

Orgenesis Inc.  
Form 10-Q  
October 15, 2015

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

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

**For the Quarterly Period Ended August 31, 2015**

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

**For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 000-54329**

**ORGENESIS INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of incorporation or  
organization)

**98-0583166**

(I.R.S. Employer Identification No.)

**20271 Goldenrod Lane  
Germantown, MD 20876**

(Address of principal executive offices) (zip code)

**(480) 659-6404**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

Yes  No .

As of October 15, 2015, there were 98,237,674 shares of registrant's common stock outstanding.

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**ORGENESIS INC.**  
**FORM 10-Q**  
**FOR THE NINE MONTHS ENDED AUGUST 31, 2015**

**TABLE OF CONTENTS**

**PART I UNAUDITED FINANCIAL INFORMATION**

<u>ITEM 1.</u>	<u>CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u>	<u>3</u>
<u>ITEM 2.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>28</u>
<u>ITEM 3.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>39</u>
<u>ITEM 4.</u>	<u>CONTROLS AND PROCEDURES</u>	<u>39</u>

**PART II OTHER INFORMATION**

<u>ITEM 1.</u>	<u>LEGAL PROCEEDINGS</u>	<u>40</u>
<u>ITEM 1A.</u>	<u>RISK FACTORS</u>	<u>40</u>
<u>ITEM 2.</u>	<u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	<u>40</u>
<u>ITEM 3.</u>	<u>DEFAULTS UPON SENIOR SECURITIES</u>	<u>40</u>
<u>ITEM 4.</u>	<u>MINE SAFETY DISCLOSURES</u>	<u>40</u>
<u>ITEM 5.</u>	<u>OTHER INFORMATION</u>	<u>41</u>
<u>ITEM 6.</u>	<u>EXHIBITS</u>	<u>42</u>
	<u>SIGNATURES</u>	<u>44</u>

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

**ORGENESIS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**In U.S. dollars**  
**(Unaudited)**

	<b>August 31,</b>	<b>November 30,</b>
	<b>2015</b>	<b>2014</b>
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 264,330	\$ 1,314,052
Restricted cash	5,160	-
Accounts receivable	847,476	-
Prepaid expenses and other receivables	394,242	104,958
Receivables on account of grant	1,223,434	810,516
Inventory	264,748	-
<b>TOTAL CURRENT ASSETS</b>	<b>2,999,390</b>	<b>2,229,526</b>
<b>NON CURRENT ASSETS:</b>		
Funds in respect of retirement benefits obligation	6,398	6,377
Property and equipment, net	4,320,435	13,049
Other assets	34,903	-
Intangible assets, net	18,086,631	-
Goodwill	10,102,760	-
<b>TOTAL NON CURRENT ASSETS</b>	<b>32,551,127</b>	<b>19,426</b>
<b>TOTAL ASSETS</b>	<b>35,550,517</b>	<b>2,248,952</b>

**ORGENESIS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**In U.S. dollars**  
**(Unaudited)**

	<b>August 31, 2015</b>	<b>November 30, 2014</b>
<b>Liabilities net of capital deficiency</b>		
<b>CURRENT LIABILITIES:</b>		
Short-term bank credit	552,059	14,084
Accounts payable	2,787,727	1,083,910
Accrued expenses	551,206	374,673
Employees and related payables	1,094,525	626,012
Related parties	42,362	42,362
Advance payment on account of grant	-	84,911
Current portion of loans payable	1,460,384	-
Deferred income	1,112,455	-
Convertible loans	2,792,762	2,437,368
<b>TOTAL CURRENT LIABILITIES</b>	<b>10,393,480</b>	<b>4,663,320</b>
<b>LONG-TERM LIABILITIES:</b>		
Loans payable	2,796,619	-
Warrants	4,159	559,954
Retirement benefits obligation	4,991	4,974
Convertible bonds	2,524,095	-
Deferred taxes	4,329,000	-
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>9,658,864</b>	<b>564,928</b>
<b>TOTAL LIABILITIES</b>	<b>20,052,344</b>	<b>5,228,248</b>
<b>COMMITMENTS</b>		
<b>REDEEMABLE COMMON STOCK</b>	<b>21,458,000</b>	<b>-</b>
<b>CAPITAL DEFICIENCY:</b>		
Common stock	5,584	5,597
Additional paid-in capital	13,850,643	13,152,551
Receipts on account of shares to be allotted	-	60,000
Accumulated other comprehensive loss	(134,396)	(18,368)
Accumulated deficit	(19,681,658)	(16,179,076)
<b>TOTAL CAPITAL DEFICIENCY</b>	<b>(5,959,827)</b>	<b>(2,979,296)</b>
<b>TOTAL LIABILITIES NET OF CAPITAL DEFICIENCY</b>	<b>\$ 35,550,517</b>	<b>\$ 2,248,952</b>

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

**ORGENESIS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**In U.S. dollars**  
**(Unaudited)**

	Three months ended August 31,		Nine months ended August 31,	
	2015	2014	2015	2014
<b>REVENUES</b>	\$ 936,215	\$ -	\$ 1,756,635	\$ -
<b>COST OF REVENUES</b>	1,325,739	-	2,298,718	-
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	294,360	845,599	759,586	1,936,079
<b>AMORTIZATION OF INTANGIBLE ASSETS</b>	408,380	-	801,287	-
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b>	952,053	440,058	2,811,016	2,032,073
<b>OPERATING LOSS</b>	2,044,317	1,258,657	4,913,972	3,968,152
<b>FINANCIAL EXPENSES (INCOME), net</b>	(335,932)	2,206,588	(1,303,332)	2,029,415
<b>LOSS BEFORE INCOME TAXES</b>	1,708,385	3,492,245	3,610,640	5,997,567
<b>INCOME TAX BENEFIT</b>	92,829	-	108,058	-
<b>NET LOSS</b>	\$ 1,615,556	\$ 3,492,245	\$ 3,502,582	\$ 5,997,567
<b>LOSS PER SHARE:</b>				
Basic	\$ 0.03	\$ 0.06	\$ 0.06	\$ 0.11
Diluted	\$ 0.04	\$ 0.06	\$ 0.09	\$ 0.11
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE:</b>				
Basic	55,835,950	54,916,980	55,785,950	53,672,820
Diluted	56,434,465	54,916,980	57,219,626	53,672,820
<b>OTHER COMPREHENSIVE LOSS:</b>				
Net loss	\$ 1,615,556	\$ 3,492,245	\$ 3,502,582	\$ 5,997,567
Translation adjustments	(443,737)	-	116,028	-
<b>TOTAL COMPREHENSIVE LOSS</b>	\$ 1,171,819	\$ 3,492,245	\$ 3,618,610	\$ 5,997,567

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

**ORGENESIS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN CAPITAL DEFICIENCY**  
**In U.S. dollars**  
**(Unaudited)**

	Common Stock		Additional	Receipts on	Accumulated	Accumulated	Total
	Shares	Amount	paid-in capital	Account of Shares to be allotted	Other Comprehensive Loss	Deficit	
<b>Balance at December 1, 2013</b>	51,144,621	\$ 5,114	8,635,447	\$ -	-	(10,674,975)	\$ (2,034,414)
<b>Changes during the nine months ended August 31, 2014 :</b>							
Stock-based compensation to employees and directors			1,076,428				1,076,428
Stock-based compensation to service providers			901,733				901,733
Issuance of shares and warrants	2,095,013	210	1,094,196				1,094,406
Conversions of convertible loans into shares and warrants	713,023	71	630,432				630,503
Issuance of shares along with convertible loan	500,000	50	179,950				180,000
Proceeds from exercise of stock options	623,806	62	562				624
Exercise of warrants into shares and warrants	96,154	10	49,990				50,000
Net loss - comprehensive loss						(5,997,567)	(5,997,567)
<b>Balance at August 31, 2014</b>	55,172,617	\$ 5,517	\$ 12,568,738	\$ -	\$ -	(16,672,542)	\$ (4,098,287)
<b>Balance at December 1, 2014</b>	55,970,565	\$ 5,597	\$ 13,152,551	\$ 60,000	(18,368)	(16,179,076)	(2,979,296)

**Changes during  
the nine months  
ended****August 31,  
2015 :**

Shares cancellation	(250,000)	(25)	25			
Issuance of shares	115,385	12	59,988	(60,000)		
Stock-based compensation to employees and directors			593,290			593,290
Stock-based compensation to service providers			44,789			44,789
Comprehensive loss				(116,028)	(3,502,582)	(3,618,610)
<b>Balance at August 31, 2015</b>	<b>55,835,950</b>	<b>\$ 5,584</b>	<b>13,850,643</b>	<b>\$ -</b>	<b>(134,396)</b>	<b>(19,681,658)</b>
						<b>(5,959,827)</b>

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



**ORGENESIS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**In U.S. dollars**  
**(Unaudited)**

	Nine Months Ended August 31,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,502,582)	\$ (5,997,567)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	638,079	1,978,161
Increase in retirement benefits obligation	-	1,149
Amortization expenses	871,403	-
Depreciation expenses	425,603	2,589
Change in fair value of warrants and embedded derivative	(1,191,995)	1,291,046
Change in fair value of convertible bonds	(704,503)	
Interest expense accrued on convertible loans	341,590	682,223
Changes in operating assets and liabilities:		
Increase in accounts receivable	(340,924)	-
Increase in inventory	(33,097)	-
Increase in prepaid expenses and other receivables	(785,368)	(59,477)
Increase in accounts payable	659,615	135,594
Increase in accrued expenses	293,900	424,890
Increase in employees and related payables	83,989	333,190
Increase in deferred income	875,919	-
Increase in advance payment and receivables on account of grant	431,111	110,678
Decrease in deferred taxes	(108,058)	-
Net cash used in operating activities	(2,045,318)	(1,097,524)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(498,024)	(5,464)
Amounts funded in respect of short term deposits	(5,160)	-
Acquisition of MaSTherCell, net of cash acquired, see note 4	304,644	-
Amounts funded in respect of retirement benefits obligation	-	(1,212)
Net cash used in investing activities	(198,540)	(6,676)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Short-term line of credit	537,975	13,896
Proceeds from issuance of shares and warrants	-	922,000
Proceeds from exercise of stock options	-	624
Proceeds from issuance of loans payable	817,801	-
Proceeds from exercise of warrants into shares and warrants	-	50,000
Repayment of short and long-term debt	(641,305)	100,000
Proceeds from issuance of convertible loans together with shares	650,000	1,500,000
Net cash provided by financing activities	1,364,471	2,586,520
<b>NET CHANGE IN CASH</b>	<b>(879,387)</b>	<b>1,482,320</b>
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>		
	(170,335)	-
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>1,314,052</b>	<b>50,827</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 264,330</b>	<b>\$ 1,533,147</b>

**SUPPLEMENTAL NON-CASH FINANCING ACTIVITY:**

Conversion of loans (including accrued interest) to common stock and warrants	\$	370,772
Common stock issued for rendered services	\$	37,406

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

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**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.

