

Orgenesis Inc.  
Form 10-Q  
July 17, 2018

---

**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, 2018

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, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth 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

Edgar Filing: Orgenesis Inc. - Form 10-Q

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 July 16, 2018, there were 14,569,359 shares of registrant s common stock outstanding.**

**ORGENESIS INC.**  
**FORM 10-Q**  
**FOR THE THREE AND SIX MONTHS ENDED MAY 31, 2018 AND 2017**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	<b><u>4</u></b>
<b><u>ITEM 1. Financial Statements (unaudited)</u></b>	<b><u>4</u></b>
<u>Condensed Consolidated Balance Sheets as of May 31, 2018 and November 30, 2017</u>	<u>4</u>
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended May 31, 2018 and 2017</u>	<u>6</u>
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended May 31, 2018 and 2017</u>	<u>8</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>9</u>
<b><u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b><u>26</u></b>
<b><u>ITEM 3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	<b><u>37</u></b>
<b><u>ITEM 4. Controls and Procedures</u></b>	<b><u>37</u></b>
<b><u>PART II - OTHER INFORMATION</u></b>	<b><u>38</u></b>
<b><u>ITEM 1. Legal Proceedings</u></b>	<b><u>38</u></b>
<b><u>ITEM 1A. Risk Factors</u></b>	<b><u>38</u></b>
<b><u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	<b><u>38</u></b>
<b><u>ITEM 3. Defaults Upon Senior Securities</u></b>	<b><u>38</u></b>
<b><u>ITEM 4. Mine Safety Disclosures</u></b>	<b><u>39</u></b>
<b><u>ITEM 5. Other Information</u></b>	<b><u>39</u></b>
<b><u>ITEM 6. Exhibits</u></b>	<b><u>39</u></b>
<b><u>SIGNATURES</u></b>	<b><u>40</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, 2018	November 30, 2017
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 4,502	\$ 3,519
Restricted Cash	383	-
Accounts receivable, net	1,298	1,336
Prepaid expenses and other receivables	3,408	841
Receivables from related party	1,377	691
Call option derivative	792	-
Grants receivable	749	183
Inventory	1,229	725
Total current assets	13,738	7,295
<b>NON-CURRENT ASSETS:</b>		
Call option derivative	-	339
Investments in associates, net	1,136	1,321
Property and equipment, net	7,517	5,104
Intangible assets, net	14,011	15,051
Goodwill	10,549	10,684
Other assets	82	78
Total non-current assets	33,295	32,577
<b>TOTAL ASSETS</b>	<b>\$ 47,033</b>	<b>\$ 39,872</b>

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

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

	<b>May 31, 2018</b>	<b>November 30, 2017</b>
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 2,388	\$ 3,914
Accrued expenses and other payables	1,104	1,435
Employees and related payables	2,303	2,961
Related parties	126	116
Advance payments on account of grant	1,415	1,719
Short-term loans and current maturities of long term loans	376	378
Other	107	-
Deferred income	4,596	3,611
Current maturities of convertible loans	557	2,780
<b>TOTAL CURRENT LIABILITIES</b>	<b>12,972</b>	<b>16,914</b>
<b>LONG-TERM LIABILITIES:</b>		
Loans payable	\$ 1,902	\$ 2,118
Convertible loans	-	2,415
Retirement benefits obligation	5	6
Deferred taxes	32	690
Other	199	-
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>2,138</b>	<b>5,229</b>
<b>TOTAL LIABILITIES</b>	<b>15,110</b>	<b>22,143</b>
<b>COMMITMENTS</b>		
<b>REDEEMABLE NON-CONTROLLING INTEREST</b>	<b>6,122</b>	<b>3,606</b>
<b>EQUITY:</b>		
Common stock of \$0.0001 par value, 145,833,334 shares authorized, 13,300,676 shares issued and outstanding as of May 31, 2018		
	1	1
Additional paid-in capital	76,831	55,334
Receipts on account of shares to be allotted	238	1,483
Accumulated other comprehensive income	1,076	1,425
Accumulated deficit	(52,345)	(44,120)
<b>TOTAL EQUITY</b>	<b>25,801</b>	<b>14,123</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 47,033</b>	<b>\$ 39,872</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, 2018	May 31, 2017	May 31, 2018	May 31, 2017
<b>REVENUES</b>	\$ 3,987	\$ 2,298	\$ 6,623	\$ 4,150
<b>COST OF REVENUES</b>	2,195	1,128	3,839	3,033
<b>GROSS PROFIT</b>	1,792	1,170	2,784	1,117
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	788	665	1,554	1,406
<b>AMORTIZATION OF INTANGIBLE ASSETS</b>	445	397	881	777
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b>	3,323	2,432	6,667	4,703
<b>OTHER INCOME</b>	-	-	316	-
<b>OPERATING LOSS</b>	2,764	2,324	6,002	5,770
<b>FINANCIAL (INCOME) EXPENSES, net</b>	(587)	503	2,094	2,578
<b>SHARE IN NET LOSSES OF ASSOCIATED COMPANY</b>	576	107	530	196
<b>LOSS BEFORE INCOME TAXES</b>	2,753	2,934	8,626	8,544
<b>TAX (INCOME) EXPENSES</b>	(277)	(444)	(673)	71
<b>NET LOSS</b>	\$ 2,476	\$ 2,490	\$ 7,953	\$ 8,616
<b>NET INCOME ATTRIBUTABLE TO REDEEMABLE NON-CONTROLLING INTERESTS</b>	138	-	272	-
<b>NET LOSS ATTRIBUTABLE TO THE COMPANY</b>	\$ 2,614	\$ 2,489	\$ 8,225	\$ 8,616
<b>LOSS PER SHARE:</b>				
Basic	\$ 0.20	\$ 0.26	\$ 0.69	\$ 0.93
Diluted	\$ 0.20	\$ 0.26	\$ 0.69	\$ 0.93
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED (LOSS) PER SHARE:</b>				
Basic	13,140,119	9,568,413	11,971,389	9,221,039
Diluted	13,140,119	9,568,413	11,971,389	9,221,039
<b>OTHER COMPREHENSIVE LOSS:</b>				
Net Loss	\$ 2,614	\$ 2,489	\$ 8,225	\$ 8,616
Translation adjustments	1,056	(1,084)	349	(988)
<b>TOTAL COMPREHENSIVE LOSS</b>	\$ 3,670	\$ 1,405	\$ 8,574	\$ 7,628

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			Receipts on Account of Share to be Allotted	Ac Con
	Number of Shares	Par Value	Additional Paid-in Capital		
<b>Balance at December 1, 2016</b>	9,508,068	\$ 1	\$ 45,454	\$ -	
<b>Changes during the six months ended May 31, 2017:</b>					
Stock-based compensation to employees and directors			771		
Stock-based compensation to service providers	79,167		2,066		
Issuances of shares from investments and conversion of convertible loans	328,388		2,214	595	
Comprehensive loss for the period					
Beneficial conversion feature of convertible loans and Warrants issued			2,241		
<b>Balance at May 31, 2017</b>	9,915,623	\$ 1	\$ 52,746	\$ 595	
<b>Balance at December 1, 2017</b>	9,872,659	1	55,334	1,483	
<b>Changes during the six months ended May 31, 2018:</b>					
Stock-based compensation to employees and directors			801		
Stock-based compensation to service providers			1,026		
Issuance of shares and warrant due to conversion of convertible loans	1,341,134	*	7,330		
Issuance of shares and receipts on account of shares and warrants to be allotted	1,958,806	*	11,218	(1,245)	
Beneficial conversion feature of convertible loans and Warrants issued			323		
Issuance of Shares due to exercise of warrants	128,077	*	799		
Comprehensive loss for the period					
<b>Balance at May 31, 2018</b>	13,300,676	\$ 1	\$ 76,831	\$ 238	

\*represent an amount lower than \$ 1 thousand

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)**

	Six Months Ended	
	May 31, 2018	May 31, 2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (7,953)	\$ (8,616)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,827	2,707
Share in losses of associated company	530	196
Depreciation and amortization expenses	1,282	1,207
Change in fair value of embedded derivatives	(490)	131
Change in fair value of convertible bonds	-	(110)
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	2,522	589
Changes in operating assets and liabilities:		
Increase in accounts receivable	(19)	(1,606)
Increase in inventory	(533)	(466)
Increase in related parties, net	(680)	-
Increase in Other assets	(9)	(1)
Increase in prepaid expenses and other accounts receivable	(411)	(645)
Decrease in accounts payable	(1,509)	(1,268)
Increase (decrease) in accrued expenses and other payables	(327)	168
Increase (decrease) in employee and related payables	(654)	493
Increase in deferred income	1,070	2,814
Increase (decrease) in advance payments and receivables on account of grant, net	(878)	2,557
Increase (decrease) in deferred taxes	(673)	72
Net cash used in operating activities	(6,905)	(1,778)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(2,634)	(465)
Disposals of property and equipment	-	22
Investments in associate	(345)	(459)
Net cash used in investing activities	(2,979)	(902)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Short-term line of credit	-	(21)
Proceeds from issuance of shares and warrants (net of transaction costs)	10,773	2,810
Proceeds from issuance of convertible loans (net of transaction costs)	720	3,912
Repayment of convertible loans and convertible bonds	(177)	(3,641)
Repayment of short and long-term debt	(213)	(706)
Net cash provided by financing activities	11,103	2,354
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>1,219</b>	<b>(326)</b>
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	<b>147</b>	<b>91</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>3,518</b>	<b>891</b>
<b>CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD</b>	<b>\$ 4,884</b>	<b>\$ 656</b>

**SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES**

Conversion of loans and bonds (including accrued interest) to common stock and warrants	\$	7,330
Redeemable non-controlling interest	\$	2,258
Leasing of Fixed assets	\$	337

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, 2018 and 2017**

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

*a. General*

Orgenesis Inc., a Nevada corporation, is a service and research company in the field of regenerative medicine industry with a focus on cell therapy development and manufacturing for advanced medicinal products. In addition, the Company is focused on developing novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes. The consolidated financial statements include the accounts of Orgenesis Inc., its subsidiaries MaSTherCell S.A ( MaSTherCell S.A. ), its Belgian-based subsidiary and a contract development and manufacturing organization, or CDMO, specialized in cell therapy development and manufacturing 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, Orgenesis Maryland Inc. (the U.S. Subsidiary ), a Maryland corporation, and Orgenesis Ltd., an Israeli corporation, (the Israeli Subsidiary ).

