Orgenesis Inc.
Form 10-Q
July 15, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended **May 31, 2016**

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	**98-0583166**
(State or other jurisdiction of incorporation or organization)	(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 [X] 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 [X] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ]	Smaller reporting company	[X]

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes [ ] No [X].

As of July 14, 2016, there were 110,732,129 shares of registrant s common stock outstanding.

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

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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, 2016	November 30, 2015
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 474	$ 4,168
Accounts receivable	1,712	1,173
Prepaid expenses and other receivables	1,117	1,118
Grants receivable	1,431	1,446
Inventory	413	301
Total current assets	5,147	8,206
NON CURRENT ASSETS:		
Property and equipment, net	4,787	4,296
Restricted cash	5	5
Intangible assets, net	16,683	16,653
Goodwill	10,059	9,535
Other assets	65	53
Total non current assets	31,599	30,542
TOTAL ASSETS	36,746	38,748
Liabilities and equity (net of capital deficiency)		
CURRENT LIABILITIES:		
Accounts payable	4,209	3,475
Accrued expenses	975	816
Employee and related payables	1,947	1,348
Related parties	42	42
Advance payments on account of grant	136	307
Short-term loans and current maturities of long term loans	1,249	2,829
Deferred income	1,617	1,216
Convertible loans	2,199	3,022
Convertible bonds	1,859	1,888
Price protection derivative	175	1,533
TOTAL CURRENT LIABILITIES	14,408	16,476
LONG-TERM LIABILITIES:		
Loans payable	2,514	2,540
Warrants	1,730	1,382
Retirement benefits obligation	5	5
Deferred taxes	2,562	3,327
TOTAL LONG-TERM LIABILITIES	6,811	7,254
TOTAL LIABILITIES	21,219	23,730
COMMITMENTS		
REDEEMABLE COMMON STOCK		21,458
EQUITY (CAPITAL DEFICIENCY):		

Common stock	11	6
Additional paid-in capital	39,402	14,229
Receipts on account of shares to be allotted	623	1,251
Accumulated other comprehensive loss	(202)	(1,286)
Accumulated deficit	(24,307)	(20,640)
TOTAL EQUITY (CAPITAL DEFICIENCY)	15,527	(6,440)
TOTAL LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)	$ 36,746	$ 38,748

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, 2016	May 31, 2015	May 31, 2016	May 31, 2015
REVENUES	$ 1,132	$ 820	$ 2,652	$ 820
COST OF REVENUES	1,964	973	3,444	973
GROSS PROFIT (LOSS)	(832)	(153)	(792)	(153)
RESEARCH AND DEVELOPMENT EXPENSES, net	486	290	887	465
AMORTIZATION OF INTANGIBLE ASSETS	482	393	810	393
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	2,173	1,200	3,339	1,858
OPERATING LOSS	3,973	2,036	5,828	2,869
FINANCIAL EXPENSES (INCOME), net	553	(924)	(1,219)	(967)
LOSS BEFORE INCOME TAXES	4,526	1,112	4,609	1,902
INCOME TAX BENEFIT	(634)	(15)	(942)	(15)
NET LOSS	$ 3,892	$ 1,097	$ 3,667	1,887
LOSS PER SHARE:				
Basic	$ 0.04	$ 0.02	$ 0.03	$ 0.03
Diluted	$ 0.04	$ 0.03	$ 0.04	$ 0.05
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE:				
Basic	107,583,871	55,785,407	106,693,858	55,760,675
Diluted	107,583,871	62,795,145	106,693,858	60,159,549
OTHER COMPREHENSIVE LOSS:				
Net loss	$ 3,892	$ 1,097	$ 3,667	1,887
Translation adjustments	(580)	458	(1,084)	560
TOTAL COMPREHENSIVE LOSS	$ 3,312	$ 1,555	2,583	2,447

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

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

	Common Stock		Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Number	Par Value					
Balance at December 1, 2014	55,970,565	$ 6	$ 13,152	$ 60	$ (18)	$ (16,179)	$ (2,979)
Changes during the six months ended May 31, 2015:							
Stock-based compensation to employees and directors			321				321
Stock-based compensation to service providers			57				57
Comprehensive loss for the period					(560)	(1,887)	(2,447)
Balance at May 31, 2015	55,970,565	$ 6	$ 13,530	$ 60	$ (578)	$ (18,066)	$ (5,048)
Balance at December 1, 2015	55,835,950	$ 6	$ 14,229	$ 1,251	$ (1,286)	$ (20,640)	$ (6,440)
Changes during the six months ended May 31, 2016:							
Stock-based compensation to employees and directors			865				865
Stock-based compensation to service providers			792				792
Warrants and shares to be issued due to extinguishment			114				114

of a convertible loan							
Issuances of shares from investments and conversion of convertible loans	10,502,132	1	1,948	(1,251)			698
Reclassification of redeemable common stock	42,401,724	4	21,454				21,458
Receipts on account of shares to be allotted				623			623
Comprehensive loss for the period					1,084	(3,667)	(2,583)
Balance at May 31, 2016	108,739,806	$ 11	$ 39,402	$ 623	$ (202)	$ (24,307)	$ 15,527

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,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,667)	$ (1,887)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,657	378
Loss from extinguishment of a convertible loan	229	-
Depreciation and amortization expenses	1,335	625
Change in fair value of warrants and embedded derivatives	(1,721)	(951)
Change in fair value of convertible bonds	(132)	(379)
Interest expense accrued on loans and convertible loans	56	224
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	(471)	210
Inccrease in inventory	(94)	(33)
Increase in other assets	(9)	-
Decrease (increase) in prepaid expenses and other accounts receivable	34	(789)
Increase in accounts payable	587	311
Increase in accrued expenses	150	101
Increase in employee and related payables	579	91
Increase in deferred income	332	601
Increase (decrease) in advance payments and receivables on account of grant	(87)	496
Decrease in deferred taxes	(944)	(15)
Net cash used in operating activities	(2,166)	(1,017)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(708)	(244)
Restricted cash	-	(5)
Acquisition of MaSTherCell, net of cash acquired	-	305
Net cash provided by (used in) investing activities	(708)	56
CASH FLOWS FROM FINANCING ACTIVITIES:		
Short-term line of credit	-	(14)
Proceeds from issuance of warrants into shares and warrants	975	-
Proceeds from issuance of loans payable	-	317
Repayment of short and long-term debt	(1,828)	(67)
Net cash provided by (used in) financing activities	(853)	236
NET CHANGE IN CASH AND CASH EQUIVALENTS	(3,727)	(725)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	33	(404)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,168	1,314
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 474	$ 185
SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES		

Conversion of loans (including accrued interest) to common stock and warrants	$	1,028
Reclassification of redeemable common stock to equity	$	21,458
SUPPLEMENTAL INFORMATION ON INTEREST PAID IN CASH	$	143

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, 2016 and 2015

NOTE 1 - GENERAL AND BASIS OF PRESENTATION

Orgenesis Inc. (the Company) was incorporated in the State of Nevada on June 5, 2008. The Company is developing a 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.

As discussed in Note 3, on March 2, 2015, the Company completed the acquisition of MaSTherCell SA and Cell Therapy Holding SA (collectively MaSTherCell). MaSTherCell is a Contract Development and Manufacturing Organization (CDMO) specializing in cell therapy development for advanced medicinal products. Cell therapy is the prevention or treatment of human disease by the administration of cells that have been selected, multiplied and pharmacologically treated or altered outside the body (ex vivo). MaSTherCell's CDMO activity is operated as a separate reporting segment (See Note 4).