On October 11, 2011, the Company incorporated a wholly owned subsidiary in Israel, Orgenesis Ltd. (the Israeli Subsidiary ), which is engaged in research and development. On February 2, 2012, the Israeli Subsidiary entered into an agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the Licensor ). The Israeli Subsidiary was granted a worldwide, royalty bearing, exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells, as treatment for diabetes.

On July 31, 2013, the Company incorporated a wholly owned subsidiary in Maryland, Orgenesis Maryland Inc. (the U.S. Subsidiary ), which is engaged in research and development.

On October 11, 2013, the Company incorporated a wholly owned subsidiary in Belgium, Orgenesis SPRL (the Belgian Subsidiary ), which is engaged in development and manufacturing activities together with clinical development studies in Europe, and later on to be the Company s center for activities in Europe.

As discussed in Note 4, 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*). The functional currency of MaSTherCell is the Euro ( € or Euro ).

As used in this report and unless otherwise indicated, the term Company refers to Orgenesis Inc. and the Company s wholly-owned subsidiaries ( Subsidiaries ). Unless otherwise specified, all dollar 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 August 31, 2015, and the consolidated statements of comprehensive loss for the three months and nine months ended August 31, 2015 and 2014, and the changes in capital deficiency and cash flows for the nine-months periods ended August 31, 2015 and 2014. The results for the three and nine months period ended August 31, 2015 are not necessarily indicative of the results to be expected for the year ending November 30, 2015. 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, 2014.

*Going Concern*

These unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has an accumulated deficit of \$19,798,998, 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 August 31, 2015. 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.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 1 GENERAL AND BASIS OF PRESENTATION (cont.)**

Management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders. However, there is no assurance that the Company will be successful with those initiatives.

The 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.

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

The accounting policies adopted are generally consistent with those of the previous financial year. Due to the acquisition of MaSTerCell new accounting policies had to be adopted as described below.

*Use of Estimates*

The preparation of the interim condensed consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to fair value of assets and liabilities, goodwill and intangible assets, stock-based compensation expense, deferred income taxes and revenue recognition. Management bases its estimates on various assumptions, which it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

*Business Combination*

The Company allocates the purchase price of an acquired business to the tangible and intangible assets acquired and liabilities assumed based upon their estimated fair values on the acquisition date. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Acquired in-process backlog, customer relations, brand name and know how are recognized at fair value. The purchase price allocation process requires management to make significant estimates and assumptions, especially at the acquisition date with respect to intangible assets. Direct transaction costs associated with the business combination are expensed as incurred. The allocation of the consideration transferred in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date. The Company includes the results of operations of the business that it has acquired in its consolidated results prospectively from the date of acquisition.

*Inventory*

Inventory is stated at the lower of cost or market value with cost determined under the first-in-first-out (FIFO) cost method. The entire balance of inventory at August 31, 2015, consists of raw material.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)***Property and Equipment*

Property and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the related assets.

Annual rates of depreciation are presented in the table below:

	<b>Weighted Average Useful Life (Years)</b>
Good Manufacturing Practice ("GMP") unit installation	10
Laboratory equipment	5
Office equipment	5

*Intangible Assets*

Intangible assets and their useful lives are as follows:

	<b>Weighted Average Useful Life (Years)</b>	<b>Amortization recorded at comprehensive loss line item</b>
Backlog	1.75	Cost of revenue
Customer Relationships	7.75	Amortization of intangible assets
Brand	9.75	Amortization of intangible assets
Know How	11.75	Amortization of intangible assets

Intangible assets are recorded at acquisition cost less accumulated amortization and impairment. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the asset are expected to be generated.

*Goodwill*

Goodwill represents the excess of the purchase price of acquired businesses over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired. The goodwill impairment test is applied by performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is considered not more likely than not that the fair value of the reporting unit is less than the carrying amount, further testing of goodwill for impairment would not be required. Otherwise, goodwill impairment is tested using a two-step approach.

The first step involves comparing the fair value of a company's reporting units to their carrying amount. If the fair value of the reporting unit is determined to be greater than its carrying amount, there is no impairment. If the reporting unit's carrying amount is determined to be greater than the fair value, the second step must be completed to measure the amount of impairment, if any. The second step involves calculating the implied fair value of goodwill by deducting the fair value of all tangible and intangible assets, excluding goodwill, of the reporting unit from the fair value of the reporting unit as determined in step one. The implied fair value of the goodwill in this step is compared to the carrying value of goodwill. If the implied fair value of the goodwill is less than the carrying value of the goodwill, an impairment loss equivalent to the difference is recorded.





**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

*Impairment of Long-lived Assets*

The Company reviews its property and equipment, intangible assets subject to amortization and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset class may not be recoverable. Indicators of potential impairment include: an adverse change in legal factors or in the business climate that could affect the value of the asset; an adverse change in the extent or manner in which the asset is used or is expected to be used, or in its physical condition; and current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of the asset. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted cash flows.

*Revenue Recognition*

The Company recognizes revenue for services linked to cell process development and cell manufacturing services based on individual contracts in accordance with ASC 605, *Revenue Recognition*, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred or services have been provided; the seller's price to the buyer is fixed or determinable and collectability is reasonably assured. The Company determines that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. In addition, the Company determines that services have been delivered in accordance with the arrangement. The Company assesses whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Service revenues are recognized as the services are provided.

The Company assesses cash collectability based on a number of factors, including past collection history with the client and the client's creditworthiness. If the Company determines that collectability is not reasonably assured, it defers revenue recognition until collectability becomes reasonably assured, which is generally upon receipt of the cash. The Company's arrangements are generally non-cancellable, though clients typically have the right to terminate their agreement for cause if the Company materially fails to perform. Cell manufacturing services are generally distinct arrangements whereby the Company is paid for time and materials or for fixed monthly amounts. Revenue is recognized when efforts are expended or contractual terms have been met.

The Company also incurs revenue corresponding to invoicing to customers of some consumables which are incidental to the services provided as foreseen in the clinical services contracts. The company bills customers for reimbursable expenses and immediately recognizes these billings in revenue, as the revenue is deemed earned.

*Fair value option*

Topic 815 provides entities with an option to report certain financial assets and liabilities at fair value with subsequent changes in fair value reported in earnings. The election can be applied on an instrument by instrument basis. The company elected the fair value option to its convertible bonds. See also Note 4.

*Newly Issued Accounting Pronouncements*

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.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

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 August 31, 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 amount and nature of such financing over the next twelve months.

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.

In September 2015, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2015-16 (ASU 2015-16) "Simplifying the Accounting for Measurement Period Adjustments". ASU 2015-16 require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in ASU 2015-16 require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in ASU 2015-16 require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. For public business entities, the amendments in ASU 2015-16 are effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The amendments in ASU 2015-16 should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not been issued. For all other entities, the amendments in ASU 2015-16 are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments in ASU 2015-16 should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not yet been made.

available for issuance.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

In July 2015, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2015-11 (ASU 2015-11) "Simplifying the Measurement of Inventory". According to ASU 2015-11 an entity should measure inventory within the scope of this update at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in ASU 2015-11 more closely align the measurement of inventory in GAAP with the measurement of inventory in International Financial Reporting Standards (IFRS). The Board has amended some of the other guidance in Topic 330 to more clearly articulate the requirements for the measurement and disclosure of inventory. However, the Board does not intend for those clarifications to result in any changes in practice. Other than the change in the subsequent measurement guidance from the lower of cost or market to the lower of cost and net realizable value for inventory within the scope of ASU 2015-11, there are no other substantive changes to the guidance on measurement of inventory. For public business entities, the amendments in ASU 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. For all other entities, the amendments in ASU 2015-11 are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments in ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period.

The Board decided that the only disclosures required at transition should be the nature of and reason for the change in accounting principle. An entity should disclose that information in the first annual period of adoption and in the interim periods within the first annual period if there is a measurement-period adjustment during the first annual period in which the changes are effective.

**NOTE 3 - FAIR VALUE PRESENTATION**

The fair value measurement guidance clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in the valuation of an asset or liability. It establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under the fair value measurement guidance are described below:

*Level 1* - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities;

*Level 2* - Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;

*Level 3* - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).



**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 3 - FAIR VALUE PRESENTATION (cont.)**

As of August 31, 2015, the Company's liabilities that are measured at fair value and classified as level 3 fair value are as follows:

	August 31, 2015		November 30, 2014	
	Level 3	Total	Level 3	Total
Warrants	\$ 4,159	\$ 4,159	\$ 559,954	\$ 559,954
Embedded derivatives*	452,100	452,100	\$ 992,000	\$ 992,000
Convertible bonds	\$ 2,524,095	\$ 2,524,095		

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

The fair value of the 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. The fair value of the convertible bonds described in Note 4 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 August 31, 2015:

	Warrants	Embedded derivative	Convertible bonds
Fair value of shares of common stock	\$ 0.4	\$ 0.4	\$ 0.4
Expected volatility	91%	86%	92%
Discount on lack of marketability	-	-	21.72%
Risk free interest rate	0.1%	0.04%-0.35%	0.41%
Expected term (years)	0.08	0.2-0.8	1.05
Expected dividend yield	0%	0%	0%

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 3 - FAIR VALUE PRESENTATION (cont.)**

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 9 months ended August 31, 2015:

	Warrants	Embedded derivatives	Convertible bonds
Balance at beginning of period	\$ 559,954	\$ 992,000	\$ -
Additions	-	96,300	3,234,000
Changes in fair value related to warrants expired*	(520,954)	-	-
Changes in fair value during the period	(34,841)	(636,200)	(704,503)
Translation adjustments	-	-	(5,402)
Balance at end of period	\$ 4,159	\$ 452,100	\$ 2,524,095

(\*) During the nine months ended August 31, 2015, 1,726,718 warrants have expired. There were no transfers to Level 3 during the nine months ended August 31, 2015.