The Company's 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 through a world-wide network of CDMOs joint venture partners. The Company's trans-differentiation technologies for treating diabetes, which will be referred to as the cellular therapy ( CT ) business, is based on a technology licensed by Tel Hashomer Medical Research ( THM ) to the Israeli Subsidiary that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and trans-differentiating (converting) them into pancreatic beta cell-like insulin-producing cells.

On March 14, 2016, the Company and CureCell Co., Ltd. ( CureCell ) entered into a Joint Venture Agreement (the CureCell JVA ) pursuant to which the parties are collaborating in the contract development and manufacturing of cell therapy products in Korea. As to the Company exercise of the "call option" to which it was entitled under the CureCell JVA agreement see note 10(12).

On May 10, 2016, the Company and Atvio Biotech Ltd., ( Atvio ) entered into a Joint Venture Agreement (the Atvio 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. As to the Company exercise of the "call option" to which it was entitled under the Atvio JVA agreement see note 10(12).

On June 28, 2018, the Company and a newly formed Delaware subsidiary of the Company which is engaged in the contract manufacturing for cell therapy companies (CDMO) ("Masthercell Global") entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business, which included entry into a Stock Purchase Agreement (the "SPA") with an affiliate of Great Point Partners, LLC, a manager of private equity funds focused on growing small to medium sized health care companies ("Great Point"), pursuant to which such Great Point affiliate purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the "Masthercell Global Preferred Stock"), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for cash consideration to be paid into Masthercell Global of up to \$25 million, subject to certain adjustments. See Note 10(12).

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.

On November 16, 2017, the Company implemented a reverse stock split of its outstanding shares of common stock at a ratio of 1-for-12 shares. The reverse stock split has been reflected in these condensed consolidated financial statements.

On March 13, 2018, the Company's common stock began to be quoted and traded on the Nasdaq Capital Market under the symbol ORGS.

*a. Liquidity*

As of May 31, 2018, the Company accumulated losses of approximately \$52.3 million. Although the Company is showing positive revenue and gross profit trends in its CDMO division, the Company expects to incur further losses in the CT division.

To date, the Company has been funding operations primarily from the proceeds from private placements of the Company's convertible debt and equity securities and from revenues generated by MaSTherCell S.A. From December 1, 2017 through May 31, 2018, the Company received, through MaSTherCell S.A., proceeds of approximately \$5.7 million in revenues and accounts receivable from customers, and \$11.7 million from the private placement to accredited investors of the Company's equity and equity linked securities and convertible loans, out of which \$2.5 million are from the institutional investor with whom the Company entered into definitive agreements in January 2017 for the private placement of units of the Company's securities for aggregate subscription proceeds of \$16 million. The subscription proceeds are payable on a periodic basis through August 2018. In addition, from June 1, 2018 through July 16, 2018, the Company raised \$7.8 million from the private placement to assignees of the investor referred to above of unsubscribed units under such investor's subscription agreement, the exercise of warrants by an investor, and received, through Masthercell Global, \$10.3 million as part of Great Point investment and proceeds of approximately \$2.1 million in accounts receivable from customers of MaSTherCell S.A. See also note 10, Subsequent Events.

*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, 2018, and the consolidated statements of comprehensive loss for the three and six months ended May 31, 2018 and 2017, and the changes in equity and cash flows for the six-month period ended May 31, 2018 and 2017. The interim results are not necessarily indicative of the results to be expected for the year ending November 30, 2018. 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, 2017.

**NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The accounting policies adopted are consistent with those of the previous financial year, except as noted below regarding the adoption of new accounting pronouncements.

*Recently Issued Accounting Pronouncements- adopted by the Company*

1) In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a Consensus of the FASB Emerging Issues Task Force) ( ASU 2016-18 ), which requires entities to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for annual reporting periods (including interim periods within those annual reporting periods) beginning after December 15, 2017. The Company adopted this standard in the three months ended May 31, 2018. The Company did not have restricted cash in the previously presented period. Therefore, there is no impact for the new adoption on previously reported periods.

2) In July 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and

Hedging (Topic 815)", ("ASU 2017-11"). This update was issued to address complexities in accounting for certain equity-linked financial instruments containing down round features. The amendment changes the classification analysis of these financial instruments (or embedded features) so that equity classification is no longer precluded. The amendments in ASU 2017-11 are effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company elected to early adopt the standard effective September 1, 2017, retrospectively. Following is the results of the adoption on the Company's condensed consolidated financial statements previously reported:

**Shareholders Equity**

	<b>As reported Previously</b>	<b>May 31, 2017 Impact of adoption In thousands</b>	<b>As revised</b>
Additional paid-in capital	\$ 48,898	\$ 3,838	\$ 52,736
Accumulated deficit	\$ (39,392)	\$ (977)	\$ (40,369)
Total equity	\$ 9,898	\$ 2,861	\$ 12,759

**Statement of Comprehensive Loss**

	<b>Six months ended May 31, 2017</b>			<b>Three months ended May 31, 2017</b>		
	<b>As reported Previously</b>	<b>Impact of adoption</b>	<b>As revised In thousands</b>	<b>As reported Previously</b>	<b>Impact of adoption</b>	<b>As revised</b>
Financial expenses, net	\$ 3,520	\$ (942)	\$ 2,578	\$ (1,428)	\$ 1,931	\$ 503
Loss before income taxes	\$ 9,486	\$ (942)	\$ 8,544	\$ 1,003	\$ 1,931	\$ 2,934
Net loss	\$ 9,558	\$ (942)	\$ 8,616	\$ 559	\$ 1,931	\$ 2,490

**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 is comprised of 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.

**CT Business**

The CT Business activity is based on our technology 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. This segment is comprised of all entities aside from MaSTherCell.

The CODM does not review assets by segment, therefore the measure of assets has not been disclosed for each segment.



Edgar Filing: Orgenesis Inc. - Form 10-Q

Reconciliation of segment performance to loss for the three months ended May 31, 2018:

Segment data for the six months ended May 31, 2018 is as follows:

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 7,715	\$ -	\$ (1,092)	\$ 6,623*
Cost of revenues	(3,918)	-	388	(3,530)
<b>Gross profit (loss)</b>	<b>3,797</b>	<b>-</b>	<b>(704)</b>	<b>3,093</b>
Research and development expenses, net	-	(1,866)	704	(1,162)
Operating expenses	(2,183)	(2,995)	-	(5,178)
Other income	316	-	-	316
<b>Operating profit (loss)</b>	<b>1,930</b>	<b>(4,861)</b>		<b>(2,931)</b>
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(1,240)	(4)		
<b>Segment performance</b>	<b>690</b>	<b>(4,865)</b>		

\* The Company's revenues consist of: \$5,019 from services and \$1,604 from goods sold.

Reconciliation of segment performance to loss for the six months ended May 31, 2018:

	Six months ended May 31, 2018 in thousands
<b>Segment performance</b>	(4,175)
Stock-based compensation	(1,827)
Financial expenses, net	(2,094)
Share in losses of associated companies	(530)
Loss before income tax	\$ (8,626)

Segment data for the three months ended May 31, 2018 is as follows:

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 4,534	\$ -	\$ (547)	\$ 3,987*
Cost of revenues	(2,193)	-	148	(2,045)
<b>Gross profit (loss)</b>	<b>2,341</b>	<b>-</b>	<b>(399)</b>	<b>1,942</b>
Research and development expenses, net	-	(979)	399	(580)
Operating expenses	(1,101)	(1,639)	-	(2,740)
Other income	-	-	-	-

<b>Operating profit (loss)</b>	1,240	(2,618)	(1,378)
Adjustments to presentation of segment			
Adjusted EBIT			
Depreciation and amortization	(643)	(2)	
<b>Segment performance</b>	597	(2,620)	

\* The Company's revenues consist of: \$2,993 from services and \$994 from goods sold.

**Three months  
ended May  
31, 2018  
in thousands**

<b>Segment performance</b>	(2,023)
Stock-based compensation	(741)
Financial expenses, net	587
Share in losses of associated companies	(576)
Loss before income tax	(2,753)

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

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 4,749	\$ -	\$ (599)	\$ 4,150*
Cost of revenues	(2,919)	-	308	(2,611)
<b>Gross profit (loss)</b>	1,830	-	(291)	1,539
Research and development expenses, net		(1,244)	291	(953)
Operating expenses	725	(4,790)	-	(4,065)
<b>Operating profit (loss)</b>	2,555	(6,034)	-	(3,479)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(1,200)	(7)		
<b>Segment performance</b>	1,355	(6,041)		

\* The Company's revenues consist of: \$3,585 from services and \$565 from goods sold.

Reconciliation of segment performance to loss for the six months ended May 31, 2017:

**Six months  
ended May  
31, 2017  
in thousands**

<b>Segment performance</b>	(4,686)
Stock-based compensation	(1,084)
Financial expenses, net	(2,578)
Share in losses of associated companies	(196)
Loss before income tax	\$ (8,544)

Edgar Filing: Orgenesis Inc. - Form 10-Q

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

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 2,605	\$ -	\$ (307)	\$ 2,298*
Cost of revenues	(1,058)	-	141	(917)
<b>Gross profit (loss)</b>	1,547	-	(166)	1,381
Research and development expenses, net	-	(643)	166	(477)
Operating expenses	(987)	(1,200)	-	(2,187)
<b>Operating profit (loss)</b>	560	(1,843)	-	(1,283)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(608)	(7)		
<b>Segment performance</b>	(48)	(1,850)		

\* The Company's revenues consist of: \$2,202 from services and \$96 from goods sold.

Reconciliation of segment performance to loss for the three months ended May 31, 2017:

	Three months ended May 31, 2017 in thousands
<b>Segment performance</b>	(1,898)
Stock-based compensation	(426)
Financial expenses, net	(503)
Share in losses of associated companies	(107)
Loss before income tax	\$ (2,934)

*Geographic, Product and Customer Information*

Substantially all the Company's revenues and long-lived assets are in Belgium through its subsidiary, MaSTherCell. Net revenues from single customers from the CDMO segment that exceed 10% of total net revenues are:

Customer	Six Months Ended		Three Months Ended	
	May 31, 2018	May 31, 2017	May 31, 2018	May 31, 2017
	(in thousands)			
<b>Customer A</b>	\$ 1,791	\$ 1,961	\$ 896	\$ 771
<b>Customer B</b>	2,257	-	1,300	-
<b>Customer C</b>	2,157	1,095	1,186	803
<b>Customer D</b>	\$ -	\$ 958	\$ -	\$ 703



**NOTE 4 CONVERTIBLE LOAN AGREEMENTS**

(a) During the six months ended May 31, 2018, the Company entered into several unsecured convertible loan agreements with accredited or offshore investors for an aggregate amount of \$720 thousand. The loans bear an annual interest rate of 6% and mature in six months or two years from the closing date, unless earlier converted subject to the terms defined in the agreements.

