Orgenesis Inc.
Form 10-Q
April 14, 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 February 29, 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 April 14, 2016, there were 108,739,806 shares of registrant s common stock outstanding.

ORGENESIS INC.
FORM 10-Q
FOR THE THREE MONTHS ENDED FEBRUARY 29, 2016

TABLE OF CONTENTS

PART I UNAUDITED FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	February 29, 2016	November 30, 2015
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 933	$ 4,168
Accounts receivable	1,694	1,173
Prepaid expenses and other receivables	973	1,118
Grants receivable	1,037	1,446
Inventory	418	301
Total current assets	5,055	8,206
NON CURRENT ASSETS:		
Property and equipment, net	4,564	4,296
Restricted cash	5	5
Intangible assets, net	16,707	16,653
Goodwill	9,812	9,535
Other assets	57	53
Total non current assets	31,145	30,542
TOTAL ASSETS	36,200	38,748
Liabilities and equity (net of capital deficiency)		
CURRENT LIABILITIES:		
Accounts payable	2,865	3,475
Accrued expenses	992	816
Employee and related payables	1,643	1,348
Related parties	42	42
Advance payments on account of grant	247	307
Short-term loans and current maturities of long term loans	1,211	2,829
Deferred income	1,415	1,216
Convertible loans	2,013	3,022
Convertible bonds	1,787	1,888
Price protection derivative	197	1,533
TOTAL CURRENT LIABILITIES	12,412	16,476
LONG-TERM LIABILITIES:		
Loans payable	2,534	2,540
Warrants	1,450	1,382
Retirement benefits obligation	5	5
Deferred taxes	3,117	3,327
TOTAL LONG-TERM LIABILITIES	7,106	7,254
TOTAL LIABILITIES	19,518	23,730
COMMITMENTS		
REDEEMABLE COMMON STOCK		21,458
EQUITY (CAPITAL DEFICIENCY):		

Common stock	11	6
Additional paid-in capital	37,801	14,229
Receipts on account of shares to be allotted	67	1,251
Accumulated other comprehensive loss	(782)	(1,286)
Accumulated deficit	(20,415)	(20,640)
TOTAL EQUITY (CAPITAL DEFICIENCY)	16,682	(6,440)
TOTAL LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)	$ 36,200	$ 38,748

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

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

	Three Months Ended	
	February 29, 2016	February 28, 2015
REVENUES	$ 1,520	$
COST OF REVENUES	1,480	
GROSS PROFIT	40	
RESEARCH AND DEVELOPMENT EXPENSES, net	401	175
AMORTIZATION OF INTANGIBLE ASSETS	328	
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	1,166	659
OPERATING LOSS	(1,855)	(834)
FINANCIAL INCOME, net	1,772	44
LOSS BEFORE INCOME TAXES	(83)	(790)
INCOME TAX BENEFIT	308	
NET INCOME (LOSS)	$ 225	$ (790)
EARNING (LOSS) PER SHARE:		
Basic	$ 0.002	$ (0.01)
Diluted	$ 0.001	$ (0.02)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED EARNING (LOSS) PER SHARE:		
Basic	103,127,025	55,735,394
Diluted	103,127,025	56,288,938
OTHER COMPREHENSIVE INCOME (LOSS):		
Net income (loss)	$ 225	$ (790)
Translation adjustments	504	(102)
TOTAL COMPREHENSIVE INCOME (LOSS)	$ 729	$ (892)

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					
	Number	Par Value	Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Loss	Accumulat Deficit
Balance at December 1, 2014	55,970,565	$ 6	$ 13,152	$ 60	$ (18)	$ (16,1
Changes during the three months ended February 28, 2015:						
Stock-based compensation to employees and directors			159			
Stock-based compensation to service providers			90			
Comprehensive loss for the period					(102)	(7
Balance at February 28, 2015	55,970,565	$ 6	$ 13,401	$ 60	$ (120)	$ (16,9
Balance at December 1, 2015	55,835,950	$ 6	$ 14,229	$ 1,251	$ (1,286)	$ (20,6
Changes during the three months ended February 29, 2016:						
Stock-based compensation to employees and directors			120			
Stock-based compensation to service providers			50			
Issuances of shares from investments and conversion of convertible loans	10,502,132	1	1,948	(1,251)		
Reclassification of redeemable	42,401,724	4	21,454			

common stock						
Receipts on account of shares to be allotted				67		
Comprehensive income for the period					504	2
Balance at February 29, 2016	108,739,806	$ 11	$ 37,801	$ 67	$ (782)	$ (20,4

