

Orgenesis Inc.  
Form 10-Q  
July 24, 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 May 31, 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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging Growth Company

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.

---

Edgar Filing: Orgenesis Inc. - Form 10-Q

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes [ ] No [X]

As of July 24 2017, there were 121,141,095 shares of registrant s common stock outstanding.

---

**ORGENESIS INC.**  
**FORM 10-Q**  
**FOR THE THREE AND SIX MONTHS ENDED MAY 31, 2017 AND 2016**

**TABLE OF CONTENTS**

		<b>Page</b>
<b>PART I.</b>	<b><u>UNAUDITED FINANCIAL INFORMATION</u></b>	
<b>ITEM 1.</b>	<u>Financial Statements (unaudited)</u>	<u>4</u>
	<u>Condensed Consolidated Balance Sheets as of May 31, 2017 and November 30, 2016</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended May 31, 2017 and 2016</u>	<u>6</u>
	<u>Condensed Consolidated Statements of Changes in Equity for the Six Months Ended May 31, 2017 and 2016</u>	<u>7</u>
	<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended May 31, 2017 and 2016</u>	<u>8</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>9</u>
<b>ITEM 2.</b>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>19</u>
<b>ITEM 3.</b>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>25</u>
<b>ITEM 4.</b>	<u>Controls and Procedures</u>	<u>25</u>
<b>PART II.</b>	<b><u>OTHER INFORMATION</u></b>	
<b>ITEM 1.</b>	<u>Legal Proceedings</u>	<u>28</u>
<b>ITEM 1A.</b>	<u>Risk Factors</u>	<u>28</u>
<b>ITEM 2.</b>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>28</u>
<b>ITEM 3.</b>	<u>Defaults Upon Senior Securities</u>	<u>28</u>
<b>ITEM 4.</b>	<u>Mine Safety Disclosures</u>	<u>28</u>
<b>ITEM 5.</b>	<u>Other Information</u>	<u>29</u>
<b>ITEM 6.</b>	<u>Exhibits</u>	<u>29</u>
<b><u>SIGNATURES</u></b>		

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

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

	May 31, 2017	November 30, 2016
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 658	\$ 891
Accounts receivable, net	2,961	1,229
Prepaid expenses and other receivables	1,453	779
Grants receivable	134	906
Inventory	904	400
Total current assets	6,110	4,205
<b>NON CURRENT ASSETS:</b>		
Property and equipment, net	4,807	4,573
Restricted cash	6	5
Intangible assets, net	14,969	15,050
Goodwill	10,048	9,584
Investments in associate, net	252	-
Other assets	75	70
Total non-current assets	30,157	29,282
<b>TOTAL ASSETS</b>	<b>36,267</b>	<b>\$ 33,487</b>

**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)

	May 31, 2017	November 30, 2016
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES:</b>		
Short-term bank credit	\$ -	\$ 21
Accounts payable	3,541	4,554
Accrued expenses and other payables	1,375	1,205
Employees and related payables	2,219	1,680
Related parties	42	42
Advance payments on account of grant	2,101	243
Short-term loans and current maturities of long term loans	647	1,111
Deferred income	4,264	1,273
Current maturities of convertible loans	1,958	2,541
Convertible bonds	-	1,818
Price protection derivative	-	76
Investments in associate, net	-	12
<b>TOTAL CURRENT LIABILITIES</b>	<b>16,147</b>	<b>14,576</b>
<b>LONG-TERM LIABILITIES:</b>		
Loans payable	3,284	3,291
Convertible loans	1,772	1,059
Warrants	2,861	1,843
Retirement benefits obligation	5	5
Put option derivative	273	273
Deferred taxes	2,027	1,862
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>10,222</b>	<b>8,333</b>
<b>TOTAL LIABILITIES COMMITMENTS EQUITY:</b>	<b>26,369</b>	<b>22,909</b>
Common stock	12	12
Additional paid-in capital	48,898	41,605
Receipts on account of shares to be allotted	596	-
Accumulated other comprehensive loss	(216)	(1,205)
Accumulated deficit	(39,392)	(29,834)
<b>TOTAL EQUITY</b>	<b>9,898</b>	<b>10,578</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 36,267</b>	<b>\$ 33,487</b>