The Company has performed a sensitivity analysis of the expected volatility assumption of the embedded derivatives and convertible bonds and the results were immaterial.

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, 2014:

	Warrants	Embedded derivatives
Balance at beginning of period	\$ 1,157,954	\$ -
Additions	-	574,000
Changes in fair value during the period	(348,000)	418,000
Changes in fair value related to warrants expired	(250,000)	-
Balance at end of period	\$ 559,954	\$ 992,000

There were no transfers to Level 3 during 2014.

**NOTE 4 ACQUISITION OF MASTHERCELL***Description of the Transaction*

The Company entered into a share exchange agreement (the "Share Exchange Agreement") dated November 3, 2014 and addendum 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 \$24,593,000 (the "Consideration Share pricing"). Out of the Consideration Shares, 8,173,483 shares may be allocated to the bondholders of MaSTherCell in case of conversion, see "MaSTherCell convertible bonds" below.

MaSTherCell SA and Cell Therapy Holding SA are companies incorporated in Belgium. Cell Therapy Holding SA currently owns 50% of the issued and outstanding shares of MaSTherCell SA. The companies were incorporated and launched in 2011. All MaSTherCell shares were purchased either through Cell Therapy Holding SA or directly



through MaSTherCell.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 4 ACQUISITION OF MASTHERCELL (cont.)**

MaSTherCell is a technology-driven, customer-oriented CDMO specializing in cell therapy development for advanced medicinal products. To perform its services, MaSTherCell has a production and laboratory facility (the GMP Unit ) that received the good manufacturing practice (GMP) authorization for production of advanced medicinal therapeutic products (ATMP) by the Belgian Drug Agency (AFMPS).

As part of the agreement the, parties agreed on certain post closing conditions mainly post closing financing of \$10 million and a valuation which meets threshold of \$45 million. In the event that the company will not achieve those conditions within eight (8) months of the closing date, then MaSTherCell has 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, in dollars. The Consideration shares are requiring mezzanine classification and reflected on the balance sheet as redeemable common stock.

The MaSTherCell acquisition is accounted for as a business combination. The results of operations of MaSTherCell have been included in the Company s condensed consolidated statements of operations starting from March 2, 2015, the date on which the Company obtained effective control of MaSTherCell. The revenue and net loss from operations of MaSTherCell for the period from March 2, 2015, the acquisition date to August 31, 2015 was approximately \$1.9 million and \$1.3 million, respectively.

*MaSTherCell Convertible Bonds*

On September 18, 2014, MaSTherCell entered into convertible bond agreements with certain of MaSTherCell s existing and new investors raising €1.6 million (the Convertible Bonds ). The bonds bear interest at an annual rate of 3%. As part of the original terms, each bond can be converted into 0.36 class A common shares of MaSTherCell (the Conversion Shares ). As part of the Share Exchange Agreement, the parties agreed that, in case of conversion of the Convertible Bonds upon Uplisting (listing of Orgenesis Inc shares on NASDAQ or any other national exchange in the United States of America which provides at least the same level of liquidity) within 14 months of the closing date, the bondholders will be entitled to convert to a total of 8,173,483 out of the Consideration Shares.

In case the bondholders elect not to convert the convertible bonds, or in case they are not allowed to convert in the absence of Uplisting within 14 months from the closing date and the convertible bonds remain a liability of MaSTherCell, then the Consideration shares will be reduced by the amount remaining outstanding to the bondholders. To that effect, the number of Consideration shares to be released back to the company, shall be determined by dividing the subscription amount of the outstanding convertible bonds plus interest owed thereunder (converted into USD according to the currency exchange rate applicable on the day of conversion) by the consideration and by applying the resulting quotient to actual total number of Consideration shares.

The company records the convertible bonds on its consolidated balance sheet at their fair value, see Note 3.

*Fair Value of Consideration Transferred*

The Company accounted for the acquisition of MaSTherCell as a business combination under the acquisition method of accounting. On the acquisition date, the fair value of the total consideration transferred to acquire MaSTherCell was as follows:

Total purchase consideration:

Redeemable common stock	\$ 24,592,000
Less Convertible loan *	3,134,000
Total fair value of consideration transferred	\$ 21,458,000

\* After a deduction of \$100 thousand relating to interest to MaSTherCell bondholders.

**ORGENESIS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****For the Three and Nine Months Period Ended August 31, 2015****(Unaudited)****NOTE 4 ACQUISITION OF MASTHERCELL (cont.)**

The following table summarizes the provisional allocation of purchase price to the fair values of the assets acquired and liabilities assumed as of the acquisition date:

Total assets acquired:	
Cash and cash equivalents	\$ 304,644
Property and equipment, net	4,236,075
Inventory	231,199
Other assets	1,667,057
Other Intangible assets (a)	18,977,000
Goodwill (b)	10,102,760
Total assets	35,518,735
Total liabilities assumed:	
Deferred income	946,549
Deferred tax	4,440,000
Loan payables, including convertible loans	6,998,084
Other liabilities	1,676,102
Total liabilities	14,060,735
Total consideration transferred	\$ 21,458,000

- (a) The allocation of the purchase price to the net assets acquired and liabilities assumed resulted in the recognition of other intangible assets which comprised of: Customer Relationships of \$349,000, Know How of \$17,037,000, Backlog of \$250,000 and Brand Name of \$1,341,000. These other intangible assets have a useful life between 1.75 and 11.75 years. The useful life of the other intangible assets for amortization purposes was determined considering the period of expected cash flows generated by the assets used to measure the fair value of the intangible assets adjusted as appropriate for the entity-specific factors, including legal, regulatory, contractual, competitive, economic or other factors that may limit the useful life of intangible assets.

The fair value of the Know How was estimated using a relief of royalties approach. Under this method, the fair value of the Know How is equal to the royalty fee that the owner of the Know How could profit from if he was to license the Know How out.

The fair values of the Backlog was estimated using the income approach. An income and expense forecast was built based upon Backlog revenue estimates and the cost to perform each contract. On this basis, a free cash flow for the asset was derived, under several assumptions.

Customer Relationships and Brand Name were estimated using a discounted cash flow method with the application of the multi-period excess earnings method. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows attributable only to the subject intangible asset after deducting contributory asset charges. An income and expenses forecast was built based upon specific intangible asset revenue and expense estimates.

- (b) The primary items that generate goodwill include the value of the synergies between the acquired company and the Company and the acquired assembled workforce, neither of which qualifies for recognition as an intangible

asset.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 4 ACQUISITION OF MASTHERCELL (cont.)**

The Company's purchase price allocation is preliminary. The fair values of acquired assets and liabilities may be further adjusted as additional information becomes available during the measurement period. Additional information may become available subsequently and may result in changes in the values allocated to various assets and liabilities includes, but is not limited to, any changes in the values allocated to tangible and identified intangible assets acquired and liabilities assumed during the measurement period and may result in material adjustments to goodwill.

*Pro forma Impact of Business Combination*

The unaudited pro forma condensed financial results have been prepared using the acquisition method of accounting and are based on the historical financial information of the Company and MaSTherCell. The unaudited pro forma condensed financial results have been prepared for illustrative purposes only and do not purport to be indicative of the results of operations that actually would have resulted had the acquisition of MaSTherCell occurred at the beginning of the fiscal year, or of future results of the combined entities. The unaudited pro forma condensed financial information does not reflect any operating efficiencies and expected realization of cost savings or synergies associated with the acquisition.

Unaudited supplemental pro forma combined results of operations:

	<b>Three Months Ended August 31,</b>		<b>Nine Months Ended August 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenue	\$ 936,215	\$ 550,178	\$ 2,872,827	\$ 1,081,086
Net loss	\$ 1,616,414	\$ 4,188,068	\$ 4,143,739	\$ 9,054,857
Net loss per common share:				
Basic	\$ 0.03	\$ 0.08	\$ 0.07	\$ 0.17
Diluted	\$ 0.03	\$ 0.08	\$ 0.09	\$ 0.18

Adjustments for the unaudited supplemental pro forma combined results of operations are as follows:

	<b>Three Months Ended August 31,</b>		<b>Nine Months Ended August 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Amortization of intangibles	\$	\$ 540,191	\$ 469,177	\$ 1,620,573
Deferred income		109,373	94,509	328,118
Deferred tax		(72,710)	(63,643)	(218,129)
Transaction costs		-	(258,178)	258,178
Convertible bonds		(435,711)	(376,500)	(1,307,134)
Total	\$ -	\$ 141,143	\$ (134,635)	\$ 681,606

*Acquisition-related Costs*

Acquisition-related expenses consist of transaction costs which represent external costs directly related to the acquisition of MaSTherCell and primarily include expenditures for professional fees such as legal, accounting and other directly related incremental costs incurred to close the acquisition by both the Company and MaSTherCell.



**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 5 PROPERTY AND EQUIPMENT**

Acquisition-related expenses for the nine months periods ending August 31, 2015 were \$258 thousand for both periods. These expenses were recorded to selling and general administrative expense in the condensed consolidated statements of comprehensive loss.

The following table represents the components of property and equipment:

	<b>August 31, 2015</b>	<b>November 30, 2014</b>
Cost:		
GMP Unit Installation, net	\$ 3,573,312	\$ -
Office furniture	49,979	3,761
Lab equipment	1,104,920	5,901
Computers	31,497	12,601
	4,759,708	22,263
Less accumulated depreciation	(439,273)	(9,214)
	\$ 4,320,435	\$ 13,049

Depreciation expenses for the three and nine months ended August 31, 2015 were \$227,969 and \$425,603 respectively. Depreciation expenses for the year ended November 30, 2014, were \$4,551.

**NOTE 6 INTANGIBLE ASSETS AND GOODWILL**

Other intangible assets consisted of the following:

	<b>August 31, 2015</b>
Cost:	
Know how	\$ 17,032,188
Backlog	249,929
Customer relationships	348,902
Brand name	1,340,621
	18,971,640
Less accumulated amortization	(885,009)
	\$ 18,086,631

Intangible assets amortization expenses were \$871,403 and \$0 for the nine months ended August 31, 2015 and 2014, respectively.

Estimated aggregate amortization expenses for each of the five succeeding years ending November 30 is as follows:

	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Amortization expenses	\$ 1,307,104	1,742,805	1,601,503	1,601,503	\$ 1,601,503

In the nine months period ended August 31, 2015, no impairment was recognized to the goodwill. The entire change in the goodwill balance since the acquisition of MaSTherCell, is a result of translation adjustments, which are recorded in other comprehensive loss.