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

Basis of Presentation

These unaudited condensed consolidated financial statements of the Company and its subsidiaries 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, 2016, and the consolidated statements of comprehensive loss for the three and six months ended May 31 2016 and 2015, and the changes in equity (capital deficiency) and cash flows for the six months period ended May 31, 2016 and 2015. The results for the six months ended May 31, 2016 are not necessarily indicative of the results to be expected for the year ending November 30, 2016. 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, 2015.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As of May 31, 2016, the Company had not achieved profitable operations, had accumulated losses of $24.3 million (since inception), had a negative cash flows from operating activities, had a working deficiency of $9.3 million and expects to incur further losses in the development of its business. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company s continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability. The Company needs to raise significant funds on an immediate basis in order to continue to meet its liquidity needs, realize its business plan and maintain operations. The Company s current cash resources are not sufficient to support its operations as presently conducted or permit it to take advantage of business opportunities that may arise. Management of the Company is continuing its efforts to secure funds through equity and/or debt instruments for its operations.

The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. There can be no assurance that management will be successful in implementing a business plan or that the successful implementation of a business plan will actually improve the Company s operating results. Presently, the Company does not have any financing commitment from any person, and there can be no assurance that additional capital will be available to the Company on commercially acceptable terms or at all. If the Company is unable to obtain the necessary capital, the Company may have to cease operations.

The Company has been funding its operations primarily from the proceeds from the private placements of its convertible and equity securities. From December 2015 through May 2016, the Company received proceeds of approximately $975 thousand from the proceeds of the private placement to certain accredited investors of its unsecured equity stock. In addition, between June 1 and July 14, 2016, the Company raised an additional $1.4 million from the proceeds of private placement of its securities.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies adopted are consistent with those of the previous financial year except as described below.

Newly Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09 (ASU 2014-09), *Revenue from Contracts with Customers*. ASU 2014-09 will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity s contracts with customers. The guidance is effective for the interim and annual periods beginning on or after December 15, 2016 (early adoption is not permitted). The guidance permits the use of either a retrospective or cumulative effect transition method. On July 9, 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company is currently evaluating the impact of this standard.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern* (Subtopic 205-40), Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity s liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Prior to this, there was no guidance under U.S. GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern or to provide related footnote disclosures. The amendments in this update provide that guidance. In doing so, the amendments reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt , (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management s plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management s plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). For the period ended November 30, 2015, management evaluated the Company s ability to continue as a going concern and concluded that substantial doubt has not been alleviated about the Company s ability to continue as a going concern. While the Company continues to explore further significant sources of financing, management s assessment was based on the uncertainty related to the availability, amount and nature of such financing over the next twelve months.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The pronouncement requires equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. ASU 2016-01 requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset, and eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost. These changes become effective for the Company's fiscal year beginning January 1, 2018. The expected adoption method of ASU 2016-01 is being evaluated by the Company and the adoption is not expected to have a significant impact on the

Company s consolidated financial position or results of operations.

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-06, *Contingent Put and Call Options in Debt Instruments* (Topic 815), which requires that embedded derivatives be separated from the host contract and accounted for separately as derivatives if certain criteria are met. One of those criteria is that the economic characteristics and risks of the embedded derivatives are not clearly and closely related to the economic characteristics and risks of the host contract (the clearly and closely related criterion). The amendments in this Update clarify what steps are required when assessing whether the economic characteristics and risks of call (put) options are clearly and closely related to the economic characteristics and risks of their debt hosts, which is one of the criteria for bifurcating an embedded derivative. Consequently, when a call (put) option is contingently exercisable, an entity does not have to assess whether the event that triggers the ability to exercise a call (put) option is related to interest rates or credit risks. The amendments are an improvement to GAAP because they eliminate diversity in practice in assessing embedded contingent call (put) options in debt instruments. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted for all entities. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, as part of its simplification initiative. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early application is permitted for all entities. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

NOTE 3 ACQUISITION OF MASTHERCELL

Description of the Transaction

The Company entered into a share exchange agreement dated November 3, 2014, as subsequently amended (the "Share Exchange Agreement" or "SEA"), with MaSTherCell SA, Cell Therapy Holding SA (collectively MaSTherCell). Pursuant to the Share Exchange Agreement, which closed on March 2, 2015 in exchange for all of the issued and outstanding shares of MaSTherCell, the Company issued to the shareholders of MaSTherCell an aggregate of 42,401,724 shares (the Consideration Shares) of common stock at a price of $0.58 per share for an aggregate price of $24.6 million. Out of the Consideration Shares, 8,173,483 shares will be allocated to the bondholders of MaSTherCell in case of conversion.

On November 12, 2015, the Company and MaSTherCell and each of the shareholders of MaSTherCell (the MaSTherCell Shareholders), entered into an amendment (Amendment No. 2) to the Share Exchange Agreement. Under Amendment No. 2, the MaSTherCell Shareholders option to unwind the transaction as contained in the original Share Exchange Agreement (the Unwind Option) was extended to November 30, 2015. In addition the Company agreed to remit to MaSTherCell, by way of an equity investment, the sum of EUR 3.8 million by November 30, 2015 (the Initial Investment), to be followed by a subsequent equity investment by December 31, 2015 in MaSTherCell of EUR 1.2 million. The extended right of the MaSTherCell Shareholders to unwind the transaction could have been exercised by them only if the Company had not achieved the Post Closing Financing and/or completed the Initial Investment (as defined) by November 30, 2015.

In connection with the equity investment, on December 10, 2015 the Company agreed to invest EUR 2.2 million in MaSTherCell equity in addition to the Initial Investment, which additional amount becomes due upon the request of the MaSTherCell board of directors, of whom Company directors/officers currently represent a majority. The Company s agreement represents an increase of EUR 1 million over the amount which the Company was previously obligated to invest in MaSTherCell under the Share Exchange Agreement as additional equity and replaces any funding obligation that the Company had under the SEA, as amended.

On December 10, 2015 the Company remitted to MaSTherCell the Initial Investment of € 3.8 million or $4.1 million (out of the original obligation for investment of €6 million), in compliance with its obligations as required under the Share Exchange Agreement. As a result, the Unwind Option was canceled and all the shares that were issued, have been reclassed from redeemable common stock into equity.

During the three months ended May 31, 2016, the Company remitted to MaSTherCell an additional $328 thousand (€ 286 thousand), in compliance with its obligations. On June and July 2016, an additional $1 million (€ 896 thousand was remitted to MaSTherCell (See also Note 11).

NOTE 4 - SEGMENT INFORMATION

The Chief Executive Officer ("CEO") is the Company s chief operating decision-maker ("CODM"). Following the acquisition of MaSTherCell, management has determined that there are two operating segments, 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.

CDMO

The CDMO activity is operated by MaSTherCell, which specializes in cell therapy development for advanced medicinal products. MaSTherCell is providing two types of services to its customers: (i) process and assay development services and (ii) GMP contract manufacturing services. The CDMO segment includes only the results of MaSTherCell.

CTB

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

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

Adjusted EBIT is a non-GAAP financial measure that the Company believes that provides useful information to investors and others in understanding and evaluating the Company's operating results in the same manner as the Company's management and board of directors.