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		Six Months Ended	
	May 31, 2017	May 31, 2016	May 31, 2017	May 31, 2016
<b>REVENUES</b>	\$ 2,298	\$ 1,132	\$ 4,150	\$ 2,652
<b>COST OF REVENUES</b>	1,128	1,964	3,033	3,444
<b>GROSS PROFIT (LOSS)</b>	1,170	(832)	1,117	(792)
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	665	486	1,406	887
<b>AMORTIZATION OF INTANGIBLE ASSETS</b>	397	482	778	810
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b>	2,432	2,173	4,703	3,339
<b>OPERATING LOSS</b>	2,324	3,973	5,770	5,828
<b>FINANCIAL EXPENSES (INCOME), net</b>	(1,428)	553	3,520	(1,219)
<b>SHARE IN LOSSES OF ASSOCIATED COMPANY</b>	107	-	196	-
<b>LOSS BEFORE INCOME TAXES</b>	1,003	4,526	9,486	4,609
<b>TAX EXPENSES (BENEFIT)</b>	(444)	(634)	72	(942)
<b>NET LOSS</b>	\$ 559	\$ 3,892	\$ (9,558)	\$ (3,667)
<b>EARNINGS (LOSS) PER SHARE:</b>				
Basic	\$ 0.005	\$ 0.04	\$ 0.09	\$ 0.03
Diluted	\$ 0.005	\$ 0.04	\$ 0.09	\$ 0.04
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:</b>				
Basic	114,820,844	107,583,871	110,652,320	106,693,858
Diluted	114,820,844	107,583,871	110,652,320	106,693,858
<b>OTHER COMPREHENSIVE LOSS:</b>				
Net Loss	\$ 559	\$ 3,892	\$ (9,558)	\$ (3,667)
Translation adjustments	(1,083)	(580)	(989)	(1,084)
<b>TOTAL COMPREHENSIVE LOSS (INCOME)</b>	\$ (524)	\$ 3,312	\$ (8,569)	\$ (2,583)

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)

	Common Stock		Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total	
	Number	Par Value						
<b>Balance at December 1, 2015</b>	55,835,950	\$ 6	\$ 14,229	\$ 1,251	\$ (1,286)	\$ (20,640)	\$ (6,440)	
<b>Changes during the six months ended May 31, 2016:</b>								
Stock-based compensation to employees and directors			865				865	
Stock-based compensation to service providers			792				792	
Warrants and shares to be issued due to extinguishment of a convertible loan			114				114	
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				623			623	
Comprehensive income for the period					1,084	(3,667)	(2,583)	
<b>Balance at May 31, 2016</b>	108,739,806	\$ 11	\$ 39,402	\$ 623	\$ (202)	\$ (24,307)	\$ 15,527	
<b>Balance at December 1, 2016</b>	114,096,46	1	12	41,605	-,-	(1,205)	(29,834)	10,578



**Changes during  
the six months  
ended May 31,  
2017:**

Stock-based compensation to employees and directors			771			771
Stock-based compensation to service providers	950,000	-	2,067			2,067
Issuance of warrants and beneficial conversion feature of convertible loans			2,241			2,241
Issuance of shares and receipts on account of shares and warrants to be allotted	3,940,636	-	2,214	596		2,810
Comprehensive loss for the period					989	(9,558)
<b>Balance at May 31, 2017</b>	118,987,097 \$	12 \$	48,898 \$	596 \$	(216) \$	(39,392) \$

**\*Including outstanding contingent shares.**

**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)**

	<b>Six months ended</b>	
	<b>May 31,</b>	<b>May 31,</b>
	<b>2017</b>	<b>2016</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (9,558)	\$ (3,667)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,708	1,657
Loss from extinguishment of a convertible loan	-	229
Share in losses of associated company	196	
Depreciation and amortization expenses	1,207	1,335
Change in fair value of warrants and embedded derivatives	1,073	(1,721)
Change in fair value of convertible bonds	(110)	(132)
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	589	56
Changes in operating assets and liabilities:		
Increase in accounts receivable	(1,606)	(471)
Increase in inventory	(466)	(94)
Increase in other assets	(1)	(9)
(Increase) decrease in prepaid expenses and other accounts receivable	(645)	34
(Decrease) increase in accounts payable	(1,268)	587
Increase in accrued expenses and other payables	168	150
Increase in employee and related payables	493	579
Increase in deferred income	2,814	332
Increase (decrease) in advance payments and receivables on account of grant, net	2,557	(87)
Increase (decrease) in deferred taxes	72	(944)
Net cash used in operating activities	(1,777)	(2,166)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(464)	(708)
Disposals of property and equipment	22	-
Investments in Associates	(460)	-
Net cash used in investing activities	(902)	(708)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Short-term line of credit	(21)	-
Proceeds from issuance of shares and warrants (net of transaction costs)	2,810	975
Proceeds from issuance of convertible loans (net of transaction costs)	3,912	-
Repayment of convertible loans and convertible bonds	(3,641)	-
Repayment of short and long-term debt	(706)	(1,828)
Net cash provided by (used in) financing activities	2,354	(853)
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(325)</b>	<b>(3,727)</b>
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	<b>92</b>	<b>33</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>891</b>	<b>4,168</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 658</b>	<b>\$ 474</b>

**SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES**

Conversion of loans (including accrued interest) to common stock and warrants	\$	1,028
Reclassification of redeemable common stock to equity	\$	21,458

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

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Six Months Ended May 31, 2017 and May 31, 2016**

**NOTE 1 - GENERAL AND BASIS OF PRESENTATION**

Orgenesis Inc., a Nevada corporation, is a biopharmaceutical company with expertise and experience in cell therapy development and manufacturing specializing in cell therapy development for advanced medicinal products serving the regenerative medicine industry.

