Orgenesis Inc. Form 10-Q April 14, 2015

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-Q**

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

For the Quarterly Period Ended February 28, 2015

or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 O ACT OF 1934	OR 15(d) OF THE SECURITIES EXCHANGE
For the Transition Period from	to

Commission file number: <u>000-54329</u>

### ORGENESIS INC.

(Exact name of registrant as specified in its charter)

#### **Nevada**

<u>98-0583166</u>

(State or other jurisdiction of incorporation or organization)

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

20271 Goldenrod Lane Germantown, MD 20876

(Address of principal executive offices) (zip code)

#### (480) <u>659-6404</u>

(Registrant s telephone number, including area code)

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

Yes [X] No [ ]

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

Yes [X] No [ ]

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

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ]	Smaller reporting company [X]
(Do not check if a smaller reporting comp	pany)
Indicate by check mark whether the regist	trant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
[ ] Yes [X] No	
As of April 14, 2015, there were 98,487,6	574 shares of registrant s common stock outstanding.

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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)

	F	ebruary 28, 2015	N	ovember 30, 2014
<u>Assets</u>				
CURRENT ASSETS:				
Cash and cash equivalents	\$	520,125	\$	1,314,052
Restricted cash		5,043		-
Prepaid expenses and other accounts receivable		676,732		104,958
Receivables on account of grant		-		810,516
TOTAL CURRENT ASSETS		1,201,900		2,229,526
FUNDS IN RESPECT OF RETIREMENT BENEFITS OBLIGATION		6,253		6,377
PROPERTY AND EQUIPMENT, NET		18,424		13,049
TOTAL ASSETS		1,226,577		2,248,952
Liabilities net of capital deficiency				
CURRENT LIABILITIES:				
Short-term bank credit		-		14,084
Accounts payable		524,318		1,083,910
Accrued expenses		246,893		374,673
Employees and related payables		548,720		626,012
Related parties		42,362		42,362
Advance payment on account of grant		551,988		84,911
Convertible loan		2,523,473		2,437,368
TOTAL CURRENT LIABILITIES		4,437,754		4,663,320
LONG-TERM LIABILITIES:				
Warrants		407,000		559,954
Retirement benefits obligation		4,878		4,974
TOTAL LONG-TERM LIABILITIES		411,878		564,928
TOTAL LIABILITIES		4,849,632		5,228,248
COMMITMENTS (Note 3)				
CAPITAL DEFICIENCY:				
Common stock of \$0.0001 par value - authorized: 1,750,000,000 shares at				
February 28, 2015 and November 30, 2014; issued and outstanding:				
55,970,565 shares at February 28, 2015 and November 30, 2014.		5,597		5,597
Additional paid-in capital		13,400,932		13,152,551
Receipts on account of shares to be allotted		60,000		60,000
Accumulated other comprehensive loss		(120,298)		(18,368)
Accumulated deficit		(16,969,286)		(16,179,076)
TOTAL CAPITAL DEFICIENCY		(3,623,055)		(2,979,296)
TOTAL LIABILITIES NET OF CAPITAL DEFICIENCY	\$	1,226,577	<u>\$</u>	2,248,952
The accompanying notes are an integral part of these condensed cons	solid	lated financia	l sta	tements.

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

### Three Months Ended February 28.

February 28,			,
	2015	_	2014
\$	175,617	\$	605,111
	659,091		512,109
	834,708		1,117,220
	(44,498)		(407,906)
	790,210		709,314
	101,930		-
\$	892,140	\$	709,314
\$	0.01	\$	0.01
\$	0.02	\$	0.01
	55,735,394		52,085,973
	56,288,938		52,085,973
	\$	\$ 175,617 659,091 834,708 (44,498) 790,210 101,930 \$ 892,140 \$ 0.01 \$ 0.02	\$ 175,617 \$ 659,091 834,708 (44,498) 790,210 \$ 101,930 \$ 892,140 \$ \$ 0.01 \$ 0.02 \$ \$ 55,735,394

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 paid-in	Receipts or Account of Shares to be
	Shares	Shares Amount		allotted
Balance at December 1, 2013	51,144,621 \$	5,114	8,635,447	\$
Changes during the three months ended February 28, 2014 :				
Stock-based compensation related to options				
granted to employees and directors	-	-	442,113	
Stock-based compensation related to options				
granted to consultants		-	8,510	
Issuance of shares and warrants	1,128,849	113	586,888	
Commitment shares issued	250,000	25	(25)	
Proceeds from exercise of stock options	623,806	62	562	
Shares to be issued for services rendered			6,319	
Net loss - comprehensive loss	-	-	-	
Balance at February 28, 2014	53,147,276 \$	5,314 \$	9,679,814	
Balance at December 1, 2014	55,970,565 \$	5,597 \$	3 13,152,551	60,00
Changes during the three months ended February 28, 2015 :				
Stock-based compensation related to options				
granted to employees and directors			158,803	
Stock-based compensation related to options and shares				
granted to service providers			89,578	
Comprehensive loss				
Balance at February 28, 2015	55,970,565 \$	5,597	13,400,932	\$ 60,00
The accompanying notes are an integral part of these cond	oncod concolidate	d financial	stataments	

