

Orgenesis Inc.
Form 10-Q
April 16, 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 **February 28, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
(Do not check if a smaller reporting company)		Emerging Growth Company	<input type="checkbox"/>

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 April 16, 2018, there were 10,897,053 shares of registrant's common stock outstanding.

ORGENESIS INC.
FORM 10-Q
FOR THE THREE MONTHS ENDED FEBRUARY 28, 2018 AND 2017

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I - FINANCIAL INFORMATION</u>	4
<u>ITEM 1. Financial Statements (unaudited)</u>	4
<u>Condensed Consolidated Balance Sheets as of February 28, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended February 28, 2018 and 2017</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended February 28, 2018 and 2017</u>	8
<u>Notes to Condensed Consolidated Financial Statements</u>	9
<u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>ITEM 3. Quantitative and Qualitative Disclosures about Market Risk</u>	26
<u>ITEM 4. Controls and Procedures</u>	26
<u>PART II - OTHER INFORMATION</u>	28
<u>ITEM 1. Legal Proceedings</u>	28
<u>ITEM 1A. Risk Factors</u>	28
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
<u>ITEM 3. Defaults Upon Senior Securities</u>	29
<u>ITEM 4. Mine Safety Disclosures</u>	29
<u>ITEM 5. Other Information</u>	29
<u>ITEM 6. Exhibits</u>	29
<u>SIGNATURES</u>	31

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

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

	February 28,	November
	2018	30,
		2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,225	\$ 3,519
Accounts receivable, net	1,202	1,336
Prepaid expenses and other receivables	909	841
Receivables from related party	615	691
Grants receivable	737	183
Inventory	881	725
Total current assets	8,569	7,295
NON-CURRENT ASSETS:		
Call option derivative	339	339
Investments in associates, net	1,712	1,321
Property and equipment, net	5,617	5,104
Intangible assets, net	15,076	15,051
Goodwill	11,013	10,684
Other assets	85	78
Total non-current assets	33,842	32,577
TOTAL ASSETS	\$ 42,411	\$ 39,872

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)

	February 28,	November
	2018	30,
		2017
Liabilities and equity		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,838	\$ 3,914
Accrued expenses and other payables	1,452	1,435
Employees and related payables	2,343	2,961
Related parties	-	116
Advance payments on account of grant	1,703	1,719
Short-term loans and current maturities of long term loans	391	378
Deferred income	4,870	3,611
Current maturities of convertible loans	1,567	2,780
TOTAL CURRENT LIABILITIES	16,164	16,914
LONG-TERM LIABILITIES:		
Loans payable	2,085	2,118
Convertible loans	482	2,415
Retirement benefits obligation	6	6
Deferred taxes	312	690
TOTAL LONG-TERM LIABILITIES	2,885	5,229
TOTAL LIABILITIES	19,049	22,143
COMMITMENTS		
REDEEMABLE NON-CONTROLLING INTEREST	3,884	3,606
EQUITY:		
Common stock of \$0.0001 par value, 145,833,334 shares authorized, 10,273,301 shares issued and outstanding as of February 28, 2018	1	1
Additional paid-in capital	61,079	55,334
Receipts on account of shares to be allotted	5,997	1,483
Accumulated other comprehensive income	2,132	1,425
Accumulated deficit	(49,731)	(44,120)
TOTAL EQUITY	19,478	14,123
TOTAL LIABILITIES AND EQUITY	\$ 42,411	\$ 39,872

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

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

	Three Months Ended	
	February 28,	February 28,
	2018	2017
REVENUES	\$ 2,636	\$ 1,852
COST OF REVENUES	1,644	1,905
GROSS PROFIT (LOSS)	992	(53)
RESEARCH AND DEVELOPMENT EXPENSES, net	766	741
AMORTIZATION OF INTANGIBLE ASSETS	436	381
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	3,344	2,271
OTHER INCOME	316	-
OPERATING LOSS	3,238	3,446
FINANCIAL EXPENSES, net	2,681	2,075
SHARE IN NET INCOME (LOSSES) OF ASSOCIATED COMPANY	46	(89)
LOSS BEFORE INCOME TAXES	5,873	5,610
TAX (INCOME) EXPENSES	(396)	516
NET LOSS	\$ 5,477	\$ 6,126
NET INCOME ATTRIBUTABLE TO REDEEMABLE NON-CONTROLLING INTERESTS	134	-
NET LOSS ATTRIBUTABLE TO THE COMPANY	5,611	6,126
LOSS PER SHARE:		
Basic	\$ 0.52	\$ 0.66
Diluted	\$ 0.52	\$ 0.66
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:		
Basic	10,775,877	9,285,429
Diluted	10,775,877	9,285,429
OTHER COMPREHENSIVE LOSS:		
Net Loss	\$ 5,611	\$ 6,126
Translation adjustments	(707)	95
TOTAL COMPREHENSIVE LOSS	\$ 4,904	\$ 6,221