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

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

Segment data for the six months ended May 31, 2015 is as follows:

	CDMO	CTB	Corporate and Eliminations	Consolidated
		(in thousands)		
Net revenues from external customers	$ 951	$	$ (131)	$ 820
Cost of revenues	(743)			(743)
Research and development expenses, net		(517)	131	(386)
Operating expenses	(664)	(893)		(1,557)
Depreciation and amortization expense	(622)	(3)		(625)
Segment Performance	$ (1,078)	$ (1,413)		(2,491)
Stock-based compensation			(378)	(378)
Financial income (expenses), net			967	967
Loss before income taxes				$ (1,902)

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

	CDMO	CTB	Corporate and Eliminations	Consolidated
		(in thousands)		
Net revenues from external customers	$ 1,403	$	$ (271)	$ 1,132
Cost of revenues	(1,932)		180	(1,752)
Research and development expenses, net		(376)	91	(285)
Operating expenses	(458)	(429)		(887)
Depreciation and amortization expense	(693)	(1)		(694)

Segment Performance	$ (1,680)	$ (806)		(2,486)
Share-based compensation			(1,487)	(1,487)
Financial income (expenses), net			(553)	(553)
Loss before income taxes				$ (4,526)

Segment data for the three months ended May 31, 2015 is as follows:

	CDMO	CTB	Corporate and Eliminations	Consolidated
		(in thousands)		
Net revenues from external customers	$ 951	$	$ (131)	$ 820
Cost of revenues	(743)			(743)
Research and development expenses, net		(290)	131	(159)
Operating expenses	(664)	(534)		(1,198)
Depreciation and amortization expense	(622)	(3)		(625)
Segment Performance	$ (1,078)	$ (827)		(1,905)
Stock-based compensation			(131)	(131)
Financial income (expenses), net			924	924
Loss before income taxes				$ (1,112)

Geographic, Product and Customer Information

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

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

	Three Months Ended May 31, 2016	Six Months Ended May 31, 2016
	(in thousands)	
Customer A	$ 830	$ 1,594
Customer B	$ 420	$ 981

The Company has included adjusted EBIT in this Quarterly Report on Form 10-Q because it is a key measure used to evaluate the Company s financial and operating performance, generate future operating plans and make strategic decisions for the allocation of capital. Accordingly, the Company believes that adjusted EBIT provides useful information to investors and others in understanding and evaluating the operating results in the same manner as our management and board of directors. While the Company believes that this non-GAAP financial measure is useful in evaluating its business, this information should be considered as supplemental in nature and is not meant as a substitute for the related financial information prepared in accordance with US GAAP.

NOTE 5 CONVERTIBLE LOAN AGREEMENTS

1) During the year ended November 30, 2015 and 2014, the Company entered into six convertible loan agreements (out of which five during 2015) with new investors for a total amount of $1 million (the Convertible Loans), interest is calculated at 6% annually and was payable, along with the principal on or before the maturity date.

On April 27, 2016 and December 23, 2015, the holders of all the Convertible Loans and the Company agreed to convert the Convertible Loans and accrued interest into units of the Company s common stock, each unit comprising one share of the Company s common stock and one three-year warrant to purchase an additional share of the Company s common stock at an exercise price of $0.52. Upon conversion of the Convertible Loans, the Company issued an aggregate of 1,976,330 shares of Common stock and three year warrants to purchase up to an additional 1,976,330 shares. Furthermore, in the event the Company issues any common shares or securities convertible into

common shares in a private placement for cash at a price less than $0.52 (the New Issuance Price) on or before December 23, 2016, the Company will issue, for no additional consideration, additional common shares to subscribers, according to the mechanism defined in the agreements. This provision does not apply to issuance of shares under options, issuance of shares under existing rights to acquire shares, nor issuance of shares for non-cash consideration.

The Company allocated the principal amount of the convertible loans and the accrued interest thereon based on their fair value.

The table below presents the fair value of the instruments issued as of the conversion dates and the allocation of the proceeds (for the fair value as of May 31, 2016, see Note 10):

	Total Fair Value (in thousands)	
	December 23, 2015	April 27, 2016
Warrants component	$ 323	$ 13
Price protection derivative component	34	2
Shares component	614	32
Total	$ 971	$ 47

2) On April 27, 2016, the Company entered into an assignment and assumption of debt agreement with Nine Investments Ltd. (Nine Investments) and Admiral Ventures Inc. (Admiral). Pursuant to the terms of a Convertible Loan Agreement dated May 29, 2014, as amended on December 2014 (collectively, the "Loan Agreement"), Nine Investments agreed to assign and transfer to Admiral all of the Company s obligations for the outstanding amount of the Loan Agreement. Additional amendments to the provisions of the Loan Agreement were executed as follows:

a) Extend the due date of the loan of $1.5 million through September 30, 2016;
b) The Company paid to Admiral an extension fee in the form of 288,461 units, each unit was comprised of one common share and one, three-year warrant for one common share at an exercise price of $0.52 per common share. The fair value of the warrants as of the grant date was $34 thousand. Using the Black-Scholes model, the shares were valued at the fair value of the Company s common stock as of April 27, 2016, or $0.28; and
c) The Company shall accrue additional interest totalling $55 thousand for the period from January 31, 2015 to December 31, 2015. In addition the interest rate shall be 12% per annum commencing from January 1, 2016.

The Company accounted for the above changes as an extinguishment of the old debt and issuance of a new debt. As a result, a loss of $229 thousand was recorded within financial expenses.

NOTE 6 COMMITMENTS

Collaboration Agreements

1) On March 14, 2016, the Israel subsidiary, entered into a collaboration agreement with CureCell Co., Ltd. (CureCell), initially for the purpose of applying for a grant from the Korea Israel Industrial R&D Foundation ("Koril-RDF") for pre-clinical and clinical activities related to the commercialization of Orgenesis Ltd. s AIP cell therapy product in Korea ("Koril Grant"). Subject to receiving the Koril Grant, the Parties agreed to carry out at their own expense their respective commitments under the work plan approved by Koril-RDF and any additional work plan to be agreed between the Israeli Subsidiary and CureCell. The Israeli Subsidiary will own sole rights to any intellectual property developed from the collaboration which is derived under the Israeli Subsidiary s AIP cell therapy product, information licensed from THM. Subject to obtaining the requisite approval needed to commence commercialization in Korea, the Israel subsidiary has agreed to grant to CureCell, or a fully owned subsidiary thereof, under a separate sub-license agreement an exclusive sub-license to the intellectual property underlying the Company s API product solely for commercialization of the Israel subsidiary products in Korea. As part of any such license, CureCell has agreed to pay annual license fees, ongoing royalties based on net sales generated by CureCell and its sublicensees, milestone payments and sublicense fees. Under the agreement, CureCell is entitled to share in the net profits derived by the Israeli Subsidiary from world-wide sales (except for sales in Korea) of any product developed as a result of the collaboration with CureCell. Additionally, CureCell was given the first right to obtain exclusive commercialization rights in Japan of the AIP product, subject to CureCell procuring all of the regulatory approvals

required for commercialization in Japan.

2) On March 14, 2016, the Company and CureCell Co., Ltd. (CureCell) of Korea entered into a Joint Venture Agreement (the JVA) pursuant to which the parties will collaborate in the contract development and manufacturing of cell therapy products in Korea. The parties intend to pursue the joint venture through a newly established Korean company (the JV Company) which the Company by itself, or together with a designee, will hold a 50% participating interest therein, with the remaining 50% participating interest being held by CureCell. Under the JVA, CureCell is to procure, at its sole expense, a GMP facility and appropriate staff in Korea for the manufacture of the cell therapy products. The Company will share with CureCell the Company s know-how in the field of cell therapy manufacturing, which know-how will not include the intellectual property included in the license from the Tel Hashomer Hospital in Israel to the Israeli subsidiary. In addition, each party shall be required to perform its respective obligations according to a detailed work plan to be agreed upon by CureCell and Company within no later than 30 days following the execution of the JVA. Under the JVA, the Company and CureCell each undertook to remit, within two years of the execution of the JVA, $2 million to the JV Company, of which $1 million is to be in cash and the balance in an in-kind investment, the scope and valuation of which shall be preapproved in writing by CureCell and the Company. The Company s funding will be made by way of a convertible loan to the JV Company or the joint venture (if the JV Company is not established). The JVA provides that, under certain specified conditions, the Company can require CureCell 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 the then valuation of the JV Company.

