

Orgenesis Inc.
Form 10-Q
April 19, 2017

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 February 28, 2017

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.)

20271 Goldenrod Lane
Germantown, MD 20876

(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

Edgar Filing: Orgenesis Inc. - Form 10-Q

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

| | | | |
|---|--------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| (Do not check if a smaller reporting company) | | Emerging Growth Company | <input type="checkbox"/> |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 April 19, 2017, there were 119,163,378 shares of registrant's common stock outstanding.

ORGENESIS INC.
FORM 10-Q
FOR THE THREE MONTHS ENDED FEBRUARY 28, 2017

TABLE OF CONTENTS

| | <u>Page</u> |
|--|------------------|
| PART I. UNAUDITED FINANCIAL INFORMATION | |
| ITEM 1. Financial Statements (unaudited) | |
| <u>Condensed Consolidated Balance Sheets as of February 28, 2017 and November 30, 2016</u> | <u>3</u> |
| <u>Condensed Consolidated Statements of Operations for the Three Months Ended February 28, 2017 and February 29, 2016</u> | <u>5</u> |
| <u>Condensed Consolidated Statements of Changes in Equity (Capital Deficiency) as of February 28, 2017 and February 29, 2016</u> | <u>6</u> |
| <u>Condensed Consolidated Statements of Cash Flows for the Three months Ended February 28, 2017 and February 29, 2016</u> | <u>8</u> |
| <u>Notes to Condensed Consolidated Financial Statements</u> | <u>9</u> |
| ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | <u>19</u> |
| ITEM 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u> | <u>27</u> |
| ITEM 4. <u>Controls and Procedures</u> | <u>27</u> |
| PART II. OTHER INFORMATION | |
| ITEM 1. <u>Legal Proceedings</u> | <u>29</u> |
| ITEM 1A. <u>Risk Factors</u> | <u>29</u> |
| ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | <u>29</u> |
| ITEM 3. <u>Defaults Upon Senior Securities</u> | <u>29</u> |
| ITEM 4. <u>Mine Safety Disclosures</u> | <u>30</u> |
| ITEM 5. <u>Other Information</u> | <u>30</u> |
| ITEM 6. <u>Exhibits</u> | <u>30</u> |
| SIGNATURES | <u>31</u> |

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

ORGENESIS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. Dollars in Thousands)
(Unaudited)

| | February 28, 2017 | November 30, 2016 |
|--|----------------------|----------------------|
| Assets | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 3,872 | \$ 891 |
| Accounts receivable, net | 1,533 | 1,229 |
| Prepaid expenses and other receivables | 1,317 | 779 |
| Grants receivable | 13 | 906 |
| Inventory | 614 | 400 |
| Investments in associate, net | 79 | |
| Total current assets | 7,428 | 4,205 |
| NON CURRENT ASSETS: | | |
| Property and equipment, net | 4,584 | 4,573 |
| Restricted cash | 5 | 5 |
| Intangible assets, net | 14,626 | 15,050 |
| Goodwill | 9,557 | 9,584 |
| Other assets | 72 | 70 |
| Total non-current assets | 28,844 | 29,282 |
| TOTAL ASSETS | \$ 36,272 | \$ 33,487 |

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

ORGENESIS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. Dollars in Thousands)
(Unaudited)

| | February 28, 2017 | November 30, 2016 |
|--|------------------------------|------------------------------|
| Liabilities and equity (net of capital deficiency) | | |
| CURRENT LIABILITIES: | | |
| Short-term bank credit | \$ - | \$ 21 |
| Accounts payable | 4,056 | 4,554 |
| Accrued expenses and other payables | 2,041 | 1,205 |
| Employees and related payables | 1,589 | 1,680 |
| Related parties | 42 | 42 |
| Advance payments on account of grant | 2,205 | 243 |
| Short-term loans and current maturities of long term loans | 734 | 1,111 |
| Deferred income | 2,721 | 1,273 |
| Current maturities of convertible loans | 4,625 | 2,541 |
| Convertible bonds | 108 | 1,818 |
| Price protection derivative | 2 | 76 |
| Investments in associate, net | - | 12 |
| TOTAL CURRENT LIABILITIES | 18,123 | 14,576 |
| LONG-TERM LIABILITIES: | | |
| Loans payable | 3,314 | 3,291 |
| Convertible loans | 1,679 | 1,059 |
| Warrants | 4,790 | 1,843 |
| Retirement benefits obligation | 5 | 5 |
| Put option derivative | 273 | 273 |
| Deferred taxes | 2,373 | 1,862 |
| TOTAL LONG-TERM LIABILITIES | 12,434 | 8,333 |
| TOTAL LIABILITIES | 30,557 | 22,909 |
| COMMITMENTS | | |
| EQUITY: | | |
| Common stock | 12 | 12 |
| Additional paid-in capital | 45,062 | 41,605 |
| Receipts on account of shares to be allotted | 774 | |
| Accumulated other comprehensive loss | (1,300) | (1,205) |
| Accumulated deficit | (38,833) | (29,834) |
| TOTAL EQUITY | 5,715 | 10,578 |
| TOTAL LIABILITIES AND EQUITY | \$ 36,272 | \$ 33,487 |

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

ORGENESIS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. Dollars in thousands, except share and loss per share amounts)
(Unaudited)

| | Three Months Ended | |
|---|---------------------------|---------------------|
| | February 28, | February 29, |
| | 2017 | 2016 |
| REVENUES | \$ 1,852 | \$ 1,520 |
| COST OF REVENUES | 1,905 | 1,480 |
| GROSS PROFIT (LOSS) | (53) | 40 |
| RESEARCH AND DEVELOPMENT EXPENSES, net | | |
| | 741 | 401 |
| AMORTIZATION OF INTANGIBLE ASSETS | | |
| | 381 | 328 |
| SELLING, GENERAL AND ADMINISTRATIVE EXPENSES | | |
| | 2,271 | 1,166 |
| OPERATING LOSS | (3,466) | (1,855) |
| FINANCIAL INCOME (EXPENSES), net | (4,948) | 1,772 |
| SHARE IN LOSSES OF ASSOCIATED COMPANY | | |
| | (89) | |
| LOSS BEFORE INCOME TAXES | (8,483) | (83) |
| INCOME TAX BENEFIT (EXPENSES) | (516) | 308 |
| NET INCOME (LOSS) | \$ (8,999) | \$ 225 |
| EARNINGS (LOSS) PER SHARE: | | |
| Basic | \$ (0.08) | \$ 0.002 |
| Diluted | \$ (0.08) | \$ 0.001 |
| WEIGHTED AVERAGE NUMBER OF SHARES USED | | |
| IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE: | | |
| Basic | 111,425,081 | 103,127,025 |
| Diluted | 111,425,081 | 103,127,025 |
| OTHER COMPREHENSIVE LOSS: | | |
| Net income (loss) | \$ (8,999) | \$ 225 |
| Translation adjustments | (95) | 504 |
| TOTAL COMPREHENSIVE INCOME (LOSS) | \$ (9,094) | \$ 729 |

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

ORGENESIS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. Dollars in thousands, except share amounts)
(Unaudited)

*Including outstanding contingent share.

| Common Stock | | | | | | | |
|--|---------------|------------------|-----------------------------------|--|---|----------------------------|--------------|
| | Number | Par Value | Additional Paid-in Capital | Receipts on Account of Share to be Allotted | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total |
| Balance at December 1, 2015 | 55,835,950 | \$ 6 | \$ 14,229 | \$ 1,251 | (1,286) | (20,640) | (6,440) |
| Changes during the three months ended February 29, 2016: | | | | | | | |
| Stock-based compensation to employees and directors | | | 120 | | | | 120 |
| Stock-based compensation to service providers | | | 50 | | | | 50 |
| Issuances of shares from investments and conversion of convertible loans | 10,502,132 | 1 | 1,948 | (1,251) | | | (698) |
| Reclassification of redeemable common stock* | 42,401,724 | 4 | 21,454 | | | | 21,458 |
| Receipts on account of shares to be allotted | | | | 67 | | | 67 |
| Comprehensive income for the period | | | | | 504 | 225 | 729 |
| Balance at February 29, 2016 | 108,739,806 | \$ 11 | \$ 37,801 | \$ 67 | (782) | (20,415) | 16,682 |
| Balance at December 1, | 114,096,461 | \$ 12 | \$ 41,605 | \$ - | (1,205) | (29,834) | 10,578 |