The loans provide that the entire principal amount and accrued interest automatically convert into a Unit, consisting of one share of Common Stock and one three-year warrant exercisable into an additional share of common stock at a per share exercise price of \$6.24, upon certain conditions, including the listing of the Company's shares on a U.S. exchange. In addition, the Company issued to certain investors 40,064 three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24.

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 \$193 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. The transaction costs for the convertible notes received during the three months ended May 31, 2018 were approximately \$89 thousand, out of which \$31 thousand are stock-based compensation due to issuance of warrants (See also Note 7(b)). Through May 31, 2018, \$650 thousand in principal amount out of these convertible loans were converted into units of the Company's securities. See additional information in Note 4b.

(b) During the six months ended May 31, 2018, holders of approximately \$8.4 million in principal and accrued interest of convertible loans ("converted amounts") with maturity dates between June 2018 and January 2020 converted these outstanding amounts, in accordance with the terms specified in such loans, into units of the Company's securities at a deemed per unit conversion rate of \$6.24, with each unit comprised of: (i) one (1) share of the Company's Common Stock and (ii) one warrant, exercisable for a period of three years from the date of issuance, for an additional share of Common Stock, at a per share exercise price of \$6.24. As a result of these conversions, the holders are entitled to 1,341,134 shares of Common Stock and three-year warrants for an additional 1,341,134 shares of common stock at a per share exercise price of \$6.24.

The Company allocated the converted amounts based on the fair value of the warrants and the shares. The table below presents the converted amounts of the proceeds as of the closing date:

	Proceed Allocation (in thousands)
Warrants component	\$ 3,297
Shares component	5,071
Total	\$ 8,368

The fair value of these warrants determined using a Black-Scholes Model based on the following assumptions:

	<b>Six Months Ended May 31, 2018</b>
Value of one common share	\$7.61-\$13.85
Dividend yield	0%
Expected stock price volatility	90.6%-94.12%
Risk free interest rate	2.29%-2.43%
Expected term (years)	3

These loans had beneficial conversion features ("BCF"), therefore the Company recognized the unamortized BCF as of the conversion date as interest expenses.

(c) In March 2018, a former Israel-based consultant exercised warrants issued in November 2016 to purchase shares of the Company's Common Stock. A related party of such consultant submitted at the same time notice of its intention to convert into shares of the Company's common stock the principal amount and accrued interest of approximately \$382 thousand outstanding under a loan originally advanced to the Company in November 2016. The exercise price in the warrants and conversion price were fixed at \$0.52 per share (pre-reverse stock split implemented by the Company in November 2017). There is a significant disagreement between the Company and these two entities as to the number of shares of Common Stock issuable to these entities, and they contend that the number of shares of Common Stock issuable to them should not take into account the reverse stock split. The Company rejects these contentions in their entirety and, based on the advice of specially retained counsel, believes that these claims are without legal merit and not made in good faith. The Company intends to vigorously defend its interests and pursue other avenues of legal address. Through its counsel, the Company has advised these entities that unless they withdraw their request within a specified period, the Company will cancel the above referenced agreements and these parties right to receive any shares of the Company's Common Stock. In April 2018, the Company withdrew the aforementioned agreements and deposited the principle amount and accrued interest of the loan in an escrow account presented as restricted shares in the balance sheet as of May 31, 2018.

## NOTE 5 COMMITMENTS

### *"MSA" with Adva Biotechnology Ltd.*

On January 28, 2018, the Company and Adva Biotechnology Ltd. ( Adva ), entered into a Master Services Agreement ( MSA ), under which the Company and/or its affiliates are to provide certain services relating to development of products to Adva, as may be agreed between the parties from time to time. Under the MSA, the Company undertook to provide Adva with in kind funding in the form of materials and services having an aggregate value of \$749,900 at the Company's own cost in accordance with a project schedule and related mutually acceptable project budget. The Company entered into agreement with Atvio Biotech Ltd, its Israeli-based joint venture, to fulfill its obligations pursuant this MSA. In March 2018, the Company incurred a total expense of \$82 thousand.

In consideration for and subject to the fulfillment by the Company of such in-kind funding commitment, Adva agreed that upon completion of the development of the products, the Company and/or its affiliates and Adva shall enter into a supply agreement pursuant to which for a period of eight (8) years following execution of such supply agreement, the Company and/or its affiliates (as applicable) is entitled (on a non-exclusive basis) to purchase the products from Adva at a specified discount pricing from their then standard pricing . The Company and/or its affiliates were also granted a non-exclusive worldwide right to distribute such products, directly or through any of their respective contract development and manufacturing organization (CDMO) service centers during such term. The MSA shall remain in effect for 10 years unless earlier terminated in accordance with its terms.

### *Grants*

On December 18, 2017, MaSTherCell, as coordinator of the Icone project with a consortium of private and public searchers, received the approval of a new grant from the Walloon Region with a direct financial support of Euro 1 million (\$1.2 million) in program for development of iPS-derived Cortical Neurons. The program started in 2017 for a 4-year period until 2021. After 2 years, project partners will make a decision continue the program upon pre-defined scientific milestone achievements. During the six months ended May 31, 2018, MaSTherCell received an advance payment of Euro 0.6 million (\$0.7 million).

**NOTE 6 EQUITY***Financings*

1) In January 2017, the Company entered into definitive agreements with an institutional investor for the private placement of 2,564,115 units of the Company's securities for aggregate subscription proceeds to the Company of \$16 million at \$6.24 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 \$6.24. The subscription proceeds are payable on a periodic basis through September 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, 2018 the investor remitted to the Company \$2.5 million, in consideration of which, the investor is entitled to 400,643 shares of the Company's Common Stock and three-year warrants to purchase up to an additional 400,643 shares of the Company's Common Stock at a per share exercise price of \$6.24.

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>Proceeds Allocation</b> (in thousands)
Warrants component	\$ 910
Shares component	1,590
Total	\$ 2,500

The fair value of these warrants determined using a Black-Scholes Model based on the following assumptions:

	<b>Six Months Ended May 31, 2018</b>
Value of one common share \$	6.5-\$14.68
Dividend yield	0%
Expected stock price volatility	90.6%-93.8%
Risk free interest rate	1.99%-2.73%
Expected term (years)	3

In connection with certain installments of the investment, the Company undertook to pay a fee of 5% resulting in the payment of \$25 thousand (classified as Additional Paid-in Capital in the statement of equity) and the issuance of 4,006 restricted shares of Common Stock. The fair value of the shares as of the date of grant was \$29 thousand using the share price on the date of grant.

Through May 31, 2018 the Company has received a total of \$8,000 thousand out of the committed \$16,000 thousand subscription proceeds. See also note 10(9).

2) During the six months ended May 31, 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of 1,237,649 units. Each unit is comprised of (i) one share of the Company's common stock and (ii) three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24, for aggregate proceeds to the Company of approximately \$7.7 million.

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>Proceeds Allocation</b> (in thousands)	
Warrants component	\$ 2,956
Shares component	4,767
Total	\$ 7,723

In connection with \$2.8 million out of these private placements, the Company undertook to pay a fee of 8%, resulting in the payment of \$224 thousand and the issuance of 21,630 three-year warrants to purchase each up to an additional one share of the Company's Common Stock exercisable at \$6.24 to \$12.39 per share. The fair value of the warrants as of the date of grant was \$125 thousand using a Black Scholes option pricing model.

#### **NOTE 7 STOCK BASED COMPENSATION**

##### *a. Options Granted to employees*

Below is a table summarizing the terms of options granted to an employee during the six months ended May 31, 2018:

	<b>No. of options granted</b>	<b>Exercise price</b>	<b>Vesting period</b>	<b>grant (in thousands)</b>	<b>Expiration period</b>
Employee	50,000	\$ 4.42	Quarterly over a period of 1 year	\$ 163	10 years
MaSTherCell's employee	15,000	\$ 8.43	Quarterly over a period of 2 years	\$ 99	10 years
MaSTherCell's* employees	55,300	\$ 8.43	Quarterly over a period of 2 years	\$ 391	10 years
MaSTherCell's* employees	134,050	\$ 8.43	Quarterly over a period of 4 years	\$ 991	10 years

\* In May 2018, the compensation committee of the Company's Board of Directors (the Compensation Committee) approved the option grants for MaSTherCell's employees under the Company's 2017 Equity Incentive Plan. The grant date on the option is in June 2018.

The fair value of these option grants is based on the following assumptions:

<b>Six Months Ended</b>	
<b>May 31, 2018</b>	
Value of one common share	\$4.42-\$9.22

Edgar Filing: Orgenesis Inc. - Form 10-Q

Dividend yield	0%
Expected stock price	
volatility	90%-97%
Risk free interest rate	2.11%-3.04%
Expected term (years)	5-7

*b. Options Granted to non-employees*

Below is a table summarizing all the options granted to consultants and service providers during the six months ended May 31, 2018:

	<b>No. of options granted</b>	<b>Exercise price</b>	<b>Vesting period</b>	<b>Fair value at grant (in thousands)</b>	<b>Expiration period</b>
Non-employee	5,200	\$ 4.42	6-month period Annual over a period of 5 year	\$ 20	10 years
Non-employee	8,333	\$ 6.4		\$ 48	10 years

The fair value of these option grants is based on the following assumptions:

	<b>Six Months Ended May 31, 2018</b>
Value of one common share	\$4.42-\$6.4
Dividend yield	0%
Expected stock price volatility	97%-98%
Risk free interest rate	2.33%-2.54%
Expected term (years)	5

*c. Shares and Warrants Granted to non-employees*

1) During the six months ended May 31, 2018, the Company granted to several consultants 30,174 warrants with each exercisable at \$6.24 to \$15.41 per share for three years as a success fee with respect to the issuance of the convertible loans and part of the private placement. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was \$156 thousand.

2) In December 2017, the Company entered into investors relation services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to grant the consultant 100,000 shares of restricted common stock, of which the first 25,000 shares will vest after 30 days from the signing date, and 75,000 shares are to vest monthly over 15 months commencing February 2018. As of May 31, 2018, 45,000 shares are vested. The fair value of the shares was \$862 thousand using the fair value of the shares at May 31, 2018, out of which \$367 thousand was recognized during the three months ended May 31, 2018. The unrecognized costs will be utilized on a monthly basis until May 2019.