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

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

	Common Stock		Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Number	Par Value					
Balance at December 1, 2016	9,508,068	\$ 1	\$ 45,454	\$ -	\$ (1,205)	\$ (31,753)	\$ 12,497
Changes during the three months ended February 28, 2017:							
Stock-based compensation to employees and directors			386				386
Stock-based compensation to service providers			418				418
Issuance of warrants and beneficial conversion feature of convertible loans			2,154				2,154
Receipts on account of shares and warrants to be allotted			499	774			1,273
Comprehensive loss for the period					(95)	(6,126)	(6,221)
Balance at February 28, 2017	9,508,068	\$ 1	\$ 48,911	\$ 774	\$ (1,300)	\$ (37,879)	\$ 10,507
Balance at December 1, 2017	9,872,659	\$ 1	\$ 55,334	\$ 1,483	\$ 1,425	\$ (44,120)	\$ 14,123
Changes during the three months ended February 28, 2018:							
Stock-based compensation to employees			386				386

and directors							
Stock-based compensation to service providers			704				704
Beneficial conversion feature of convertible loans and Warrants issued			324				324
Conversion of convertible loans			1,720	4,148			5,868
Issuance of shares and receipts on account of shares and warrants to be allotted	400,642	*	2,611	366			2,977
Comprehensive loss for the period					707	(5,611)	(4,904)
Balance at February 28, 2018	10,273,301 \$	1	61,079 \$	5,997 \$	2,132 \$	(49,731)	\$ 19,478

*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)

	Three months ended	
	February 28, 2018	February 28, 2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (5,477)	\$ (6,126)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,090	679
Share in (income) losses of associated company	(46)	89
Depreciation and amortization expenses	637	592
Change in fair value of embedded derivatives	117	1,065
Change in fair value of convertible bonds	-	14
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	2,447	323
Changes in operating assets and liabilities:		
Increase (decrease) in accounts receivable	175	(308)
Decrease in inventory	(134)	(215)
Decrease in related parties, net	(18)	-
Decrease in prepaid expenses and other accounts receivable	(567)	(541)
Decrease in accounts payable	(263)	(662)
Increase (decrease) in accrued expenses and other payables	(27)	754
Decrease in employee and related payables	(668)	(89)
Increase in deferred income	1,140	1,452
Increase (decrease) in advance payments and receivables on account of grant, net	(101)	2,855
Increase (decrease) in deferred taxes	(396)	517
Net cash provided by (used in) operating activities	(2,091)	399
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(553)	(253)
Disposals of property and equipment	-	19
Investments in associate	(345)	(180)
Net cash used in investing activities	(898)	(414)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Short-term line of credit	-	(21)
Proceeds from issuance of shares and warrants (net of transaction costs)	3,082	1,323
Proceeds from issuance of convertible loans (net of transaction costs)	720	3,812
Repayment of convertible loans and convertible bonds	(177)	(1,736)
Repayment of short and long-term debt	(85)	(342)
Net cash provided by financing activities	3,540	3,036
NET CHANGE IN CASH AND CASH EQUIVALENTS	551	3,021
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	155	(40)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,519	891
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 4,225	\$ 3,872

SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES

Conversion of loans and bonds (including accrued interest) to common stock and warrants	\$	5,868	
---	----	-------	--

SUPPLEMENTAL INFORMATION ON INTEREST PAID IN CASH		\$	155
--	--	----	-----

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

ORGENESIS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the Three Months Ended February 28, 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), 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

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 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, our common stock began to be quoted and traded on the The Nasdaq Capital Market under the symbol "ORGS."

a. Liquidity

As of February 28, 2018, the Company accumulated losses of approximately \$49.7 million. Although we are now showing positive revenue and gross profit trends in our CDMO division, we expect to incur further losses in the CT division.