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

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

	Three months ended	
	February 29, 2016	February 28, 2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 225	$ (790)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	170	249
Depreciation and amortization expenses	641	1
Change in fair value of warrants and embedded derivatives	(1,803)	(183)
Change in fair value of convertible bonds	(157)	
Interest expense accrued on loans and convertible loans	8	116
Changes in operating assets and liabilities:		
Increase in accounts receivable	(489)	
Increase in inventory	(109)	
Increase in other assets	(2)	
Decrease (increase) in prepaid expenses and other accounts receivable	164	(610)
Decrease in accounts payable	(692)	(515)
Increase (decrease) in accrued expenses	172	(128)
Increase (decrease) in employee and related payables	286	(77)
Increase in deferred income	165	
Decrease in advance payments and receivables on account of grant	388	1,296
Decrease in deferred taxes	(308)	
Net cash used in operating activities	(1,341)	(641)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(354)	(6)
Restricted cash		(5)
Net cash used in investing activities	(354)	(11)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Short-term line of credit		(14)
Proceeds from issuance of warrants into shares and warrants	225	
Repayment of short and long-term debt	(1,733)	
Net cash used in financing activities	(1,508)	(14)
NET CHANGE IN CASH AND CASH EQUIVALENTS	(3,203)	(666)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(32)	(128)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,168	1,314
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 933	$ 520
SUPPLEMENTAL NON-CASH FINANCING ACTIVITY		
Conversion of loans (including accrued interest) to common stock and warrants	$ 973	
Reclassification of redeemable common stock to equity	$ 21,458	

SUPPLEMENTAL INFORMATION ON INTEREST PAID IN CASH	$ 136

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

ORGENESIS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the Three Months Ended February 29, 2016 and February 28, 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 February 29, 2016, and the consolidated statements of comprehensive income (loss) for the three months ended February 29, 2016 and February 28, 2015, and the changes in equity (capital deficiency) and cash flows for the three-months periods ended February 29, 2016 and February 28, 2015. The results for the three months ended February 29, 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. The Company has net losses for the period from inception (June 5, 2008) through February 29, 2016 of $20.4 million, as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following February 29, 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 private equity markets.

The consolidated financial statements do not include any adjustments that may be necessary should the Company be unable 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. If the Company raises 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, the Company 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 the Company is unable to obtain the necessary capital, the Company may have to cease operations.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 (the "Share Exchange Agreement") dated March 2, 2015 with MaSTherCell SA, Cell Therapy Holding SA (collectively MaSTherCell). According to the Share Exchange Agreement, 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 $24,593 thousand). Out of the Consideration Shares, 8,173,483 shares will be allocated to the bondholders of MaSTherCell in case of conversion.

As part of the agreement the parties agreed on certain post closing conditions. In the event that the Company did not achieve those conditions within eight (8) months of the closing date, MaSTherCell had an option to unwind the transaction. (the Unwind Option) by delivering to the Company all of the Consideration Shares plus any amount that the Company has advanced or invested in MaSTherCell.

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 was extended to November 30, 2015, furthermore 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.

On December 10, 2015, the Company entered into definitive agreements with accredited investors relating to a private placement for aggregate proceeds to the Company of $4,278 thousand. From the proceeds of the Private Placement, on December 10, 2015 the Company remitted to MaSTherCell the Initial Investment of € 3.8 million or $4,103 thousand (out of the original obligation for investment of €5 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.

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 Company's technology that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and differentiating (converting) them into pancreatic beta cell-like insulin producing cells for patients with Type 1 Diabetes. This segment is comprised of all entities aside from MaSTherCell.

The 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.

Prior to the acquisition of MaSTherCell, the Company operated as one reporting segment. For this reason, the Company does not disclose comparative data for the three months ended February 28, 2015.

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

	CDMO	CTB	Corporate and Eliminations	Consolidated
		(in thousands)		
Net revenues from external customers	$ 1,571	$	$ (51)	$ 1,520
Cost of revenues	(1,288)		119	(1,169)
Research and development expenses, net		(298)	(68)	(366)
Operating expenses	(607)	(422)		(1,029)
Depreciation and amortization expense	(640)	(1)		(641)
Segment Performance	$ (964)	$ (721)		(1,685)

Share-based compensation	(170)	(170)
Financial income, net	1,772	1,772
Loss before income taxes		(83)

Geographic, Product and Customer Information

Substantially all 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 February 29, 2016 (in thousands)
Customer A	$ 764
Customer B	$ 562

NOTE 5 CONVERTIBLE LOAN AGREEMENTS

During the year ended November 30, 2015, the Company entered into five convertible loan agreements with new investors for a total amount of $950 thousand (the 2015 Convertible Loans), interest is calculated at 6% annually and was payable, along with the principal on or before the maturity date.