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

**Three Months Ended** February 28, 2015 2014 CASH FLOWS FROM OPERATING ACTIVITIES: Net loss \$ \$ (709,314)(790,210)Adjustments required to reconcile net loss to net cash used in operating activities: Stock-based compensation related to options granted to employees and 442,113 directors 158,803 Stock-based compensation related to options and shares granted to service pproviders 89,578 8,510 Increase (decrease) in retirement benefits obligation 576 (96)Shares to be issued for services rendered 6,319 Depreciation expenses 1,374 867 Change in fair value of warrants and embedded derivative (182,954)(419,774)Acrrued interest loans 116,105 6,722 Changes in operating assets and liabilities: Decrease (increase) in prepaid expenses and other accounts receivable (609,961)7,602 (514,753)32,038 Increase (decrease) in accounts payable Increase (decrease) in accrued expenses (127,779)105,342 Increase (decrease) in employees and related payables 18,983 (77,292)Increase in advance payment and receivables on account of grant 1,296,616 Net cash used in operating activities (500,016)(640,569)**CASH FLOWS FROM INVESTING ACTIVITIES:** Purchase of property and equipment (6,749)Restricted cash (5,043)Amounts funded in respect of retirement benefits obligation (1,055)124 Net cash used in investing activities (11,668)(1,055)**CASH FLOWS FROM FINANCING ACTIVITIES:** Maturity of Short-term line of credit (14,084)Proceeds from issuance of shares and warrants 587,625 Proceeds from issuance of convertible loans together with shares 100,000 Net cash provided by (used in) financing activities (14,084)687,625 **NET CHANGE IN CASH** 186,554 (666,321)EFFECT ON EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS (127,606)

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

1,314,052

520,125

\$

**CASH AT BEGINNING OF PERIOD** 

**CASH AT END OF PERIOD** 

50,827

237,381

# ORGENESIS INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the Three Month Period Ended February 28, 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 it is 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.

On October 11, 2011, the Company acquired 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 will be engaged in development and manufacturing activities together with clinical development studies in Europe, and later on to be the Company's center for the Company's activities in Europe.

As used in this report and unless otherwise indicated, the term Company refers to Orgenesis Inc. and the Company s wholly-owned subsidiaries (Subsidiaries). As of the date of this filing, the foregoing terms do not include MaSTherCell SA, as described below. Unless otherwise specified, all dollar amounts are expressed in United States dollars.

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 ) and each of the shareholders of MaSTherCell, which provides for the acquisition by the Company of all of the issued and outstanding shares of MaSTherCell from the shareholders of the MaSTherCell in exchange for the issuance of \$24,593,000 in value of shares of common stock in the capital of the Company (the Acquisition ). See also note 7a.

These unaudited condensed consolidated financial statements of the Company and its Subsidiaries have been prepared in accordance with U.S. GAAP, pursuant to the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial statements. Accordingly, they do not contain all information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, the unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of February 28, 2015, and the consolidated statements of comprehensive loss, changes in capital deficiency and of cash flows for the three month periods ended February 28, 2015 and 2014. The results for the three month period ended February 28, 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.

# ORGENESIS INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the Three Month Period Ended February 28, 2015 (Unaudited)

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

In June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, Development Stage Entities (Topic 915), Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (ASU 2014-10). The amendments in ASU 2014-10 remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from accounting principles generally accepted in the United States of America (U.S. GAAP). In addition, the amendments eliminate the requirements for development stage entities to: (i) present inception-to-date information in the statements of income, cash flows, and shareholder equity; (ii) label the financial statements as those of a development stage entity; (iii) disclose a description of the development stage activities in which the entity is engaged; and (iv) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The presentation and disclosure requirements in Accounting Standard Codification ( ASC ) Topic 915, Development Stage Entities are no longer required for interim and annual reporting periods beginning after December 15, 2014. The revised consolidation standards will take effect in annual periods beginning after December 15, 2015, however, early adoption is permitted. The Company has elected to early adopt the provisions of ASU No. 2014-10 for its unaudited condensed consolidated financial statements that are included in this quarterly report.

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. Currently, there is no guidance under U.S. GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern or to provide related footnote disclosures. The amendments in this Update provide that guidance. In doing so, the amendments should 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 February 28, 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.

# ORGENESIS INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the Three Month Period Ended February 28, 2015 (Unaudited)

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

#### 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 \$16,969,286, as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following February 28, 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 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 - 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).