In addition, the Company is developing a novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes. The cell therapy technology is based on the research 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.

The combination of proprietary cell therapy trans-differentiation technologies for the treatment of diabetes and a revenue-generating contract development and manufacturing service business provides the Company with unique capabilities.

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 May 31, 2017, and the consolidated statements of comprehensive loss for the three and six months ended May 31, 2017 and 2016, and the changes in equity and cash flows for the six months period ended May 31, 2017 and 2016. The interim results, 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 May 31, 2017, the Company had not achieved profitable operations, had accumulated losses of approximately \$39 million (since inception) and expects to incur further losses in the development of its business. Presently, the Company does not have sufficient cash 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. In the event that the remaining subscription proceeds from a private placement with an institutional investor referred to below, in the aggregate net amount of \$13 million (out of \$16 million) will not be paid periodically through May 2018, then the Company will need to raise significant funds in order to continue to meet its liquidity needs, realize its business plan and maintain operations. The Company's current

cash balance is 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 generate quality of earnings from its CDMO business and to secure funds through equity and/or debt instruments for its operations and business opportunities investments.

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 May 2017, the Company received, through MaSTherCell, proceeds of approximately \$5.22 million in revenues and accounts receivable from customers and \$4.5 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 six months ended May 31, 2017, \$2 million was remitted by such investor and, in June and July 2017, an additional \$1 million was remitted. From June 1, 2017 through July 24, 2017, the Company raised an additional \$1 million from the proceeds of the private placement to certain accredited investors of its equity linked securities.

## **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.

### *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.

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 six months ended May 31, 2017 is as follows:

	CDMO	CTB	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 4,749	-	(599)	4,150
Cost of revenues	(2,919)		308	(2,611)
Research and development expenses, net		(1,244)	291	(953)
Operating expenses	725	(4,790)	-	(4,065)
Depreciation and amortization expenses	(1,200)	(7)	-	(1,207)
Segment Performance	\$ 1,355	(6,041)	-	(4,686)
Stock-based compensation			(2,708)	(2,708)
Financial income (expenses), net*			(1,896)	(1,896)
Share in losses of associated company			(196)	(196)
Loss before income taxes			-	(9,486)

\* Excluding \$1,624 thousand stock based compensation included in financial expenses.

Segment data for the six months ended May 31, 2016 is as follows:

	CDMO	CTB	Corporate and Eliminations (in thousands)	Consolidated
Net revenues from external customers	\$ 2,974	\$	(322)	\$ 2,652
Cost of revenues	(3,220)		299	(2,921)
Research and development expenses, net		(674)	23	(651)
Operating expenses	(1,065)	(851)		(1,916)
				(1,335)
Depreciation and amortization expense	(1,333)	(2)		
Segment Performance	\$ (2,644)	\$ (1,527)		(4,171)
Share-based compensation			(1,657)	(1,657)
Financial income, net			1,219	1,219
Loss before income taxes				\$ (4,609)

Segment data for the three months ended May 31, 2017 is as follows:

	CDMO	CTB	Corporate and Eliminations (in thousands)	Consolidated
Net revenues from external customers	\$ 2,605	-	(307)	2,298
Cost of revenues	(1,058)	-	141	(917)
Research and development expenses, net		(643)	166	(477)
Operating expenses	(987)	(1,200)		(2,187)
				(615)
Depreciation and amortization expense	(608)	(7)		
Segment Performance	\$ (48)	(1,850)	-	(1,898)
Share-based compensation			(1,489)	(1,489)

Edgar Filing: Orgenesis Inc. - Form 10-Q

Financial income (expenses), net*	2,491	2,491
Share in losses of associated company	(107)	(107)
Loss before income taxes		(1,003)

11

---



Edgar Filing: Orgenesis Inc. - Form 10-Q

\* Excluding \$1,084 thousand stock based compensation included in financial expenses.

Segment data for the three months ended May 31, 2016 is as follows:

	CDMO	CTB	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	\$ 1,403	\$	\$ (271)	\$ 1,132
Cost of revenues	(1,932)		180	(1,752)
Research and development expenses, net		(376)	91	(285)
Operating expenses	(458)	(429)		(887)
Depreciation and amortization expense	(693)	(1)		(694)
Segment Performance	\$ (1,680)	\$ (806)	-	(2,486)
Share-based compensation			(1,487)	(1,487)
Financial income (expenses), net			(553)	(553)
Loss before income taxes				\$ (4,526)

*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		Six Months Ended	
	May 31, 2017	May 31, 2016	May 31, 2017	May 31, 2016
	(in thousands)			
Customer A	\$ 771	\$ 830	\$	\$ 1,594
Customer B	-	420		981
Customer C	803		1,095	
Customer D	\$ 703	\$	\$ 958	\$

**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 six months ended May 31, 2017, the Company entered into several unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of \$2.75 million. The loans bear an annual interest rate of 6% and mature in two years from the date of issuance, unless converted earlier.