On December 23, 2015, the holders of all the 2015 Convertible Loans and the Company agreed to convert the 2015 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 2015 Convertible Loans, the Company issued an aggregate of 1,870,638 shares of Common stock and three year warrants to purchase up to an additional 1,870,638 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) 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 date and the allocation of the proceeds (for the fair value as of February 29, 2016, see Note 9):

	Total Fair Value (in thousands)
Warrants component	$ 323
Price protection derivative component	34
Shares component	616
Total	$ 973

NOTE 6 COMMITMENTS

Collaboration Agreements

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 shall 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.

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 manufactuing, 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.

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 first quarter of 2016, the Company entered into definitive agreements with accredited investors relating to a private placement (the Private Placement) of (i) 432,693 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 432,693 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 $225 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 9).

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 February 29, 2016, see Note 9):

	Total Fair Value (in thousands)
Warrants component	$ 67
Price protection derivative component	9
Shares component	149
Total	$ 225

NOTE 8 EARNING (LOSS) PER SHARE

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

	Three Months Ended	
	February 29, 2016	February 28, 2015
	(in thousands, except per share data)	
Basic:		
Income (loss) for the period	$ 225	$ (790)
Weighted average number of common shares outstanding	103,127,025	55,735,394
Earning (loss) per common share	$ 0.002	$ (0.01)
Diluted:		
Income (loss) for the period	$ 225	(790)
Changes in fair value of embedded derivative and interest expense on convertible bonds	(104)	
Change in fair value of warrants		153
Income (loss) for the period	$ 121	(943)
Weighted average number of shares used in the computation of basic loss per share	103,127,025	55,735,394
Number of dilutive shares related to warrants		553,543
Weighted average number of common shares outstanding	103,127,025	56,288,937
Earning (loss) per common share	$ 0.001	$ (0.02)

Diluted earning per share does not include 12,899,314 shares underlying outstanding options, 17,933,512 shares issuable upon exercise of warrants and 1,100,000 shares upon conversion of convertible notes for the three months ended February 29, 2016, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted loss per share does not include 15,267,559 shares underlying outstanding options, 350,000 shares due to stock-based compensation to service providers, 2,682,256 shares issuable upon exercise of warrants and 701,796 shares upon conversion of loans for the three months ended February 28, 2015, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 9 - FAIR VALUE PRESENTATION

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

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
Level 2: Observable inputs that are based on inputs not quoted on active markets, but corroborated by market data.
Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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

As of February 29, 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):

	February 29, 2016 Level 3	**November 30, 2015** Level 3
Warrants (1)	$ 1,450	$ 1,382
Price protection derivative (1)	197	1,533
Embedded derivatives*(1)	177	289
Convertible bonds (2)	$ 1,787	$ 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 the 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 and 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 February 29, 2016:

	Price Protection Derivative and Warrants	Embedded Derivative
Fair value of shares of common stock	$ 0.33	$ 0.33
Expected volatility	84%-89%	84%
Discount on lack of marketability	13%	-
Risk free interest rate	0.38%-0.9%	0.38%
Expected term (years)	0.7-2.9	0.33
Expected dividend yield	0%	0%
Expected capital raise dates	Q2 2016,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 three months ended February 29, 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	390			43
Conversion		(10)		
Changes in fair value during the period	(322)	(102)	(157)	(1,379)
Translation adjustments			56	
Balance at end of the period	$ 1,450	$ 177	$ 1,787	$ 197

(*) There were no transfers to Level 3 during the three months ended February 29, 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 February 29, 2016	$ 1,268	$ **1,450**	$ 1,618

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 February 29, 2016	$ 192	$ **196**	$ 199

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

	Base -10%	Base	Base+10%
	(in thousands)		
As of February 29, 2016	$ 168.1	$ **177**	$ 185.8

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 have expired. There were no transfers to Level 3 during the twelve months ended November 30, 2015.