**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 7 CONVERTIBLE LOAN AGREEMENTS**

In June 2015, the Company entered into three convertible loan agreements with new investors for a total amount of \$650,000 as follow:

	<b>Grant date</b>	<b>Maturity Date</b>	<b>August 31, 2015</b>
Convertible loan (1)	June 9, 2015	December 9, 2015	\$ 50,000
Convertible loan (2)	June 16, 2015	December 16, 2015	250,000
Convertible loan (3)	June 24, 2015	December 31, 2015	350,000
			\$ 650,000

Interest is calculated at 6% annually and is payable, along with the principal on or before the maturity date.

The lenders have the right to convert all or part of the loan (principal and the accrued interest) into shares of the Company's common stock at a price per share equal to 0.75 of the Market Price (as defined below) (the "Conversion Price"), provided that the Conversion Price will not be less than \$0.40 (the "Floor Price"). Market Price is defined as the average closing trading price for the Company's common shares on the OTCQB for the five trading days prior to the lender's notice of conversion being delivered to the Company.

The loan amount shall automatically convert into units that include one common share and one warrant exercisable into one additional common share, upon the Qualified Offering (as defined below) at the same terms as the Qualified Offering. A Qualified Offering is defined as an offering of securities of the Company with gross proceeds equal to or greater than \$6 million and with a price per share of the common stock underlying such Qualified Offering equal to or greater than the Floor Price.

In the event the Company issues any common shares or securities convertible into common shares at a price less than the Floor Price (the "New Issuance Price"), the Floor Price shall be reduced for any unpaid or unconverted loan amount to the New Issuance Price.

The conversion right is detachable from the loan and classified as a derivative due to down-round protection (full ratchet and anti-dilution provisions). Therefore, the Company allocated the conversion derivative from the loan based on its fair value. The allocation of conversion right represents a discount to the loan and will be accreted until the Maturity date of the loans.

The table below presents the fair value as of the Closing Date:

	<b>Loan component</b>	<b>Embedded derivative component</b>
Convertible loan (1)	\$ 42,300	\$ 7,700
Convertible loan (2)	214,800	35,200
Convertible loan (3)	296,600	53,400
	\$ 553,700	\$ 96,300

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 8 LOANS***a. Terms of Long-term Loans*

	Currency of loan	Interest Rate August 31, 2015	Year of Maturity	August 31, 2015
Long-term loan a (1)	Euro	4.05%	2022	\$ 1,198,408
Long-term loan b (2)	Euro	6%-7.5%	2023	1,147,541
Long-term loan c (3)	Euro	5.5%-6%	2022-2024	519,698
Long-term loan d (4)	Euro	5.5%	2020	324,941
				\$ 3,190,588
Current portion of Loans payable				393,969
				\$ 2,796,619

- (1) On August 1, 2012 MaSTherCell received a loan from ING Bank in Belgium ( ING ) in the amount of €1.4 million to finance the construction of the GMP Unit. With respect to this loan, ING requested a business pledge on the Company assets for a value of € 1.4 million.
- (2) On August 13, 2012, MaSTherCell received a loan from a Belgian investment fund in the amount of €1 million. This loan includes two components as follows:
- \* Loan in the amount of € 0.5 million that bears interest at an annual rate of 6%.
  - \* Loan in the amount of € 0.5 million that bears interest at an annual rate of 7.5%.
- (3) On August 6, 2012, MaSTherCell received a loan from a Belgian venture capital fund in the amount of € 250 thousand which bears interest at an annual rate of 6 %. On February 10, 2014, MaSTherCell received from the same venture capital fund a second loan in amount of € 250,000 which bears an annual interest rate of 5.50%.
- (4) On April 23, 2015 MaSTherCell received a loan from the same Belgian investment fund mentioned in section 3 above in the amount of €290 thousand which bears interest at an annual rate of 5.5%.

*b. Terms of Short-term Loans and Current Portion of Loans Payable*

	Currency of loan	Interest Rate August 31, 2015	August 31, 2015
Current portion of loans payable a	Euro	4.05%	\$ 157,542
Current portion of loans payable b	Euro	6%-7.5%	153,388
Current portion of loans payable c	Euro	5.5-6%	83,039
			\$ 393,969
Short term-loan *	Euro	libor rate	560,242
Short term-loan **	Euro	7%	506,173
			\$ 1,460,384

- \* On February 21, 2014, MaSTherCell received a loan from ING in the amount of €800,000. In respect of this loan, ING has requested a pledge on the receivable linked to the grant for a value of €853,000. During the period MaSTherCell reimbursed an amount of €300,000, the maturity date of the remaining loan will be December 31,

2015.

On September 16, 2013 MaSTHerCell received from ING bank in Belgium a short term credit facility for a maximum amount of €200,000. The rate used is EURIBOR 3 months plus a margin defined by the bank. On August 31, 2015 MaSTHerCell reimbursed the loan.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 8 LOANS (cont.)**

\*\* On July 27, 2015, MaSTerCell received a loan from three shareholders for a total amount of €450,000, which bears an annual interest rate of 7%.

In occurrence of the Unwind Option as defined in the MaSTerCell agreements, the lenders shall convene a general meeting of shareholders to vote on a conversion of the loan in to MaSTerCell shares . In the absence of Unwind, the maturity date of the loan will be November 30, 2015. Interest shall be payable either upon reimbursement of the loan or upon conversion of the loan into capital.

**NOTE 9 COMMITMENTS**

*a. Tel Hashomer Medical Research, Infrastructure and Services Ltd.*

On February 2, 2012, the Company's Israeli Subsidiary entered into a licensing agreement with Tel Hashomer Medical Research, Infrastructure and Services Ltd (the Licensor ). According to the agreement, the Israeli Subsidiary was granted a worldwide royalty bearing an exclusive license to certain information regarding a molecular and cellular approach directed at converting liver cells into functional insulin producing cells as a treatment for diabetes.

As consideration for the licensed information, the Israeli Subsidiary will pay the following to the Licensor:

- 1) A royalty of 3.5% of net sales;
- 2) 16% of all sublicensing fees received;
- 3) An annual license fee of \$15,000, which commenced on January 1, 2012 and shall be paid once every year thereafter (the Annual Fee ). The Annual Fee is non-refundable, but it shall be credited each year due, against the royalty noted above, to the extent that such are payable, during that year; and
- 4) Milestone payments as follows:
  - a) \$50,000 on the date of initiation of phase I clinical trials in human subjects;
  - b) \$50,000 on the date of initiation of phase II clinical trials in human subjects;
  - c) \$150,000 on the date of initiation of phase III clinical trials in human subjects; and
  - d) \$750,000 on the date of initiation of issuance of an approval for marketing of the first product by the FDA.
  - e) \$2,000,000, when worldwide net sales of Products have reached the amount of \$150,000,000 for the first time, (The Sales Milestone ).

As of August 31, 2015, the Israeli Subsidiary has not reached any of these milestones.

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Israeli Subsidiary and/or consolidation of the Israeli Subsidiary or the Company into or with another corporation ( Exit ), the Licensor shall be entitled to choose whether to receive from the Israeli Subsidiary a one-time payment based, as applicable, on the value of either 5,563,809 shares of common stock of the Company at the time of the Exit or the value of 1,000 shares of common stock of the Israeli Subsidiary at the time of the Exit.

On May, 2014, the Israeli Subsidiary entered into a research service agreement with the Licensor. According to the agreement, the Licensor will perform a study at the facilities and use the equipment and personnel of the Chaim Sheba Medical Center (the Hospital ), for the consideration of approximately \$92,000 for a year. In May 2015, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately \$110,000.



**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 9 COMMITMENTS (cont.)**

*b. Mintz, Levin, Ferris, Glovsky and Popeo, P.C.*

On February 2, 2012, the Company entered into an agreement with its patent attorneys, Mintz, Levin, Ferris, Glovsky and Popeo, P.C. ( Mintz Levin ) for professional services related to patent registration. In addition to an amount of \$80,000 paid to Mintz Levin, the Company issued 1,390,952 shares of common stock. The Company will pay an additional \$50,000 upon consummation of certain criteria that the company will meet. As of August 31, 2015, the Company has not reached any of the milestones.

On March 27, 2013, the Company signed an agreement with Mintz Levin in which 16% of the Company's fees will be converted to shares of common stock of the Company at market price. On July 14, 2014, \$13,395 of fees incurred were converted into 25,759 shares of common stock.

*c. Pall Life Science Belgium BVBA*

On May 6, 2013, the Company entered into a Process Development Agreement with Pall Life Science Belgium BVBA (formerly ATMI BVBA), a Belgian Company that is a wholly owned Subsidiary of Pall Corporation ( Pall ), a U.S. publicly-traded company. According to the agreement, Pall will provide services in cell research. The Company will use Pall's unique technology while the Company will provide to Pall the required materials for purpose of the study. According to the agreement, the Company will pay per achieved phase, as defined in the agreement, with a total consideration of €606,500 for all services. As of August 31, 2015, the Company received services in total value of \$306,890 and provided materials on amount of \$284,875.

*d. MaSTherCell SA*

On July 3, 2014 (prior to the initiation of the transaction detailed in Note 4), the Company's Belgian Subsidiary entered into a service agreement with MaSTherCell SA ( MaSTherCell ), pursuant to which MaSTherCell will conduct certain clinical tests related to diabetes treatment research. The Belgian Subsidiary will pay MaSTherCell an amount of €962,500 with 30% payable upon the date of approval of the DGO6 grant (as defined in Note 8(f)) with the balance being invoiced monthly. Services commence upon approval of the DGO6.

The term of the service agreement will run until all work is completed or by either party providing 30 days' written notice of termination.

On March 2, 2015, the Company acquired MaSTherCell. See also Note 4.

*e. Maryland Technology Development Corporation*

On June 30, 2014, the Company's U.S. Subsidiary entered into a grant agreement with Maryland Technology Development Corporation ( TEDCO ). TEDCO was created by the Maryland State Legislature in 1998 to facilitate the transfer and commercialization of technology from Maryland's research universities and federal labs into the marketplace and to assist in the creation and growth of technology based businesses in all regions of the State. TEDCO is an independent organization that strives to be Maryland's lead source for entrepreneurial business assistance and seed funding for the development of startup companies in Maryland's innovation economy. TEDCO administers the Maryland Stem Cell Research Fund to promote State funded stem cell research and cures through financial assistance to public and private entities within the State. Under the agreement, TEDCO has agreed to give the U.S Subsidiary an amount not to exceed \$406,431 (the Grant ). The Grant will be used solely to finance the costs to conduct the research project entitled Autologous Insulin Producing (AIP) Cells for Diabetes during a period of two years.