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. From December 1,

2017 through February 28, 2018, the Company received, through MaSTherCell, proceeds of approximately \$2.6 million in revenues and accounts receivable from customers and \$3.8 million from the private placement to accredited investors of the Company's equity and equity linked securities and convertible loans, out of which \$0.5 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 March 1, 2018 through April 15, 2018, the Company raised \$6.7 million from the proceeds of a private placement to certain accredited investors of equity and equity-linked securities and exercise of warrants by an investor and received, through MaSTherCell, proceeds of approximately \$1.1 million in accounts receivable from its customers.

Basis of Presentation

These unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. GAAP, pursuant to the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial statements. Accordingly, they do not contain all information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, the unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of February 28, 2018, and the consolidated statements of comprehensive loss for the three months ended February 28, 2018 and 2017, and the changes in equity and cash flows for the three-month period ended February 28, 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.

Recently Issued Accounting Pronouncements- adopted by the Company

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

	February 28, 2017		
	As reported	Impact	As revised
	Previously	of	
		adoption	
		In thousands	
Additional paid-in capital	\$ 45,062	\$ 3,838	\$ 48,900
Accumulated deficit	\$ (38,833)	\$ 954	\$ (37,879)
Total equity	\$ 5,715	\$ 4,792	\$ 10,507

Statement of Comprehensive loss**Three months ended February 28, 2017**

	As reported Previously	Impact of adoption In thousands	As revised
Financial expenses, net	\$ 4,948	\$ (2,873)	\$ 2,075
Loss before income taxes	\$ 8,483	\$ (2,873)	\$ 5,610
Net loss	\$ 8,999	\$ (2,873)	\$ 6,126

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.

Segment data for the three months ended February 28, 2018 is as follows:

	CDMO	CTB	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	\$ 3,181	\$ -	\$ (545)	\$ 2,636*
Cost of revenues	(1,725)	-	240	(1,485)
Gross profit (loss)	1,456	-	(305)	1,151
Research and development expenses, net	-	(887)	305	(582)
Operating expenses	(1,080)	(1,356)	-	(2,436)
Other income	316	-	-	316
Operating profit (loss)	692	(2,243)	-	(1,551)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(595)	(2)		

Segment performance	97	(2,245)
----------------------------	----	---------

11

Reconciliation of segment performance to loss for the three months ended February 28, 2018:

	Three months ended February 28, 2018 in thousands
Segment performance	(2,148)
Stock-based compensation	(1,090)
Financial expenses, net	(2,681)
Share in losses of associated companies	46
Loss before income tax	\$ (5,873)

* The Company's revenues consist of: \$2,026 from services and \$610 from goods sold.

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

	CDMO	CTB	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	\$ 2,144	\$	\$ (292)	\$ 1,852*
Cost of revenues	(1,861)		167	(1,694)
Gross profit (loss)	283		(125)	158
Research and development expenses, net		(601)	125	(476)
Operating expenses	1,712	(3,590)		(1,878)
Operating profit (loss)	1,995	(4,191)	-	(2,196)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(592)			
Segment performance	1,403	(4,191)		

* The Company's revenues consist of: \$1,384 from services and \$468 from goods sold.

Reconciliation of segment performance to loss for the three months ended February 28, 2017:

	Three months ended February 28, 2017 in thousands
Segment performance	(2,788)
Stock-based compensation	(679)
Financial expenses, net	(2,054)
Share in losses of associated companies	(89)
Loss before income tax	\$ (5,610)

Geographic, Product and Customer Information

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

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

	Three Months Ended	
	February 28, 2018	February 28, 2017
	(in thousands)	
Customer A	\$ 894	\$ 1,189
Customer B	957	-
Customer C	971	292
Customer D	\$ -	\$ 255

NOTE 4 CONVERTIBLE LOAN AGREEMENTS

(a) During the three months ended February 28, 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 February 28, 2018 were approximately \$89 thousand, out of which \$31 thousand are stock-based compensation due to issuance of warrants (See also Note 7(c)). Through February 28, 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 three months ended February 28, 2018, holders of approximately \$6.8 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 1,087,960 shares of Common Stock and three-year warrants for an additional 1,087,960 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	\$	2,641
Shares component		4,147
Total	\$	6,788

As of February 28, 2018, these shares have not been issued therefore the Company recorded the Shares component in Receipts on Account of Shares to be Allotted.