The notes provide that the entire principal amount under the notes and accrued interest automatically convert into units as in the agreement upon the earlier to occur of any of the following: (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 (adjusted for certain capital events such as stock splits) for fifty (50) consecutive trading days, or (iii) the listing of the Company's Common Stock on a U.S. National Exchange.

Since the closing price of the Company's publicly traded stock is greater than the effective conversion price on the closing date, the conversion feature is considered "beneficial" to the holders and equal to \$1.94 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 \$273 thousand, out of which \$94 thousand was the fair value of 250,479 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 using the Black-Scholes valuation model.

(c) During the six months ended May 31, 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 March 7, 2017, was \$494 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 remaining 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). In consideration for the extension, the Company issued to the bondholder warrants to purchase 102,822 shares of the Company's Common Stock, exercisable over a three-year period at a per share exercise price of \$0.52. The fair value of those warrants as of the date of grant was \$20 thousand using the Black-Scholes valuation model.

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

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.

(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. 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.

On March 1, 2017, the Company repaid \$1.5 million on account of the original principal amount of the loan. As of May 31, 2017, the Company was in arrears in its payment obligations under such agreement. See also Note 10(c).

## 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).

### *Loans*

During January 12, 2017, the Company entered into a loan agreement with MaSTherCell to advance to it up to €1 million. Amounts outstanding under the loan bear yearly annual interest at a rate of 6%. In January 2017 MaSTherCell received from the Company the aggregate amount of \$1.1 million (€1 million). On May 22, 2017, the Company converted the loan into the equity capital of MaSTherCell.

## NOTE 6 EQUITY

### *Financings*

1) During the six months ended May 31, 2017, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement (the Private Placement ) of (i) 1,286,944 shares of the Company's Common Stock and (ii) three year warrants to purchase up to an additional 1,056,021 and 230,923 shares of the Company's Common Stock at a per share exercise price of \$0.52 and \$0.65 respectively. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of \$699 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:

	<b>Total Fair Value</b>	
	(in thousands)	
Warrants component	\$	251
Shares component		448
<b>Total</b>	<b>\$</b>	<b>699</b>



As of May 31, 2017, 230,923 shares have not been issued and therefore the Company has recorded \$87 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 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.

During the six months ended May 31, 2017 the investor remitted to the Company \$2 million, in consideration of which, the investor is entitled to receive 3,846,153 shares of the Company's Common Stock and three year warrants to purchase up to an additional 3,846,153 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:

	<b>Total Fair Value</b>	
	(in thousands)	
Warrants component	\$	723
Shares component		1,277
Total	\$	2,000

As of May 31, 2017, 961,538 shares have not been issued therefore the Company recorded \$281 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 \$100 thousand and the issuance of 192,308 restricted shares of Common Stock. The fair value of the shares as of the date of grant was \$145 thousand using the share price on the date of grant.

## **NOTE 7 STOCK BASED COMPENSATION**

### *a. Options Granted to Employees and Directors*

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

	<b>No. of options granted</b>	<b>Exercise price</b>	<b>Fair value at grant (in thousands)</b>	<b>Expiration period</b>
Directors	2,000,000	\$0.4	\$558	10 years
Employees	5,300,000	\$0.4	\$1,480	10 years

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 a consulting agreements for the provision of professional services for a period of one year. Under the terms of the agreement, the Company granted to a consultants 200,000 options exercisable at \$0.40 per share. The options are to 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 May 31,		Six Months Ended May 31,	
	2017	2016	2017	2016
	(in thousands, except per share data)			
<b>Basic:</b>				
Loss for the period	\$ 559	\$ 3,892	\$ 9,558	\$ 3,667
Weighted average number of common shares outstanding	114,820,844	107,583,871	110,652,320	106,693,858
Loss per common share	\$ 0.005	\$ 0.04	\$ 0.09	\$ 0.03
<b>Diluted:</b>				
Loss for the period	\$ 559	\$ 3,892	\$ 9,558	\$ 3,667
Changes in fair value of embedded derivative and interest expense on convertible bonds				92
Loss for the period	559	3,892	9,558	3,759
Weighted average number of shares used in the computation of basic and diluted loss per share	114,820,844	107,583,871	110,652,320	106,693,858
Loss per common share	0.005	0.04	0.09	0.04

Diluted loss per share does not include 50,393,832 shares underlying outstanding options and warrants and 12,517,870 shares upon conversion of convertible notes for the three and six months ended May 31, 2017, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted loss per share does not include 16,954,564 shares underlying outstanding options, 19,769,959 shares issuable upon exercise of warrants, 1,150,000 shares due to service providers and 4,793,603 shares upon conversion of convertible notes for the three and six months ended May 31, 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 May 31, 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):

	<b>May 31, 2017</b>	<b>November 30, 2016</b>
	<u>Level 3</u>	<u>Level 3</u>
Warrants (1)	\$ 2,861	\$ 1,843
Price protection derivative (1)	-	76
Embedded derivatives convertible loans*(1)	383	240
Put option derivatives	273	273
Convertible bonds (2)	\$ -	\$ 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.