**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 9 COMMITMENTS (cont.)**

On July 22, 2014, the U.S Subsidiary received an advance payment of \$203,216 on account of the grant. Through August 31, 2015, the company spent the full amount of the grant. On September 21, 2015 the U.S Subsidiary received the second advance payment in amount of \$203,216. Through August 31, 2015, the company spent \$5,145. The amount of grant that was spent through August 31, 2015, was recorded as a deduction of research and development expenses in the statement of comprehensive loss.

*f. Department De La Gestion Financiere Direction De L analyse Financiere ( DGO6 )*

On November 17, 2014, the Company's Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DGO6) for a €2.015 million support program for the research and development of a potential cure for Type 1 Diabetes. The Financial support is composed of a €1,085,000 (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of €930,000 (60% of budgeted costs) of the experimental development part of the research program. The grants will be paid to the Belgian Subsidiary over a period of approximately 3 years. The grants are subject to certain conditions with respect to the Belgian Subsidiary work in the Walloon Region, the Belgian Subsidiary own investment in these projects and certain other conditions and contain a repayment provision upon attaining a favorable outcome.

In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. On December 9 and 16, 2014, the Belgian Subsidiary received €651,000 and €558,000 under the grant, respectively. Up to August 31, 2015, an amount of \$1,133,134 was recorded as deduction of research and development expenses and as of August 31, 2015, an amount of \$122,239 was recorded as a Receivables on account of grant.

On March 20, 2012, MaSTherCell had been granted an investment grant from the DGO6 for an amount of €1,421,000. This grant is related to the investment in the production facility with a coverage of 32% of the investment planned. A first payment of €568,000 has been received in August 2013. The remaining part is expected to be paid by the end of 2015.

*g. Israel-U.S Binational Industrial Research and Development Foundation ( BIRD )*

On December 21, 2014, the Company received a notification from BIRD that its wholly owned Subsidiary, Orgenesis Ltd., and its research and development partner, were approved by BIRD's Board of Governors for a conditional grant of \$800,000 for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project). On September 9, 2015, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with BIRD and its research and development partner. BIRD will give a conditional grant of \$800,000 for a joint research and development project for the use Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project). The Project started on 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.

Up to August 31, 2015, an amount of \$135,000 was recorded as deduction of research and development expenses and as Receivables on account of grant. On September 21, 2015, the Israeli Subsidiary received \$100,000 under the grant.

*h. Leases*

On April 4, 2012, MaSTherCell signed an operational lease agreement for the rent of a facility in order to build the production area. The agreement was for a period of 18 years starting on April 4, 2012 and expiring on March 20,

2030. The costs per year are €90,000. On November 23, 2012, MaSTherCell signed another operational lease agreement for the rent of offices for a period of 15 years starting from November 23, 2012 and expiring on November 30, 2027. The costs per year are €46,000. On February 1, 2015, MaSTherCell signed an amendment to the operational lease agreement for the rent of offices for a period of 12 years starting from February 1, 2015 and expiring on November 30, 2027. The additional costs per year are €28,000. On January 2015 the Israeli subsidiary signed an operational lease agreement for the rent of labs and office which will be used for the research and development activities in Israel. The costs per year are NIS 120,000.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 9 COMMITMENTS (cont.)**

The detail of securities granted to the banks in the context of the financial loans are described under Note 8.

**NOTE 10 CAPITAL DEFICIENCY**

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

There were no significant capital transactions during the nine months ended August 31, 2015, other than Share Exchange Agreement with MaSTherCell. For further discussion regarding capital transactions during 2014, refer to the Company's Form 10-K for November 30, 2014 as filed with the SEC on February 19, 2015.

Loss per share

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

	<b>Three Months Ended August 31,</b>		<b>Nine Months Ended August 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Basic:</b>				
Loss for the period	\$ 1,615,556	\$ 3,492,245	\$ 3,502,582	\$ 5,997,567
Weighted average number of common shares outstanding	55,835,950	54,916,980	55,785,950	53,672,820
Loss per common share	\$ 0.03	\$ 0.06	\$ 0.06	\$ 0.11
<b>Diluted:</b>				
Loss for the period	\$ 1,615,556		\$ 3,502,582	
Change in fair value of embedded derivative and interest expenses on convertible bonds	352,527		848,559	
Change in fair value of warrants	21,841		554,841	
Total Loss for the period	\$ 1,989,924		\$ 4,905,982	
Weighted average number of shares used in the computation of basic loss per share	55,835,950		55,785,950	
Number of dilutive shares related to convertible bonds	577,236		1,086,109	
Number of dilutive shares related to warrants	21,279		347,567	
Weighted average number of common shares outstanding	56,434,465		57,219,626	
Loss per common share	\$ 0.04	\$ *0.06	\$ 0.09	\$ *0.11

\* For the three and nine months ended August 31, 2014, the effect of the warrants was anti-dilutive, therefore the diluted loss per share is equal to the basic loss per share.



**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 10 CAPITAL DEFICIENCY (Cont.)**

Basic loss per share does not include 42,401,724 of redeemable common stock since the contingent criteria regarding the unwind option has not been met as of August 31, 2015.

Diluted loss per share does not include 42,401,724 redeemable common stock, 12,899,314 shares underlying outstanding options, 2,942,256 shares issuable upon exercise of warrants for the nine and three months ended August 31, 2015, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted loss per share does not include 15,567,725 shares underlying outstanding options, 6,153,205 shares issuable upon exercise of warrants for the nine and three months ended August 31, 2014, because the effect of their inclusion in the computation would be anti-dilutive.

**NOTE 11 STOCK BASED COMPENSATION**

*a. Global Share Incentive Plan*

On May 23, 2012, the Company's board of directors adopted the global share incentive plan (2012) ("Global Share Incentive Plan (2012)"). Under the Global Share Incentive Plan (2012), 12,000,000 shares of common stock have been reserved for the grant of options, which may be issued at the discretion of the Company's board of directors from time to time. Under this plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years.

*b. Options Granted to Employees and Directors*

- 1) On August 22, 2014, the Company approved an aggregate of 2,762,250 stock options to the Company's Chief Executive Officer that are exercisable at \$0.0001 per share. Out of the total approved, 414,304 options vested immediately with a fair value as of the date of grant of \$260,981 using the Black-Scholes valuation model, 1,242,996 options will vest quarterly over 4 years, with a fair value as of the date of grant of \$782,997 using the Black-Scholes valuation model, and 1,104,950 options were not granted yet. All the options expire on August 22, 2024.
- 2) During the nine months ended August 31, 2015, the Company agreed to grant an aggregate of 1,641,300 stock options to the Company's Chief Executive Officer of the U.S. Subsidiary that are exercisable at \$.001 per share. As of August 31, 2015, the terms of such grant have not been finalized and there has been no stock-based compensation recorded for the period.
- 3) On June 18, 2015, the Company approved an aggregate of 500,000 stock options to two directors that are exercisable at the market price on date of grant, \$0.53 per share. The options vest immediately and expire on June 18, 2020. The fair value of those options as of the date of grant was \$179,098 using the Black-Scholes valuation model.

*c. Options Granted to Consultant*

- 1) On March 4, 2015 the Company executed a consulting agreement with Professor Itamar Raz. Prof. Raz has agreed to be appointed to the Company's Board of Advisors committee, in consideration for an hourly

fee for attending in person meetings and meetings via conference call. In addition the Company granted to Prof. Raz 100,000 options exercisable at the market price on date of grant, \$0.65 per share. The options vest in 5 equal annual installments from the date of grant and expire on February 9, 2020. The fair value of those options as of the date of grant was \$41,503 using the Black-Scholes valuation model.

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Three and Nine Months Period Ended August 31, 2015**  
**(Unaudited)**

**NOTE 11 STOCK BASED COMPENSATION (cont.)**

- 2) On June 18, 2015, the Company agreed to grant to Dr. Michael Rossbach 100,000 options exercisable at the market price on date of grant, \$0.53 per share. The options vest in 5 equal annual installments from the date of grant and expire on June 18, 2020. The fair value of those options as of the date of grant was \$33,035 using the Black-Scholes valuation model.
- 3) On June 18, 2015, the Company agreed to grant to Dr. Karin Hehenberger 250,000 options exercisable at the market price on date of grant, \$0.53 per share. As of August 31, 2015, the terms of such grant have not been finalized and there has been no stock-based compensation recorded for the period.

The fair value of each stock option grant is estimated at the date of grant using the Black-Scholes valuation model. The volatility is based on historical volatilities of companies in comparable stages as well as the historical volatility of companies in the industry and, by statistical analysis of the daily share-pricing model. The volatility of stock-based compensation granted after November 30, 2013 is based on historical volatility of the Company for the last two years. The expected term is equal to the contractual life, based on management estimation for the expected dates of exercising of the options.

There were no additional option grants to employees and directors, non-employees or shares issued for services during the nine-months period ended August 31, 2015.

*d. Shares Issued to Consultants*

On September 4, 2014, the Company entered into a consulting agreement for professional services for a term of twelve months. Under the terms of the agreement, the Company agreed to pay the consultant 500,000 shares of restricted common stock, with 250,000 vesting on date of grant and the balance vesting over 12 months. The shares were valued at the fair value of the Company's common stock with respect to the first vesting as of the date of grant on September 4, 2014, which was \$0.64. On April 8, 2015, upon mutual agreement, the Company and the consultant agreed to cancel the consulting agreement without any further obligations or responsibilities of either party and to cancel the 250,000 shares of common stock that had not yet been granted.

With respect to the second vesting, in the nine months ended August 31, 2015, the Company recorded income of \$68,630.