2016

**Changes during
the three
months ended
February 28,
2017:**

| | | | | | | |
|---|-------------|-------|-----------|--------|------------|-------------|
| Stock-based compensation to employees and directors | | | 386 | | | 386 |
| Stock-based compensation to service providers | | | 418 | | | 418 |
| Issuance of warrants and beneficial conversion feature of convertible loans | | | 2,154 | | | 2,154 |
| Receipts on account of shares and warrants to be allotted | | | 499 | 774 | | 1,273 |
| Comprehensive loss for the period | | | | | (95) | (8,999) |
| Balance at February 28, 2017 | 114,096,461 | \$ 12 | \$ 45,062 | \$ 774 | \$ (1,300) | \$ (38,833) |
| | | | | | | \$ 5,715 |

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

ORGENESIS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. Dollars in thousands)
(Unaudited)

| | Three months ended | |
|--|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income (loss) | \$ (8,999) | \$ 225 |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 679 | 170 |
| Share in losses of associated company | 89 | |
| Depreciation and amortization expenses | 592 | 641 |
| Change in fair value of warrants and embedded derivatives | 3,938 | (1,803) |
| Change in fair value of convertible bonds | 14 | (157) |
| Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature) | 323 | 8 |
| Changes in operating assets and liabilities: | | |
| Increase in accounts receivable | (308) | (489) |
| Increase in inventory | (215) | (109) |
| Increase in other assets | | (2) |
| Decrease (increase) in prepaid expenses and other accounts receivable | (541) | 164 |
| Decrease in accounts payable | (662) | (692) |
| Increase in accrued expenses and other payables | 754 | 172 |
| Increase (decrease) in employee and related payables | (89) | 286 |
| Increase in deferred income | 1,452 | 165 |
| Increase in advance payments and receivables on account of grant, net | 2,855 | 388 |
| Increase (decrease) in deferred taxes | 517 | (308) |
| Net cash provided by (used in) operating activities | 399 | (1,341) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of property and equipment | (253) | (354) |
| Disposals of property and equipment | 19 | |
| Investments in Associates | (180) | |
| Net cash used in investing activities | (414) | (354) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Short-term line of credit | (21) | |
| Proceeds from issuance of shares and warrants | 1,323 | 225 |
| Proceeds from issuance of convertible loans (net of transaction costs) | 3,812 | |
| Repayment of convertible loans and convertible bonds | (1,736) | |
| Repayment of short and long-term debt | (342) | (1,733) |
| Net cash provided by (used in) financing activities | 3,036 | (1,508) |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | 3,021 | (3,203) |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS | (40) | (32) |
| | 891 | 4,168 |

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD

| | | | |
|---|-------|----|-----|
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | 3,872 | \$ | 933 |
|---|-------|----|-----|

SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES

| | | | |
|---|--|----|-----|
| Conversion of loans (including accrued interest) to common stock and warrants | | \$ | 973 |
|---|--|----|-----|

| | | | |
|---|--|----|--------|
| Reclassification of redeemable common stock to equity | | \$ | 21,458 |
|---|--|----|--------|

SUPPLEMENTAL INFORMATION ON INTEREST PAID IN

| | | | |
|-------------|--------|----|-----|
| CASH | \$ 155 | \$ | 136 |
|-------------|--------|----|-----|

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

ORGENESIS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the Three Months Ended February 28, 2017 and February 29, 2016

NOTE 1 - GENERAL AND BASIS OF PRESENTATION

Orgenesis Inc. (the Company) was incorporated in the state of Nevada on June 5, 2008, under the name Business Outsourcing Services, Inc. Effective August 31, 2011, the Company completed a merger with its subsidiary, Orgenesis Inc., a Nevada corporation which was incorporated solely to effect a change in its name. As a result, the Company changed its name from Business Outsourcing Services, Inc. to Orgenesis Inc. The consolidated financial statements include the accounts of Orgenesis Inc., MaSTherCell S.A (MaSTherCell), its Belgian based subsidiary and a contract development manufacturing organization, or CDMO (see also note 3), specialized in cell therapy development for advanced medicinal products; Orgenesis SPRL (the Belgian Subsidiary), a Belgian based subsidiary which is engaged in development and manufacturing activities together with clinical development studies in Europe, and later on to be the Company's center for activities in Europe; Orgenesis Maryland Inc. (the U.S. Subsidiary) a Maryland corporation, and Orgenesis Ltd. (the "Israeli Subsidiary") an Israeli corporation.

The Company is a regenerative therapy company with expertise and experience in cell therapy development and manufacturing.

The Company's cell therapy technology derives from published work of Prof. Sarah Ferber, the Company's Chief Science Officer and a researcher at Tel Hashomer Medical Research (THM), a leading medical hospital and research center in Israel, who established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and transdifferentiating (converting) them into pancreatic beta cell-like insulin-producing cells. Its development activities with respect to cell-derived and related therapies, which are conducted through the Israeli Subsidiary, have, to date, been limited to laboratory and preclinical testing.

On May 10, 2016, the Company and Atvio Biotech Ltd., (Atvio) entered into a Joint Venture Agreement (the JVA) pursuant to which the parties agreed to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in Israel.

On March 14, 2016, the Company and CureCell Co., Ltd. (CureCell) entered into a Joint Venture Agreement (the JVA) pursuant to which the parties agreed to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in Korea. As of February 28, 2017, the Joint Venture company, as stipulated in the JVA, has not incorporated.

As used in this report and unless otherwise indicated, the term Company refers to Orgenesis Inc. and its subsidiaries (Subsidiaries). Unless otherwise specified, all amounts are expressed in United States dollars.

Basis of Presentation

These unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. GAAP, 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 February 28, 2017, and the consolidated statements of comprehensive loss for the three months ended February 28, 2017 and February 29, 2016, and the changes in equity and cash flows for the three months period ended February 28, 2017 and February 29, 2016. The results for the three months ended February 28, 2017, are not necessarily indicative of the results to be expected for the year ending November 30, 2017. 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, 2016.

Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As of February 28, 2017, the Company had not achieved profitable operations, has accumulated losses of approximately \$38.8 million (since inception), has a working capital deficiency of \$10.7 million and expects to incur further losses in the development of its business. Presently, the Company does not have sufficient cash and other resources to meet its requirements in the following twelve months. These factors raise substantial doubt about the Company's ability 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. The Company needs to raise significant funds on an immediate basis in order to continue to meet its liquidity needs, realize its business plan and maintain operations. The Company's current cash resources are not sufficient to support its operations as presently conducted or permit it to take advantage of business opportunities that may arise. Management of the Company is continuing its efforts to secure funds through equity and/or debt instruments for its operations.

The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. There can be no assurance that management will be successful in implementing a business plan or that the successful implementation of a business plan will actually improve the Company's operating results. If the Company is unable to obtain the necessary capital, the Company may have to cease operations.

The Company has been funding its operations primarily from the proceeds from private placements of the Company's convertible debt and equity securities and from revenues generated by MaSTherCell. From December 2016 through February 2017, the Company received, through MaSTherCell, proceeds of approximately \$2.8 million in revenues and accounts receivable from customers, \$4.1 million from the private placement to accredited investors of its equity and equity linked securities and convertible loans. In addition, in January 2017 the Company entered into definitive agreements with an institutional investor for the private placement of units of the Company's securities for aggregate subscription proceeds to the Company of \$16 million. The subscription proceeds are payable on a periodic basis through August 2018. During the three months ended February 28, 2017, \$1 million was remitted by such investor and in April 2017 an additional \$0.5 million was remitted. From March 1, 2017 through April 18, 2017, the Company raised an additional \$0.3 million from the proceeds of the private placement to certain accredited investors of its equity and equity linked securities and \$0.6 million in revenues and accounts receivable from customers.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies adopted are consistent with those of the previous financial year.