Additionally, since these loans include beneficial conversion features ("BCF"), the Company recognized the unamortized BCF as of the conversion date as interest expenses.

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 "Icône" 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. In December 2017, 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 August 2018. Each periodic payment of subscription proceeds will be evidenced by the Company's standard securities subscription agreement.

During the three months ended February 28, 2018 the investor remitted to the Company \$0.5 million, in consideration of which, the investor is entitled to 80,128 shares of the Company's Common Stock and three-year warrants to purchase up to an additional 80,128 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:

	Proceed Allocation	
	(in thousands)	
Warrants component	\$	187
Shares component		313
Total	\$	500

As of February 28, 2018, all of these shares have not been issued and therefore the Company has recorded \$294 thousand in receipts on account of shares to be allotted in the statement of equity. In connection therewith, 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 February 28, 2018 the Company has received a total of \$5,000 thousand out of the committed \$16 million subscription proceeds. See also note 10(a).

2) During the three months ended February 28, 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of 413,736 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 \$2.6 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:

	Proceed Allocation	
	(in thousands)	
Warrants component	\$	972
Shares component		1,609
Total	\$	2,581

As of February 28, 2018, these shares have not been issued therefore the Company recorded \$1.6 million net of transaction costs in Receipts on Account of Shares to be Allotted.

In connection with \$1 million out of these private placements, the Company undertook to pay a fee of 8%, resulting in the payment of \$80 thousand and the issuance of 9,078 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 warrants as of the date of grant was \$45 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 three months ended February 28, 2018:

	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Employee	50,000	\$4.42	Quarterly over a period of 1 year	\$163	10 years

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

	Three Months Ended February 28, 2018
Value of one common share	\$4.42
Dividend yield	0%
Expected stock price volatility	97%
Risk free interest rate	2.11%
Expected term (years)	5

b. Options Granted to non-employees

Below is a table summarizing all the options granted to consultants and service providers during the three months ended February 28, 2018:

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

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

	Three Months Ended February 28, 2018
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)	10

c. Shares and Warrants Granted to non-employees

1) During the three months ended February 28, 2018, the Company granted to several consultants 17,622 warrants each exercisable at \$6.24 to \$10.03 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 \$76 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 February 28, 2018, 30,000 shares are vested. The fair value of the shares was \$790 thousand using the fair value of the shares at February 28, 2018, out of which \$229 thousand was recognized during the three months ended February 28, 2018. The unrecognized costs will be utilized on a monthly basis until May 2019.

3) 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 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 February 28, 2018, 30,000 shares vested. The fair value of the shares was \$751 thousand using the fair value of the shares at February 28, 2018, out of which \$229 thousand was recognized during the three months ended February 28, 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 eligible to \$20 thousand a 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) 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.

NOTE 8 LOSS PER SHARE

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

	Three Months Ended	
	February 28, 2018	February 28, 2017
	(in thousands, except per share data)	
Basic:		
Loss for the period	\$ (5,611)	\$ (6,126)
Weighted average number of common shares outstanding	10,775,877	9,285,429
Loss per common share	\$ 0.52	\$ 0.66
Diluted:		
Earnings (loss) for the period	(5,611)	(6,126)
Weighted average number of shares used in the computation of basic and diluted loss per share	10,775,877	9,285,429
Loss per common share	\$ 0.52	\$ 0.66

Diluted loss per share does not include 4,981,019 shares underlying outstanding options and warrants and 1,176,286 shares upon conversion of convertible notes for the three months ended February 28, 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 months ended February 28, 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 February 28, 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):

	February 28, 2018	November 30, 2017
	<u>Level 3</u>	<u>Level 3</u>
Embedded derivatives convertible loans*(1)	\$ 154	\$ 37
Call/Put option derivatives	\$ (339)	\$ (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 following table presents the assumptions that were used for the models as of February 28, 2018:

	Embedded Derivative
Fair value of shares of Common Stock	\$ 7.9
Expected volatility	128%
Risk free interest rate	1.58%
Expected term (years)	0.17
Expected dividend yield	0%

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 three months ended February 28, 2018:

	<u>Embedded Derivatives</u>	<u>Put Option Derivative</u>
Balance at beginning of the year	\$ 37	\$ (339)
Repayment	(14)	-
Changes in fair value during the period	131	-
Balance at end of the year	\$ 154	\$ (339)

(*) There were no transfers to Level 3 during the three months ended February 28, 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:

	<u>Embedded Derivatives</u>		<u>Convertible Bonds</u>		<u>Put Option Derivative</u>
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

- a. In March 2018, the institutional investor referred to in Note 6(1), remitted to the Company \$2 million in subscription proceeds entitling such investor to 320,513 shares of Common Stock and three-year warrants for an additional 320,513 shares. The Company has received as of April 16, 2018 a total of \$7 million out of the committed \$16 million subscription proceeds.
- b. In March 2018, a holder of 128,077 warrants issued in November 2015 exercised his 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 \$0.8 million.
- c. During March and April 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of (i) 622,387 units. Each unit is 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, for aggregate proceeds to the Company of \$3.9 million.
- d. In March 2018, holders of \$741 thousand in principal and accrued interest of convertible loans with maturity dates between July 2018 and January 2020 converted these outstanding amounts, in accordance with the terms specified in such notes, 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 Company will issue 118,736 shares of Common Stock and three-year warrants for an additional 118,736 shares of common stock at a per share exercise price of \$6.24.
- e. 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 \$381 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.

f. In March 2018, the Company entered into a definitive agreement with an accredited investor relating to a private placement of (i) 160,256 units of the Company's securities. Each unit is 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, for aggregate proceeds to the Company of \$1 million. The subscription proceeds were remitted in full through April 16, 2018.

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 other terms of these terms and similar 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 History

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

On October 11, 2011, we incorporated Orgenesis Ltd. as our wholly-owned subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license from Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (THM), a private company duly incorporated under the laws of Israel, patents and know-how related to the development of AIP (Autologous Insulin Producing) cells. Through Orgenesis Ltd., we became engaged in our CT business.

On November 6, 2014, we entered into an agreement with the shareholders of MaSTherCell S.A. to acquire MaSTherCell S.A. On March 2, 2015, we closed on the acquisition of MaSTherCell whereby it became a wholly-owned subsidiary of Orgenesis. Through MaSTherCell, we became engaged as a contract development and manufacturing organization (CDMO). Currently, the Company s revenues are generated through MaSTherCell.

Corporate Overview

We are 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 and our CDMO joint venture partners 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 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, and our international joint ventures, 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 and transdifferentiating them into pancreatic beta cell-like Autologous Insulin Producing (AIP) cells for patients with Type 1 Diabetes. Moreover, those cells were 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. 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.

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 \$1.9 million for the three months ended February 28, 2017 to \$2.6 million for the three months ended February 28, 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 Developments

Following the SFPI investment in MaSTherCell in November 2017, MaSTherCell decided to expand its facilities with a dedicated, late-stage clinical and commercial unit, anticipated to be operational by the end of 2018. This new asset will provide the most up-to-date commercial capabilities in Europe with five state-of-the-art advanced therapy manufacturing units and extended Good Manufacturing Practice (GMP)-accredited quality control (QC) laboratories.

Additionally, on January 22, 2018, we announced a strategic organizational regrouping of our CDMO global manufacturing services offerings. The planned CDMO regrouping will utilize the global MaSTherCell brand, except for Atvio Biotech Ltd. (Atvio), for its unique technology and innovation activity located in Israel and serving the global cell and gene therapy markets. The primary purpose of the strategic regrouping is to create a more efficient CDMO corporate organization that can optimally utilize resources from the parent, Orgenesis Inc., and more efficiently broaden, streamline and harmonize the CDMO service offerings on a global basis utilizing the quality and standards of our flagship Belgian-based subsidiary, MaSTherCell S.A.

On March 13, 2018, our common stock began to be quoted and traded on the The Nasdaq Capital Market under the symbol "ORGS."