3) In December 2017, the Company entered into an investor relations services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to grant the consultant 95,000 shares of restricted common stock, of which the first 25,000 shares will vest after 30 days from the signing date, and 70,000 shares are to vest monthly over 14 months commencing February 2018. As of May 31, 2018, 45,000 shares vested. The fair value of the shares was \$819 thousand using the fair value of the shares at May 31, 2018, out of which \$367 thousand was recognized during the three months ended May 31, 2018. The unrecognized costs will be utilized on a monthly basis until April 2019.

4) In January 2018, the Company entered into consulting agreement with financial advisor for a period of one year. Under the terms of the agreements, the consultant was paid \$20 thousand per month for three months and 19,000 units of the Company securities. Each unit is comprised of (i) one share of the Company's common stock and (ii) a three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24. The fair value of the units as of the date of grant was \$171, out of which \$62 thousand reflect the fair value of the warrants using the Black-Scholes valuation model.

5) On July 6, 2018, as part of an amendment to a prior agreement, the Company issued to a consultant additional 6,629 units of share and warrants for the purchase of the Company's common stock, exercisable at a per share exercise price of \$6.24. See also note 10(6).

6) In April 2018, a U.S.-based accredited investor who held 128,077 warrants issued in November 2015, exercised their warrants into 128,077 shares of the Company's Common Stock at a per share exercise price of \$6.24, for aggregate proceeds to the Company of \$799 thousand.

## NOTE 8 LOSS PER SHARE

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

	Six Months Ended		Three Months Ended	
	May 31,		May 31,	
	2018	2017	2018	2017
(in thousands, except per share data)				
<b>Basic:</b>				
Loss for the period	\$ 8,225	\$ 8,616	\$ 2,614	\$ 2,489
Weighted average number of common shares outstanding	11,971,389	9,221,039	13,140,119	9,568,413
Loss per common share	\$ 0.69	\$ 0.93	\$ 0.20	\$ 0.26
<b>Diluted:</b>				
Loss for the period	\$ 8,225	\$ 8,616	\$ 2,614	\$ 2,489
Changes in fair value of embedded derivative and interest expense on convertible bonds	-	-	-	-
Loss for the period	\$ 8,225	\$ 8,816	\$ 2,614	\$ 2,489
Weighted average number of shares used in the computation of basic and diluted loss per share	11,971,389	9,221,039	13,140,119	9,568,413
Loss per common share	\$ 0.69	\$ 0.93	\$ 0.20	\$ 0.26

Diluted loss per share does not include 6,048,269 shares underlying outstanding options and warrants and 201,416 shares upon conversion of convertible notes for the six months ended May 31, 2018, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted loss per share does not include 4,059,824 shares underlying outstanding options and warrants and 1,354,257 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.

## 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, 2018, and November 30, 2017, the Company's assets and liabilities that are measured at fair value and classified as level 3 fair value are as follows (in thousands):

	<b>May 31, 2018</b>	<b>November 30, 2017</b>
	Level 3	Level 3
Embedded derivatives convertible loans*(1)	\$ -	\$ 37
Call/Put option derivatives	\$ (792)	\$ (339)

\* 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 is determined by using a Black-Scholes Model.

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, 2018:

	<b>Embedded Derivatives</b>	<b>Put Option Derivative</b>
Balance at beginning of the year	\$ 37	\$ (339)
Repayment	(14)	-
Changes in fair value during the period	(23)	(453)
Balance at end of the year	\$ -	\$ (792)

(\*) There were no transfers to Level 3 during the three months ended May 31, 2018.

The table below sets forth a summary of the changes in the fair value of the Company's financial assets and liabilities classified as Level 3 for the year ended November 30, 2017:

	<b>Embedded Derivatives</b>	<b>Convertible Bonds</b>	<b>Put Option Derivative</b>
Balance at beginning of the year	\$ 240	\$ 1,818	\$ 273
Repayment	(876)	(1,827)	
Changes in fair value during the period	662	22	(612)
Translation adjustments	11	(13)	
Balance at end of the year	\$ 37	\$ -	\$ (339)

(\*) There were no transfers to Level 3 during the twelve months ended November 30, 2017.

## NOTE 10 - SUBSEQUENT EVENTS

1) In connection with the Subscription and Shareholders Agreement entered into on November 15, 2017 by and among the Company, MaSTherCell S.A. and the Belgian Sovereign Funds Société Fédérale de Participations et d'Investissement ( SFPI ), SPFI has paid into MaSTherCell S.A. the balance of Euro 1.9 million (approximately \$2.3 million) on June 13, 2018. The Company reflected the impact of this payment as other receivable and redeemable non-controlling interest in the balance sheet as of May 31, 2018.

2) On June 11, 2018, a holder of \$181 thousand in principal and accrued interest of a convertible loan outstanding from November 2014 converted these outstanding amounts, in accordance with the terms specified in such note, into shares of the Company's common stock at a deemed conversion price of \$4.80 per share. As a result of this conversion, the Company will issue 37,662 shares of common stock.

3) On June 15, 2018, the Compensation Committee approved the grant under the Company's 2017 Equity Incentive Plan of options for an aggregate of 30,500 shares to two employees, at a per share exercise price of \$8.91. The options are to vest quarterly over eight quarters commencing July 1, 2018.

On June 26, 2018, the Compensation Committee approved the grant under the Company's 2017 Equity Incentive Plan of options for an aggregate of 8,600 shares to two consultants, exercisable at a per share exercise price of \$8.34. The options vested upon grant.

4) On June 28, 2018, the Compensation Committee approved the grant under the Company's 2017 Equity Incentive Plan of options for 250,000 shares to the Company's Chief Executive Officer in accordance with the terms of the employment agreement dated March 30, 2017, as subsequently amended. The options are exercisable into the Company's common stock at a per share exercise price of \$8.36 and vest in two semi-annual installments of 125,000 options in each of the sixth and twelfth month anniversary from the date of grant.

5) On July 6, 2018, the Compensation Committee issued to two consultants warrants for the purchase of an aggregate of 13,558 shares of common stock, exercisable at a per share exercise price of \$11.19.

6) On July 6, 2018, as part of an amendment to a prior agreement, the Company issued to a consultant 6,629 warrants for the purchase of the Company's common stock, exercisable at a per share exercise price of \$6.24. In addition, the Company issued the consultant 6,629 shares of the Company's common stock. See also note 7c4.

7) On June 18, 2018, a holder of 8,569 investor warrants issued on January 17, 2017 exercised such warrants into 8,569 shares of the Company's Common Stock at a per share exercise price of \$6.24, for aggregate proceeds to the Company of \$53,471.

8) In July 2018, the Company entered into definitive agreements with assignees of the institutional investor referred to in Note 6(1) whereby these assignees remitted \$4.5 million in respect of the units available under the original subscription agreement that have not been subscribed for, entitling such investors to 692,308 units, with each unit being comprised of (i) one share of the Company's common stock and (ii) one three-year warrant to purchase up to an additional one share of the Company's common stock at a per share exercise price of \$6.24.

9) In July 2018, the Company raised \$1 million from the institutional investor referred to in Note 6 (1) entitling such investor to 160,256 shares of Common Stock and three-year warrants for an additional 160,256 shares. Following this remittance and those under item 8 above, the Company has received, as of July 16, 2018, a total of \$12.5 million out of the committed \$16 million subscription proceeds under such agreement.

10) On June 19, 2018, the Company and Mircod Limited, a company formed under the laws of Cyprus ( "Mircod" ) entered into a Collaboration and License Agreement (the "Collaboration Agreement" ) for the research, development and commercialization of potential key technologies related to biological sensing for our clinical development and manufacturing projects (the "Development Project" ). Within 45 days of the execution of the Collaboration Agreement, the parties are to approve a written project development plan outlining each party's responsibilities with respect to the Development Project, and we will be funding the projected development costs as outlined in the development plan. Under the terms of the Collaboration Agreement, the Company remitted to Mircod an upfront payment of \$50,000.

Under the Collaboration Agreement, all results of such collaboration ( "Project Results" ) shall be jointly owned by Mircod and the Company. The Company was granted an exclusive, worldwide sub licensable license under Mircod's

right in such Project Results to use and commercialize Project Results in consideration for a royalty of 5% of Net Sales (as defined in the Collaboration Agreement) of products incorporating Project Results.

Subject to completion of the Development Project, Mircod and the Company are to negotiate and enter into a manufacturing and supply agreement under which Mircod is to manufacture and supply products incorporating the Project Results and, at the Company's request, to provide support and maintenance service for such products. If for whatever reason the parties fail to enter into such manufacturing and supply agreement within 90 days of the completion of the Development Project or if Mircod is unable to perform such services, the Company is entitled to manufacture the products, in which event Mircod will be entitled to a payment of \$80,000 and royalties on Net Sales are to increase to 8% of Net Sales.

11) On June 28, 2018, the Company and Masthercell Global Inc., a Delaware company and a newly formed subsidiary of Orgenesis the Company that holds the Company's CDMO business ( Masthercell Global ), Great Point Partners, LLC, a manager of private equity funds focused on growing small to medium sized health care companies ( Great Point ), and certain of Great Point's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business. In connection therewith, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company ( GPP-II ) and an affiliate of Great Point entered into Stock Purchase agreement (the SPA ) pursuant to which GPP-II purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the Masthercell Global Preferred Stock ), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for cash consideration to be paid into Masthercell Global of up to \$25 million, subject to certain adjustments (the Consideration ). Orgenesis holds 622,000 shares of Masthercell Global's Common Stock, representing 62.2% of the issued and outstanding equity share capital of Masthercell Global. An initial cash payment of \$11.8 million of the Consideration was remitted at closing, with a follow up payment of \$6,600,000 to be made in each of years 2018 and 2019 (the Future Payments ), or an aggregate of \$13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis' shareholders approve on or before December 31, 2019 certain provisions of the Stockholders' Agreement entered into by these parties. None of the future Consideration amounts, if any, will result in an increase in GPP-II's equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing. Notwithstanding the foregoing, GPP-II may, in its sole discretion, elect to pay all or a portion of the future Consideration amounts even if the financial targets described above have not been achieved and the Orgenesis Stockholder Approval has not been obtained.

In connection with the entry into the SPA described above, each of the Company, Masthercell Global and GPP-II entered into the Masthercell Global Inc. Stockholders' Agreement (the Masthercell Global Stockholders Agreement ) providing for certain restrictions on the disposition of Masthercell Global securities, the provisions of certain options and rights with respect to the management and operations of Masthercell Global, a right to exchange the Masthercell Global Preferred Stock for shares of Orgenesis common stock and certain other rights and obligations. In addition, after the earlier of the second anniversary of the closing or certain enumerated circumstances, GPP-II is entitled to effectuate a spinoff of Masthercell Global and the Masthercell Global Subsidiaries (the Spinoff ). The Spinoff is required to reflect a market value determined by one of the top ten independent accounting firms in the U.S. selected by GPP, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and the Masthercell Global Subsidiaries of at least \$50 million. In addition, upon certain enumerated events, GPP-II is entitled, at its option, to put to the Company (or, at Company's discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global or, alternatively, purchase from the Company its share capital in Masthercell Global at a purchase price equal to the fair market value of such equity holdings as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II.