3) On May 10, 2016 (the Effective Date), the Company and Atvio Biotech Ltd., a newly formed Israeli company (Atvio) entered into a Joint Venture Agreement (the JVA) pursuant to which the parties agreed to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in the State of Israel. The parties intend to pursue the joint venture through Atvio, in which the Company will have a 50% participating interest therein. Under the JVA, Atvio is to procure, at its sole expense, a GMP facility and appropriate staff in Israel. The Company will share with Atvio the Company s know-how in the field of cell therapy manufacturing, which know-how will not include the intellectual property included in the license from the Tel Hashomer Hospital in Israel to the Israeli Subsidiary. The parties are to create a mutually agreeable work plan within 60 days following the execution of the JVA, detailing each party s respective obligations. Subject to the adoption of a work plan acceptable to the Company, the Company shall remit to Atvio $1 million to defray the costs associated with the setting up and the maintenance of the GMP facility, all or part of which may be contributed by way of in kind services as agreed to in the work plan. The Company s funding will be made by way of a convertible loan to Atvio, which shall be convertible at the Company s option at any time into 50% of the then outstanding equity capital immediately following such conversion. In addition, within a year from the Effective Date the Company has the option to require the Atvio shareholders to transfer the Company the entirety of their interest in Atvio for the consideration specified in the agreement. Within three years from the Effective Date, the Atvio shareholders shall have the option to require the Company to purchase from Atvios' shareholders their entire interest in Atvio for the consideration specified in the agreement. As of May 31, 2016, no activities have begun in Atvio.

Grants

1) On April 2016, the Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a budgeted EUR 1,304 thousand support program for the development of a potential cure for Type 1 Diabetes. The financial support is awarded to the Belgium subsidiary as a recoverable advance payment at 55% of budgeted costs, or for a total of EUR 717 thousand ($800 thousand). The grant will be paid to Orgenesis over the project period.

2) On May 26, 2016, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with KORIL and CureCell. KORIL will give a conditional grant of up to $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use of Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project). The Project started on June 1, 2016. Upon the conclusion of product development, the grant shall be repaid at the yearly rate of 2.5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting on June

1, 2016. On June 2016, the Israeli Subsidiary received $160 thousand under the grant.

NOTE 7 EQUITY

a. *Share Capital*

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

b. *Financings*

During the six months ended May 31, 2016, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement (the Private Placement) of (i) 1,875,002 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 1,875,002 shares of the Company s Common Stock at a per share exercise price of $0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of $975 thousand. Furthermore, in the event the Company issues any common shares or securities convertible into common shares in a private placement for cash at a price less than $0.52 (the New Issuance Price) within a year from the issuance date, the Company will issue, for no additional consideration, additional common shares to subscribers in the $0.52 per share which total each subscriber s subscription proceeds divided by the New Issuance Price, minus the number of shares already issued to such subscriber. This provision does not apply to issuance of shares under options, issuance of shares under existing rights to acquire shares, nor issuance of shares for non-cash consideration (See also Note 10).

The Company allocated the proceeds from the private placement based on the fair value of the warrants and the price protection derivative components. The residual amount was allocated to the shares.

The table below presents the fair value of the instruments issued as of the closing dates and the allocation of the proceeds (for the fair value as of May 31, 2016, see Note 10):

		Total Fair Value (in thousands)
Warrants component	$	265
Price protection derivative component		37
Shares component		673
Total	$	975

NOTE 8 STOCK BASED COMPENSATION

a. Options Granted to Employees and Directors

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

b. Options Granted to Consultant

On March 1, 2016 the Company entered into a consulting agreement for professional services for a period of one year. Under the terms of the agreement, the Company granted to a consultant 1 million options exercisable at $0.30 per share. The options shall vest quarterly over a period of one year, but shall immediately vest prior to such one-year period if there is an acquisition of 40% or more of the Company or upon funding of $5 million or more in financing. The fair value of those options as of the date of grant was $187 thousand using the Black-Scholes valuation model.

c. Shares Issued to Consultants

1) On March 1, 2016, the Company entered into a consulting agreement for professional services for a period of one year. Under the terms of the agreement, the Company agreed to grant the consultant 250 thousand shares of restricted common stock. The fair value of the Company s common stock as of the date of grant was $0.30. In addition, the Company will pay a retainer fee of $10,000 per month, consisting $5,000 cash per month and $5,000 shall be payable in shares of the Company s common stock at a value equal to the price paid for the equity capital raise

of at least $3 million (the financing). The cash fee per month and shares shall be issued upon completion of the financing. As of May 31, 2016, the financing was not completed and, therefore, no expenses were recorded in connection with the shares.

2) On April 27, 2016, the Company entered into a consulting agreement for professional services for a period of one year with two consultants. Under the terms of the agreements, the Company agreed to grant the consultants an aggregage of 1.2 million shares of restricted common stock that vested on grant date. The fair value of the Company s common stock as of the date of grant was $0.28.

3) On May 1, 2016, the Company entered into a consulting agreement for professional services for a period of one year. Under the terms of the agreement, the Company agreed to grant a consultant 1 million shares of restricted common stock, of which the first 350,000 shares will vest immediately, 350,000 shares are to vest 90 days following the agreement date and 300,000 shares are schedule to vest 180 following the agreement date. The fair value of the Company s common stock as of the date of grant of the first tranche was $0.28. With respect to each subsequent tranche, the fair value of the Company s common stock as of May 31, 2016, was $0.35.

NOTE 9 LOSS PER SHARE

The following table sets forth the calculation of basic and diluted earnings (loss) per share for the periods indicated:

	Three Months Ended		Six Months Ended	
	May 31,		May 31,	
	2016	2015	2016	2015
	(in thousands, except per share data)			
Basic:				
Loss for the period	$ 3,892	$ 1,097	$ 3,667	$ 1,887
Weighted average number of common shares outstanding	107,583,871	55,785,407	106,693,858	55,760,675
Loss per common share	$ 0.04	$ 0.02	$ 0.03	$ 0.03
Diluted:				
Loss for the period	$ 3,892	$ 1,097	$ 3,667	$ 1,887
Changes in fair value of embedded derivative and interest expense on convertible bonds		592	92	560
Change in fair value of warrants		380		526
Loss for the period	3,892	2,069	$ 3,759	2,973
Weighted average number of shares used in the computation of basic loss per share	107,583,871	55,785,407	106,693,858	55,760,675
Number of dilutive shares related to convertible bonds		6,554,728		3,894,438
Number of dilutive shares related to warrants		455,010		504,436
Weighted average number of common shares outstanding	107,583,871	62,795,145	106,693,858	60,159,549
Loss per common share	$ 0.04	$ 0.03	$ 0.04	$ 0.05

Diluted loss per share does not include 16,954,564 shares underlying outstanding options, 19,769,959 shares issuable upon exercise of warrants, 1,150,000 shares due to stock-based compensation to service providers and 4,793,603 shares upon conversion of convertible notes for the six and three months ended May 31, 2016, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted loss per share does not include 42,401,724 redeemable common stock, 15,367,559 shares underlying outstanding options, 350,000 shares due to stock-based compensation to service providers, 2,682,256 shares issuable upon exercise of warrants for the six and three months ended May 31, 2015, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 10 - 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, 2016 and November 30, 2015 the Company s liabilities that are measured at fair value and classified as level 3 fair value are as follows (in thousands):

		May 31, 2016 Level 3		**November 30, 2015** Level 3
Warrants (1)	$	1,730	$	1,382
Price protection derivative (1)		175		1,533
Embedded derivatives*(1)		260		289
Convertible bonds (2)	$	1,859	$	1,888

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

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

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

Stage A - The model calculates a number of potential future share prices of the Company based on the volatility and risk-free interest rate assumptions.
Stage B - the embedded derivative value is calculated "backwards" in a way that takes into account the maximum value between holding the bonds until maturity or converting the bonds.