NOTE 3 - SEGMENT INFORMATION

The Chief Executive Officer ("CEO") is the Company's chief operating decision-maker ("CODM").

Based on the Company's organizational structure, its business activities and information reviewed by the CODM for the purposes of allocating resources and assessing performance, management has determined that there are two operating segments,

CDMO

The CDMO activity is comprised of a specialization in cell therapy development for advanced therapeutic products and providing two types of services to its customers: (i) process and assay development services and (ii) cGMP contract manufacturing services. The CDMO activities include the operations of MaSTherCell and Atvio.

CTB

The Cellular Therapy Business (CTB) activity is based on the technology licensed by the Israeli Subsidiary, that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and differentiating (converting) them into pancreatic beta cell-like insulin producing cells for patients with Type 1 Diabetes.

Edgar Filing: Orgenesis Inc. - Form 10-Q

The Company assesses the performance based on a measure of "Adjusted EBIT" (earnings before financial expenses and tax, and excluding share-based compensation expenses and non-recurring income or expenses). The measure of assets has not been disclosed for each segment.

Segment data for the three months ended February 28, 2017 is as follows:

| | CDMO | CTB | Corporate and Eliminations (in thousands) | Consolidated |
|--|----------|------------|--|--------------|
| Revenues from external customers | \$ 2,144 | \$ | (292) | \$ 1,852 |
| Cost of revenues | (1,861) | | 167 | (1,694) |
| Research and development expenses, net | | (601) | 125 | (476) |
| Operating expenses | 1,712 | (3,590) | | (1,878) |
| Depreciation and amortization expenses | (592) | | | (592) |
| Segment Performance | \$ 1,314 | \$ (4,191) | | (2,788) |
| Stock-based compensation | | | (679) | (679) |
| Financial income (expenses), net | | | (4,927) | (4,927) |
| Share in losses of associated company | (89) | | | (89) |
| Loss before income taxes | | | | \$ (8,483) |

Segment data for the three months ended February 29, 2016 is as follows:

| | CDMO | CTB | Corporate and Eliminations (in thousands) | Consolidated |
|--|----------|----------|--|--------------|
| Net revenues from external customers | \$ 1,571 | \$ | (51) | \$ 1,520 |
| Cost of revenues | (1,288) | | 119 | (1,169) |
| Research and development expenses, net | | (298) | (68) | (366) |
| Operating expenses | (607) | (422) | | (1,029) |
| Depreciation and amortization expense | (640) | (1) | | (641) |
| Segment Performance | \$ (964) | \$ (721) | | (1,685) |
| Share-based compensation | | | (170) | (170) |
| Financial income, net | | | 1,772 | 1,772 |
| Loss before income taxes | | | | (83) |

Geographic, Product and Customer Information

Substantially all the Company's revenues and long lived assets are located in Belgium.

Revenues from single customers from the CDMO segment that exceed 10% of total net revenues are:

| | Three Months Ended | |
|-------------------|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Customer A | \$ 1,189 | \$ 764 |
| Customer B | - | 562 |
| Customer C | 292 | - |
| Customer D | \$ 255 | - |

NOTE 4 CONVERTIBLE LOAN AGREEMENTS

(a) On January 12, 2017, the Company repaid the outstanding principal amount and accrued interest in total amount of \$51 thousand of convertible loans that were issued during September 2016. The transaction had no material impact on the comprehensive loss for the period.

(b) During the three months ended February 28, 2017 the Company entered into several unsecured convertible notes agreements with accredited or offshore investors for an aggregate amount of \$2.65 million. The loans bear an annual interest rate of 6% and mature in two years, unless converted earlier.

The notes provide that the entire principal amount under the notes and accrued interest automatically convert into Units (as defined below) upon the earlier to occur of any of the following (each a Conversion Event): (i) the closing of an offering of equity securities of the Company with gross proceeds to the Company greater than \$10 million (ii) the trading of the Company's common stock, par value \$0.0001 per share (the Common Stock) on the over-the counter market or an exchange at a weighted average price of at least \$0.52 for fifty (50) consecutive trading days, or (iii) the listing of the Company's Common Stock on a U.S. National Exchange (each a Conversion Event). At any time, the holder may convert the principal amount and accrued interest outstanding into Units above. In addition, if a Conversion Event does not occur within 12 months of the issuance date of the note, then the holder, at its option, may convert the outstanding principal amount and accrued interest under this note into either (i) Units as provided above, or (ii) solely into shares of the Company's Common Stock at a per share conversion price of \$0.40.

Since the closing price of the Company's publicly traded stock is greater than the effective conversion price on the measurement date, the conversion feature is considered "beneficial" to the holders and equal to \$1.85 million. The difference is treated as issued equity and reduces the carrying value of the host debt; the discount is accreted as deemed interest on the debt.

The transaction costs were approximately \$261 thousand, out of which \$90 thousand was the fair value of 241,299 warrants granted to three holders as a success fee, exercisable at \$0.52 per share for three years. The fair value of those warrants as of the date of grant was evaluated by using the Black-Scholes valuation model.

(c) During the three months ended February 28, 2017, the Company entered into several unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of \$0.8 million. The notes have 0% or 6% interest rate and are scheduled to mature between six months and one year unless converted earlier. At any time, all or a portion of the outstanding principal amount and accrued but unpaid interest thereon may be converted at the Holder's option into shares of the Company common stock at a price of \$0.52 per share. The Company also issued to the investors three-year warrants to purchase up to 1,746,063 shares of the Company's Common Stock at a per share exercise price of \$0.52

Since the closing price of the Company's publicly traded stock is greater than the effective conversion price on the measurement date, the conversion feature is considered "beneficial" to the holders and equal to \$81 thousand. The difference is treated as issued equity and reduces the carrying value of the host debt; the discount is accreted as

deemed interest on the debt.

(d) On January 23, 2017, the Company and a Non-U.S. institutional investor, entered into an agreement pursuant to which the investor advanced to the Company \$400,000 at per annum rate of 6% and with a maturity date of April 23, 2017.

The transaction costs were approximately \$71 thousand, out of which \$35 thousand as stock based compensation due to issuance of 76,923 warrants and 32,051 shares. The fair value of those warrants as of the date of grant was evaluated by using the Black-Scholes valuation model.

The principal amount and accrued interest were repaid by the Company on March 7, 2017 and, in accordance with the terms of the agreement, the Company issued to the investor 650,000 restricted shares of the Company's Common Stock. The fair value of the shares as of February 28, 2017, was \$520 thousand and was recorded as financial expenses.

(e) In January 2017 MaSTherCell repaid all but one of its bondholders and the aggregate payment amounted to \$1.7 million (€1.5 million). On January 17, 2017, the remain bondholder agreed to extend the duration of his Convertible bond with a principal amount of \$106 thousand (€ 100 thousand) until March 21, 2017, (the New Maturity Date) and the convertible bonds continued to accrue interest as provided in the original agreement. In consideration of the extension, the Company agreed to issue to the bondholder warrants to purchase 102,822 shares of Company Common Stock, exercisable over a three-year period at a per share exercise price of \$0.52. Under the agreement, on the New Maturity Date, the bondholder can elect to sell his bonds to the Company at a price equal to their face value, or convert the entire outstanding principal amount into common stock of the Company at the rate provided for in the original agreement for the acquisition of MaSTherCell. The fair value of those warrants as of the date of grant was \$20 thousand using the Black-Scholes valuation model.

The Company returned from the escrow arrangement entered into in March 2015 in connection with the MaSTherCell acquisition a total of 3,157,716 consideration shares to treasury, in accordance with the terms of the MaSTherCell acquisition agreement. These shares will be retired and cancelled.

On March 20, 2017, the remain bondholder agreed to convert his convertible bonds into 488,182 shares of the Company's Common Stock.