The Stockholders' Agreement further provides that GPP-II is entitled, at any time, to convert its share capital in Masthercell Global for the Company's common stock in an amount equal to the lesser of (a)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged, as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II and the Company, divided by (ii) the average closing price per share of Orgenesis Common Stock during the thirty (30) day period ending on the date that GPP-II provides the exchange notice (the Exchange Price ) and (b)(i) the fair market value of GPP-II's shares of Masthercell Global

Preferred Stock to be exchanged assuming a value of Masthercell Global equal to three and a half (3.5) times the revenue of Masthercell Global during the last twelve (12) complete calendar months immediately prior to the exchange divided by (ii) the Exchange Price; provided, that in no event will (A) the Exchange Price be less than a price per share that would result in Orgenesis having an enterprise value of less than \$250,000,000 and (B) the maximum number of shares of Orgenesis Common Stock to be issued shall not exceed 2,704,247 shares of outstanding Orgenesis Common Stock (representing approximately 19.99% of then outstanding Orgenesis Common Stock), unless Orgenesis obtains shareholder approval for the issuance of such greater amount of shares of Orgenesis Common Stock in accordance with the rules and regulations of the Nasdaq Stock Market.

Great Point, Masthercell Global and the Company entered into an advisory agreement pursuant to which Great Point is to provide management services to Masthercell Global for which Great Point will be compensated at an annual base compensation equal to the greater of (i) \$250,000 per each 12 month period or (ii) 5% of the EBITDA for such 12 month period, payable in quarterly installments; provided, that these payments will (A) begin to accrue immediately, but shall not be paid in cash to Great Point until such time as Masthercell Global generates EBITDA of at least \$2,000,000 for any 12 month period or the sale of or change in control of Masthercell Global, and (B) shall not exceed an aggregate annual amount of \$500,000.

Contemporaneous with the execution of the SPA and the Masthercell Global Stockholders Agreement, the Company and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which Company contributed to Masthercell Global the Orgenesis assets relating to the CDMO business (as defined below), including the CDMO subsidiaries. In furtherance thereof, Masthercell Global, as Orgenesis assignee, acquired all of the issued and outstanding share capital of Atvio Biotech Ltd. ( Atvio ), the Company's Israel based CDMO partner since May 2016, and 94.2% of the share capital of Curecell Co. Ltd. ( Curecell ), the Company's Korea based CDMO partner since March 2016. Orgenesis exercised the call option to which it was entitled under the joint venture agreements with each of these entities to purchase from the former shareholders their equity holding. The consideration for the outstanding share equity in each of Atvio and Curecell consisted solely of Company Common Stock. In respect of the acquisition of Atvio, Orgenesis Inc. will be issuing to the former Atvio shareholders an aggregate of 84,085 shares of Company Common Stock. In respect of the acquisition of Curecell, the Company agreed to issue to the former Curecell shareholders an aggregate of 195,927 shares of Orgenesis Common Stock subject to a third-party valuation. Together with MaSTherCell S.A., Atvio and Curecell are directly held subsidiaries under Masthercell Global.

12) On July 11, 2018, the Company and HekaBio K.K., a corporation organized under the laws of Japan ( HB ) entered into a Joint Venture Agreement (the JVA ) pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products (hereinafter the Products ) in Japan. The parties intend to pursue the joint venture through a newly established Japanese company (hereinafter the JV Company ) which the Company by itself, or together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB. HB will fund, at its sole expense, all costs associated with obtaining the requisite regulatory approvals for conducting clinical trials, as well as performing all clinical and other testing required for market authorization of the Products in Japan.

Under the JVA, each party may invest up to \$10 million, which may take the form of a loan, if required, as determined by the steering committee. The terms of such investment, if any, will be on terms mutually agreeable to the parties, provided that the minimum pre-money valuation for any such investment shall not be less than \$10 million. Additionally, HB was granted an option to effect an equity investment in the Company in up to \$15 million within the next 12 months on mutually agreeable terms. If such investment is in fact consummated, the Company agreed to invest in the JV Company by way of a convertible loan an amount to HB's pro-rata participating interest in the JV Company, which initially will be at 51%. Such loan may then be converted by the Company into share capital of the JV company at an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million. Under the JVA, the Company can require HB to sell to the Company its participating (including equity) interest in the JV Company in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million.

13) On July 11, 2018, the Company and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Caman Islands ( India Partner ) entered into a Joint Venture Agreement (the India JVA ) pursuant to which the parties will collaborate in the in the development and/or marketing, clinical development and commercialization of cell therapy products in India (the Cell Therapy Products ). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products.

The India JVA becomes effective upon the consummation of an equity investment by the India partner in the Company of \$5 million within 150 days of the execution of the India JVA through the purchase of units of Orgenesis securities at a per unit purchase price payable into the Company of \$6.24, with each unit comprised of one share of Company common stock and three-year common stock purchase warrant for an additional share of common stock at a per share exercise price of \$6.24. Subject to the consummation of such equity investment in the Company, the Company is to advance to the JV Company a convertible loan in the amount of \$5 million. The loan is convertible into equity capital of the JV Company at an agreed upon formula for determining JV Company valuation. The investment in the Company by the India Partner would be the consummation of the previously disclosed private placement subscription agreement entered into in December 2016 between the Company and an affiliate of the India Partner pursuant to which the closing of such subscription agreement was by the terms thereof delayed until such time as terms comprising the India JV were mutually agreed to.

Under the India JVA, the India Partner agreed to invest in the JV \$10 million within 12 months of the incorporation of the JV Company. If for whatever reason such investment is not made by the India Partner within such time, then Orgenesis is authorized to convert its above-referenced loan into 50% of the equity capital of the JV Company on a fully diluted basis, provided that if the pre-money valuation of the JV Company is then independently determined to be less than \$5 million, then such conversion to be effected in the basis of such valuation.

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

### *Forward-Looking Statements*

This Quarterly Report on Form 10-Q contains or may contain forward-looking statements within the meaning of 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements 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 and 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 a vertically integrated service and research company in the field of the regenerative medicine industry with a focus on cell therapy development and manufacturing for advanced medicinal products serving the regenerative medicine industry. In addition, we are focused on developing novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes, with 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. Our hybrid business model of combining 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 mission of accelerating the development and ultimate marketing of breakthrough life-improving medical treatments.

We seek to differentiate our company from other cell therapy companies through MaSTherCell Global, which consists of MaSTherCell and our CDMO subsidiaries in Korea and Israel, who have built a unique and fundamental base platform of know-how and expertise for manufacturing in 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. MaSTherCell Global strives to provide services that are all compliant with GMP requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III through commercialization.

We have leveraged the recognized expertise and experience in cell process development and manufacturing of MaSTherCell, Atvio and Curecell, in Israel and Korea, to build a global and fully integrated bio-pharmaceutical company in the cell therapy development and manufacturing area. We believe that cell therapy companies need to be global in order to truly succeed. In furtherance of that belief, we intend to expand our establishment of CDMO facilities to the United States and other international markets. 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 will be mobilized for our internal development projects, allowing us to be in a position to bring new products to the patients faster and in a cost-effective way.

Our trans-differentiation technologies for treating diabetes, which we refer to as our cellular therapy ( CT ) business, is based on a technology licensed by our Israeli Subsidiary, that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver or other tissues and transdifferentiating them into pancreatic beta cell-like Autologous Insulin Producing ( AIP ) cells for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases. Moreover, those cells may be found to be resistant to autoimmune attack and to produce insulin in a glucose-sensitive manner in relevant animal models which significantly broadens the potential of the technology for other therapeutics areas; this has yet to be proven in human clinical trials. Our trans-differentiation technology for diabetes is based on the work of Prof. Sarah Ferber, our Chief Science Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. ( THM ) in Israel. Our development plan calls for conducting additional preclinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating clinical trials. In parallel, we work on establishing the GMP manufacturing process which development is already accomplished.

In furtherance of our CT business, we are pursuing strategic partnerships to bring autologous cell and gene therapies to the clinic. In pursuit of this, the following factors are enabling this objective:

Strategic relationships with other local partners in international countries where we currently may not operate. We intend to pursue working directly with hospitals and strategic groups to build relationships with the hospitals in making available supply and future on-site manufacturing of therapeutic products, either for the clinical stage or for the marketing stage. We intend to focus the partnerships on our in-house technologies, although we can also support third party services by utilizing our CDMO business.

Therapeutic collaborations licensed from academic centers around the world. Because of the expected close relationships built with these academic hospitals, we also intend to build the service, CRO and preclinical framework to support the development of these products.

Developing and licensing of technology systems. We expect that the development and licensing of certain technologies, such as interconnectivity systems (i.e. Internet of Things), automated systems, sensor technologies, media supply and other technology developments will enable us to manufacture on site in a closed system.

Additional CDMO expansion through Masthercell Global. We intend expand our existing global CDMO network in order to seek additional partnerships in the global CDMO business that allow us to expand local manufacturing needs during the clinical stage that have unique know-how regarding the market and a close relationship with third parties that may in the future want to use our existing CDMO network to supply their products.

We operate our CDMO and the CT business as two separate business segments.

#### *Revenue Model*

Companies developing cell therapies need to decide early on in their approach to the transition from the lab to the clinic regarding the manufacturing and production of the cells necessary for their respective treatments. Of the

companies active in this market, only a small number have established their own GMP manufacturing facilities due to the high costs and expertise required to develop and maintain such production centers. In addition to the limitations imposed by a limited number of trained personnel and high infrastructure/operational costs, we believe that the industry faces a need for custom innovative process development and manufacturing solutions. In this context, we have grown total revenue from \$6.4 million in our fiscal year November 30, 2016 to \$10.1 million for fiscal year November 30, 2017 and from \$4.1 million for the six months ended May 31, 2017 to \$6.6 million for the six months ended May 31, 2018. The increased revenues derive from an increase in the volume of the services provided by our CDMO segment, namely our Belgian-based subsidiary, MaSTherCell, through its customer service contracts with existing customers and the entry into new customer service contracts with leading biotech companies, as well as from revenues generated from existing manufacturing agreements.