The following table presents the assumptions that were used for the models as of May 31, 2016:

	Price Protection Derivative and Warrants	**Embedded Derivative**
Fair value of shares of common stock	$ 0.35	$ 0.35
Expected volatility	88%-91%	91%
Discount on lack of marketability	14%	-
Risk free interest rate	0.27%-1.03%	0.39%
Expected term (years)	2.4-3	0.33
Expected dividend yield	0%	0%

Expected capital raise dates	Q3 2016, Q1 2018	-

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

The following table presents the assumptions that were used for the models as of November 30, 2015:

	Price Protection Derivative and Warrants	Embedded Derivative	Convertible Bonds
Fair value of shares of common stock	$ 0.33	$ 0.33	$ 0.33
Expected volatility	87%-98%	87%	88%
Discount on lack of marketability	14%	-	18%
Risk free interest rate	0.44%-1.24%	0.11%-0.49%	0.42%
Expected term (years)	0.9-3	0.08-0.87	0.8
Expected dividend yield	0%	0%	0%
Expected capital raise dates	Q2 2016-Q4 2016, Q4 2017	-	-

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, 2016:

	Warrants	Embedded Derivatives	Convertible Bonds	Price Protection Derivative
		(in thousands)		
Balance at beginning of the period	$ 1,382	$ 289	$ 1,888	$ 1,533
Additions	601			73
Conversion		(10)		
Changes in fair value during the period	(253)	(11)	(132)	(1,431)
Changes in fair value due to extinguishment of convertible loan		(8)		
Translation adjustments			103	
Balance at end of the period	$ 1,730	$ 260	$ 1,859	$ 175

There were no transfers to Level 3 during the three months ended May 31, 2016.

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

	Base -10%	Base	Base+10%
		(in thousands)	
As of May 31, 2016	$ 1,499	$ **1,730**	$ 1,949

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

	Base -10%	Base	Base+10%
		(in thousands)	
As of May 31, 2016	$ 174	$ **175**	$ 177

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

	Base -10%	Base	Base+10%
		(in thousands)	
As of May 31, 2016	$ 222	$ **260**	$ 298

The table below sets forth a summary of the changes in the fair value of the Company s financial liabilities classified as Level 3 for the year ended November 30, 2015:

	Warrants	Embedded Derivatives	Convertible Bonds	Price Protection Derivative
		(in thousands)		
Balance at beginning of the year	$ 560	$ 992	$	$
Additions	1,390	112	3,234	1,526
Changes in fair value related to warrants expired*	(525)			7
Changes in fair value during the period	(43)	(814)	(1,221)	
Translation adjustments			(125)	
Balance at end of the year	$ 1,382	$ 289	$ 1,888	$ 1,533

(*) During the twelve months ended November 30, 2015, 1,826,718 warrants had expired. There were no transfers to Level 3 during the twelve months ended November 30, 2015.

NOTE 11 - SUBSEQUENT EVENTS

In June and July 2016, the Company entered into several unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of $877.5 thousand. The term of the notes is for two years with an interest rate of 6% per annum. The entire principal amount under the notes and accrued interest shall automatically convert into Units (as defined below) upon the earlier to occur of any of the following: (i) the closing of an offering of equity securities of the Company with gross proceeds to the Company greater than $10 million (Qualified Offering) (ii) the trading of the Company s common stock on the over-the counter market or an exchange at a weighted average price of at least $0.52 for fifty (50) consecutive trading days, or (iii) the listing of the Company s Common Stock on a U.S. National Exchange (each a Conversion Event). Each $0.52 of principal amount and accrued interest due shall 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 $0.52, provided that, if more favorable to the holder, any principal amount and accrued interest due shall convert into securities on the same basis as such securities are sold in the Qualified Offering. At any time, the holder may convert the principal amount and accrued interest outstanding into Units as provided above. In addition, if a Conversion Event does not occur within 12 months of the issuance date hereof, then the holder, at its option, may convert the outstanding principal amount and accrued interest under this note into either (i) Units as provided above, or (ii) shares of the Company s common stock at a per share conversion price of $0.40.

In June and July 2016, the Company entered into definitive agreements with accredited investors relating to a private placement (the Private Placement) of (i) 1,004,807 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 1,004,807 shares of the Company s Common Stock at a per share exercise price of $0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of $522.5 thousand. Furthermore, in certain events (according to terms defined in the agreements) the Company will issue, for no additional consideration, additional common shares to subscribers which total each Subscriber s subscription proceeds divided by the New Issuance Price, minus the number of shares already issued to such subscriber.

From the above investments, the Company remitted to MaSTherCell $1 million (€ 896 thousand, in compliance with its obligations.

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

Forward-Looking Statements

This report contains forward-looking statements. The following discussion should be read in conjunction with the financial statements and related notes contained in our Annual Report on Form 10-K, as filed with the Securities & Exchange Commission on February 29, 2016 (and amended on March 30, 2016). Certain statements made in this discussion are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are projections in respect of future events or financial performance. In some cases, you can identify forward-looking statements by terminology such as may, should, expects, plans, anticipates, b estimates, predicts, potential or continue or the negative of these terms or other comparable terminolo Forward-looking statements made in a quarterly report on Form 10-Q may include statements about our:

- ability to obtain sufficient capital or strategic business arrangements to fund our operations and realize our business plan;
- ability to grow the business of MaSTherCell, which we recently acquired, our Contract Development and Manufacturing Organization (CDMO) business;
- belief as to whether a meaningful and profitable global market can be established for our CDMO business for cell therapy;
- intention to develop to the clinical stage a new technology to transdifferentiate liver cells into functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- belief that our treatment seems to be safer than other options;
- belief that one of our principal competitive advantages is our cell trans-differentiation technology being developed by our Israeli Subsidiary;
- expectations regarding our Israeli Subsidiary s ability to obtain and maintain intellectual property protection for our technology and therapies;
- ability to commercialize products in light of the intellectual property rights of others;
- ability to obtain funding for operations, including funding necessary to prepare for clinical trials and to complete such clinical trials;
- future agreements with third parties in connection with the commercialization of our technologies;
- size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- plans to integrate and support our manufacturing facilities in Belgium;
- success as it is compared to competing therapies that are or may become available;
- ability to attract and retain key scientific or management personnel and to expand our management team;
- accuracy of estimates regarding expenses, future revenue, capital requirements, profitability, and needs for additional financing;
- belief that Diabetes Mellitus will be one of the most challenging health problems in the 21st century and will have staggering health, societal and economic impacts;
- need to raise additional funds on an immediate basis which may not be available on acceptable terms or at all;
- research facility in Israel and the surrounding Middle East political situation which may materially adversely affect our Israeli Subsidiary s operations and personnel;
- relationship with Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (THM) and the risk that THM may cancel the License Agreement;
- expenditures not resulting in commercially successful products; and
- extensive industry regulation, and how that will continue to have a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled Risk Factors set forth in our Annual Report on Form 10-K, as filed with the

Securities & Exchange Commission on February 29, 2016 (and amended on March 30, 2016), any of which may cause our company s or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks may cause the Company s or its industry s actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity or performance. Moreover, neither the company nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The company is under no duty to update any forward-looking statements after the date of this report to conform these statements to actual results.

As used in this quarterly report and unless otherwise indicated, the terms we, us, "our," Orgenesis or the Compa refer to Orgenesis Inc. and its wholly-owned Subsidiaries, Orgenesis Ltd. (the Israeli Subsidiary), Orgenesis SPRL (the Belgian Subsidiary), Orgenesis Maryland, Inc. (the U.S. Subsidiary) and MaSTherCell SA (MaSTherCell), ou Belgian-based subsidiary. Unless otherwise specified, all dollar amounts are expressed in United States dollars.

Corporate Overview

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

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

Our Belgian-based subsidiary, MaSTherCell, is a contract development manufacturing organization, or CDMO, specialized in cell therapy development for advanced medicinal products. In the last decade, cell therapy medicinal products have gained significant importance, particularly in the fields of ex-vivo gene therapy, immunotherapy and regenerative medicine. While academic and industrial research has led scientific development in the sector, industrialization and manufacturing expertise remains insufficient. MaSTherCell plans to fill this need by providing two types of services to its customers: (i) process and assay development services and (ii) Good Manufacturing Practices (GMP) contract manufacturing services. These services offer a double advantage to MaSTherCell's customers. First, customers can continue focusing their financial and human resources on their product/therapy, while relying on a trusted source for their process development/production. Second, it allows customers to profit from MaSTherCell's expertise in cell therapy manufacturing and all related aspects.