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

### *Forward-Looking Statements*

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or the Company's future financial performance. In some cases, you can identify forward-looking statements by terminology such as *may*, *should*, *expects*, *plans*, *anticipates*, *believes*, *estimates*, *predicts*, *potential* negative of these terms or other comparable terminology. Forward-looking statements made in a quarterly report on Form 10-Q includes statements about the Company's:

- plans to identify and acquire products that it believes will be prospective for acquisition and development;
- intention to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy;
- belief that its treatment seems to be safer than other options;
- belief that its major competitive advantage is in its cell transformation technology;
- marketing plan;
- expectations regarding its ability to obtain and maintain intellectual property protection for its technology and therapies;
- ability to commercialize its products in light of the intellectual property rights of others;
- ability to obtain funding for its 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 its technologies;
- size and growth potential of the markets for its product candidates, and its 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 its manufacturing facilities in Belgium;
- success compared to competing therapies that are or may become available;
- ability to attract and retain key scientific or management personnel and to expand its management team;
- accuracy of its estimates regarding expenses, future revenue, capital requirements, profitability, and needs for additional financing;
- fluctuations in the trading price of its common stock; 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;
- needs to raise additional funds in the future which may not be available on acceptable terms or at all;
- research facility in Israel and the surrounding Middle East which may materially adversely affect its Israeli Subsidiary's operations and personnel;
- risk that Tel Hashomer - Medical Research, Infrastructure and Services Ltd. ( 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 its business, especially its 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 the Company's Annual Report on Form 10-K for the year ended November 30, 2014 that was filed on February 19, 2015 and the company's Form 8-K/A filed on March 25, 2015, any of which may cause the Company's or its 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 the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity or performance. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

As used in this quarterly report on Form 10-Q and unless otherwise indicated, the term "Company" refers 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"). Unless otherwise specified, all dollar amounts are expressed in United States dollars.

### *Corporate Overview*

We are developing a technology that we are bringing to the clinical stage 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. In addition, through our acquisition of MaSTherCell, we are building a fully-integrated biopharmaceutical company focused not only on developing our transdifferentiation technologies for Type 1 Diabetes, but also vertically integrating manufacturing that can optimize our abilities to scale-up our technologies for clinical trials and eventual commercialization. Furthermore, we also consider our manufacturing abilities to serve as a risk mitigant for our business since MaSTherCell is building its manufacturing business to serve other cell therapy markets in such areas as cell-based cancer immunotherapies.

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

On August 5, 2011, the Company entered into a letter of intent with Prof. Sarah Ferber and Ms. Vered Caplan according to which, inter alia, Prof. Ferber has agreed to use commercially reasonable efforts to cause THM to license to the Company all of the assets associated with "Methods Of Inducing Regulated Pancreatic Hormone Production" and "Methods of Inducing Regulated Pancreatic Hormone Production In Non-Pancreatic Islet Tissues".

Effective August 31, 2011, the Company implemented a 35 to 1 forward stock split of its authorized and issued and outstanding common stock. As a result, its authorized capital has increased from 50,000,000 shares of common stock with a par value of \$0.0001 to 1,750,000,000 shares of common stock with a par value of \$0.0001. On February 27, 2012, the Company filed a Certificate of Correction with the Secretary of State of the State of Nevada, correcting the par value of 1,750,000,000 shares of common stock that was incorrectly stated as \$0.001 to 1,750,000,000 shares of common stock with a par value of \$0.0001. Unless otherwise noted, all references in this quarterly report to number of shares, price per share or weighted average number of shares outstanding have been adjusted to reflect the stock split on a retroactive basis.

On October 11, 2011, the Company incorporated Orgenesis Ltd. as its wholly-owned Israeli Subsidiary under the laws of Israel. On February 2, 2012, Orgenesis Ltd. signed and closed a definitive agreement to license patents and knowhow related to the development of autologous insulin producing ("AIP") cells. Based on the licensed knowhow and patents, its intention is to develop to the clinical stage a new technology for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using therapeutic agent (i.e., PDX-1, and additional pancreatic transcription factors in an adenovirus-vector) that efficiently converts a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his own therapeutic tissue. The Company believes that its major competitive advantage is in its cell transformation technology.



The development of AIP cells is based on the licensed patents and knowhow of THM and Prof. Ferber. This technology was licensed based on the published work of Prof. Ferber who has developed this technology, as a researcher in THM, and has 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 business by further developing our technology to a clinical stage. We intend to dedicate most of our capital to research and development with no expectation of revenue from product sales in the foreseeable future. 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.

#### *Recent Corporate Developments*

Since the commencement of the year through August 31, 2015, the Company experienced the following corporate developments:

#### **Department De La Gestion Financiere Direction De L analyse Financiere ( DG06 )**

On November 17, 2014, the Company's Belgian Subsidiary received the formal approval from the Walloon Region, Belgium (Service Public of Wallonia, DG06) for a €2.015 million support program for the research and development of a potential cure for Type 1 Diabetes. The Financial support is composed of a €1,085,000 (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of €930,000 (60% of budgeted costs) of the experimental development part of the research program. The grants will be paid to the company over a period of approximately 3 years. The grants are subject to certain conditions with respect to the Company's work in the Walloon Region, the Company's own investment in these projects and certain other conditions and contain a repayment provision upon attaining a favorable outcome. In addition, the DG06 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. On December 9 and 16, 2014, the Company received €651,000 and €558,000 under the grant, respectively.

#### **Israel-U.S. Binational Industrial Research and Development Foundation ( BIRD )**

On December 21, 2014, the Company received a notification from the Israel-U.S. Binational Industrial Research and Development Foundation ( BIRD ) that its wholly owned Subsidiary, Orgenesis Ltd., and its research and development partner, have been approved by BIRD's Board of Governors for a conditional grant of \$800,000 for a joint research and development project for the use of Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project ). On September 9, 2015, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with BIRD and its research and development partner. On September 21, 2015, the Company received \$100,000 under the grant.

#### **Nine Investments Limited Convertible loan agreement**

On December 31, 2014, the Company executed an amendment to convertible loan agreement with Nine Investments Limited to extend the due date of the loan of \$1,500,000 from December 31, 2014 to January 31, 2015. As of the date of this report, the Company has not finalized the terms and revised maturity date of this loan, although it believes it will be successful in extending the agreement upon mutually agreeable terms as soon as practicable.



## Share Exchange Agreement with MaSTherCell SA

The Company entered into a share exchange agreement (the "Share Exchange Agreement") dated November 3, 2014 and addendum dated March 2, 2015 with MaSTherCell SA, Cell Therapy Holding SA (collectively the "Target" or MaSTherCell ) and each of the shareholders of the Target, which provides for the acquisition by the Company of all of the issued and outstanding shares of the Target from the shareholders of the Target in exchange for the issuance of \$24,593,000 in value of shares of common stock in the capital of the Company (the Acquisition ).

MaSTherCell SA and Cell Therapy Holding SA are companies limited by shares incorporated in Belgium. Cell Therapy Holding SA functions as a holding company and prior to the acquisition, owned 50% of the issued and outstanding shares of MaSTherCell SA. The companies were incorporated and launched in 2011. In exchange for all of the issued and outstanding shares of the Target, the Company issued to the shareholders of the Target an aggregate of 42,401,724 shares of its common stock (the Consideration Shares ) at a deemed price of \$0.58 per share for an aggregate deemed price of \$24,593,000. The Share Exchange Agreement provided that the price of the Consideration Shares was to be calculated based on the average of all closing trading prices for the Company's common stock as traded on the OTC stock market for the 30 trading days immediately preceding the closing date, provided that the Consideration Shares were to be priced at no more than \$0.80 per share and no less than \$0.50 per share. The Consideration Shares were issued to 11 non-U.S. persons (as that term is defined in Regulation S of the Securities Act of 1933) in an offshore transaction relying on Regulation S and/or Section 4(a)(2) of the Securities Act of 1933.

## Escrow Agreement

As of February 27, 2015, the Company and the shareholders and bondholders of the Target and Securities Transfer Corporation, the Company's transfer agent, entered into an escrow agreement (the Escrow Agreement ) pursuant to which the shareholders of the Target agreed not to sell any of their Consideration Shares for a period of one year after the closing of the Share Exchange Agreement, and thereafter 1/12th of each Target shareholder's Consideration Shares will be released and eligible for sale during each subsequent calendar month. The Share Exchange Agreement and the Escrow Agreement provide that in the event that the Company has not achieved a post-closing financing and a valuation which meets the agreed threshold within eight months of the closing date of the Share Exchange Agreement, then the shareholders of the Target may, by notice to the Company, unwind the transaction in exchange for return of all of the Consideration Shares plus any amount that the Company has advanced or invested in the Target.

The Share Exchange Agreement and the Escrow Agreement further provide that in case of conversion of MaSTherCell SA's current outstanding convertible bonds (the Convertible Bonds ) (such conversion may occur at the option of the bondholders of MaSTherCell SA if the Company achieves a listing of its shares on a U.S. stock exchange within 14 months of the closing of the Share Exchange Agreement), the shareholders of the Target (other than the former bondholders of MaSTherCell SA) must (i) exchange the shares of MaSTherCell SA to be issued upon conversion of the Convertible Bonds (the Conversion Shares ) for a number of Consideration Shares held by the shareholders of the Target; and (ii) transfer the Conversion Shares to the Company for no additional consideration. The Share Exchange Agreement and the Escrow Agreement further provide that in case the bondholders of MaSTherCell SA elect not to convert the Convertible Bonds, or in case the bondholders of MaSTherCell SA are not allowed to convert the Convertible Bonds in the absence of listing of the Company's shares on a U.S. stock exchange within 14 months of the closing of the Share Exchange Agreement and the Convertible Bonds remain a liability of MaSTherCell SA, then the number of the Consideration Shares will be reduced by the amount that was due at the closing of the Share Exchange Agreement to those bondholders who do not convert their Convertible Bonds. The number of Consideration Shares to be cancelled for this purpose will be determined by dividing the subscription amount of the outstanding Convertible Bonds plus interest owed thereunder by \$24,593,000 and by applying the resulting quotient to the actual total number of Consideration Shares. In such a case, each shareholder of the Target, other than the bondholders of MaSTherCell SA, agreed to give up for cancellation a part of its Consideration Shares that will be proportionate to such shareholder's share in the total number of Consideration Shares issued at the closing of the Share Exchange Agreement.



### Director Appointments

Pursuant to the Share Exchange Agreement and effective as the closing of the Share Exchange Agreement on March 2, 2015, Chris Buyse and Hugues Bultot, two nominees of the shareholders of the Target, were appointed as directors of the Company. Messrs. Buyse and Bultot have no family relationships with each other or any other officer or director of the Company. Upon the closing of the Share Exchange Agreement, Mr. Bultot received 5,050,454 of the Consideration Shares in exchange for the shares of the Target.