*Results of Operations*Comparison of the Three Months Ended February 28, 2018 to the Three Months Ended February 28, 2017

Our financial results for the three months ended February 28, 2018 are summarized as follows in comparison to the three months ended February 28, 2017:

	<u>Three Months Ended February</u>	
	<u>28,</u>	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Revenues	\$ 2,636	\$ 1,852
Cost of sales	1,644	1,905
Research and development expenses, net	766	741
Amortization of intangible assets	436	381
Selling, general and administrative expenses	3,344	2,271
Share in net income (losses) of associated company	46	(89)
Financial expense, net	2,681	2,075
Other income	316	-
Loss before income taxes	\$ 5,873	\$ 5,610

Revenues

	<u>Three Months Ended February</u>	
	<u>28,</u>	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Services	\$ 2,026	\$ 1,384
Goods	610	468
Total	\$ 2,636	\$ 1,852

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 February 28, 2018 were \$2,636 thousand, as compared to \$1,852 thousand for the corresponding period in 2017, representing an increase of 42%, compared to the same period last year. The increase in revenues for the three months ended February 28, 2018 compared to the corresponding period in 2017 is attributable to an increase of \$1.1 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

	<u>Three Months Ended February</u>	
	<u>28,</u>	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 767	\$ 1,034
Professional fees and consulting services	-	87
Raw materials	651	518
Depreciation and amortization expenses, net	159	210
Other expenses	67	56
	\$ 1,644	1,905

Cost of revenues for the three months ended February 28, 2018 were \$1,644 thousand as compared to \$1,905 thousand, during the same period in 2017, representing a decrease of 14%. The decrease in salaries and related expenses for the three months ended in February 2018 as compared to the corresponding period in 2017 is primarily 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.

Research and Development Expenses

	<u>Three Months Ended February</u>	
	<u>28,</u>	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 286	\$ 293
Stock-based compensation	182	267
Professional fees and consulting services	187	44

Edgar Filing: Orgenesis Inc. - Form 10-Q

Lab expenses	115	174
Other research and development expenses	114	41
Less grant	(118)	(78)
	\$ 766	\$ 741

23

Research and development expenses for the three months ended February 28, 2018 were \$766 thousand, as compared to \$741 thousand for the same period in 2017, representing an increase of 3%. The increase in research and development expenses in the three-month period in 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 transdifferentiating technology with first indication in Diabetes Type I to the next the stage towards clinical trials.

Selling, General and Administrative Expenses

	<u>Three Months Ended February</u>	
	<u>28,</u>	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 803	\$ 224
Stock-based compensation	908	393
Accounting and legal fees	328	401
Professional fees	764	394
Rent and related expenses	281	244
Business development	308	124
Expenses related to a joint venture	-	258
Other general and administrative expenses	(48)	233
Total	\$ 3,344	\$ 2,271

Selling, general and administrative expenses for the three months ended February 28, 2018 were \$3,344 thousand as compared to \$2,271 thousand for the same period in 2017, representing an increase of 47%. The increase in selling, general and administrative expenses in the three-month period in 2018 is primarily attributable to the following: (i) An increase of \$579 thousand in salaries compared to the same period in 2017 as a result of 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 of costs into general and administration expenses. (ii) An increase of \$515 thousand in non-cash stock-based compensation resulting from grants of options to consultants and key personnel during the first quarter of 2018. (iii) An increase in professional fees, 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.

Financial Expenses, net

	<u>Three Months Ended February</u>	
	<u>28,</u>	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Increase in fair value financial liabilities and assets measured at fair value	\$ 117	\$ 1,069
Stock-based compensation related to warrants granted to bondholder	-	20
Stock-based compensation related to shares to be issued to creditor	-	520
Interest expense on convertible loans and loans	2,481	399

Edgar Filing: Orgenesis Inc. - Form 10-Q

Foreign exchange loss, net		72		63	
Other expenses		11		4	
Total		\$	2,681	\$	2,075

24

Financial expenses, net for the three months ended February 28, 2018, increase by 29%, or \$606 thousand, compared to the same period in 2017. The increase in financial expenses is mainly attributable to an increase of \$2,082 thousand in interest expenses on convertible loans mainly due to recognition of the unrecognized discount related to BCF as additional interest expenses upon conversion of convertible loans. The increase was partially offset by a decrease of \$952 thousand in the change of the fair value of convertible notes converted in 2017 and \$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.

