 99.1 | Global Share Incentive Plan (2012) (incorporated by reference to our current report on Form 8-K filed on May 31, 2012) |
| 99.2 | Appendix Israeli Taxpayers Global Share Incentive Plan (incorporated by reference to our current report on Form 8-K filed on May 31, 2012) |
| 99.3 | Audit Committee Charter (incorporated by reference to our current report on Form 8-K filed on January 15, 2013) |
| 99.4 | Compensation Committee Charter (incorporated by reference to our current report on Form 8-K filed on January 15, 2013) |
| 101* | Interactive Data Files pursuant to Rule 405 of Regulation S-T. |

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/ Vered Caplan

Vered Caplan

President, Chief Executive Officer, and Chairperson of the Board

(Principal Executive Officer)

Date: October 15, 2014

/s/ Neil Reithinger

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: October 15, 2014