We are leveraging the expertise and experience of MaSTherCell in cell process development and manufacturing capability in order to build a fully integrated bio-pharmaceutical company in the cell therapy development and manufacturing area.

We were incorporated in the state of Nevada on June 5, 2008, under the name Business Outsourcing Services, Inc. Effective August 31, 2011, we completed a merger with our subsidiary, Orgenesis Inc., a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we changed our name from Business Outsourcing Services, Inc. to Orgenesis Inc. Our common stock is currently listed on the OTC Market, QB tier, under the symbol ORGS .

Recent Corporate Developments

During the last completed fiscal quarter ended May 31, 2016, we have experienced the following corporate developments:

Formation of Atvio Biotech Ltd. and Entrance into Joint Venture Agreement

On May 10, 2016, Orgenesis Inc. (the Company) and Atvio Biotech Ltd., a newly formed Israeli company (Atvio) entered into a Joint Venture Agreement (the JVA) pursuant to which the parties agreed to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine in the State of Israel. The parties intend to pursue the joint venture through Atvio, in which the Company will hold a 50% participating interest therein, with the remaining 50% participating interest being held by the other shareholders of Atvio. Under the JVA, Atvio is to procure, at its sole expense, a GMP facility and appropriate staff in Israel. The Company will share with Atvio the Company s know-how in the field of cell therapy manufacturing, which knowhow will not include the intellectual property included in the license from the Tel Hashomer Hospital in Israel to Orgenesis Ltd., the Company s subsidiary. The parties are to create a mutually agreeable work plan within 60 days following the execution of the JVA, detailing each party s respective obligations. Subject to the adoption of a work plan acceptable to the Company, the Company shall remit to Atvio $1 million to defray the costs associated with the setting up and the maintenance of the GMP facility, all or part of which may be contributed by way of in kind services as agreed to in the work plan. The Company s funding will be made by way of a convertible loan to Atvio, which shall be convertible at the Company s option at any time into 50% of the then outstanding equity capital immediately following such conversion.

The JVA provides that, under certain specified conditions, either the Company can require the Atvio Shareholders to sell to the Company their participating (including equity) interest in Atvio or the Atvio Shareholders can require the Company to purchase their respective participating and equity holdings in Atvio, in each case in consideration for the issuance of the Company s common stock based on the then specified valuation of Atvio.

Results of Operations

Comparison of the Three and Six Months Ended May 31, 2016 to the Three and Six Months Ended May 31, 2015

Revenue and Cost of Sales

For the three and six months ended May 31, 2016, our total revenues were approximately $1,132 and $2,652 thousand, respectively, as opposed to $820 thousand for each of the comparable periods in 2015. The increase in revenue is attributable to CDMO activities that commenced pursuant to the acquisition of MaSTherCell in March 2015 and the increase in the volume of services and sales of consumables due to a new customer.

Expenses

The Company s expenses for the three and six months ended May 31, 2016 are summarized as follows in comparison to its expenses for the three and six months ended May 31, 2015:

	Three Months Ended May 31,		Six Months Ended May 31,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Revenues	$ 1,132	$ 820	$ 2,652	$ 820
Cost of sales	1,964	973	3,444	973
Research and development expenses, net	486	290	887	465
Amortization of intangible assets	482	393	810	393
Selling, general and administrative expenses	2,173	1,200	3,339	1,858
Financial expenses (income), net	553	(924)	(1,219)	(967)
Loss before income taxes	$ 4,526	$ 1,112	$ 4,609	$ 1,902

Cost of Sales

	Three Months Ended May 31,		Six Months Ended May 31,	
	2016	2015	2016	2015

	(in thousands)		(in thousands)	
Salaries and related expenses	$ 841	$ 301	$ 1,507	$ 301
Professional fees and consulting services	258	123	329	123
Raw Material	608	278	884	278
Amortization and depreciation expenses, net	211	229	523	229
Other expenses	46	42	201	42
Total	$ 1,964	$ 973	$ 3,444	$ 973

Cost of sales for the three and six months ended May 31, 2016 increased by 200% and 354%, or $991 thousand and $2,471 thousand, respectively, compared to the three and six months ended May 31, 2015. The increase in costs of sales for the six months ended May 31, 2016, compared to the same period last year was due to the full period results of MaSTherCell for the 2016 period. Furthermore, the increase of 118% ($815 thousand) in the six months ended was due to recruitment of new employees as part of our plans to expand our capacity in the manufacturing facility in Belgium and due to the need to increase our professional employees force following a new customer that we had from June 2015.

There was also an increase in professional fees and consulting services in the three and six months ended May 31, 2016, compared to the three and six months ended May 31, 2015, primarily due to approximately $160 thousand with a new service provider. There was also an increase in raw materials in the three and six months ended May 31, 2016, compared to the three and six months ended May 31, 2015, due to the expansion of MaSTherCell production activities, increase in the number of customers and the execution of two qualification runs. Additionally, there was an increase in the amortization and depreciation expenses in the six months ended May 31, 2016, compared to the six months ended May 31, 2015, due to the depreciation expenses of equipment purchased for two production rooms and a new clean room.

Research and Development Expenses, net

	Three Months Ended May 31,		Six Months Ended May 31,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Salaries and related expenses	$ 316	$ 139	$ 567	$ 257
Stock-based compensation	200	35	234	77
Professional fees and consulting services	65	132	156	255
Lab expenses	187	96	278	158
Other research and development expenses	48	79	93	115
Less grant	(330)	(191)	(441)	(397)
Total	$ 486	$ 290	$ 887	$ 465

The decrease in professional fees and consulting services and the increase in salaries and related expenses in the three and six months ended May 31, 2016, compared to the three and six months ended May 31, 2015, is primarily due to the merger with MaSTherCell, which was one of our subcontractors for the DGO6 project before the acquisition. In addition, part of the increase in salaries and related expenses is due to an increase in the volume of work that was done by MaSTherCell as opposed to the corresponding period in 2015. The increase in stock-based compensation expenses in the three and six months ended May 31, 2016, compared to the same period last year, is mainly due to a new options grant for one of the executives in amount of $154 thousand. The increase in lab expenses in the three and six months ended May 31, 2016, compared to the same period last year is mainly due to a final experiment held by Pall Life Science Belgium BVBA (Pall) and the tech transfer held in second quarter of the work done by Pall to MaSTherCell.

Selling, General and Administrative Expenses

	Three Months Ended May 31,		Six Months Ended May 31,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Salaries and related expenses	$ 205	$ 366	$ 409	$ 481
Stock-based compensation	1,286	95	1,423	301
Accounting and legal fees	220	164	548	351
Professional fees	66	300	259	382
Rent and related expenses	186	107	337	107
Business development	144	103	228	138

Other general and administrative expenses	66	65	135	98
Total	$ 2,173	$ 1,200	$ 3,339	$ 1,858

Selling, general and administrative expenses for the three and six months ended May 31, 2016 increased by 81% and 80%, or $973 thousand and $1,481 thousand, respectively, compared to the three and six months ended May 31, 2015. The main increase in costs related to selling, general and administrative activities is due to MaSTherCell activities of $399 thousand during the six months ended May 31, 2016 which was consolidated only from March 2, 2015.

Furthermore the decrease in salaries and related expenses in the three and six months ended May 31, 2016 compared to the corresponding period last year is due to decrease in the number of management positions. The increase in accounting and legal fees expenses is mainly due legal fees expenses on a new patent applications that we submitted in twelve countries.

The increase in stock-based compensation expenses due to new grants for two executives on April 27, 2016 in the amount of $468 thousand and stock-based compensation related to options and shares granted to 7 consultants following new agreements in the amount of $732 thousand. This increase was partially offset by a decrease of $123 thousand in professional fees due to reduced reliance on outside professionals as compared to the same period last year. The increase in rent and related expenses in the three and six months ended May 31, 2016 compared to the same period last year is due to rent of additional offices. The increase in business development expenses in the three and six months ended May 31, 2016 compared to the same period last year is due to an increase in the number of conferences we attended for marketing our CMO business during 2016 and travel expenses, respectively, for our subsidiary MaSTherCell.