Working Capital Deficiency

	February 28, 2018	November 30, 2017
	(in thousands)	
Current assets	\$ 8,569	\$ 7,295
Current liabilities	16,164	16,914
Working capital deficiency	\$ (7,595)	\$ (9,619)

Current assets increased by \$1,274 thousand, which was primarily attributable to an increase in cash and cash equivalents due to proceeds from private placements of debt and equity securities during the first quarter of 2018 and increase of \$554 thousand in grants receivables which was mainly attributed 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.

Current liabilities decreased by \$750 thousand, which was primarily attributable to a decrease (i) of \$1.2 million in current maturities of convertible loans due to the conversion of convertible loans into Common Stock in the first quarter of 2018 and (ii) of \$618 thousand in employees and related payables relating primarily to a thirteen month salary accrual that was paid in December 2017. The decrease was partly offset by an increase of \$1,259 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

	Three Months Ended February 28,	
	2018	2017
	(in thousands)	
Net loss	\$ (5,477)	\$ (6,126)
Net cash provided by (used in) operating activities	(2,091)	399
Net cash used in investing activities	(898)	(414)
Net cash provided by financing activities	3,540	3,036
Increase in cash and cash equivalents	\$ 551	\$ 3,021

Since inception, we have funded our operations primarily through the sale of our securities and, more recently, through revenue generated from the activities of MaSTherCell, our Belgian Subsidiary. As of February 28, 2018, we had negative working capital of \$7.6 million, including cash and cash equivalents of \$4.3 million.

Net cash used in operating activities was approximately \$2.1 million for the three months ended February 28, 2018, as compared with net cash provided by operating activities of approximately \$0.4 million for the same period in 2017. We successfully expanded 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.

Net cash used in investing activities for the three months ended February 28, 2018 was approximately \$0.9 million as compared with approximately \$0.4 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 three months ended February 28, 2018, our financing activities consisted of (i) proceeds from private placements of our convertible debt and equity securities in amount of approximately \$3.1 million through the issuance of 483,864 restricted shares of common stock and three-year common stock purchase warrants for an additional 483,864 shares of our common stock 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 February 28, 2018, \$650 thousand in principal amount out of 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;

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 \$10.5 million in private placements of our equity and equity-linked securities and convertible loans.

For the three months ended November 30, 2017, 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 February 2018, we received, through MaSTherCell, proceeds of approximately \$2.6 million in revenues and accounts receivable from customers and \$3.8 million from the private placement to accredited investors of our equity and equity linked securities and convertible loans, out of which \$0.5 million is 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. The subscription proceeds are payable on a periodic basis through August 2018.

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.

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

26

As of February 28, 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 February 28, 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 will 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 February 28, 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 February 28, 2018 without registration under the Securities Act:

a. During the three months ended February 28, 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. 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 February 28, 2018 were approximately \$89 thousand, out of which \$31 thousand are stock-based compensation due to issuance of warrants (See also Note 7(c)). Through February 28, 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 three months ended February 28, 2018, holders of approximately \$6.8 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 1,087,960 shares of Common Stock and three-year warrants for an additional 1,087,960 shares of common stock at a per share exercise price of \$6.24.

c. 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 August 2018. Each periodic payment of subscription proceeds will be evidenced by the Company's standard securities subscription agreement.

During the three months ended February 28, 2018 the investor remitted to the Company \$0.5 million, in consideration of which, the investor is entitled to 80,128 shares of the Company's Common Stock and three-year warrants to purchase up to an additional 80,128 shares of the Company's Common Stock at a per share exercise price of \$6.24.

d. During the three months ended February 28, 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of 413,736 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 \$2.6 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

None.

ITEM 6. EXHIBITS

Exhibits required by Item 601 of Regulation S-K

No.	Description
(31)	Rule 13a-14(a)/15d-14(a) Certification
31.1*	<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>
--------------	---

No.	Description
(32)	Section 1350 Certification
<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>
(101)*	Interactive Data Files
<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: April 16, 2018

/s/ Neil Reithinger

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting
Officer)

Date: April 16, 2018