### MaSTherCell's Business

MaSTherCell is a Contract Development and Manufacturing Organization (CDMO) specialized 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*). 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 aims 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 partner for their process development/production. Second, it allows customers to profit from MaSTherCell's expertise in cell therapy manufacturing and all related aspects.

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.

### *Competition*

Insulin therapy is used for Insulin-Dependent Diabetes Mellitus (IDDM) patients who are not controlled with oral medications, but this therapy has well-known and well-characterized disadvantages. Weight gain is a common side effect of insulin therapy, which is a risk factor for cardiovascular disease. Injection of insulin causes pain and inconvenience for patients. Patient compliance and inconvenience of self-administering multiple daily insulin injections is also considered a disadvantage of this therapy. The most serious adverse effect of insulin therapy is hypoglycemia. The global diabetes market comprising the insulin, insulin analogues and other anti-diabetic drugs has been evolving rapidly. Today's overall diabetes market is dominated by a handful of participants such as Novo Nordisk A/S, Eli Lilly and Company, Sanofi-Aventis, Takeda Pharmaceutical Company Limited, Pfizer Inc., Merck KGaA, and Bayer AG.

From a manufacturing standpoint, MaSTherCell competes with a number of companies both directly and indirectly. Key competitors include the following CDMOs: Lonza Group Ltd, Progenitor Cell Therapy, LLC (PCT), Pharmacell BV, WuxiAppTec (WuXi PharmaTech (Cayman) Inc.), Cognate Bioservices Inc., Apceth GmbH & Co. KG, Eufets GmbH, Fraunhofer Gesellschaft, Cellfor cure SASU, Cell Therapy Catapult Limited and Molmed S.p.A. Our services differ from these companies in two major aspects:



Quality and Expertise of Our Services: Clients identify the excellence of our facility, quality system, and people as a major differentiating point compared to competitors; and

32

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**Flexible and Tailored Approach:** Our philosophy is to build a true partnership with our clients and adapt ourselves to the clients' needs, which entails no off-the-shelf process nor in-house technology platform, but a dedicated person in plant (of client), joint steering committees on each project and dedicated project managers. In addition, MaSTherCell is the only CDMO located in Belgium which logistically offers an ideal location given the high concentration of companies active in cell therapy (potential clients and companies with complementary knowhow, products and services).

### *Employees*

We have approximately 37 full-time employees, of which 33 are dedicated to our manufacturing facilities at MaSTherCell.

### *Results of Operations*

#### Comparison of the Three and Nine Months Ended August 31, 2015 to the Three and Nine Months Ended August 31, 2014

#### **Revenue**

The Company recognizes revenue through MaSTherCell which bills for services linked to cell process development and cell manufacturing services based on individual contracts in accordance with ASC 605, *Revenue Recognition*. Cell manufacturing services are generally distinct arrangements whereby the Company is paid for time and materials or for fixed monthly amounts.

The Company also incurs revenue corresponding to invoicing to customers of some consumables which are incidental to the services provided as foreseen in the clinical services contracts. On a monthly basis, the Company bills customers for reimbursable expenses and immediately recognizes these billings in revenue, as the revenue is deemed earned.

For the three and nine months ended August 31, 2015, our total revenues were \$936,215 and \$1,756,635, as compared to zero for the same period last year, respectively. The increase in revenue is due to our acquisition of MaSTherCell and the revenues they recognize from services and sales of consumables.

#### **Expenses**

The Company's expenses for the three and nine months ended August 31, 2015 are summarized as follows in comparison to its expenses for three and nine months ended August 31, 2014:

	<b>Three Months Ended August 31,</b>		<b>Nine Months Ended August 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenues	\$ (936,215)	\$ -	(1,756,635)	\$ -
Cost of sales	1,325,739	-	2,298,718	-
Research and development expenses, net	294,360	845,599	759,586	1,936,079
Amortization of intangible assets	408,380	-	801,287	-
General and administration expenses	952,053	440,058	2,811,016	2,032,073
Financial expenses (income), net	(335,932)	2,206,588	(1,303,332)	2,029,415
Loss before income taxes	\$ 1,708,385	\$ 3,492,245	3,610,640	5,997,567



**Research and Development Expenses**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>August 31,</b>		<b>August 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Salaries and related expenses	\$ 135,634	263,162	392,701	\$ 652,178
Stock-based compensation	10,778	344,051	87,395	704,215
Professional fees and consulting services	85,445	284,143	340,627	567,767
Lab expenses	160,382	43,079	318,782	67,673
Other research and development expenses	52,474	3,701	167,755	36,783
Less - grant	(150,353)	(92,537)	(547,674)	(92,537)
<b>Total</b>	<b>\$ 294,360</b>	<b>\$ 845,599</b>	<b>759,586</b>	<b>\$ 1,936,079</b>

The decrease in salaries and related expenses and in stock based compensation in the three and nine months ended August 31, 2015, compared to the same period last year is mainly due to lower compensation expense for certain executives that are no longer employed by the Company. The increase in grant incomes is due to work performed under grants approved from DGO6 in the Belgian Subsidiary, TEDCO in the U.S. Subsidiary and BIRD for the Israeli Subsidiary for the Company's research and development activities. The lab expenses in the three and nine months ended August 31, 2015 were due to developing our technology to a clinical stage and expanding research activities.

**Selling, General and Administrative Expenses**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>August 31,</b>		<b>August 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Salaries and related expenses	\$ 199,896	\$ 52,664	\$ 680,818	\$ 179,044
Stock-based compensation	248,912	151,917	550,684	317,863
Accounting and legal fees	42,315	102,132	393,124	253,798
Professional fees	233,389	92,458	615,372	1,062,708
Rent and related expenses	86,414	-	193,821	-
Business development	98,236	5,165	236,330	113,647
Other general and administrative expenses	42,891	35,722	140,867	105,013
<b>Total</b>	<b>\$ 952,053</b>	<b>\$ 440,058</b>	<b>\$ 2,811,016</b>	<b>\$ 2,032,073</b>

The increase in salaries and related expenses for the three and nine months ended August 31, 2015, compared to the same period last year is due to the increase in the number of employees following the acquisition of MaSTherCell. In addition, there was an increase in legal and accounting fees due to the various material transactions that occurred, mainly the acquisition of MaSTherCell. The rent and related expenses as of the three and nine months ended August 31, 2015 arise from the offices of MaSTherCell. The decrease in professional fees for the nine months ended August 31, 2015, compared to the same period last year is due to a reduction in the reliance on outside professionals as compared to the same period last year.

**Financial Expenses (Income), net**

	Three Months Ended August 31,		Nine Months Ended August 31,	
	2015	2014	2015	2014
Increase (decrease) in fair value of warrants, embedded derivative and convertible bonds	\$ (566,540)	\$ 1,893,000	\$ (1,896,498)	\$ 1,291,046
Interest expense on loans and convertible debts	172,116	280,770	439,525	547,223
Funding fees to Kodiak				135,000
Foreign exchange loss, net	14,613	31,221	76,697	52,131
Other financial expenses, net	43,879	1,597	76,944	4,015
Total	\$ (335,932)	\$ 2,206,588	\$ (1,303,332)	\$ 2,029,415

The increase in financial income in the three and nine months ended August 31, 2015, compared to the same period last year is mainly attributable to decrease in fair value of warrants, embedded derivative and convertible bonds, which is a non-cash metric that is based on the Company's share price as of the measurement date and reflects the issuance of beneficial warrants that were granted during 2014. Due to a decrease in the Company's shares price during the period, there was a resultant income impact. The funding fees to Kodiak in the nine months ended August 31, 2014, represent the fair value of 250,000 shares of common stock issued to Kodiak as part of a stock purchase agreement with Kodiak.

*Liquidity and Financial Condition***Working Capital Deficiency**

	August 31, 2015	November 30, 2014
Current assets	\$ 2,999,390	\$ 2,229,526
Current liabilities	10,393,480	4,663,320
Working Capital Deficiency	\$ (7,394,090)	\$ (2,433,794)

The increase in current assets is mainly due to an increase in accounts receivable, inventory and prepaid expenses and other receivables due to the acquisition of MaSTherCell. This was offset by a decrease in the Company's cash that was used during the nine-month period ending August 31, 2015 to fund research and development expenses.

**Cash Flows**

	Nine Months Ended August 31,	
	2015	2014
Net loss	\$ (3,502,582)	\$ (5,997,567)
Net cash used in operating activities	(2,045,318)	(1,097,524)
Net cash used in investing activities	(198,540)	(6,676)
Net cash provided by financing activities	1,364,471	2,586,520
Increase (decrease) in cash and cash equivalents	\$ (879,387)	\$ 1,482,320

Our cash and cash equivalents balance decreased to \$0.26 million at August 31, 2015 from \$1.3 million at November 30, 2014. The decrease in cash and cash equivalents during the nine months ended August 31, 2015 was primarily due to cash flows used in operating activities in an amount of \$2.05 million and cash used in investing activities of \$0.2 million. The decrease in cash and cash equivalents was largely offset by net cash provided by financing activities in the amount of \$1.36 million which is primarily due to proceeds from loans payable.

Net cash used in operations of approximately \$2.05 million for the nine months ended August 31, 2015 increased mainly due to increases in accounts receivable of \$341 thousand, prepaid expenses of \$785 thousand and change in fair value of convertible bonds of \$705 thousand, but was offset by an increases in accounts payable of \$660 thousand, accrued expenses of \$294 thousand, deferred income of \$875 thousand and payments on grant receivables of \$431 thousand.

Net cash provided by investing activities for the nine months ended August 31, 2015 was \$199 thousand and consisted primarily net of cash that was acquired as part of MaSTherCell acquisition in the amount of \$305 thousand which was offset by purchase of property and equipment for the manufacturing activities of MaSTherCell in amount of \$498 thousand.

Net cash provided by financing activities for the nine months ended August 31, 2015 was \$1,360 thousand and consisted primarily of loans payable totaling \$1,467 thousand and a short term line of credit of \$538 thousand, but was offset by repayments of short and long term debt of \$641 thousand.

### ***Going Concern***

The unaudited interim condensed consolidated financial statements contained in this report 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 August 31, 2015 of \$19,681,658, as well as negative cash flows from operating activities. Company's management estimate that the cash and cash equivalents balance as of August 31, 2015 of \$264,330 will allow the Company to continue its operations and activities for a period of less than one quarter, without additional funding. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following August 31, 2015. 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 believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders. However, there is no assurance that the Company will be successful with those initiatives.

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.