Financial Expenses (Income), net

	Three Months Ended May 31,		Six Months Ended May 31,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Increase (decrease) in fair value of warrants and financial liabilities measured at fair value	$ 347	$ (1,147)	$ (1,612)	$ (1,330)
Interest expense on loans and convertible loans	176	151	359	267
Foreign exchange loss, net	32	43	39	62
Other expenses	(2)	29	(5)	34
Total	$ 553	$ (924)	$ (1,219)	$ (967)

The increase in financial income for the six months ended May 31, 2016, compared to the same period of 2015, is mainly attributable to a decrease of $762 thousand in the fair value of warrants, the price protection derivative and the embedded derivative. This was offset by a decrease of $247 thousand in the income from changes in fair value of convertible bonds. The main reason is the Company's updated assumptions related to the probabilities of activating the anti-dilution mechanism due to an increase in the quantity of the new instruments that were issued as part of a future offering. This increase was partially offset by an increase of $177 thousand of interest expense of the MaSTherCell loans.

Liquidity and Financial Condition

Since inception, we have funded our operations primarily through the sale of our securities and, more recently, through revenue generated from the activities of MaSTherCell, our Belgian Subsidiary. As of May 31, 2016, we had negative working capital of $9.3 million, including cash and cash equivalents of $0.5 million.

Working Capital Deficiency

	May 31, 2016	November 30, 2015
	(in thousands)	
Current assets	$ 5,147	$ 8,206
Current liabilities	14,408	16,476
Working capital deficiency	$ (9,261)	$ (8,270)

The decrease in current assets is mainly due to a decrease of $3.7 million in cash and cash equivalents that were used for, among other things, the repayment of short and long-term debt and expanding the capacity of the manufacturing

facility in Belgium in order to meet customers demands. This was partially offset by an increase in the amount of $0.5 million in accounts receivable. The decrease in current liabilities is mainly due to a decrease of $1.5 million in short-term loans and current maturities of long term loans, $1 million in convertible loans following the conversion to equity and $1.4 million in price protection derivative. This was offset by an increase in the amount of $1.5 million in accounts payable, accrued expenses and employee and related payables.

Cash Flows

	Six Months Ended May 31,	
	2016	2015
	(in thousands)	
Net loss	$ (3,667)	$ (1,887)
Net cash used in operating activities	(2,166)	(1,017)
Net cash provided by (used in) investing activities	(708)	56
Net cash provided by (used in) financing activities	(853)	236
Decrease in cash and cash equivalents	$ (3,727)	$ (725)

The increase in net cash used in operating activities for the six months ended May 31, 2016, compared to the six months ended May 31, 2015, was mainly due to the CDMO activities that commenced pursuant to the acquisition of MaSTherCell in March 2015 and the expansion of the production activity that included, among other things, almost doubling the number of employees.

The increase in net cash used in investing activities for the six months ended May 31, 2016, compared to the six months ended May 31, 2015, was mainly due to the expanding of the manufacturing activities of MaSTherCell in Belgium.

The increase in net cash used in financing activities for the six months ended May 31, 2016, compared to the six months ended May 31, 2015, was due to the repayment of short and long-term loans in amount of $1.7 million on the CDMO segment, which was offset by proceeds from issuance of shares, and warrants in the amount of approximately $1 million during the six months ended May 31, 2016, compared to proceeds from issuance of loans payable in the the six months ended May 31, 2015 in the amount of $317 thousand.

We need to raise additional operating capital on an immediate basis. Management believes that our current cash resources will allow us to conduct operations as presently conducted through October 2016. Without additional sources of cash and/or the deferral, reduction, or elimination of significant planned expenditures, we will not have the cash resources to remain as a going concern thereafter.

The factors that can impact our ability to continue to fund our operating needs through fiscal 2016 include, but are not limited to:

- Our ability to expand revenue volume at MaSTherCell, which is highly dependent on finite manufacturing facilities;
- Our ability to maintain manufacturing costs at MaSTherCell as expected; and
- Our continued need to reduce our cost structure while simultaneously expanding the breadth of our business, continuing the development of our technology, enhancing our technical capabilities, and pursing new business opportunities.

If we cannot effectively manage these factors, including closing new revenue opportunities from existing and new customers for our CDMO business, we will need to raise additional capital to support our business. Except for the credit facility discussed below, we have no commitments for any such funding, and there are no assurances that such additional sources of liquidity can be obtained on terms acceptable to the Company, or at all. If the Company is unable to obtain adequate financing or financing on terms satisfactory to the Company, the Company will not have the cash resources to continue as a going concern.

Going Concern

The unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (June 5, 2008) through May 31, 2016 of $24.3 million, as well as negative cash flows from operating activities. Company's management

estimates that the cash and cash equivalents balance as of May 31, 2016 of $474 thousand is not sufficient to fund the Company s operational and clinical development activities for the twelve months following May 31, 2016. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives for operations, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or through other private sources. During the quarter ended May 31, 2016, we raised net proceeds of $750 from the proceeds of private placements to qualified investors.

Management is in ongoing financing discussions with third party investors and existing shareholders with a view to secure the needed financing. However, there is no assurance that the Company will be successful with those initiatives.

The interim condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability. If we raise additional funds through the issuance of equity, the percentage ownership of current shareholders could be reduced, and such securities might have rights, preferences or privileges senior to its common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, we may not be able to take advantage of prospective business endeavors or opportunities, which could significantly and materially restrict its future plans for developing its business and achieving commercial revenues. If we are unable to obtain the necessary capital, the Company may have to cease operations.

We expect that our operating expenses will increase over the next twelve months to continue our development activities. We expect to raise money through equity financing via the sale of our common stock or through debt financing via convertible notes. If we cannot raise the money that we need in order to continue to operate our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail. If we are unsuccessful in raising additional financing, we may need to curtail, discontinue or cease operations.

On September 9, 2015, the Israeli Subsidiary entered into a Pharma Cooperation and Project Funding Agreement (CPFA) with BIRD and Pall Corporation, a U.S. company. BIRD will give a conditional grant of $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use of Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project). The Project started on March 1, 2015. Upon the conclusion of product development, the grant shall be repaid at the rate of 5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting on March 1, 2015. During the six months ended May 31, 2016, the Israeli Subsidiary received an additional $100 thousand under the grant.

During the six months ended May 31, 2016, the Company entered into definitive agreements with accredited and qualified investors relating to a private placement (the Private Placement) of (i) 1,875,002 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 1,875,002 shares of the Company s Common Stock at a per share exercise price of $0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of $975 thousand. Furthermore, in the event the Company issues any common shares or securities convertible into common shares in a private placement for cash at a price less than $0.52 (the New Issuance Price) within a year from the issuance date, the Company will issue, for no additional consideration, additional common shares to subscribers in the $0.52 per share which total each subscriber s subscription proceeds divided by the New Issuance Price, minus the number of shares already issued to such subscriber. This provision does not apply to issuance of shares under options, issuance of shares under existing rights to acquire shares, nor issuance of shares for non-cash consideration.

On April 2016, the Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a budgeted EUR 1,304 thousand ($1,455 thousand) support program for the development of a potential cure for Type 1 Diabetes. The financial support is awarded to the Belgium subsidiary as a recoverable advance payment at 55% of budgeted costs, or for a total of EUR 717 thousand ($800 thousand). The grant will be paid to us over the project period.

On May 26, 2016, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with KORIL and CureCell. KORIL will give a conditional grant up to $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells

for the Treatment of Diabetes (the Project). The Project started on June 1, 2016. Upon the conclusion of product development, the grant shall be repaid at the yearly rate of 2.5% of gross sales. The grant will be used solely to finance the costs to conduct the research of the project during a period of 18 months starting on June 1, 2016. In June 2016, the Israeli Subsidiary received $160 thousand under the grant.