NOTE 10 - SUBSEQUENT EVENTS

a. On March 11, 2016, the Company entered into definitive agreement with an investor relating to a private placement of (i) 769,232 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 769,232 shares of the Company s common stock at a per share exercise price of $0.52. The purchased securities will be issued pursuant to subscription agreements between the Company and the purchaser for aggregate proceeds to the Company of $400 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) through the first anniversary of 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.

b. In 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. The grant will be paid to Orgenesis over a period of 1 year.

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 amended and filed with the Securities & Exchange Commission 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 impact;
- 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 amended and

filed with the Securities & Exchange Commission 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 intend to leverage the expertise and experience of MaSTherCell, our subsidiary, in cell process development and manufacturing capability, 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 .

18

Cell Therapy and Regenerative Medicine Field

Regenerative medicine is generally the process of replacing or regenerating human cells, tissues or organs to restore normal function. Our business model is focused on two of these areas. First, through our wholly-owned CDMO subsidiary, MaSTherCell, we are afforded a unique and fundamental base platform of experience and expertise with a multitude of cell types in development. MaSTherCell is strategically positioning us in a way that allows us to participate in the cell therapy field on multiple levels as the cell therapy industry evolves. Our goal is to nurture our reputation as a premier service provider in the regenerative medicine industry by continuing to leverage the experience and expertise of MaSTherCell as a recognized leader of cell therapy manufacturing and development. Second, on our clinical development side, through our Israeli Subsidiary, our goal is to advance a unique product that combines cell-based therapy and regenerative medicine, Autologous Insulin Producing (AIP) cells, into clinical development. AIP cells utilize the technology of cellular trans-differentiation to transform an autologous adult liver cell into an adult, fully functional and physiologically glucose-responsive pancreatic-like insulin producing cell. Treatment with AIP cells is expected to provide Type 1 Diabetes patients with long-term insulin independence. Because the AIP cells are autologous, this benefit should be achieved and maintained without the need for concomitant immunosuppressive therapy.

All living complex organisms start as a single cell that replicates, differentiates (matures) and perpetuates in an adult organism throughout its lifetime. 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). To date, the most common type of cell therapy has been the replacement of mature, functioning cells through blood and platelet transfusions. Since the 1970s, first bone marrow and then blood and umbilical cord-derived stem cells have been used to restore bone marrow, as well as blood and immune system cells damaged by the chemotherapy and radiation that are used to treat many cancers. These types of cell therapies are standard practice world-wide and are typically reimbursed by insurance.

Within the field of cell therapy, research and development using stem cells to treat a host of diseases and conditions has greatly expanded. Stem cells (in either embryonic or adult forms) are primitive and undifferentiated cells that have the unique ability to transform into or otherwise affect many different cells, such as white blood cells, nerve cells or heart muscle cells. Our cell therapy development efforts do not use stem cells, but rather are focused on the use of fully mature, adult cells; for our purposes in the treatment of diabetes, our cells are derived from the liver or other adult tissue and are transdifferentiated to become adult AIP cells.

There are two general classes of cell therapies: Patient Specific Cell Therapies (PSCTs) and Off-the-Shelf Cell Therapies (OSCTs). In PSCTs, cells collected from a person (donor) are transplanted into, or used to develop a treatment for a patient (recipient) with or without modification. In cases where the donor and the recipient are the same individual, these procedures are referred to as autologous . In cases in which the donor and the recipient are not the same individual, these procedures are referred to as allogeneic. A notable form of autologous PSCT involves the use of autologous cells to create vaccines directed against tumor cells in the body which has been demonstrated to be effective and safe in clinical trials. Our treatment for diabetes focuses on PSCTs using autologous cells. Autologous cells offer a low likelihood of rejection by the patient and we believe the long-term benefits of these PSCTs can best be achieved with an autologous product.

Various cell therapies are in clinical development for an array of human diseases, including autoimmune, oncologic, neurologic and orthopedic diseases, among other indications. Orgenesis, as well as other companies, are developing cell therapies that are designed to address cancers, ischemic repair and immune modulation. While no assurances can be given regarding future medical developments, we believe that the field of cell therapy holds the promise to better the human experience and minimize or ameliorate the pain and suffering from many common diseases and/or from the process of aging.