### ***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 on the U.S. for tech transfer and manufacturing scale-up;

purchase equipment needed for its cell production process;  
 hire key personnel including, but not limited to, a chief medical officer, chief science officer and chief operating officer;  
 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 (in certified labs).

The Company estimates its operating expenses for the next 12 months as of August 31, 2015 to be as follows:

GMP process development and validation	\$ 2,200,000
Manufacturing and scale-up	4,500,000
General and administrative	1,300,000
Total	\$ 8,000,000

While the above cash requirements do contemplate the Company's expected cash needs for the scale-up of manufacturing for the Company's products in the U.S. Market in conjunction with MaSTherCell, they do not contemplate the potential cash needs of MaSTherCell's current operations in their existing markets.

#### *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.

#### *Significant Accounting Policies*

##### *Business Combination*

We allocated the purchase price of business we acquired to the tangible and intangible assets acquired and liabilities assumed based upon their estimated fair values on the acquisition date. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Acquired in-process backlog, customer relations, brand name and know how are recognized at fair value. The purchase price allocation process require from us to make significant estimates and assumptions, especially at the acquisition date with respect to intangible assets. Direct transaction costs associated with the business combination are expensed as incurred. The allocation of the consideration transferred in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date. We included the results of operations of the business that we acquired in the consolidated results prospectively from the date of acquisition.





### *Intangible Assets*

Intangible assets are recorded at acquisition cost less accumulated amortization and impairment. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method over their estimated period of useful life, which is determined by identifying the period over which the cash flows are expected to be generated.

### *Goodwill*

Goodwill represents the excess of the purchase price of acquired businesses over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired. The goodwill impairment test is applied by performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is considered not more likely than not that the fair value of the reporting unit is less than the carrying amount, further testing of goodwill for impairment would not be required. Otherwise, goodwill impairment is tested using a two-step approach.

### *Impairment of Long-lived Assets*

We are reviewing the property and equipment, intangible assets subject to amortization and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset class may not be recoverable. Indicators of potential impairment include: an adverse change in legal factors or in the business climate that could affect the value of the asset; an adverse change in the extent or manner in which the asset is used or is expected to be used, or in its physical condition; and current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of the asset. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted cash flows.

### *Revenue Recognition*

We recognize the revenue for services linked to cell process development and cell manufacturing services based on individual contracts in accordance with ASC 605, *Revenue Recognition*, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred or services have been provided; the seller's price to the buyer is fixed or determinable and collectability is reasonably assured. We determine that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. In addition, we determine that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Service revenues are recognized as the services are provided.

We are assessing cash collectability based on a number of factors, including past collection history with the client and the client's creditworthiness. If we determine that collectability is not reasonably assured, we defer revenue recognition until collectability becomes reasonably assured, which is generally upon receipt of the cash. Our arrangements are generally non-cancellable, though clients typically have the right to terminate their agreement for cause if we materially fails to perform. Cell manufacturing services are generally distinct arrangements whereby we are paid for time and materials or for fixed monthly amounts. Revenue is recognized when efforts are expended or contractual terms have been met.

We also incurs revenue corresponding to invoicing to customers of some consumables which are incidental to the services provided as foreseen in the clinical services contracts. We bills customers for reimbursable expenses and

immediately recognize these billings in revenue, as the revenue is deemed earned.

A comprehensive discussion of the Company's significant accounting policies is included in the Management's Discussion and Analysis of Financial Condition and Results of Operations section in the Company's annual report on Form 10-K for the fiscal year ended November 30, 2014 filed with the SEC on February 19, 2015.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### **Currency Exchange Risk**

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

#### **Interest Rate Risk**

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

### **ITEM 4. CONTROLS AND PROCEDURES**

#### *Disclosure Controls and Procedures*

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's 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 August 31, 2015. 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 staff:

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

Our management feels 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.

#### *Changes in Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting during the three months ended August 31, 2015 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

#### *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 August 31, 2015 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 August 31, 2015 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

The Company knows of no material pending legal proceedings to which the Company or its Subsidiaries are a party or of which any of its properties, or the properties of its Subsidiaries, are the subject. In addition, the Company does not know of any such proceedings contemplated by any governmental authorities.

The Company knows of no material proceedings in which any of the Company's directors, officers or affiliates, or any registered or beneficial stockholder is a party adverse to the Company or its Subsidiaries or has a material interest adverse to the Company or its Subsidiaries.

### **ITEM 1A. RISK FACTORS**

An investment in the Company's common stock involves a number of very significant risks. You should carefully consider the risk factors included in the "Risk Factors" section of the Annual Report on Form 10-K for the year ended November 30, 2014 that was filed on February 19, 2015 and our Form 8-K/A filed on March 25, 2015, in addition to other information contained in those reports and in this quarterly report in evaluating the Company and its business before purchasing shares of its common stock. The Company's business, operating results and financial condition could be adversely affected due to any of those risks. You could lose all or part of your investment due to any of these risks.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

### **ITEM 5. OTHER INFORMATION**

None.



**ITEM 6. EXHIBITS**

Exhibits required by Regulation S-K:

<b>No.</b>	<b>Description</b>
3.1	Articles of Incorporation (incorporated by reference to an exhibit to a registration statement on Form S1 filed on April 2, 2009)
3.2	Certificate of Change (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.3	Articles of Merger (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 2, 2011)
3.4	Certificate of Amendment to Articles of Incorporation (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.5	Amended and Restated Bylaws (incorporated by reference to an exhibit to a current report on Form 8-K filed on September 21, 2011)
3.6	Certificate of Correction dated February 27, 2012 (incorporated by reference to an exhibit to a current report on Form 8-K/A filed on March 16, 2012)
10.1	Term sheet with Mediapark Investments Limited (incorporated by reference to the Company's current report on Form 8-K filed on December 16, 2013)
10.2	Convertible Loan Agreement dated December 6, 2013 with Mediapark Investments Limited (incorporated by reference to the Company's current report on Form 8-K filed on December 16, 2013)
10.3	Investment Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to the Company's current report on Form 8-K filed on December 16, 2013)
10.4	Registration Rights Agreement dated December 13, 2013 with Kodiak Capital Group, LLC (incorporated by reference to the Company's current report on Form 8-K filed on December 16, 2013)
10.5	Form of subscription agreement (incorporated by reference to the Company's current report on Form 8-K filed on March 4, 2014)
10.6	Form of warrant (incorporated by reference to the Company's current report on Form 8-K filed on March 4, 2014)
10.7	Consulting Agreement dated April 3, 2014 with Aspen Agency Limited (incorporated by reference to the Company's current report on Form 8-K filed on April 7, 2014)
10.8	Stock Option Agreement dated April 3, 2014 with Aspen Agency Limited (incorporated by reference to the Company's current report on Form 8-K filed on April 7, 2014)
10.9	Personal Employment Agreement dated April 16, 2014 by and between Orgenesis Ltd. and Joseph Tenne (incorporated by reference to the Company's current report on Form 8-K filed on April 16, 2014)
10.10	Form of subscription agreement with form of warrant (incorporated by reference to the Company's current report on Form 8-K filed on April 28, 2014)
10.11	Convertible Loan Agreement dated May 29, 2014 with Nine Investments Limited (incorporated by reference to the Company's current report on Form 8-K filed on May 30, 2014)
10.12	Services Agreement between Orgenesis SPRL and MaSTherCell SA dated July 3, 2014 incorporated by reference to the Company's current report on Form 8-K filed on July 7, 2014)
10.13	Financial Consulting Agreement dated August 1, 2014 with Eventus Consulting, P.C., (incorporated by reference to the Company's current report on Form 8-K filed on August 5, 2014)
10.14	Personal Employment Agreement dated August 1, 2014 by and between Orgenesis, Inc. and Neil Reithinger (incorporated by reference to the Company's current report on Form 8-K filed on August 5, 2014)
10.15	Personal Employment Agreement dated as of July 23, 2014 by and between Orgenesis Maryland Inc. and Scott Carmer (incorporated by reference to the Company's current report on Form 8-K filed on August 6, 2014)
10.16	Personal Employment Agreement dated August 22, 2014 by and between Orgenesis Ltd. and Vered Caplan (incorporated by reference to the Company's current report on Form 8-K filed on August 25, 2014)

10.17 Share Exchange Agreement dated November 6, 2014 with MaSTherCell SA and Cell Therapy Holding SA (collectively MaSTherCell ) and each of the shareholders of MaSTherCell (incorporated by reference to the Company s current report on Form 8-K filed on November 10, 2014)

No.	Description
10.18	Addendum 1 to Share Exchange Agreement dated March 2, 2015 with MaSTherCell SA, Cell Therapy Holding SA and their shareholders (incorporated by reference to the Company's current report on Form 8-K filed on March 5, 2015)
10.19	Escrow Agreement dated February 27, 2015 with the shareholders of MaSTherCell SA and Cell Therapy Holding SA and bondholders of MaSTherCell SA and Securities Transfer Corporation (incorporated by reference to the Company's current report on Form 8-K filed on March 5, 2015)
10.20	Orgenesis Inc. Board of Advisors Consulting Agreement dated March 16, 2015 (incorporated by reference to the Company's current report on Form 8-K filed on March 17, 2015)
21.1	List of Subsidiaries of Orgenesis Inc.
31.1*	<u>Certification Statement of the Chief Executive Officer pursuant to Section 302 of the SarbanesOxley Act of 2002</u>
31.2*	<u>Certification Statement of the Chief Financial Officer pursuant to Section 302 of the SarbanesOxley Act of 2002</u>
32.1*	<u>Certification Statement of the Chief Executive Officer pursuant to Section 906 of the SarbanesOxley Act of 2002</u>
32.2*	<u>Certification Statement of the Chief Financial Officer pursuant to Section 906 of the SarbanesOxley Act of 2002</u>
99.1	Global Share Incentive Plan (2012) (incorporated by reference to the Company's current report on Form 8-K filed on May 31, 2012)
99.2	Appendix Israeli Taxpayers Global Share Incentive Plan (incorporated by reference to the Company's current report on Form 8-K filed on May 31, 2012)
99.3	Audit Committee Charter (incorporated by reference to the Company's current report on Form 8-K filed on January 15, 2013)
99.4	Compensation Committee Charter (incorporated by reference to the Company's current report on Form 8-K filed on January 15, 2013)
101*	Interactive Data Files pursuant to Rule 405 of Regulation ST.

\*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: October 15, 2015

*/s/ Neil Reithinger*

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: October 15, 2015