In June and July 2016, the Company entered into several unsecured convertible note agreements with accredited and qualified investors for $877.5 thousand. The term of the notes was for two years with an interest rate of 6% per annum. The entire principal amount under the notes and accrued interest shall automatically convert into Units (as defined below) upon the the earlier to occur of any of the following: (i) the closing of an offering of equity securities of the Company with gross proceeds to us greater than $10 million (Qualified Offering) (ii) the trading of the Company s common stock on the over-the counter market or an exchange at a weighted average price of at least $0.52 for fifty (50) consecutive trading days, or (iii) the listing of the Company s Common Stock on a U.S. National Exchange (each a Conversion Event). Upon the occurrence of a Conversion Event, each $0.52 of principal amount and accrued interest due is to 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 $0.52, provided that, if more favorable to the holder, any principal amount and accrued interest due shall convert into securities on the same basis as such securities are sold in the Qualified Offering. At any time, the holder may convert the principal amount and accrued interest outstanding into Units as provided above. In addition, if a Conversion Event does not occur within 12 months of the issuance date hereof, then the holder, at its option, may convert the outstanding principal amount and accrued interest under this note into either (i) Units as provided above, or (ii) shares of the Company s common stock at a per share conversion price of $0.40.

In June and July 2016, the Company entered into definitive agreements with accredited investors relating to a private placement (the Private Placement) of (i) 1,004,807 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 1, 004,807 shares of the Company s Common Stock at a per share exercise price of $0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of $522.5 thousand. Furthermore, in certain events (according to terms defined in the agreements) the Company will issue, for no additional consideration, additional common shares to subscribers which total each Subscriber s subscription proceeds divided by the New Issuance Price, minus the number of shares already issued to such subscriber.

From the above investments, the Company remitted to MaSTherCell $1 million (€ 896 thousand, in compliance with its obligations.

During 2016 and 2015, we have received certain grant funding and have relied and expect to continue to rely on such funding to further our clinical development in the future.

Cash Requirements

Subject to raising adequate funds, our plan of operation over the next 12 months is to:

- initiate regulatory activities in Europe and the United States;
- locate suitable facility in the U.S. for tech transfer and manufacturing scale-up;
- purchase equipment needed for its cell production process;
- hire key personnel including in GMP implementation and general and administrative;
- collaborate with clinical centers and regulators to carry out clinical studies and clinical safety testing;
- identify optional technologies for scale up of the cells production process; and
- initialize efforts to validate the manufacturing process.

The Company estimates its operating capital needs for the next 12 months as of May 31, 2016 to be as follows (in thousands):

GMP process development and validation	$	2,200
Scale-up of Manufacturing		3,500
General and administrative		1,300
Working capital		3,000
Total	$	10,000

The above amounts do not include the additional $2.2 million (EUR 2 million) per Amendment No. 2 that we are obligated to remit to MaSTherCell that becomes due upon the request of the MaSTherCell board of directors, of whom Company directors/officers currently represent a majority.

Future Financing

We will require additional funds to implement our growth strategy for our business. In addition, while we have received various grants that have enabled us to fund our clinical developments, these funds are largely restricted for use for other corporate operational and working capital purposes. Therefore, we will need to raise additional capital to both supplement our clinical developments that are not covered by any grant funding and to cover our operational expenses. These funds may be raised through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of the Company s shares. There can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. If we are not able to obtain the additional financing on a timely basis should it be required, or generate significant material revenues from operations, we will not be able to meet its other obligations as they become due and will be forced to scale down or perhaps even cease the our operations.

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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.

Recent Accounting Pronouncements

See Note 2 for a discussion of Recently Issued Accounting Pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Currency Exchange Risk

Due to our acquisition of MaSTherCell, currency exchange rates impact our financial performance. The majority of our balance sheet exposure relates to Euro-denominated assets and liabilities as a result of our acquisition of MaSTherCell. Further, our total revenues are in Euros and as such our results of operations are directly impacted by Euro-denominated cash flows. We will continue to monitor exposure to currency fluctuations. Instruments that may be used to protect us against future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations. We do not use derivative financial instruments for speculative or trading purposes.

Interest Rate Risk

We are exposed to market risks resulting from changes in interest rates due to short term-loan which bears interest of libor rate. We do not use derivative financial instruments to limit exposure to interest rate risk.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company s reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to the Company s management, including the Company s president and chief executive officer (who is the Company s principal executive officer) and the Company s chief financial officer, treasurer, and secretary (who is the Company s principal financial officer and principal accounting officer) to allow for timely decisions regarding required disclosure. In designing and evaluating the Company s disclosure controls and procedures, the Company s management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and the Company s management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The ineffectiveness of the Company s disclosure controls and procedures was due to material weaknesses identified in the Company s internal control over financial reporting, described below.

Management s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over the Company s financial reporting. In order to evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002. Our management, with the participation of the Company s principal executive officer and principal financial officer has conducted an assessment, including testing, using the criteria in Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission

(COSO) (2013). Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation. Based on this evaluation, the Company s management concluded its internal control over financial reporting was not effective as of May 31, 2016. The ineffectiveness of the Company s internal control over financial reporting was due to the following material weaknesses which are indicative of many small companies with small number of staff:

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

Our management believes the weaknesses identified above have not had any material affect on our financial results. However, we are currently reviewing our disclosure controls and procedures related to these material weaknesses and expect to implement changes in the next fiscal year as resources allow, including identifying specific areas within our governance, accounting and financial reporting processes to add adequate resources to potentially mitigate these material weaknesses.

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

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

Management s Remediation Plan

We plan to take steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this quarterly report on Form 10-Q, we have not been able to remediate the material weaknesses identified above. To remediate such weaknesses, we plan to implement the following changes in the next fiscal year as resources allow:

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

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

Management believes that despite our material weaknesses set forth above, our condensed financial statements for the quarter ended May 31, 2016 are fairly stated, in all material respects, in accordance with US GAAP.

Changes in Internal Control Over Financial Reporting

During the three months ended May 31, 2016, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect the Company s internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company knows 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, the Company does not

know of any such proceedings contemplated by any governmental authorities.

The Company knows 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, 2015, as filed with the Securities & Exchange Commission on February 29, 2016 (and amended on March 30, 2016), 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 its 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 six months ended May 31, 2016 without registration under the Securities Act:

During the six months ended May 31, 2016, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement (the Private Placement) of (i) 1,875,002 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 1,875,002 shares of the Company s Common Stock at a per share exercise price of $0.52. The purchased securities were issued pursuant to subscription agreements between the Company and the purchasers for aggregate proceeds to the Company of $975 thousand. Furthermore, in the event the Company issues any common shares or securities convertible into common shares in a private placement for cash at a price less than $0.52 (the New Issuance Price) within a year from the issuance date, the Company will issue, for no additional consideration, additional common shares to subscribers in the $0.52 per share which total each subscriber s subscription proceeds divided by the New Issuance Price, minus the number of shares already issued to such subscriber. This provision does not apply to issuance of shares under options, issuance of shares under existing rights to acquire shares, nor issuance of shares for non-cash consideration.

All of the securities issued in the transactions described above were issued without registration under the Securities Act in reliance upon the exemptions provided in Section 4 (a) (2) of the Securities Act or Regulation S under such Securities Act. Except with respect to securities sold under Regulation S, the recipients of securities in each such transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Appropriate legends were affixed to the share certificates issued in all of the above transactions. Each of the recipients represented that they were accredited investors within the meaning of Rule 501(a) of Regulation D under the Securities Act, or had such knowledge and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in its common stock. All recipients had adequate access, through their relationships with the Company and its officers and directors, to information about the Company. None of the transactions described above involved general solicitation or advertising.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits required by Regulation S-K:

No.	Description
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1*	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2*	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002

*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, and Chairperson of the Board
(Principal Executive Officer)
Date: July 15, 2016

/s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: July 15, 2016