Diabetes Mellitus (DM), or simply diabetes, is a metabolic disorder usually caused by a combination of hereditary and environmental factors, and results in abnormally high blood sugar levels (hyperglycemia). Diabetes occurs as a result of impaired insulin production by the pancreatic islet cells. The most common types of the disease are Type-1 Diabetes (T1D) and Type-2 Diabetes (T2D). In T1D, the onset of the disease follows an autoimmune attack of -cells that severely reduces -cell mass. T1D usually has an early onset and is sometimes also called juvenile diabetes. In T2D, the pathogenesis involves insulin resistance, insulin deficiency and enhanced gluconeogenesis, while late progression stages eventually leads to -cell failure and a significant reduction in -cell function and mass. T2D often occurs later in life and is sometimes called adult onset diabetes. Both T1D and late-stage T2D result in marked hypoinsulinemia, reduction in -cell function and mass and lead to severe secondary complications, such as myocardial infarcts, limb amputations, neuropathies and nephropathies and even death. In both cases, patients become insulin-dependent, requiring either multiple insulin injections per day or reliance on an insulin pump.

We believe that diabetes will be one of the most challenging health problems in the 21st century, and will have a staggering health, societal, and economic impact. Diabetes is currently the fourth or fifth leading cause of death in most developed countries. There also is substantial evidence that it is an epidemic in many developing and newly industrialized nations.

Threats from Pancreas Islet Transplantation and Cell Therapies

For some patients with severe and difficult to control diabetes (hypoglycemic unawareness), islet transplants are considered. Pancreatic islets are the cells in the pancreas that produce insulin. Physicians use enzymes to isolate the islets from the pancreas of a deceased donor. Because the islets are fragile, transplantation must occur soon after they are removed. Typically, a patient receives at least 10,000 islet equivalents per kilogram of body weight, extracted from pancreases obtained from different donors. Patients often require two separate transplants to achieve insulin independence.

Transplants are often performed by an interventional radiologist, who uses x-rays and ultrasound to guide placement of a catheter - a small plastic tube - through the upper abdomen and into the portal vein of the liver. The islets are then infused slowly through the catheter into the liver. The patient receives a local anesthetic and a sedative. In some cases, a surgeon may perform the transplant through a small incision, using general anesthesia.

Because the islets are obtained from cadavers that are unrelated to the patient, the patient needs to be treated with drugs that inhibit the immune response so that the patient doesn t reject the transplant. In the early days of islet transplantation, the drugs were so powerful that they actually were toxic to the islets; improvements in the procedure are widely used and are now referred to as the Edmonton Protocol.

Studies and Reports

Since reporting their findings in the June 2000 issue of the New England Journal of Medicine, researchers at the University of Alberta in Edmonton, Canada, have continued to use and refine Edmonton Protocol to transplant pancreatic islets into selected patients with T1D that is difficult to control.

In 2005, the researchers published 5-year follow-up results for 65 patients who received transplants at their center and reported that about 10 percent of the patients remained free of the need for insulin injections at 5-year follow-up. Most recipients returned to using insulin because the transplanted islets lost their ability to function over time, potentially due to the immune suppression protocol, which prevents the immune rejection of the implanted cells. The researchers noted, however, that many transplant recipients were able to reduce their need for insulin, achieve better glucose stability, and reduce problems with hypoglycemia, also called low blood sugar level.

In its 2006 annual report, the Collaborative Islet Transplant Registry, which is funded by the National Institute of Diabetes and Digestive and Kidney Diseases, presented data from 23 islet transplant programs on 225 patients who received islet transplants between 1999 and 2005. According to the report, nearly two-thirds of recipients achieved insulin independence - defined as being able to stop insulin injections for at least 14 days - during the year following transplantation. However, other data from the report showed that insulin independence is difficult to maintain over time. Six months after their last infusion of islets, more than half of recipients were free of the need for insulin injections, but at 2-year follow-up, the proportion dropped to about one-third of recipients. The report described other benefits of islet transplantation, including reduced need for insulin among recipients who still needed insulin, improved blood glucose control, and greatly reduced risk of episodes of severe hypoglycemia.

In a 2006 report of the Immune Tolerance Network s international islet transplantation study, researchers emphasized the value of transplantation in reversing a condition known as hypoglycemia unawareness. People with hypoglycemia unawareness are vulnerable to dangerous episodes of severe hypoglycemia because they are not able to recognize that their blood glucose levels are too low. The study showed that even partial islet function after transplant can eliminate hypoglycemia unawareness.

Pancreatic islet transplantation (cadaver donors) is an allogeneic transplant, and, as in all allogeneic transplantations, there is a risk for graft rejection and patients must receive lifelong immune suppressants. Though this technology has shown good results clinically, there are several setbacks, such as patients being sensitive to recurrent T1D autoimmune attacks and a shortage in tissues available for islet cells transplantation.