(f) On February 27, 2017, the Company and Admiral Ventures Inc. (Admiral) entered into an agreement resolving the payment of amounts owed to Admiral. Under the terms of the settlement agreement, Admiral extended the maturity date to June 30, 2018. The Company agreed to pay to Admiral, on or before March 1, 2017, between \$0.3 million and \$1.5 million on account of the \$1.9 million owed and outstanding to Admiral. Further, beginning April 2017, the Company agreed to make a monthly payment of \$125 thousand on account of remaining unpaid balance and also agreed to remit 25% of all amounts received from equity financing raised above \$1 million and 20% of such amounts above \$500 thousand on account of amounts owed. The Company accounted for the above changes as a modification of the old debt.

As of the date of the approval of these financial statements, the Company repaid \$1.5 million on account of the original principal amount of the loan.

NOTE 5 COMMITMENTS

Grants

In April 2016, the Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) (DGO6) for a budgeted €1.3 million (\$1.5 million) support program for CTB activity. The financial support is awarded to the Belgian subsidiary Orgenesis as a recoverable advance payment at 55% of budgeted costs, or for a total of €0.7 million thousand (\$0.8 million). The grant will be paid over the project period. On

December 19, 2016, the Belgian Subsidiary received a first payment of €359 thousand (\$374 thousand).

On October 8, 2016, the Belgian subsidiary received the formal approval from the DGO6 for an additional budget of €12.3 million (\$12.8 million) support program for the GMP production of AIP cells for two clinical trials that will be performed in Germany and Belgium. The project will be held during a period of three years commencing January 1, 2017. The financial support is awarded to the Belgium subsidiary at 55% of budgeted costs, a total of €6.8 million (\$7 million). The grant will be paid over the project period. On December 19, 2016, the Belgian Subsidiary received a first payment of €1.7 million (\$1.8 million).

NOTE 6 EQUITY*a. Share Capital*

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

b. Financings

1) During the three months ended February 28, 2017, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement (the Private Placement) of (i) 621,404 shares of the Company's Common Stock and (ii) three year warrants to purchase up to an additional 621,404 shares of the Company's Common Stock at a per share exercise price of \$0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of \$323 thousand.

The Company allocated the proceeds from the Private Placement based on the fair value of the warrants and the shares. The table below presents the fair value of the instruments issued as of the closing dates and the allocation of the proceeds:

| | Total Fair Value | |
|--------------------|-----------------------------|------------|
| | (in thousands) | |
| Warrants component | \$ | 116 |
| Shares component | | 207 |
| Total | \$ | 323 |

As of the February 28, 2017 the shares have not been issued and therefore the Company has recorded \$207 thousand in Receipts on Account of Shares to be Allotted, in the statement of equity.

2) In January 2017, the Company entered into definitive agreements with an institutional investor for the private placement of 30,769,231 units of the Company's securities for aggregate subscription proceeds to the Company of \$16 million at \$0.52 price per unit. Each unit of securities placed is comprised of one share of the Company's Common Stock and a warrant, exercisable over a three-years period from the date of issuance, to purchase one additional share of Common Stock at a per share exercise price of \$0.52. The subscription proceeds are payable on a periodic basis through August 2018. Each periodic payment of subscription proceeds will be evidenced by the Company's standard securities subscription agreement.

On February 16, 2017, the investor and the Company closed on the initial payment of \$1 million of the subscription proceeds and, in connection therewith, the Company issued to the investor 1,923,077 shares of the Company's Common Stock and three year warrants to purchase up to an additional 1,923,077 shares of the Company's Common Stock at a per share exercise price of \$0.52. The Company allocated the proceeds based on the fair value of the warrants and the shares. The table below presents the allocation of the proceeds as of the closing date:

| | Total Fair Value |
|--------------------|-----------------------------|
| | (in thousands) |
| Warrants component | \$ 357 |
| Shares component | 643 |
| Total | \$ 1,000 |

As of February 28, 2017, the shares have not been issued therefore the Company recorded \$567 thousand net of transaction costs in Receipts on Account of Shares to be Allotted.

In connection therewith, the Company undertook to pay a fee of 5%, resulting in the payment of \$50 and the issuance of 96,154 restricted shares of Common Stock. The fair value of the shares as of the date of grant was \$67 thousand using share price at the grant day.

NOTE 7 STOCK BASED COMPENSATION

a. Options Granted to Employees and Directors

On April 27, 2016, the Company approved an aggregate of 1,104,950 stock options to the Company's Chief Executive Officer exercisable at \$0.0001 per share and an aggregate of 1,641,300 stock options to the then Chief Executive Officer of the U.S. Subsidiary exercisable at \$0.28 per share. The options vested immediately with a fair value as of the date of grant of \$622 thousand using the Black-Scholes valuation model.

On December 9, 2016, the Company granted to the employees and directors 7,300,000 options, which are summarized on the table below:

| | No. of options granted | Exercise price | Vesting period | Fair value at grant (in thousands) | Expiration period |
|-----------|-----------------------------------|-----------------------|-------------------------------------|---|------------------------------|
| Directors | 2,000,000 | \$ 0.4 | Quarterly vested over 2 years | \$ 558 | 10 |
| Employees | 5,300,000 | \$ 0.4 | Quarterly vested over 4 years | \$ 1,480 | 10 |

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for the last two years. The expected term is the mid-point between the vesting date and the maximum contractual term for each grant equal to the contractual life. The fair value of each option grant is based on the following assumptions:

| | |
|---------------------------------|---------|
| Value of one common share | \$ 0.39 |
| Dividend yield | 0% |
| Expected stock price volatility | 94% |
| Risk free interest rate | 1.89% |
| Expected term (years) | 5 |

b. Options and Warrants Granted to Consultants

On December 9, 2016, the Company entered into consulting agreements for professional services for a period of one year. Under the terms of the agreement, the Company granted to consultants 200,000 options exercisable at \$0.4 per share. The options shall vest quarterly over a period of one year. The fair value of those options as of the date of grant was \$68 thousand using the Black-Scholes valuation model.

NOTE 8 LOSS PER SHARE

The following table sets forth the calculation of basic and diluted loss per share for the period indicated:

| | Three Months Ended | |
|---|---------------------------|----------------------|
| | February 28, 2017 | February 29, 2016 |
| (in thousands, except per share data) | | |
| Basic: | | |
| Earnings (loss for the period) | \$ (8,999) | \$ 225 |
| Weighted average number of common shares outstanding | 111,425,081 | 103,127,025 |
| Earnings (loss) per common share | \$ (0.08) | \$ 0.002 |
| Diluted: | | |
| Earnings (loss) for the period | \$ (8,999) | \$ 225 |
| Changes in fair value of embedded derivative and interest expense on convertible bonds | | (104) |
| Earnings (loss) for the period | (8,999) | 121 |
| Weighted average number of shares used in the computation of basic and diluted loss per share | 111,425,081 | 103,127,025 |
| Earnings (loss) per common share | \$ (0.08) | \$ 0.001 |

Diluted loss per share does not include 48,717,893 shares underlying outstanding options and warrants and 16,251,087 shares upon conversion of convertible notes for the three months ended February 28, 2017, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted earnings per share does not include 30,832,826 shares underlying outstanding options and warrants, and 1,100,000 shares upon conversion of convertible notes for the three months ended February 29, 2016, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 9 - FAIR VALUE PRESENTATION

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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

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

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

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs, to the extent possible, and considers credit risk in its assessment of fair value.

As of February 28, 2017, and November 30, 2016, the Company's liabilities that are measured at fair value and classified as level 3 fair value are as follows (in thousands):

| | February 28, 2017 | November 30, 2016 |
|--|------------------------------|------------------------------|
| | <u>Level 3</u> | <u>Level 3</u> |
| Warrants (1) | \$ 4,790 | \$ 1,843 |
| Price protection derivative (1) | 2 | 76 |
| Embedded derivatives convertible loans*(1) | 1,312 | 240 |
| Put option derivatives | 273 | 273 |
| Convertible bonds (2) | \$ 108 | \$ 1,818 |

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

(1) The fair value of the warrants, price protection derivative and embedded derivatives is determined by using a Monte Carlo Simulation Model. This model, in contrast to a closed form model, such as the Black-Scholes Model, enables the Company to take into consideration the conversion price changes over the conversion period of the loan, and therefore is more appropriate in this case.