## *Recent Significant Developments*

### **Funding from SFPI**

On November 15, 2017, we, MaSTherCell and the Belgian Sovereign Funds Société Fédérale de Participations et d'Investissement ( SFPI ) entered into a Subscription and Shareholders Agreement (the Agreement ) pursuant to which SFPI completed an equity investment in MaSTherCell in the aggregate amount of €5million (approximately \$5.9 million), for approximately 16.7% of MaSTherCell. Following the SFPI investment in MaSTherCell, in November 2017, MaSTherCell announced the expansion by 600m<sup>2</sup> of its facility in Belgium with a dedicated, late-stage clinical and commercial cGMP unit, anticipated to be operational by the fourth quarter of 2018. This new expansion enables MaSTherCell to augment its commercial capabilities in Europe with five state-of-the-art advanced manufacturing units and extended GMP-accredited quality control (QC) laboratories. On June 13, 2018, SPFI has paid into MaSTherCell S.A. the balance of Euro 1.9 million (approximately \$2.3 million).

### **Collaboration Agreements/ Joint Ventures**

On June 19, 2018, we and Mircod Limited, a company formed under the laws of Cyprus ( Mircod ) entered into a Collaboration and License Agreement for the research, development and commercialization of potential key technologies related to biological sensing for our clinical development and manufacturing projects (the Development Project ). Within 45 days of the execution of the Collaboration Agreement, the parties are to approve a written project development plan outlining each party's responsibilities with respect to the Development Project, and we will be funding the projected development costs as outlined in the development plan. Under the terms of the Collaboration Agreement, we remitted to Mircod an upfront payment of \$50,000.

On July 11, 2018, we and HekaBio K.K., a corporation organized under the laws of Japan ("HB") entered into a Joint Venture Agreement (the "JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products (hereinafter the "Products") in Japan. The parties intend to pursue the joint venture through a newly established Japanese company (hereinafter the "JV Company") which the Company by itself, or together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB. HB will fund, at its sole expense, all costs associated with obtaining the requisite regulatory approvals for conducting clinical trials, as well as performing all clinical and other testing required for market authorization of the Products in Japan.

On July 11, 2018, we and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Caman Islands ("India Partner") entered into a Joint Venture Agreement (the "India JVA") pursuant to which the parties will collaborate in the in the development and/or marketing, clinical development and commercialization of cell therapy products in India (the "Cell Therapy Products"). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products.

The India JVA becomes effective upon the consummation of an equity investment by the India partner in the Company of \$5 million through the purchase of units of Orgenesis securities at a per unit purchase price payable into the Company of \$6.24, with each unit comprised of one share of Company common stock and three-year common stock purchase warrant for an additional share of common stock at a per share exercise price of \$6.24.

### **Consolidation of CDMO Entities and Strategic Funding**

On June 28, 2018, the Company and Masthercell Global Inc., a Delaware company and a newly formed subsidiary of Orgenesis the Company that holds our business relating to the third party contract manufacturing for cell therapy companies (CDMO) ( Masthercell Global ), Great Point Partners, LLC, a manager of private equity funds focused on growing small to medium sized health care companies ( Great Point ), and certain of Great Point's affiliates, entered into

a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business. In connection therewith, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company ( "GPP-II" ) and an affiliate of Great Point entered into Stock Purchase agreement (the "SPA" ) pursuant to which GPP-II purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the "Masthercell Global Preferred Stock" ), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for cash consideration to be paid into Masthercell Global of up to \$25 million, subject to certain adjustments (the "Consideration" ). Orgenesis holds 622,000 shares of Masthercell Global's Common Stock, representing 62.2% of the issued and outstanding equity share capital of Masthercell Global. An initial cash payment of \$11.8 million of the Consideration was remitted at closing, with a follow up payment of \$6,600,000 to be made in each of years 2018 and 2019 (the "Future Payments" ), or an aggregate of \$13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis' shareholders approve certain provisions of the Stockholders' Agreement referred to below on or before December 31, 2019. None of the future Consideration amounts, if any, will result in an increase in GPP-II's equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing. The proceeds of the investment will be used to fund the activities of Masthercell Global and its consolidated subsidiaries. Notwithstanding the foregoing, GPP-II may, in its sole discretion, elect to pay all or a portion of the future Consideration amounts even if the financial targets described above have not been achieved and the Orgenesis Stockholder Approval has not been obtained.

Masthercell Global, through the Masthercell Global Subsidiaries, will be engaged in the business of providing manufacturing and development services to third parties related to cell therapy products, and the creation and development of technology, and optimizations in connection with such manufacturing and development services for third parties. Under the terms of these agreements, the Company agreed that so long as it owns equity in Masthercell Global and for two years thereafter it will not engage in the CDMO Business, except through Masthercell Global (but may continue to engage in its other areas of business). In addition, except for certain limited circumstances, each of Orgenesis and GPP-II agreed to not recruit or solicit or hire any officer or employee of Masthercell Global that was or is involved in the CDMO Business.

We intend, through our direct subsidiaries, to continue to engage in the manufacturing, researching, marketing, developing, selling and commercializing (either alone or jointly with third parties) products that are not directly related to the CDMO business, including, joint ventures, collaboration, partnership or similar arrangement with a third party.

### *Results of Operations*

#### Comparison of the Three Months Ended May 31, 2018 to the Three Months Ended May 31, 2017

Our financial results for the three months ended May 31, 2018 are summarized as follows in comparison to the three months ended May 31, 2017:

	<b>Three Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Revenues	\$ 3,987	\$ 2,298
Cost of sales	2,195	1,128
Research and development expenses, net	788	665
Amortization of intangible assets	445	397
Selling, general and administrative expenses	3,323	2,432
Share in losses of associated company	(576)	(107)
Financial expense (income), net	(587)	503
Loss before income taxes	\$ 2,753	\$ 2,934

**Revenues**

	<b>Three Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Services	\$ 2,993	\$ 2,202
Goods	994	96
<b>Total</b>	<b>\$ 3,987</b>	<b>\$ 2,298</b>

All revenues were derived from our Belgian Subsidiary, MaSTherCell S.A. We believe that revenue diversification by source in the CDMO segment, together with a leading position in immunotherapy and, in particular, CAR T-cell therapy development and manufacturing, strengthen MaSTherCell's resilience in the industry.

Our revenues for the three months ended May 31, 2018 were \$3,987 thousand, as compared to \$2,298 thousand for the corresponding period in 2017, representing an increase of 73.5%. The increase in revenues for the three months ended May 31, 2018 compared to the corresponding period in 2017 is attributable to an increase of \$1.7 million in the volume of the services provided by MaSTherCell, resulting primarily from the extension of existing customer service contracts with biotech clients, as well as from revenues generated from existing manufacturing agreements.

In January 2017, MaSTherCell signed a master service agreement with Servier for the development of a manufacturing platform for allogeneic cell therapies. Under the master service agreement, MaSTherCell is developing a CAR T-cell therapy manufacturing platform, which will enable industrial and commercial manufacturing of Servier's cell therapy products. This is a critical step in the development of these products for later stage clinical trials.

In June 2017, MaSTherCell signed an agreement with CRISPR Therapeutics to develop and manufacture allogeneic CAR T-cell therapies. MaSTherCell will be responsible for the development and cGMP manufacturing of CTX101 for use in clinical studies. CTX101 is an allogeneic CAR T-cell therapy currently in development by CRISPR Therapeutics for the treatment of CD19 positive malignancies.

**Expenses**Cost of Revenues

	<b>Three Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Salaries and related expenses	\$ 975	\$ 502
Professional fees and consulting services	-	87
Raw materials	992	238
Depreciation and amortization expenses, net	169	211
Other expenses	59	90
	<b>\$ 2,195</b>	<b>\$ 1,128</b>

Cost of revenues for the three months ended May 31, 2018 were \$2,195 thousand, as compared to \$1,128 thousand, during the same period in 2017, representing an increase of 94.6%. The increase for the three months ended in May 31, 2018, as compared to the corresponding period in 2017 is primarily attributed to the following: (i) An increase in salaries and related expenses primarily attributable to an increase of 77% in head-count in production and development department. The increase was partially offset by a decrease attributable to an internal transformation program implemented in MaSTherCell in the second quarter of 2017 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 laboratory managers to general manager positions in order to reflect the current period's business activity. Consequently, these changes in business positions resulted in a

subsequent shift of costs into general and administration expenses. (ii) An increase of \$760 thousand in raw materials due to the growth in the volume of the services provided by MaSTherCell, as well as from revenues generated from existing manufacturing agreements.

Research and Development Expenses

	<b>Three Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Salaries and related expenses	\$ 365	\$ 258
Stock-based compensation	157	186
Professional fees and consulting services	253	66
Lab expenses	149	377
Other research and development expenses	104	55
Less grant	(240)	(277)
<b>Total</b>	<b>\$ 788</b>	<b>\$ 665</b>

Research and development expenses for the three months ended May 31, 2018 were \$788 thousand, as compared to \$665 thousand for the same period in 2017, representing an increase of 18%. The increase in research and development expenses in the three months ended May 31, 2018 is primarily attributable to professional fees and salaries and related expenses incurred as a result of an increase in our pre-clinical studies in the U.S., Israel and Belgium. The increase in research and development expenses reflects management's focus on moving our trans-differentiation technology with first indication in Type 1 Diabetes to the next the stage towards clinical trials.

Selling, General and Administrative Expenses

	<b>Three Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Salaries and related expenses	\$ 1,101	\$ 834
Stock-based compensation	580	238
Accounting and legal fees	597	453
Professional fees	210	331
Rent and related expenses	296	60
Business development	356	136
Expenses related to a joint venture	-	344
Other general and administrative expenses	183	36
<b>Total</b>	<b>\$ 3,323</b>	<b>\$ 2,432</b>

Selling, general and administrative expenses for the three months ended May 31, 2018 were \$3,323 thousand, as compared to \$2,432 thousand for the same period in 2017, representing an increase of 36.6%. The increase in selling, general and administrative expenses in the three months ended May 31, 2018 compared to the same period in 2017 is primarily attributable to the following: (i) An increase in salaries as result of additional managerial positions, as well as an internal transformation program implemented in MaSTherCell in the second quarter of 2017 to evolve from an organization based on projects to a matrix organization supported by transversal departments focusing on value creation. As part of the program, we altered the business designations of certain employees from laboratory managers to general manager positions in order to reflect the current period's business activity. Subsequently, these changes in position designation resulted in a shift costs from cost of revenues. (ii) An increase of approximately \$207 thousand in salaries as a result of bonus paid to the CEO and certain employees. (iii) An increase of \$342 thousand in non-cash stock-based compensation resulting from grants of options to consultants and key personnel during the first half of 2018. (iv) An increase of \$236 thousand is mainly results to rental of additional space for new production area and offices in MasTherCell due to an increase in the CDMO operation.