As of May 31, 2017, the convertible bonds have been repaid or converted see Note 4(e).

The following table presents the assumptions that were used for the models as of May 31, 2017:

	<b>Price Protection Derivative and Warrants</b>	<b>Embedded Derivative</b>
Fair value of shares of Common Stock	\$ 0.59	\$ 0.59
Expected volatility	95%-100%	100%
Discount on lack of marketability	16%	-
Risk free interest rate	0.47%-1.31%	0.86%-1.05%

Edgar Filing: Orgenesis Inc. - Form 10-Q

Expected term (years)	1.4-2.1	0.08-0.42
Expected dividend yield	0%	0%
Expected capital raise dates	July 31, 2017	-

---

Edgar Filing: Orgenesis Inc. - Form 10-Q

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

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 six months ended May 31, 2017:

	<b>Warrants</b>	<b>Embedded Derivatives</b> (in thousands)	<b>Convertible Bonds</b>	<b>Price Protection Derivative</b>	<b>Put Option Derivative</b>
Balance at beginning of the year	\$ 1,843	\$ 240	\$ 1,818	\$ 76	\$ 273
Changes in fair value during the period	1,018	143	22	(76)	
Repayment and conversion of convertible bonds			(1,827)		
Translation adjustments			(13)		
Balance at end of the period	\$ 2,861	\$ 383	\$ -	\$ -	\$ 273

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:

	<b>Warrants</b>	<b>Embedded Derivatives</b> (in thousands)	<b>Convertible Bonds</b>	<b>Price Protection Derivative</b>	<b>Put Option Derivative</b>
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. During June and July, 2017, the Company entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of \$1 million. 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 June and July 2017, the institutional investor referred to in Note 6b, remitted to the Company \$1 million in subscription proceeds in respect of which the Company will issue to the investor 1,923,076 shares of Common Stock and three year warrants for an additional 1,923,076 shares.

c. On July 17, 2017, the Company paid to Admiral \$125 thousand on account of the debt owed.



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

### *Forward-Looking Statements*

This Form 10-Q and other reports filed by the Company from time to time with the U.S. Securities and Exchange Commission (collectively, the Filings ) contain or may contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used in the Filings, the words anticipate, believe, estimate, expect, future, intend, plan, or the negative of these terms or expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

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

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States ( GAAP ). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this report.

### *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 for advanced medicinal products serving the regenerative medicine industry. In addition, we are focused on developing a novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes with a revenue generating contract development and manufacturing service business to serve the regenerative medicine industry. Our vertically integrated manufacturing capabilities are being used to serve to emerging technologies of other cell therapy markets in such areas as cell-based cancer immunotherapies and neurodegenerative diseases and also to optimize our abilities to scale-up our technologies for clinical trials and eventual commercialization of our proposed diabetes treatment. The combination of our own proprietary cell therapy trans-differentiation technologies for the treatment of diabetes and a revenue-generating contract development and manufacturing service business provides us with unique capabilities and supports our business philosophy of bringing to market significant life-improving medical treatments.

We seek to differentiate ourselves from other cell therapy companies by our wholly-owned, Belgian-based CDMO subsidiary, MaSTherCell S.A., and a world-wide network of partners in order to build a unique and fundamental base platform of know-how and expertise for a multitude of cell types. The goal is to industrialize cell therapy for fast, safe and cost-effective production in order to provide rapid therapies for any market around the world.

All these services are already compliant with GMP requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III through commercialization. The goal is to become the premier service provider in the regenerative medicine industry by leveraging the experience and expertise of MaSTherCell as a recognized leader in cell therapy development and manufacturing.



MaSTherCell is developing premier technologies for other cell therapy companies such as cell-based cancer immunotherapies and neoconservative diseases. Our vertical integration responds to the main challenges faced by most biotechnology companies such as cost of goods sold and logistics. Our global manufacturing network is envisioned as offering a global one-stop-shop manufacturing and logistics services and breakthrough technologies enabling promising therapies to more rapidly reach the market at a fraction of the costs.

Masthercell currently operates facilities qualified under cGMPs in Belgium. We acquired MaSTherCell in March 2015. 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.

We are leveraging the recognized expertise and experience in cell process development and manufacturing of MaSTherCell, and our international global network of CDMO 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.