(2) The fair value of the convertible bonds described in Note 7 of the Annual Report is determined by using a binomial model for the valuation of the embedded derivative and the fair value of the bond was calculated based on the effective rate on the valuation date (6%). The binomial model used the forecast of the Company share price during the convertible bond's contractual term. Since the convertible bond is in Euro and the model is in USD, the Company has used the Euro/USD forward rates for each period. In order to solve for the embedded derivative fair value, the calculation was performed as follows:

Stage A - The model calculates several potential future share prices of the Company based on the volatility and risk-free interest rate assumptions.

Stage B - the embedded derivative value is calculated "backwards" in a way that considers the maximum value between holding the bonds until maturity or converting the bonds.

The following table presents the assumptions that were used for the models as of February 28, 2017:

| | Price Protection Derivative and Warrants | Embedded Derivative |
|--------------------------------------|---|--------------------------------|
| Fair value of shares of Common Stock | \$ 0.8 | \$ 0.8 |
| Expected volatility | 96%-106% | 106% |
| Discount on lack of marketability | 16% | - |
| Risk free interest rate | 0.47%-1.31% | 0.47%-0.58% |
| Expected term (years) | 1.7-2.3 | 0.17-0.33 |
| Expected dividend yield | 0% | 0% |
| Discount on lack of marketability | | 9.9%-25.6% |
| Expected capital raise dates | April 30, 2017 | - |

The fair value of the convertible bonds is equal to their principal amount and the aggregate accrued interest.

Edgar Filing: Orgenesis Inc. - Form 10-Q

The following table presents the assumptions that were used for the models as of November 30, 2016:

| | Price Protection Derivative and Warrants | Embedded Derivative | Put option Derivative |
|---|---|--------------------------------|----------------------------------|
| Fair value of shares of common stock | \$ 0.39 | \$ 0.39 | \$ |
| Expected volatility | 94%-103% | 103% | 63% |
| Discount on lack of marketability | 16% | - | |
| Risk free interest rate | 0.57%-1.28% | 0.38%-0.62% | 0.9% |
| Expected term (years) | 1.9-2.6 | 0.08-0.42 | |
| Expected dividend yield | 0% | 0% | |
| Expected capital raise dates | Q1 2017 | - | - |
| Probability of external Investment in Atvio | | | 20% |
| Orgenesis cost of debt | | | 26% |
| Revenues Multiplier distribution | | | 3.34 |

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 three months ended February 28, 2017:

| | Warrants | Embedded Derivatives | Convertible Bonds | Price Protection Derivative | Put Option Derivative |
|---|-----------------|---------------------------------|------------------------------|--|----------------------------------|
| | | | (in thousands) | | |
| Balance at beginning of the year | \$ 1,843 | \$ 240 | \$ 1,818 | \$ 76 | \$ 273 |
| Changes in fair value during the period | 2,947 | 1,065 | 14 | (74) | |
| Repayment of convertible bonds | | | (1,719) | | |
| Translation adjustments | | 7 | (4) | | |
| Balance at end of the year | \$ 4,790 | \$ 1,312 | \$ 109 | \$ 2 | \$ 273 |

The Company has performed a sensitivity analysis of the results for the warrants fair value to changes in the assumptions for expected volatility with the following parameters:

| | Base -10% | Base | Base+10% |
|-------------------------|------------------|-----------------|-----------------|
| | | (in thousands) | |
| As of February 28, 2017 | \$ 4,575 | \$ 4,790 | \$ 4,995 |

The Company has performed a sensitivity analysis of the results for the Embedded Derivative fair value to changes in the assumptions expected volatility with the following parameters:

| | Base -10% | Base | Base+10% |
|-------------------------|------------------|-----------------|-----------------|
| | | (in thousands) | |
| As of February 28, 2017 | \$ 1,368 | \$ 1,312 | \$ 1,265 |

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 year ended November 30, 2016:

| | Warrants | Embedded Derivatives | Convertible Bonds | Price Protection Derivative | Put Option Derivative |
|---|----------|-------------------------|----------------------|-----------------------------------|--------------------------|
| | | | (in thousands) | | |
| Balance at beginning of the year | \$ 1,382 | \$ 289 | \$ 1,888 | \$ 1,533 | \$ |
| Additions | 802 | 40 | | 120 | 273 |
| Conversion | | (10) | | | |
| Changes in fair value related to Price Protection Derivative expired* | | | | (108) | |
| Changes in fair value during the period | (341) | (87) | (84) | (1,469) | |
| Changes in fair value due to extinguishment of convertible loan | | 8 | | | |
| Translation adjustments | | | 14 | | |
| Balance at end of the year | \$ 1,843 | \$ 240 | \$ 1,818 | \$ 76 | \$ 273 |

(*) During the twelve months ended November 30, 2016, 11,732,916 Price Protection Derivative have expired. There were no transfers to Level 3 during the twelve months ended November 30, 2016.

NOTE 10 - SUBSEQUENT EVENTS

- a. On March 1, 2017, the Company entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of \$100 thousand. The notes bear an annual interest rate of 6% and mature in two years from the closing date, unless earlier converted subject to the terms defined in the agreements.
- b. In March 2017, the Company entered into definitive agreements with accredited investors relating to a private placement of (i) 384,615 shares of the Company's Common Stock and (ii) three year warrants to purchase up to an additional 384,615 shares of the Company's Common Stock at a per share exercise price of \$0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of \$200 thousand.
- c. In April 2017, the institutional investor referred to in Note 6b, remitted to the Company \$500,000 in subscription proceeds in respect of which the Company will issue to the investor 961,538 shares of Common Stock and three year warrants for an additional 961,538.
- d. On March 1, 2017, the Company paid to Admiral \$1.5 million on account of the debt owed.

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

Forward-Looking Statements

This report contains forward-looking statements. The following discussion should be read in conjunction with the financial statements and related notes contained in our Annual Report on Form 10-K, as filed with the Securities & Exchange Commission on February 28, 2017. Certain statements made in this discussion are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are projections in respect of future events or financial performance. In some cases, you can identify forward-looking statements by terminology such as may, should, expects, plans, anticipates, believes, estimates, predicts, continue or the negative of these terms or other comparable terminology. Forward-looking statements made in a quarterly report on Form 10-Q may include statements about our:

- ability to continue as a going concern;
- ability to obtain sufficient capital or strategic business arrangements to maintain our operations and realize our business plan, including our financial obligations under various strategic collaboration arrangements;
- ability to develop through our Israeli subsidiary to the clinical stage a new technology to transdifferentiate liver cells into functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- belief that one of our principal competitive advantages is our cell transdifferentiation technology being developed by our Israeli subsidiary and being able to compete favorably and profitably as a CDMO in the regenerative medicine sector;
- belief that our diabetes-related treatment seems to be safer than other options;
- expectations regarding our Israeli subsidiary's ability to obtain and maintain intellectual property protection for our technology and therapies;
- ability to commercialize products in light of the intellectual property rights of others;
- ability to obtain funding necessary to start and complete such clinical trials;
- 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;
- relationship with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (THM) and the risk that THM may cancel the License Agreement;
- expenditures not resulting in commercially successful products;
- ability to grow the business of MaSTherCell, which we acquired in our fiscal year 2015, as our principal CDMO business;
- ability to fund the operational and capital requirements of our CDMO business and its global expansion;
- successful integration of our clinical and CDMO strategy;
- ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- ability to attract and retain key scientific or management personnel and to expand our management team;
- accuracy of estimates regarding expenses, future revenue, capital requirements, profitability, and needs for additional financing; and
- extensive industry regulation, and how that will continue to have a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

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, 2016, as filed with the Securities & Exchange Commission on February 28, 2017, 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 may cause the Company's or its 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. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The company is under no duty to update any forward-looking statements after the date of this report to conform these statements to actual results.