Financial Expenses, net

	<b>Three Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	\$ (606)	\$ (1,005)
Stock-based compensation related to warrants granted to bondholder	-	
Stock-based compensation related to shares to be issued to creditor	-	1,084
Interest expense on convertible loans and loans	177	288
Foreign exchange loss, net	(167)	131
Other expenses	9	5
<b>Total</b>	<b>\$ (587)</b>	<b>\$ 503</b>

Financial expenses, net for the three months ended May 31, 2018, decreased by \$1,090 thousand, compared to the same period in 2017. The decrease in financial expenses is mainly attributable to a decrease of \$1,084 thousand of stock-based compensation expenses related to convertible loan agreement repaid in 2017 as well as a decrease in interest expenses on convertible loans due to conversion of the majority of the convertible loans during the three months ended February 28, 2018.

Comparison of the Six Months Ended May 31, 2018 to the Six Months Ended May 31, 2017

Our financial results for the six months ended May 31, 2018 are summarized as follows in comparison to the six months ended May 31, 2017:

	<b>Six Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Revenues	\$ 6,623	\$ 4,150
Cost of sales	3,839	3,033
Research and development expenses, net	1,554	1,406
Amortization of intangible assets	881	777
Selling, general and administrative expenses	6,667	4,703
Share in losses of associated company	(530)	(196)
Financial expense, net	2,094	2,578
Other income	316	-
Loss before income taxes	\$ 8,626	\$ 8,544

**Revenues**

	<b>Six Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Services	\$ 5,019	\$ 3,585
Goods	1,604	565
<b>Total</b>	<b>\$ 6,623</b>	<b>\$ 4,150</b>

Our revenues for the six months ended May 31, 2018 were \$6,623 thousand, as compared to \$4,150 thousand for the corresponding period in 2017, representing an increase of 60%. The increase in revenues for the six months ended May 31, 2018 compared to the corresponding period in 2017 is attributable to an increase of \$2.2 million in the volume of the services provided by MaSTherCell, resulting primarily from the extension of existing customer service

contracts with biotech clients, as well as from revenues generated from existing manufacturing agreements. The increase was partially offset by a MaSTherCell client project closure in 2016 and a settlement in February 2018. The income derived from such settlement totaling \$316 thousand is recognized as other income for the three months ended February 28, 2018.

In January 2017, MaSTherCell signed a master service agreement with Servier for the development of a manufacturing platform for allogeneic cell therapies. Under the master service agreement, MaSTherCell is developing a CAR T-cell therapy manufacturing platform, which will enable industrial and commercial manufacturing of Servier's cell therapy products. This is a critical step in the development of these products for later stage clinical trials.

In June 2017, MaSTherCell signed an agreement with CRISPR Therapeutics to develop and manufacture allogeneic CAR T-therapies. MaSTherCell will be responsible for the development and cGMP manufacturing of CTX101 for use in clinical studies. CTX101 is an allogeneic CAR T-cell therapy currently in development by CRISPR Therapeutics for the treatment of CD19 positive malignancies.

## Expenses

### Cost of Revenues

	<b>Six Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Salaries and related expenses	\$ 1,742	\$ 1,536
Professional fees and consulting services	-	173
Raw materials	1,643	756
Depreciation and amortization expenses, net	328	422
Other expenses	126	146
	\$ 3,839	3,033

Cost of revenues for the six months ended May 31, 2018 were \$3,839 thousand, as compared to \$3,033 thousand, during the same period in 2017, representing an increase of 27%. The increase for the six months ended in May 31, 2018, as compared to the corresponding period in 2017 is primarily attributed to the following: (i) An increase in salaries and related expenses mainly results of an increase in head-count in production and development department. The Increase was partially offset by a decrease attributable to an internal transformation program implemented in MaSTherCell in the second quarter of 2017 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 laboratory managers to general manager positions in order to reflect the current period's business activity. Consequently, these changes in business positions resulted in a subsequent shift of costs into general and administration expenses. (ii) An increase of \$887 in raw materials due to increase in the volume of the services provided by MaSTherCell, as well as from revenues generated from existing manufacturing agreements.

### Research and Development Expenses

	<b>Six Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Salaries and related expenses	\$ 651	\$ 551
Stock-based compensation	339	453
Professional fees and consulting services	440	110
Lab expenses	310	550
Other research and development expenses	173	96
Less grant	(359)	(354)
Total	\$ 1,554	\$ 1,406

Edgar Filing: Orgenesis Inc. - Form 10-Q

Research and development expenses for the six months ended May 31, 2018 were \$1,554 thousand, as compared to \$1,406 thousand for the same period in 2017, representing an increase of 11%. The increase in research and development expenses in the six months ended May 31, 2018 is primarily attributable to professional fees incurred as a result of an increase in our pre-clinical studies in the U.S., Israel and Belgium. The increase in research and development expenses reflects management's focus on moving our trans-differentiation technology with first indication in Type 1 Diabetes to the next the stage towards clinical trials.

Selling, General and Administrative Expenses

	<b>Six Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Salaries and related expenses	\$ 1,903	\$ 1,059
Stock-based compensation	1,488	631
Accounting and legal fees	925	854
Professional fees	974	725
Rent and related expenses	576	304
Business development	665	260
Expenses related to a joint venture	-	602
Other general and administrative expenses	136	268
<b>Total</b>	<b>\$ 6,667</b>	<b>\$ 4,703</b>

Selling, general and administrative expenses for the six months ended May 31, 2018 were \$6,667 thousand, as compared to \$4,703 thousand for the same period in 2017, representing an increase of 42%. The increase in selling, general and administrative expenses in the six-month period in 2018 compared to the same period in 2017 is primarily attributable to the following: (i) An increase of \$844 thousand in salaries and related expenses is mainly a result of An increase in salaries as result of additional managerial positions as well as an internal transformation program implemented in MaSTherCell in the second quarter of 2017 to evolve from an organization based on projects to a matrix organization supported by transversal departments focusing on value creation. As part of the program, we altered the business designations of certain employees from laboratory managers to general manager positions in order to reflect the current period's business activity. Subsequently, these changes in position designation resulted in a shift costs from cost of revenues. (ii) An increase of \$857 thousand in non-cash stock-based compensation mainly resulting from grants of options to consultants and key personnel during the first half of 2018. (iii) An increase in professional fees and business development, primarily attributable to costs incurred in the establishment of a global CDMO network and related expenses of implementing a Quality Management System of MaSTherCell to the new production facility in Korea under our joint-venture with CureCell Co. Ltd., our CDMO partner in Korea. (iv) An increase of \$405 thousand is mainly results to rental of additional space for new production area and offices in MasTherCell due to increase in CDMO operation.

Financial Expenses, net

	<b>Six Months Ended May 31,</b>	
	<b><u>2018</u></b>	<b><u>2017</u></b>
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	\$ (489)	\$ 64
Stock-based compensation related to shares to be issued to creditor	-	1,624
Interest expense on convertible loans and loans	2,659	686
Foreign exchange loss, net	(94)	194
Other expenses	18	10
<b>Total</b>	<b>\$ 2,094</b>	<b>\$ 2,578</b>



Financial expenses, net for the six months ended May 31, 2018, decreased by 19%, or \$484 thousand, compared to the same period in 2017. The decrease in financial expenses is mainly attributable to the following: (i) An increase of \$453 thousand in the fair value of the put option of Atvio (ii) A decrease of \$1,111 thousand of stock-based compensation expenses related to convertible loan agreement repaid in 2017 (iii) A decrease of \$520 thousand of stock-based compensation expenses related to restricted shares issued in accordance with the terms of the convertible loan agreement dated January 23, 2017. The decrease was partially offset by an increase of \$2,148 thousand in interest expenses on convertible loans due to recognition of the unrecognized discount related to a beneficial conversion feature as additional interest expenses upon conversion of convertible loans.

### Working Capital

	<b>May 31, 2018</b>		<b>November 30, 2017</b>
	(in thousands)		
Current assets	\$ 13,738	\$	7,295
Current liabilities	12,972		16,914
Working capital (deficiency)	\$ 766	\$	(9,619)

Current assets increased by \$6,443 thousand, which was primarily attributable to the following: (i) An increase in cash and cash equivalents due to proceeds from private placements of debt and equity securities during the first six-month period of 2018 (ii) An increase of \$566 thousand in grant receivables primarily attributable to an approval of a new grant in MaSTherCell from Intitule ICONE with a financial support of Euro 1 million (\$1.2 million) in program for development of iPS-derived Cortical Neurons (iii) An increase of other receivables in amount of 1.9 million Euro (\$2.3 million) related to SFPI investment paid to MaSTherCell on June 13, 2018 (iv) An increase of \$792 in put option derivative due to increase of \$453 thousand in its fair value and classification of \$339 from long-term assets into current assets.

Current liabilities decreased by \$3,942 thousand, which was primarily attributable to a decrease (i) of \$2.2 million in current maturities of convertible loans due to the conversion of the outstanding amounts on these loans into units of shares of common stock and warrants in the first half of 2018 and (ii) of \$657 thousand in employees and related payables relating primarily to a thirteen-month salary accrual that was paid in December 2017. (iii) A decrease of \$1,857 thousand in account payable and accrued expenses and other payables mainly as a results of new payment schedule process and payment of debts to services providers during the six months ended May 31, 2018. The decrease was partly offset by an increase of \$985 thousand in deferred income due upfront and paid by our new and old customers under new agreements signed in the CDMO segment.

### Liquidity and Financial Condition

	<b>Six Months Ended May 31,</b>	
	<b>2018</b>	<b>2017</b>
	(in thousands)	
Net loss	\$ (7,953)	\$ (8,616)
Net cash used in operating activities	(6,905)	(1,778)
Net cash used in investing activities	(2,979)	(902)
Net cash provided by financing activities	11,103	2,354
Increase (decrease) in cash and cash equivalents	\$ 1,219	\$ (326)

Since inception, we have funded our operations primarily through private placements and debt instruments and through revenues generated from the activities of MaSTherCell, our Belgian Subsidiary. As of May 31, 2018, we had positive working capital of \$0.8 million, including cash and cash equivalents and restricted cash of \$4.9 million.