Our Cell Therapy Business

We are developing and bringing to the clinical stage a technology that is based on the published work of Prof. Sarah Ferber, our Chief Science Officer and a researcher at THM, who established a proof of concept that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and differentiating (converting) them into pancreatic beta cell-like insulin-producing cells. Furthermore, those cells were found to be resistant to the autoimmune attack and to produce insulin in a glucose-sensitive manner.

We intend to grow our cell therapy business by furthering this technology to the clinical stage. We intend to devote significant resources to process development and manufacturing in order to optimize the safety and efficacy of our future product candidates, as well as our cost of goods and time to market. Our goal is to carefully manage our fixed cost structure, maximize optionality, and drive long-term cost of goods as low as possible. We believe that operating our own manufacturing facility will provide the Company with enhanced control of material supply for both clinical trials and the commercial market, will enable the more rapid implementation of process changes, and will allow for better long-term margins.

Contract Development and Manufacturing Business

Acquisition of MaSTherCell

We acquired MaSTherCell in November 2014 pursuant to a share purchase agreement with MaSTherCell s shareholders dated as of November 12, 2014, as subsequently amended (the SEA). Under the SEA, as amended in November 2015, we agreed to remit to MaSTherCell, by way of an equity investment, 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. By agreement with the MaSTherCell shareholders, we remitted in December 2015, the sum of EUR 3.8 million or $4,103,288, in compliance with our obligations as required under the SEA. The right of the former MaSTherCell shareholders to unwind the merger with our Company terminated upon the such investment. Additionally, in connection with the equity investment, on December 10, 2015 we agreed to invest an additional 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.

In connection with the above agreements, we granted to certain former MaSTherCell shareholders, who currently hold approximately 12% of the Company s outstanding common stock, the first right to negotiate the terms of the sale of MaSTherCell, should the Company decide at a future date to sell its shares in MaSTherCell or otherwise sell equity interests in MaSTherCell (the Sale Event), on an exclusive basis, for the first thirty days following our delivery to such shareholders of notice of such intention. We agreed to accept the offer of such shareholders resulting from the Sale Event negotiations, unless our board of directors determines that a materially superior offer may be available to us if the Sale Event were open to other parties, in which case we are entitled to negotiate the Sale Event with unrelated third parties.

21

Our Plans for MaSTherCell

We are conducting our CDMO business through MaSTherCell. Subject to raising additional working capital, we intend to devote significant resources to process development and manufacturing in order to optimize the safety and efficacy of our future product candidates for our customers, as well as our cost of goods and time to market. Our goal is to carefully manage our fixed cost structure, maximize optionality, and drive long-term cost of goods as low as possible. We believe that operating our own manufacturing facility provides us with enhanced control of material supply for both clinical trials and the commercial market, will enable the more rapid implementation of process changes, and will allow for better long-term margins.

MaSTherCell's target customers are primarily cell therapy companies that are in pre- or early-stage clinical trials. This stems from the finding that these companies' processes have to be set up right from start in order for them to obtain approved products that have the simplest possible process and with the lowest possible cost of goods sold (COGS). Therefore, MaSTherCell's strategy is to build long term relationships with its customers in order to help them bring highly potent cell therapy products faster to the market and in cost-effective ways.

To provide these services MaSTherCell relies on a team of dedicated experts both from academic and industry backgrounds. It operates through state-of-the-art facilities located just 40 minutes from Brussels, which have received the final cGMP manufacturing authorization from the Belgian Drug Agency (AFMPS) in September 2013.

Recent Corporate Developments

Since the commencement of the year through February 29, 2016, we have experienced the following corporate developments:

Collaboration Agreement with Grand China Energy Group Limited

On February 18, 2016, the Company, through its Israeli Subsidiary, entered into a Collaboration Agreement (the "Collaboration Agreement) with Grand China Energy Group Limited with headquarters in Beijing, China ("Grand China") to collaborate in carrying out clinical trials and marketing the Company's autologous insulin producing cell therapy product ("API") in the Peoples Republic of China, Hong Kong and Macau (the "Territory"), based on achieving certain pre-market development milestones that include Grand China obtaining the requisite regulatory approvals for commercialization of the API, including performing all clinical and other testing required for market authorization in each jurisdiction in the Territory. Upon achieving the pre-market development milestones by Grand China, the parties will collaborate on marketing the products in the Territory. Grand China will bear all costs associated with the pre-marketing development efforts in the Territory, which is expected to last for approximately four years.