As used in this quarterly report and unless otherwise indicated, the terms we, us, our, Orgenesis or the Company to Orgenesis Inc. and its wholly-owned Subsidiaries, Orgenesis Ltd. (the Israeli Subsidiary), Orgenesis SPRL (the Belgian Subsidiary), Orgenesis Maryland, Inc. (the U.S. Subsidiary) and MaSTherCell S.A. (MaSTherCell), our Belgian-based subsidiary. Unless otherwise specified, all dollar amounts are expressed in United States dollars. Our common stock is currently listed on the OTC Market, QB tier, under the symbol ORGS.

Corporate Overview

Orgenesis Inc. is among the first of a new breed of regenerative therapy companies with expertise and unique experience in cell therapy development and manufacturing. We are a fully-integrated biopharmaceutical company focused not only on developing our trans-differentiation technologies for diabetes and vertically integrating manufacturing that can optimize our abilities to scale-up our technologies for clinical trials and eventual commercialization, but also to apply our disciplined execution to emerging technologies of other cell therapy markets in such areas as cell-based cancer immunotherapies and neurodegenerative diseases. This integrated approach supports our business philosophy of bringing to market significant life-improving medical treatments.

Our cell therapy technology for diabetes is derived from the published work of Prof. Sarah Ferber, our Chief Science Officer and a researcher at Tel Hashomer Medical Center, a leading medical hospital and research center in Israel (THM), who established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and transdifferentiating (converting) them into pancreatic beta cell-like insulin-producing cells. Furthermore, those cells were found to be resistant to autoimmune attack and to produce insulin in a glucose-sensitive manner in relevant animal models. Our development activities with respect to cell-derived and related therapies, which are conducted through our Israeli Subsidiary, have, to date, been limited to laboratory and preclinical testing. Our development plan calls for conducting additional preclinical safety and efficacy studies with respect to diabetes and other potential indications.

Our Belgian Subsidiary is a contract development manufacturing organization, or CDMO, specialized in cell therapy development for advanced medicinal products. In the last decade, cell therapy and regenerative medicine products have gained significant importance, particularly in the fields of ex-vivo gene therapy and immunotherapy. While academic and industrial research has led scientific development in the sector, industrialization and manufacturing expertise remains insufficient. MaSTherCell plans to fill this gap by providing two types of services to its customers: (i) process and assay development and optimization services and (ii) current Good Manufacturing Practices (cGMP) contract manufacturing services. These services offer a double advantage to MaSTherCell's customers. First, customers can continue allocating their financial and human resources on their product/therapy, while relying on a trusted partner for their process development/production. Second, it allows customers to leverage MaSTherCell's expertise in cell therapy manufacturing and all related aspects. As the industry continues to mature and a growing number of cell therapy companies approach commercialization, we believe that MaSTherCell is well positioned to serve as an external manufacturing source for cell therapy companies.

In furtherance of our business strategy, we are leveraging the recognized expertise and experience in cell process development and manufacturing of MaSTherCell, and our international joint ventures, to build a global and fully integrated bio-pharmaceutical company in the cell therapy development and manufacturing area. We target the international manufacturing market as a key priority through joint-venture agreements that provide development capabilities, along with manufacturing facilities and experienced staff. All of these capabilities offered to third-parties are mobilized for our internal development projects, allowing the Company to be in a position to bring new products to the patients faster and at a fraction of the costs.

Significant Recent Corporate Highlights

Our business success in the immediate future will largely depend on our ability to raise significant amounts of working capital in order to achieve our business plan and maintain operations as presently conducted and to expand the revenue generating capacity of our subsidiary MaSTherCell S.A.

Management continues in its efforts to raise operating capital. In connection therewith, in January 2017 we entered into definitive agreements with an institutional investor for the private placement of units of our securities for aggregate subscription proceeds to the Company of \$16 million. The subscription proceeds are payable on a periodic basis through August 2018. Each periodic payment of subscription proceeds will be evidenced by our standard securities subscription agreement. As of the date of this quarterly report on Form 10-Q, the investor has remitted to us \$1.5 million in subscription proceeds. Each unit is comprised of one share of our common stock and a warrant to purchase an additional share of common stock at a per share exercise price of \$0.52. Pursuant to the investment, the investor designated director to serve on our board of directors for an initial two-year period and thereafter so long as the investor holds at least 10% of the Company's outstanding Common Stock. The investor's right to designate the board designee is subject to the payment in full as provided in the definitive agreements of the remaining subscription proceeds.

On February 13, 2017, we announced that our Belgian-based subsidiary, Orgenesis SPRL, received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DG06) for a €12.3 million (approximately \$12.8 million) support program for the research and development of a potential cure for Type 1 Diabetes. The financial support was awarded to our Belgian subsidiary at 55% of budgeted costs, or a total of €6.8 million (approximately \$7 million).

We have improved our balance sheet by reducing our company's debt by the repayment of \$1.5 million in principal amount owed to an institutional investor. In accordance with the agreement with such investor, we undertook to pay down the balance owed to such investor in the approximate amount of \$0.5 million periodically on a monthly basis and from amounts raised.

As further discussed below, our subsidiary MaSTherCell S.A., had revenues of approximately \$1.85 million during the quarter representing an increase of 22% over the same period last year.

While we believe, the above developments position us to further our business development efforts and realize our business plan, we can provide no assurance that we will be successful in achieving our business plan. As discussed below, we still need to raise significant working capital to maintain operations and achieve our business plans.

*Results of Operations*Comparison of the Three Months Ended February 28, 2017 to the Three months Ended February 29, 2016

Our financial results for the three months ended February 28, 2017 are summarized as follows in comparison to the three months ended February 29, 2016:

| | Three Months Ended | |
|--|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Revenues | \$ (1,852) | \$ (1,520) |
| Cost of sales | 1,905 | 1,480 |
| Research and development expenses, net | 741 | 401 |
| Amortization of intangible assets | 381 | 328 |

Edgar Filing: Orgenesis Inc. - Form 10-Q

| | | | |
|--|----------|----|---------|
| Selling, general and administrative expenses | 2,271 | | 1,166 |
| Share in losses of associated company | 89 | | |
| Financial expenses (income), net | 4,948 | | (1,772) |
| Loss before income taxes | \$ 8,483 | \$ | 83 |
| | 21 | | |

Revenues

All revenues were derived from the Company's Belgian Subsidiary, MaSTherCell S.A.

Our revenues for the three months ended February 28, 2017 are summarized as follows in comparison to our revenues for the three months ended February 29, 2016:

| | Three Months Ended | |
|--------------|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Services | \$ 1,384 | \$ 1,231 |
| Goods | 468 | 289 |
| Total | \$ 1,852 | \$ 1,520 |

Revenues for the three months ended February 28, 2017, increased by 22% or \$332 thousand compared to the same period in 2016. The increase in revenues is attributable to an increase in the volume of the services provided by MaSTherCell resulting from the extension by MaSTherCell of existing customer service contracts and the entry into new customer service contracts with leading biotech companies and also from revenues generated from existing manufacturing agreements

Expenses

Cost of Sales

| | Three Months Ended | |
|---|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Salaries and related expenses | \$ 1,034 | \$ 666 |
| Professional fees and consulting services | 87 | 71 |
| Raw Material | 518 | 276 |
| Depreciation and amortization expenses, net | 210 | 312 |
| Other expenses | 56 | 155 |
| | \$ 1,905 | 1,480 |

Cost of sales for the three months ended February 28, 2017 increased by 29%, or \$425 thousand, compared to the same period in 2016.

Salaries and related expenses for the three months ended February 28, 2017 increased by 55%, or \$368 thousand compared to the same period in 2016. The increase in salaries and related expenses was due to recruitment by MaSTherCell of new employees to support the increase in the volume of services provided.

Raw materials for the three months ended February 28, 2017, increased by 88%, or \$242 thousand, compared to the same period in 2016 and are primarily attributable to an increase of \$179 thousand in revenues from selling goods to our customers.

Depreciation and amortization expenses (net) for the three months ended February 28, 2017 decreased by 33%, or \$102 thousand, compared to the same period in 2016, mainly due to fully amortized assets as of November 30, 2016 that are not amortized in the period.