Our cell therapy technology for diabetes is based on the research 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 for our cellular therapy business (CTB), which is conducted through our Israeli subsidiary, calls for conducting additional preclinical safety and efficacy studies with respect to diabetes and other potential indications.

#### *Significant Recent Corporate Highlights*

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 us 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 \$2 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 a 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).

As further discussed below, our subsidiary MaSTherCell S.A., had revenues of approximately \$4.1 million during the six months ended May 31, 2017 representing an increase of 55% over the same period last year.

In May 2017, we improved the equity-debt ratio of our subsidiary MaSTherCell by converting the loan advanced to it in the amount of \$1.1 million (EUR 1 million) into share capital of MaSTherCell.

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.

*Results of Operations*Comparison of the Three and Six Months Ended May 31, 2017 to the Three and Six Months Ended May 31, 2016

Our financial results for the three and six months ended May 31, 2017 are summarized as follows in comparison to the three and six months ended May 31, 2016:

	<u>Three Months Ended May 31,</u>		<u>Six Months Ended May 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	(in thousands)			
Revenues	\$ 2,298	\$ 1,132	\$ 4,150	\$ 2,652
Cost of sales	1,128	1,964	3,033	3,444
Research and development expenses, net	665	486	1,406	887
Amortization of intangible assets	397	482	778	810
Selling, general and administrative expenses	2,432	2,173	4,703	3,339
Financial expenses (income), net	(1,428)	553	3,520	(1,219)
Share in losses of associated company	107		196	
Loss before income taxes	\$ 1,003	\$ 4,526	\$ 9,486	\$ 4,609

**Revenues**

All revenues were derived from our Belgian Subsidiary, MaSTherCell S.A

Our revenues for the three and six months ended May 31, 2017 were \$2,298 thousand and \$4,150 thousand, respectively, as compared to \$1,132 thousand and \$2,652 thousand for the corresponding periods in 2016.

	<u>Three Months Ended May 31,</u>		<u>Six Months Ended May 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	(in thousands)		(in thousands)	
Services	\$ 2,202	\$ 1,055	\$ 3,585	\$ 1,344
Goods	96	77	565	1,308
Total revenues	\$ 2,298	\$ 1,132	\$ 4,150	\$ 2,652

The increase in revenues for each of the three and six months ended May 31, 2017 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 as well as from revenues generated from existing manufacturing agreements.

**Expenses**Cost of Sales

Cost of sales for the three and six months ended May 31, 2017 were \$1,128 thousand and \$3,033 thousand, respectively, a decrease of 43% and 12%, from \$1,964 thousand and \$3,444 thousand, respectively, during the same periods in 2016. The decrease in cost of sales in the 2017 periods is primarily attributable to a decrease in salaries and related expenses associated with a transformation program implemented in MaSTherCell in the beginning of the second quarter to evolve from an organization based on project to a matrix organization supported by transversal departments focusing on value creation. As part of the program we changed the business positions of certain employees from laboratories managers to general manager positions in order to reflect the current period's business activity a decrease (i) in raw material expenses due to change in nature of services provided by MaSTherCell in the 2017 periods, as we had much more development work compared to 2016 and had more production work and (ii) a decrease of depreciation and amortization expenses (net) due to fully amortized assets as of November 30, 2016 that are not amortized in the 2017 periods.



Research and Development Expenses

Research and Development Expenses for the three and six months ended May 31, 2017 were \$665 thousand and \$1,406 thousand, respectively, an increase of 37% and 59%, from \$486 thousand and \$887 thousand, respectively, in the same periods in 2016. The increase in research and development expenses in the 2017 periods is primarily attributable to an increase in lab expenses resulting from an increase in our pre-clinical studies in the U.S., Israel and Belgium. The increase in Research and Development expenses is a reflection of management's determination to move transdifferentiating technology with first indication to Diabetes Type I to the next stage towards clinical studies in 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three and six months ended May 31, 2017 were \$2,432 thousand and \$4,703 thousand, respectively, an increase of 12% and 41%, from \$2,173 and \$3,339 thousand, respectively, during the same periods in 2016. The increase in selling, general and administrative expenses in the 2017 periods is primarily attributable to an increase in (i) salaries and related expenses resulting from the retention of new senior management at MaSTherCell and new accounting staff in our financial department in Israel and (ii) accounting and legal expenses associated with exploring new strategic collaboration arrangements, new capital raising initiatives, repayment of bonds issued by MaSTherCell and application of new patents under our CTB division offset by (iii) a decrease in stock based compensation in the 2017 periods attributable to the termination of the vesting period of options and shares awarded to executives and consultants in 2016 (iv) stock-based compensation expenses of new grants of options to employees during December 2016 and (v) expenses related to a joint venture which primarily consisted of salary expenses and set up related cost of the new production facility in Korea under our joint venture with CureCell.

The Company applies a strict monitoring of the SG&A expenses and has implemented a shared services program in corporate functions to benefit from intra-group cost reduction and synergies.