Subject to the completion of the pre-marketing development milestones, the Israeli Subsidiary has agreed to grant to Grand China, or a fully owned subsidiary thereof, under a separate sub-license agreement (the "Sub-License Agreement"), an exclusive sub-license to the intellectual property underlying the API solely for commercialization of the Company's products in each such jurisdiction in the Territory where all of the pre-marketing development required to commercialize the API product have been successfully completed by Grand China. Grand China has agreed to pay annual license fees, ongoing royalties based on net sales generated by Grand China and its sublicensees, milestone payments and sublicense fees. It is anticipated that the Sub-License Agreement will also contain, among other things, minimum sales requirements as well as other provisions common in licensing agreements for international biotech licensing agreements.

The Collaboration Agreement is terminable by our Israeli Subsidiary upon certain conditions, including, but not limited to, if the clinical trials necessary to obtain the pre-marketing approval are not commenced with 12 months of the date of the execution of the agreement or if all approvals necessary for the commencement of marketing in the

Territory are not obtained within four years. The Collaboration Agreement is also terminable under certain limited conditions relating to a party's insolvency or bankruptcy related event or breach of a material term of the agreement and force majeure events.

Joint Venture Agreement with CureCell Co., Ltd.

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 (hereinafter 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 our Israeli Subsidiary. In addition, each party shall be required to exert best commercial efforts to carry out, in a timely and professional manner, 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). Additionally, the parties agreed to establish a steering committee for the management of the JV Company comprised of five members, two of which are to designated by each of the Company and CureCell and the fifth to be an independent third party industry expert acceptable to each of the Company and CureCell.

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.

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 shall 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.

Results of Operations

Comparison of the Three Months Ended February 29, 2016 to the Three Months Ended February 28, 2015

Revenue and Cost of Sales

For the three months ended February 29, 2016, our total revenues and cost of sales were approximately $1.52 and $1.48 million, respectively, as opposed to none for the corresponding period in 2015. The increase in revenue is attributable to our acquisition of MaSTherCell and the revenues they recognize from services and sales of consumables.

Expenses

The Company s expenses for the three months ended February 29, 2016 are summarized as follows in comparison to its expenses for the three months ended February 28, 2015:

	Three Months Ended February 29, 2016	Three Months Ended February 28, 2015
	(in thousands)	
Revenues	$ (1,520)	$
Cost of sales	1,480	
Research and development expenses, net	401	175
Amortization of intangible assets	328	
Selling, general and administrative expenses	1,166	659
Financial income, net	(1,772)	(44)
Loss before income taxes	$ 83	$ 790

Research and Development Expenses, net

	Three Months Ended February 29, 2016	Three Months Ended February 28, 2015
	(in thousands)	
Salaries and related expenses	$ 251	118
Stock-based compensation	34	41
Professional fees and consulting services	91	123
Lab expenses	91	63
Other research and development expenses	45	36
Less grant	(111)	(206)
Total	$ 401	$ 175

The decrease in professional fees and consulting services and the increase in salaries and related expenses in the three months ended February 29, 2016, compared to the three months ended February 28, 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 decrease in grant income is due to a $57 thousand decrease on the Tedco project, and $50 thousand decrease on the DGO6 project due to the reduction in the volume of work that was done by our Israeli subsidiary. This was offset by grant income of $18 thousand due to work performed under the grant approved from BIRD.

Selling, General and Administrative Expenses

	Three Months Ended February 29, 2016	Three Months Ended February 28, 2015
	(in thousands)	
Salaries and related expenses	$ 204	$ 114
Stock-based compensation	137	207
Accounting and legal fees	208	187
Professional fees	314	82
Rent and related expenses	151	
Business development	84	14
Other general and administrative expenses	68	55

Total	$	1,166	$	659

Selling, general and administrative expenses for the three months ended February 29, 2016 increased by 77%, or $508 thousand, compared to the three months ended February 28, 2015. The main increase in costs related to selling, general and administrative activities is due to MaSTherCell activities of $606 thousand and an increase in the amount of $22 thousand due to a new patent application. This increase was partially offset by a decrease of $70 thousand in stock-based compensation costs and a decrease of $50 thousand in professional fees due to reduced reliance on outside professionals as compared to the same period last year.