Net cash used in operating activities was approximately \$6.9 million for the six months ended May 31, 2018, as compared with net cash used in operating activities of approximately \$1.8 million for the same period in 2017. We expanded our pre-clinical studies in the U.S., Israel and Belgium. The increase reflects management's focus on moving our trans-differentiation technology with first indication in Type 1 Diabetes to the next stage towards clinical trials. We also expended our global activity of the CDMO division while maintaining the same level of cash used in operating activities as a result of the increased revenues at our subsidiary MaSTherCell, thereby increasing gross profit and generating cash to pay our ongoing operating expenses. Additionally, major part of our services providers was paid during the six months ended May 31, 2018.

Net cash used in investing activities for the six months ended May 31, 2018 was approximately \$2.9 million, as compared with approximately \$0.9 million for the same period in 2017. Net cash used in investing activities was primarily for additions to fixed assets at our subsidiary, MaSTherCell, and investments in our joint venture with CureCell.

During the six months ended May 31, 2018, our financing activities consisted of (i) proceeds from private placements of our equity securities and exercise of equity-linked instruments in the net amount of approximately \$10.7 million through the issuance of 1,766,369 restricted shares of common stock and additional 1,638,292 three-year warrants exercisable at a per share exercise price of \$6.24 and (ii) proceeds of \$720 thousand from issuance of convertible loans from July 2016 to January 2018. Through May 31, 2018, these convertible loans were converted into units of the Company's securities.

#### *Liquidity & Capital Resources Outlook*

We believe that our business plan will provide sufficient liquidity to fund our operating needs for the next 12 months. However, there are factors that can impact our ability continue to fund our operating needs, including:

- Our ability to expand sales volume, which is highly dependent on implementing our growth strategy in MaSTherCell Global;

- Restrictions on our ability to continue receiving government funding for our CT business;

- Additional CDMO expansion into other regions that we may decide to undertake; and

- The need for us to continue to invest in operating activities to remain competitive or acquire other businesses and technologies and to complement our products, expand the breadth of our business, enhance our technical capabilities or otherwise offer growth opportunities.

If we cannot effectively manage these factors, we may need to raise additional capital before such date to fund our operating needs.

From December 1, 2017 to the date of this report on Form 10-Q, we raised an aggregate of \$19.5 million in private placements of our equity and equity-linked securities and convertible loans.

For the six months ended May 31, 2018, we had 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 2017 through May 2018, we received, through MaSTherCell, proceeds of approximately \$5.7 million in revenues and accounts receivable from customers and \$11.7 million from the private placement to accredited investors of our equity and equity-linked securities and convertible loans.

The equity investment in November 2017 by SFPI in MaSTherCell of €5 million (approximately \$5.9 million), which includes the conversion of €1 million in an outstanding loan by SFPI to MaSTherCell, will cover costs associated with an expansion of MaSTherCell's manufacturing and production capabilities.

We believe that the investment consummated in June 2018 by an affiliate of Great Point in our newly formed subsidiary, Masthercell Global, which included an initial gross subscription amount of \$11.8 million and, subject to

meeting certain specified financial targets over the course of 2018 and 2019, an additional \$13.2 million, should cover the costs associated with the current business plan of Masthercell Global.

From June 1 through July 15, 2018, we raised \$1 million from the institutional investor with whom we entered into definitive agreements in January 2017 for the private placement of units of our securities for aggregate subscription proceeds to us of \$16 million payable through August 2018. In addition, during this same period, we raised \$4.5 million from assignees of such investor who purchased units under the original subscription agreement then available. Following such investments, \$12.5 million of the committed subscription amount under such institutional investor's agreement has been remitted to the Company.

*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**

*Evaluation of Disclosure Controls and Procedures*

As of May 31, 2018, we conducted an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer regarding the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"). The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods and that such disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of May 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at reasonable assurance level due to a material weakness in internal control over financial reporting, as further described below.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As disclosed in Item 9A of our Annual Report on Form 10-K for the year ended November 30, 2017, our management concluded that our internal control over financial reporting was not effective at November 30, 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. 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) Improved but insufficient segregation of duties with control objectives; and
- (ii) Insufficient 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.

We are committed to maintaining a strong internal control environment and believe that our remediation efforts specified in Item 9A of our Annual Report on Form 10-K for the year ended November 30, 2017 represent significant improvements in our control environment. We expect that our remediation efforts will continue through 2018, although the material weakness will not be considered remediated until the applicable internal controls operate for a sufficient period, and management has concluded, through testing, that these controls are operating effectively.



*Changes in Internal Control Over Financial Reporting*

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes.

Except for the material weakness and associated remediation plan, during the quarter ended May 31, 2018, 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, 2017, as filed with the Securities & Exchange Commission on February 28, 2018, 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, 2018 without registration under the Securities Act:

During the three months ended May 31, 2018, we entered into definitive agreements with accredited and other qualified investors relating to a private placement of 1,272,496 units. Each unit is comprised of (i) one share of the Company's common stock and (ii) three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24, for aggregate proceeds to the Company of approximately \$7.9 million.

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

##### *Joint Venture Agreement with HekaBio K.K.*

On July 11, 2018, the Company and HekaBio K.K., a corporation organized under the laws of Japan ("HB") entered into a Joint Venture Agreement (the "JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products (hereinafter the "Products") in Japan. The parties intend to pursue the joint venture through a newly established Japanese company (hereinafter the "JV Company") which the Company by itself, or together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB. HB will fund, at its sole expense, all costs associated with obtaining the requisite regulatory approvals for conducting clinical trials, as well as performing all clinical and other testing required for market authorization of the Products in Japan.

Subject to obtaining the requisite approval needed to commence commercialization in Japan and H's compliance with its undertakings, the Company has agreed to grant to the JV Company, under a separate sub-license agreement (the "License Agreement"), an exclusive sub-license to the intellectual property underlying the Company's Products solely for commercialization of the Company's products in Japan. It is anticipated that the License Agreement will also contain, among other things, minimum sales requirements as well as other provisions common in licensing agreements for international biotech licensing agreements. In consideration thereof, the Company is to receive royalty payments in a minimum amount of 10 percent (10%) of the net sales generated by the JV Company and/or its sublicensees with respect to the Products, as well as and any additional payments provided for in the specific licensing agreements. As part of and as a condition to the License Agreement, the JV Company will grant the Company and its affiliates a license, on a non-exclusive, worldwide (other than Japan), sublicensable royalty free and fully-paid up basis, to make use of the project intellectual property for any and all lawful purposes (outside of Japan), including without limitation, for their respective worldwide operations without further charge to the Company or any of its affiliates.

Under the JVA, each party may invest up to \$10 million, which may take the form of a loan, if required, as determined by the steering committee. The terms of such investment, if any, will be on terms mutually agreeable to the parties, provided that the minimum pre-money valuation for any such investment shall not be less than \$10 million. Additionally, HB was granted an option to effect an equity investment in the Company in up to \$15 million within the next 12 months on mutually agreeable terms. If such investment is in fact consummated, the Company agreed to invest in the JV Company by way of a convertible loan an amount to HB's pro-rata participating interest in the JV Company, which initially will be at 51%. Such loan may then be converted by the Company into share capital of the JV company at an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million. Under the JVA, the Company can require HB to sell to the Company its participating (including equity) interest in the JV Company in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million.

##### *Joint Venture Agreement with Image Securities Ltd.*

On July 11, 2018, the Company and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Caman Islands ("India Partner") entered into a Joint Venture Agreement (the "India JVA") pursuant to which the parties will collaborate in the in the development and/or marketing, clinical development and commercialization of cell therapy products in India (the "Cell Therapy Products"). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products.

The India JVA becomes effective upon the consummation of an equity investment by the India partner in the Company of \$5 million within 150 days of the execution of the India JVA through the purchase of units of Orgenesis securities at a per unit purchase price payable into the Company of \$6.24, with each unit comprised of one share of Company common stock and three-year common stock purchase warrant for an additional share of common stock at a per share exercise price of \$6.24. Subject to the consummation of such equity investment in the Company, the Company is to advance to the JV Company a convertible loan in the amount of \$5 million. The loan is convertible into equity capital of the JV Company at an agreed upon formula for determining JV Company valuation. The investment in the Company by the India Partner would be the consummation of the previously disclosed private placement subscription agreement entered into in December 2016 between the Company and an affiliate of the India Partner pursuant to which the closing of such subscription agreement was by the terms thereof delayed until such time as terms comprising the India JV were mutually agreed to.

Under the India JVA, the India Partner agreed to invest in the JV \$10 million within 12 months of the incorporation of the JV Company. If for whatever reason such investment is not made by the India Partner within such time, then Orgenesis is authorized to convert its above-referenced loan into 50% of the equity capital of the JV Company on a fully diluted basis, provided that if the pre money valuation of the JV Company is then independently determined to be less than \$5 million, then such conversion to be effected in the basis of such valuation.

#### *Issuance of Previously Subscribed Units*

Between July 13, 2018 and July 16, 2018, we accepted subscription agreements from assignees of the institutional investor who committed in February 2017 to purchase an aggregate of \$16 million of units of our securities through August 2018, at a per unit purchase price of \$6.24, where each unit is comprised of one share of common stock and one common stock purchase warrant exercisable at a per share exercise price of \$6.24. These investors purchased in the aggregate, 692,308 shares of common stock and three year warrants for an additional 692,308 shares of our common stock at per share exercise price of \$6.24.

The issuance of shares of Orgenesis common stock to these investors will be made in reliance on one or more exemptions or exclusions from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), including Section 4(a)(2) of the Securities Act, Regulation D promulgated under the Securities Act, and Regulation S promulgated under the Securities Act, and the exemption from qualification under applicable state securities laws.

#### **ITEM 6. EXHIBITS**

<b>No.</b>	<b>Description</b>
<u>10.1*</u>	<u>Collaboration and License Agreement, dated as of June 19, 2018, between Orgenesis Inc. and Mircod Limited</u>
<b>(31)</b>	<b>Rule 13a-14(a)/15d-14(a) Certification</b>
<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>
<b>(32)</b>	<b>Section 1350 Certification</b>
<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>
<b>(101)*</b>	<b>Interactive Data Files</b>
<u>101.INS</u>	<u>XBRL Instance Document</u>
<u>101.SCH</u>	<u>XBRL Taxonomy Extension Schema Document</u>
<u>101.CAL</u>	<u>XBRL Taxonomy Extension Calculation Linkbase Document</u>
<u>101.DEF</u>	<u>XBRL Taxonomy Extension Definition Linkbase Document</u>
<u>101.LAB</u>	<u>XBRL Taxonomy Extension Label Linkbase Document</u>
<u>101.PRE</u>	<u>XBRL Taxonomy Extension Presentation Linkbase Document</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 16, 2018

*/s/ Neil Reithinger*

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: July 16, 2018