Financial Expenses (Income), net

	<u>Three Months Ended May 31,</u>		<u>Six Months Ended May 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	(in thousands)		(in thousands)	
Increase (decrease) in fair value of warrants and financial liabilities measured at fair value \$	(2,946)	\$ 347	\$ 1,006	\$ (1,612)
Stock-based compensation related to warrants granted to bondholder and shares granted to creditor	1,084	-	1,624	-
Interest expense on loans and convertible loans	298	176	687	359
Foreign exchange loss, net	131	32	194	39
Other expenses	5	(2)	9	(5)
Total	\$ (1,428)	\$ 553	\$ 3,520	\$ (1,219)

Financial expenses (income), net for the three months ended May 31, 2017, decreased by 358% or \$1,981 thousand, compared to the same period in 2016. The decrease in financial expenses is mainly attributable to a decrease of \$1.9 million in the change of the fair value of warrants due to the fact that, in the three months ended May 31, 2017, there was a strong impact of the decrease in the share price, which was \$0.59 on May 31, 2017, as opposed to \$0.80 on February 28, 2017. In addition, there was a decrease of \$0.9 million in the fair value of an embedded derivative due to reimbursement of convertible loan in amount of \$1.5 million.

Financial expenses (income), net for the six months ended May 31, 2017, increased by 389% or \$4,739 thousand, compared to the same period in 2016. The increase in financial expenses is mainly attributable to an increase of \$2.6 million in the change of the fair value of warrants due to the fact that, in the six months ended May 31, 2017, there was a strong impact of the increase in the share price, which was \$0.59 on May 31, 2017, as opposed to \$0.39 on November 30, 2016. In the corresponding period there was an income of \$1.6 million due to the Company's updated assumptions related to the probabilities of activating the anti-dilution mechanism of a derivative.

In addition, part of the increase is attributable to \$20 thousand of stock-based compensation expenses related to 102,822 warrants granted to the remaining bondholder in consideration of the extension of his bonds, \$1.5 million thousand of stock-based compensation expenses related to restricted shares and options issued in accordance with a terms of the convertible loan agreements.

### Working Capital Deficiency

	<b>May 31, 2017</b>	<b>November 30, 2016</b>
	(in thousands)	
Current assets	\$ 6,110	\$ 4,205
Current liabilities	16,147	14,576
Working capital deficiency	\$ (10,037)	\$ (10,371)

Current assets increased by \$1.9 million, which was primarily attributable to an increase of \$1.7 million in accounts receivable and \$0.6 increase in prepaid expenses and other receivables mainly due to increase in the convertible loan invested in CureCell.

Current liabilities increased by \$1.6 million, which was primarily attributable to an increase of \$1.9 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 and an increase of \$3 million in deferred income due to agreements signed with new customers in the CDMO segment.

The increase was partly offset by a decrease of \$1 million in current maturities of convertible loans and short-term loans and current maturities of long term loans due to repayments of loans during the period ended May 31, 2017, a decrease of \$1.8 million in convertible bonds due to repayment and convertible bonds conversion of \$1.7 million and \$0.1 million, respectively and a decrease of \$0.3 in accounts payable, accrued expenses and other payables and employees and related payables.

### Liquidity and Financial Condition

	<b>Six Months Ended May 31,</b>	
	<b>2017</b>	<b>2016</b>
	(in thousands)	
Net loss	\$ (9,558)	\$ (3,667)
Net cash used in operating activities	(1,777)	(2,166)
Net cash used in investing activities	(902)	(708)
Net cash provided by (used in) financing activities	2,354	(853)
Decrease in cash and cash equivalents	\$ (325)	\$ (3,727)

Since inception, we have funded our operations primarily through the sale of our securities and, more recently, through revenue generated from the activities of MaSTherCell, our Belgian Subsidiary. As of May 31, 2017, we had negative working capital of \$10 million, including cash and cash equivalents of \$0.7 million.

Net cash used in operating activities was approximately \$1.8 million for the six months ended May 31, 2017, as compared with net cash used in operating activities of approximately \$2.2 million for the same period in 2016. Cash used in operating activities for the six months ended May 31, 2017 was due to expanding our global activity of the CDMO division which was partly offset due to higher revenues at our subsidiary MaSTherCell, thereby significantly increasing gross profit and generating cash to pay our ongoing operating expenses.

## Edgar Filing: Orgenesis Inc. - Form 10-Q

Net cash used in investing activities for the six months ended May 31, 2017 was approximately \$0.9 million as compared with approximately \$ 0.7 million for the same period in 2016. Net cash used in investing activities was primarily for additions to fixed assets at our subsidiary Masthercell and investments in our JV with Atvio.