Research and Development Expenses

| | Three Months Ended | |
|---|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Salaries and related expenses | \$ 293 | 251 |
| Stock-based compensation | 267 | 34 |
| Professional fees and consulting services | 44 | 91 |
| Lab expenses | 174 | 91 |
| Other research and development expenses | 41 | 45 |
| Less grant | (78) | (111) |
| Total | \$ 741 | \$ 401 |

Salaries and related expenses for the three months ended February 28, 2017 increased by 17%, or \$42 thousand compared to the same period in 2016. The increase in salaries and related expenses is primarily attributable to hiring additional two experienced employees to work as part of our research and development team instead of getting services from external consultant, accordingly the professional fees and consulting services for the three months ended February 28, 2017 decreased by \$47 thousand.

Stock-based compensation for the three months ended February 28, 2017 increased by \$233 thousand compared to the same period in 2016 and are primarily due to new grant of options to employees in December 2016.

Selling, General and Administrative Expenses

| | Three Months Ended | |
|---|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Salaries and related expenses | \$ 224 | \$ 204 |
| Stock-based compensation | 393 | 137 |
| Accounting and legal fees | 401 | 208 |
| Professional fees | 394 | 314 |
| Rent and related expenses | 244 | 151 |
| Business development | 124 | 84 |
| Expenses related to a joint venture | 258 | |
| Other general and administrative expenses | 233 | 68 |
| Total | \$ 2,271 | \$ 1,166 |

Selling, general and administrative expenses for the three months ended February 28, 2017 increased by 95%, or \$1,105 thousand, compared to the same period in 2016.

Stock-based compensation expenses during the three months ended February 28, 2017 increased by 186%, or \$256 thousand, compared to the same period in 2016 and was primarily attributable to new option grants to executives, directors and employees made on December 9, 2016 and due to new option grant made to consultant in May 2016 for which we recorded a charge in the amount of \$297 thousand.

Accounting and legal fees expenses for the three months ended February 28, 2017 increased by 93%, or \$193 thousand compared to the same period in 2016. The increase is attributable to legal fees due to the services provided in connection with exploring a new strategic collaboration, new fundraising and, repayment of the bonds.

Rent and related expenses increased by 62%, or \$93 thousand, during three months ended February 28, 2017 compared to the same period in 2016 and is primarily attributable to leasing of additional offices premises for our

subsidiary MaSTherCell.

Expenses related to a JV are comprised of our 50% participating interest in the expenses accrued during the three months ended February 28, 2017, which primarily consisted salary expenses and construction costs of the new production area in Korea under our joint venture with CureCell.

Financial Expenses (Income), net

| | Three Months Ended | |
|--|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Increase (decrease) in fair value of warrants and financial liabilities measured at fair value | \$ 3,952 | \$ (1,960) |
| Stock-based compensation related to warrants granted to bondholder | 20 | |
| Stock-based compensation related to shares to be issued to creditor | 520 | |
| Interest expense on convertible loans and loans | 389 | 185 |
| Foreign exchange loss, net | 63 | 3 |
| Other expenses | 4 | |
| Total | \$ 4,948 | \$ (1,772) |

Financial expenses (income), net for the three months ended February 28, 2017, increased by \$6,720 thousand, compared to the same period in 2016. The change in financial expenses is mainly attributable to an increase of \$4,052 thousand in fair value of warrants and financial liabilities measured at fair value due to the fact that in the three months ended February 28, 2017 there was a strong impact of the increase in the share price, which was \$0.80 on February 28, 2017 as opposed to \$0.39 on November 30, 2016. On the other hand, the decrease in fair value of warrants and financial liabilities measured at fair value for the three months ended February 29, 2016 was mainly due to updated in our assumptions related to the probabilities of activating the anti-dilution mechanism.

In addition, part of the increase is attributable to \$20 thousand of stock-based compensation expenses related to 102,822 warrants granted to the remain bondholder in consideration of the extension of his bonds, and \$520 thousand of stock-based compensation expenses related to restricted shares issued on March 7, 2017, in accordance with the terms of the convertible loan agreement dated January 23, 2017.

Working Capital Deficiency

| | February 28, 2017 | November 30, 2016 |
|----------------------------|------------------------------|------------------------------|
| | (in thousands) | |
| Current assets | \$ 7,428 | \$ 5,055 |
| Current liabilities | 18,123 | 12,412 |
| Working capital deficiency | \$ (10,695) | \$ (7,357) |

Current assets increased by \$2.4 million, which was primarily attributable to an increase of \$3 million in cash and cash equivalents due to offering of private placement of our equity and equity-linked securities in February 2017.

Furthermore, the account receivables increased by \$0.3 million and the grants receivable decreased by \$0.9 million mainly due to payment from the DGO6.

Current liabilities increased by \$5.2 million, which was primarily attributable to an increase of \$2 million in advanced payments on account of grant in connection with the new grant approved by the DGO6 to support a clinical study in Germany and Belgium.

In addition, an increase of \$2.1 million in current maturities of convertible loans, \$1.3 million increase was related to new convertible loans and the remain amount was due to changes in fair value of the old convertible loans. On March 2017, we reimbursed \$1.9 million from the outstanding amount of the current maturities of convertible loans.

Cash Flows

| | Three Months Ended | |
|---|------------------------------|------------------------------|
| | February 28, 2017 | February 29, 2016 |
| | (in thousands) | |
| Net income (loss) | \$ (8,999) | \$ 255 |
| Net cash provided by (used in) operating activities | 399 | (1,341) |
| Net cash used in investing activities | (414) | (354) |
| Net cash provided by (used in) financing activities | 3,036 | (1,508) |
| Increase (decrease) in cash and cash equivalents | \$ 3,021 | \$ (3,203) |

The increase in net cash used in operating activities for three months ended February 28, 2017, compared to the same period in 2016, is primarily attributable to our CDMO activities in Belgium.

The increase in amount of \$60 thousand in net cash used in investing activities for the three months ended February 28, 2017, compared to the same period in 2016, was due to \$180 thousand due to investment in associates, which was offset by decrease in amount of \$120 in purchase and selling of property and equipment.

The increase in amount of \$4.5 million in net cash provided by financing activities for the three months ended February 28, 2017 as compared to the same period in 2016, was attributable to the increase of \$1.1 million in the proceeds from issuance of shares and warrants, \$3.8 million in the net proceeds from issuance of convertible loans, which was offset by increase in amount of \$0.3 million due to repayment of convertible loans, convertible bonds and short and long-term debt.

Liquidity & Capital Resources

We need to raise additional operating capital in order to maintain our operations and realize our business plan. Management believes that funds on hand, as well as the subscription proceeds of \$9 million that we anticipate receiving through the end of February 2018 (out of a total of \$14.5 million subscription proceeds that we are to receive on a periodic basis through August 2018), will allow us to conduct operations as presently conducted through the end of fiscal year 2017, without the planned CDMO facility expansion. We will likely need to raise additional operating capital in fiscal 2018 in order to maintain operations and to realize our business plan. Without additional sources of cash and/or the deferral, reduction, or elimination of significant planned expenditures and debt repayment, we may not have the cash resources to continue as a going concern thereafter.

Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. As of February 28, 2017, we have not achieved profitable operations, has accumulated losses of approximately \$38.8 million (since inception), has a working capital deficiency of \$10.7 million and expects to incur further losses in the development of its business. These factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives for operations, 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.

The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. There can be no assurance that management will be successful in implementing a business plan or that the successful implementation of a business plan will actually improve the Company's operating results. If the Company is unable to obtain the necessary capital, the Company may have to cease operations.

We have been funding operations primarily from the proceeds from private placements of the our convertible and equity securities and from revenues and accounts receivable generated by MaSTherCell. From December 2016 through February 2017, we received, through MaSTherCell, proceeds of approximately \$2.8 million and \$4.1 million from the private placement to accredited investors of its equity and equity linked securities and convertible loans. In addition, in January 2017 we entered into definitive agreements with an institutional investor for the private placement of units of our securities for aggregate subscription proceeds of \$16 million. The subscription proceeds are payable on a periodic basis through August 2018. During the three months ended February 28, 2017, \$1 million was remitted by such investor and in April 2017 an additional \$0.5 million was remitted. In addition, between March 1 and April 18, 2017, we raised an additional \$0.3 million from the proceeds of a private placement to certain accredited investors of its equity and equity linked securities and \$0.6 million in revenues and accounts receivable from customers.