Financial Income, net

	Three Months Ended February 29, 2016	Three Months Ended February 28, 2015
	(in thousands)	
Decrease in fair value of warrants and financial liabilities measured at fair value	$ (1,960)	$ (183)
Interest expense on loans and convertible loans	185	116
Foreign exchange loss, net	3	19
Other expenses		4
Total	$ (1,772)	$ (44)

The increase in financial income for the three months ended February 29, 2016 compared to the same period of 2015 is mainly attributable to a decrease of $157 thousand in the convertible bonds and $1.6 million in the fair value of warrants, price protection derivative and embedded derivative. The main reason is the Company's updated assumptions related to the probabilities of activating the anti dilution mechanism.. This increase was partially offset by an increase of $121 thousand of interest expense of the MaSTherCell loans.

Liquidity and Financial Condition

Working Capital Deficiency

	February 29, 2016	November 30, 2015
	(in thousands)	
Current assets	$ 5,055	$ 8,206
Current liabilities	12,412	16,476
Working capital deficiency	$ (7,357)	$ (8,270)

The decrease in current assets is mainly due to a decrease of $3.2 million in cash and cash equivalents, which was partially offset by an increase in amount of $0.5 million in accounts receivable.

The decrease in current liabilities is mainly due to a decrease of $1.6 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.

Cash Flows

	Three months Ended February 29, 2016	Three months Ended February 28, 2015
	(in thousands)	
Net income (loss)	$ 255	$ (790)
Net cash used in operating activities	(1,341)	(641)

Net cash used in investing activities	(354)		(11)
Net cash used in financing activities	(1,508)		(14)
Increase (decrease) in cash and cash equivalents	$ (3,203)	$	(666)

The increases in net cash used in operating and investing activities for the three months ended February 29, 2016 compared to the three months ended February 28, 2015 was mainly due to the CDMO activities that commenced pursuant to the acquisition of MaSTherCell in March 2015.

The increases in cash used in financing activities for the three months ended February 29, 2016 compared to the three months ended February 28, 2015 was due to the repayment of short and long-term loans in amount of $1.7 million, which was offset by proceeds from issuance of shares, and warrants in the amount of $0.2 million.

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 August 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 August 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, 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 February 29, 2016 of $20.4 million, as well as negative cash flows from operating activities. Company's management estimates that the cash and cash equivalents balance as of February 29, 2016 of $933 thousand, is not sufficient to fund the Company s operational and clinical development activities for the twelve months following February 29, 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 private equity markets.

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. 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. If the Company raises 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, the Company 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 the Company is 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. 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 three months ended February 29, 2016, the Israeli Subsidiary received an additional $100 thousand under the grant.

On March 11, 2016, we entered into definitive agreement with an investor relating to a private placement of (i) 769,232 shares of the Company s common stock and (ii) three year warrants to purchase up to an additional 769,232 shares of the Company s common stock at a per share exercise price of $0.52. The purchased securities will be issued pursuant to subscription agreements between the Company and the purchaser for aggregate proceeds of $400 thousand. Furthermore, in the event we 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) through the first anniversary of the issuance date, we 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.

In April 2016, our Belgium 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 as a recoverable advance payment at 55% of budgeted costs, or for a total of EUR 717 thousand. The grant will be paid to the Company over a period of 1 year.

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

The Company s 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 February 29, 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 EUR 2.2 million per Amendment No. 2 under the share exchange agreement with MaSTherCell shareholders that becomes due upon the request of the MaSTherCell board of directors, of whom Company directors/officers currently represent a majority.

Future Financing

The Company will require additional funds to implement the Company s growth strategy for its business. In addition, while the Company has received various grants that have enabled the company to fund its clinical developments, these funds are largely restricted for use for other corporate operational and working capital purposes. Therefore, the Company will need to raise additional capital to both supplement the Company s clinical developments that are not covered by any grant funding and to cover the Company s 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 the company when needed or, if available, that it can be obtained on commercially reasonable terms. If the Company is not able to obtain the additional financing on a timely basis should it be required, or generate significant material revenues from operations, the Company 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 Company s operations.

Off-Balance Sheet Arrangements

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

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.

28

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 interim 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 February 29, 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, 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 February 29, 2016 are fairly stated, in all material respects, in accordance with US GAAP.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company s internal control over financial reporting during the three months ended February 29, 2016 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 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits required by Regulation S-K:

No.	Description
10.21*	Form of Subscription Agreement

10.22*	Form of Securities Purchase Agreement and Note Payable Credit Line Agreement
21.1	List of Subsidiaries of Orgenesis Inc.
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

No.	Description
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: April 14, 2016

/s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: April 14, 2016