During the six months ended May 31, 2017, our financing activities consisted of the following:

Closing on \$2.8 million net of transaction costs in private placement equity offerings through the issuance of 5,133,096 million shares of common stock and three year common stock purchase warrants for an additional 4,902,174 and 230,923 shares of our common stock exercisable at a per share exercise price of \$0.52 or \$0.65, respectively.

Closing on \$3.5 million, in private placement debt offerings through the issuance of \$1,746,063 warrants and our convertible promissory notes with maturity dates of between six and twenty four months, convertible into 7,592,930 shares of our common stock and three-year warrants to purchase up to an additional 5,288,464 shares of our common stock at a per share exercise price of \$0.52.

### *Liquidity & Capital Resources Outlook*

Management believes that funds on hand, as well as the subscription proceeds of \$14 million that we anticipate receiving on a periodic basis from June 2017 through August 2018 (out of a total of \$16 million subscription proceeds that we are to receive through such date), will allow us to conduct operations as presently conducted through the end of year 2018. We intend to raise additional operating capital in order to further expand the scope of our operations and realize our business plan of future years and will likely need to raise additional operating capital in fiscal 2019 in order to maintain operations. 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.

To meet our short and long-term liquidity needs, we expect to use existing cash balances, cash from our revenue generating activities and the subscription proceeds anticipated periodically through the end of fiscal year 2018, as well as a variety of other means, including raising capital through potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations. In addition, we will continue to seek, as appropriate, grants for expanding our facility in Belgium and scientific and clinical studies from various governmental agencies and foundations. 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.

### *Going Concern*

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. As of May 31, 2017, we have not achieved profitable operations, have accumulated losses of approximately \$39 million (since inception) and have a working capital deficiency of \$10 million. Although we are now showing positive revenue and gross profit trends in our CDMO division, we expect to incur further losses in the CTB division. Furthermore, while proceeds from additional investments in the CDMO division are expected to benefit our operations as a whole, we do expect to incur further losses in the development of our 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 our convertible debt and equity securities and from revenues generated by MaSTherCell. From December 2016 through May 2017, we received, through MaSTherCell, proceeds of approximately \$5.22 million in revenues and accounts receivable from customers and \$4.1 million from the private placement to accredited investors of our 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 six months ended May 31, 2017, \$2 million was remitted by such investor, and in June and July 2017, an additional \$1 million was remitted. In addition, between June 1, 2017 and July 24, 2017, we raised an additional \$1 million from the proceeds of a private placement to certain accredited investors of equity-linked securities.

## Cash Requirements

Our plan of operation during the next twelve months as of May 31, 2017 is to:

Continue our activities according to the work plan approved by the DGO6;  
Explore options for collaboration and additional grants in the U.S.; and  
Support our manufacturing activity in Europe.

We estimate that our operating resources and expenses for the next twelve months as of May 31, 2017 will be as follows:

Resources	\$	*31,521
Expenses		(27,266)
Total	\$	4,255

\* The amount of cash resources include the subscription proceeds we are to receive on a periodic basis through May 2018 in the aggregate net amount of \$10.5 million.

## 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. 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 was not effective as of as of May 31, 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. Management has taken 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 first quarter, we have retained qualified independent third-party personnel, to conduct a comprehensive review of our internal controls and formalization of our review and approval processes in order. The appointed qualified independent third party assessed the Company's risk management framework to manage enterprise risk and is working to design a remediation plan which among other things, prevents fraudulent transactions. The risk based approach identified by the Company reflects the awareness of an acceptable level of risk to manage the Company considering the strategy, resources and regulatory environment. This measure is expected to lead to a detailed remediation plan and, subsequently, to an improvement in our internal controls which will enable 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 hired a full time Chief Financial Officer at MaSTherCell scheduled to begin September 2017 and a full time controller in our Israeli subsidiary. 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 May 31, 2017, there were no changes in our internal control over financial reporting 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 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 May 31, 2017 without registration under the Securities Act:

During the three months ended May 31, 2017, we privately placed 1,923,076 shares of our Common Stock and three year warrants to purchase up to an additional 1,923,076 shares of the Company's Common Stock at a per share exercise price of \$0.52. The purchased securities were sold pursuant to subscription agreements between us and the institutional investor for aggregate proceeds to the Company of \$1 million.

During the three months ended May 31, 2017, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of (i) 665,539 shares of the Company's Common Stock and (ii) three year warrants to purchase up to an additional 665,539 shares of the Company's Common Stock at a per share exercise price of \$0.52 or \$0.65. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of \$376 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:

<b>No.</b>	<b>Description</b>
<u>10.1*</u>	<u>Executive Employment Agreement dated as of March 30, 2017 between Orgenesis Inc. and Vered Caplan</u>
<u>10.2*</u>	<u>Amendment No. 1 dated May 10, 2017 to Executive Employment Agreement dated as of March 30, 2017 between Orgenesis Inc. and Vered Caplan</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: July 24, 2017

*/s/ Neil Reithinger*

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting  
Officer)

Date: July 24, 2017