Cash Requirements

Our plan of operation during fiscal year 2017 is to:

- initiate regulatory activities in Europe and the United States;
- locate suitable facility in the U.S. for tech transfer and manufacturing scale-up;
- purchase equipment needed for its cell production process;
- hire key personnel including, but not limited to, a chief medical officer, US based chief science officer and chief operating officer;
- collaborate with clinical centers and regulators to carry out clinical studies and clinical safety testing;
- identify optional technologies for scale up of the cells production process; and
- initialize efforts to validate the manufacturing process (in certified labs).

We estimate that our operating resources and expenses for the next 12 months as of February 28, 2017 will be as follows:

| | |
|------------------------------------|-------------|
| Revenues | \$ 12,632 |
| Grant income | 6,982 |
| Industrial loans | 2,087 |
| Manufacturing wages | (4,736) |
| Other Manufacturing expenses | (6,512) |
| R&D wages | (1,211) |
| R&D subcontractors | (6,212) |
| Other R&D expenses | (1,816) |
| G&A expenses | (3,987) |
| Expansion of CDMO facilities | (2,621) |
| Manufacturing costs | (2,500) |
| Property and equipment investments | (2,623) |
| Total | \$ (10,517) |

Future Financing

We will require additional funds to implement our growth strategy for our business. In addition, while we have received various grants that have enabled us to fund our clinical developments, these funds are largely restricted for use for other corporate operational and working capital purposes. As mentioned above, we raised additional capital to both supplement our clinical developments that are not covered by any grant funding and to cover our operational expenses. In the first quarter of fiscal 2017, we entered into a definitive agreement with an institutional investor for the private placement of units of our securities for aggregate subscription proceeds of \$16 million. The subscription proceeds are payable on a periodic basis through August 2018, of which, through the date of this report on Form 10-Q, we have received \$1.5 million in subscription proceeds. We may raise the additional funds required 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 when needed or, if available, that can be obtained

on commercially reasonable terms. If we will not be able to obtain the additional financing on a timely basis as required, or generate significant material revenues from operations, we will not be able to meet our other obligations as they become due and will be forced to scale down or perhaps even cease our operations.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's 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 the Company's management, including the Company's president and chief executive officer (who is the Company's principal executive officer) and the Company's chief financial officer, treasurer, and secretary (who is the Company's principal financial officer and principal accounting officer) to allow for timely decisions regarding required disclosure. In designing and evaluating the Company's disclosure controls and procedures, the Company's management recognizes that controls and procedures are designed on a risk-based approach and, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. The Company's management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The continuous improvement of the Company's disclosure controls and procedures is based on material weaknesses identification in the Company's internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over the Company's 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 the Company's 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, the Company's management concluded its internal control over financial reporting required improvement as of February 28, 2017. The limitation of the Company's internal control over financial reporting was due to the applied risk-based approach which is indicative of many small companies with limited number of staff in corporate functions implying:

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

Our management believes the weaknesses identified above have not had any material effect on our financial results. Although a remediation plan was designed and implementation efforts are still in progress, management is taking additional steps to address the causes of the above weaknesses and to improve our internal control over financial reporting, including the re-design of our accounting processes and control procedures and the identification of gaps in our skills base and the expertise of our staff as required to meet the financial reporting requirements of a public company. In particular, during the completed quarter, we have retained qualified independent third party accounting personnel, to conduct a comprehensive review of our internal controls and formalization of our review and approval processes in order. This measure has led to improve our internal controls which has enabled us to expedite our month-end close process, thereby facilitating the timely preparation of financial reports and to strengthen our segregation of duties at the Company. We are also committed to hiring a full time chief financial officer at MaSTherCell. We intend to hire additional qualified staff to augment our internal accounting personnel. Finally, we are exploring implementing a new initiative to ease and automate data gathering from all affiliated companies (data warehousing) and implement quantitative and qualitative controls.

Our management will continue to monitor and evaluate the relevance of our risk-based approach and the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary and as funds allow.

Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Changes in Internal Control Over Financial Reporting

During the three months ended February 28, 2017, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting. During the completed quarter, we have strengthened the Corporate Finance function by hiring independent third party accounting personnel at MaSTherCell and one additional qualified person to assist in the internal accounting function.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We know of no material pending legal proceedings to which the Company or its Subsidiaries are a party or of which any of its properties, or the properties of its Subsidiaries, are 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 the Company's directors, officers or affiliates, or any registered or beneficial stockholder is a party adverse to the Company or its Subsidiaries or has a material interest adverse to the Company or its Subsidiaries.

ITEM 1A. RISK FACTORS

An investment in the Company's common stock involves a number of very significant risks. You should carefully consider the risk factors included in the Risk Factors section of the Annual Report on Form 10-K for the year ended November 30, 2016, as filed with the Securities & Exchange Commission on February 28, 2017, in addition to other information contained in those reports and in this quarterly report in evaluating the Company and its business before purchasing shares of our common stock. The Company's business, operating results and financial condition could be adversely affected due to any of those risks.

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

The following paragraph sets forth certain information with respect to all securities sold by us during the three months ended February 28, 2017 without registration under the Securities Act:

On February 16, 2017, an institutional investor and the Company closed on the initial payment of \$1 million of the subscription proceeds of \$16 million and, in connection therewith, the Company issued to the investor 1,923,077 shares of the Company's Common Stock and three year warrants to purchase up to an additional 1,923,077 shares of the Company's Common Stock at a per share exercise price of \$0.52

During the three months ended February 28, 2017, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement (the Private Placement) of (i) 621,404 shares of the Company's Common Stock and (ii) three year warrants to purchase up to an additional 621,404 shares of the Company's Common Stock at a per share exercise price of \$0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of \$323 thousand.

These securities were not registered under the Securities Act of 1933, as amended (the "Securities Act"), but qualified for exemption under Section 4(a)(2) of the Securities Act and Regulation S promulgated thereunder. The securities were exempt from registration under Section 4(a)(2) of the Securities Act and Regulation S because the issuance of such securities by the Company did not involve a "public offering," as defined in Section 4(a)(2) of the Securities Act, the Investor's representations that it is not a U.S. Person as that term is defined in Rule 902(k) of Regulation S, and that it is acquiring the securities for its own account for investment purposes and not as nominee or agent, and not with a view to the resale or distribution thereof, and that the Investor understands that the securities may not be sold or otherwise disposed of without registration under the Securities Act and any applicable state securities laws, or an applicable exemption therefrom.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits required by Regulation S-K:

| 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) |
| <u>10.1*</u> | <u>Joint Venture Agreement dated as of May 10, 2016 between Orgenesis Inc. and Atvio Biotech Ltd.</u> |
| <u>10.2*</u> | <u>Private Placement Subscription Agreement dated January 26, 2017 between Orgenesis Inc. and Image Securities FZC</u> |
| <u>10.3*</u> | <u>Amendment No. 1 dated February 9, 2017 to the Private Placement Subscription Agreement between Orgenesis Inc. and Image Securities FZC</u> |
| <u>31.1*</u> | <u>Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002</u> |
| <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> |
| <u>101.INS*</u> | <u>XBRL Instance Document</u> |
| <u>101.SCH*</u> | <u>XBRL Taxonomy Extension Schema</u> |
| <u>101.CAL*</u> | <u>XBRL Taxonomy Extension Calculation Linkbase</u> |
| <u>101.DEF*</u> | <u>XBRL Taxonomy Extension Definition Linkbase</u> |
| <u>101.LAB*</u> | <u>XBRL Taxonomy Extension Label Linkbase</u> |
| <u>101.PRE*</u> | <u>XBRL Taxonomy Extension Presentation Linkbase</u> |

*Filed herewith

SIGNATURES

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

ORGENESIS INC.

By:

/s/ Vered Caplan

Vered Caplan

President & Chief Executive Officer

(Principal Executive Officer)

Date: April 19, 2017

/s/ Neil Reithinger

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting
Officer)

Date: April 19, 2017