#### **NOTE 2 - FAIR VALUE PRESENTATION (cont.)**

As of February 28, 2015, the Company s assets and liabilities that are measured at fair value and classified as level 3 fair value are as follows:

	February 28, 2015			
		Level 3		<u>Total</u>
Warrants	\$	407,000	\$	407,000
Embedded derivative*	\$	962,000	\$	962,000
		Nover	nber 30,	2014
		Level 3		<u>Total</u>
Warrants	\$	559,954	\$	559,954
Embedded derivative*	\$	992,000	\$	992,000

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

The fair value of each of the warrants is determined by using a Monte Carlo type valuation model based on a risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issuance dates. Then for each path to use the Black-Scholes valuation model to estimate the value of the warrants on the last issuance date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issuance dates.

The fair value of the embedded derivative described in Note 6 is determined by using a Monte Carlo simulation model. This model, in contrast to the closed form model, such as the Black-Sholes 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 following table presents the assumptions that were used for the models as of February 28, 2015:

		Embedded
	Warrants	Derivative
Fair value of shares of common stock	\$ 0.60	\$ 0.60
Expected volatility	90%	90%
	0.02% -	
Risk free interest rate	0.10%	0.02%
Expected term (years)	0.1 0.6	0.3
Expected dividend yield	0%	0%

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 3 months ended February 28, 2015:

		Embedded
	Warrants	Derivative
Balance at beginning of period	\$ 559,954	\$ 992,000
Changes in fair value during the period*	(152,954)	(30,000)

Balance at end of period

\$

407,000 \$

962,000

\*There were no transfers to Level 3 during the three months ended February 28, 2015.

#### **NOTE 2 - 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 year ended November 30, 2014:

		Embedded
	Warrants	Derivative
Balance at beginning of period Additions	\$ 1,157,954	\$ 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

<sup>\*</sup>There were no transfers to Level 3 during 2014.

#### NOTE 3 COMMITMENTS

#### a. <u>Tel Hashomer Medical Research, Infrastructure and Services Ltd.</u>

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).

#### NOTE 3 COMMITMENTS (cont.)

As of February 28, 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 March 22, 2012, 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 \$74,000 for a year. In May 2013 and May 2014, the Israeli Subsidiary renewed the research agreement for an annual consideration of approximately \$92,000 and \$114,000, respectively.

#### 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 February 28, 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 \$794,532 (€606,500) for all services. As of February 28, 2015, the Company received services in total value of \$535,673.

#### d. MaSTherCell SA

On July 3, 2014 (prior to the initiation of the transaction detailed in Note 7), 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 3(f)) with the balance being invoiced monthly. Services will 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.

# ORGENESIS INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the Three Month Period Ended February 28, 2015 (Unaudited)

#### NOTE 3 COMMITMENTS (cont.)

On November 6, 2014, the Company entered into a share exchange agreement and addendum dated March 2, 2015 with MaSTherCell. See also Note 7.

#### e. <u>Maryland Technology Development Corporation</u>

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. On July 22, 2014, the U.S Subsidiary received an advance payment of \$203,216 on account of the grant. Through February 28, 2015, an amount of \$176,006 out of the \$203,216 was spent. The amount of grant that was spent through February 28, 2015 was recorded as a deduction of research and development expenses in the statement of operations. The excess of \$27,210 is presented on the balance sheet as of February 28, 2015 as a short term liability.

#### f. <u>Department De La Gestion Financiere Direction De La nalyse Financiere (DGO6)</u>

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 February 28, 2015, an amount of \$958,595 was recorded as deduction of research and development expenses.

#### NOTE 4 CAPITAL DEFICIENCY

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

There were no capital transactions during the three months ended February 28, 2015. 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.

#### NOTE 4 CAPITAL DEFICIENCY (cont.)

#### Loss per share

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

	Three monthes en 2015	ded Febuary 28 2014
	U.S. dollars excep	
Basic:		· F ·- ·
Loss for the period	790,210	709,314
Weighted average number of common shares outstanding	55,735,394	52,085,973
Loss per common share	0.01	0.01
Diluted:		
Loss for the period	790,210	
Change in fair value of warrants	152,954	
Total Loss for the period	943,164	
Weighted average number of shares used in the computation		
of basic loss per share	55,735,394	
Number of dilutive shares related to warrants	553,543	
Weighted average number of common shares outstanding	56,288,937	
Loss per common share	0.02	*0.01

<sup>\*</sup>The effect of the warrants was anti-dilutive, therefore the diluted loss per share for the three monthes ended Febuary 28, 2014 is equal to the basic loss per share.

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

#### NOTE 5 STOCK BASED COMPENSATION

#### a. <u>Global Share Incentive Plan</u>

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.

#### NOTE 5 STOCK BASED COMPENSATION (cont.)

#### 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 three months ended February 28, 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 February 28, 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 three-month period ended February 28, 2015.

#### NOTE 6 CONVERTIBLE LOAN AGREEMENTS

On May 29, 2014, the Company entered into a convertible loan agreement with Nine Investments Limited, a Hong Kong company (Nine Investments), pursuant to which Nine Investments loaned the Company \$1,500,000 which the Company subsequently transferred to its Belgian Subsidiary, Orgenesis SPRL, to fund a research project to develop new medical technologies and cell therapies for the treatment of diabetes. The Company received the funds on June 4, 2014 (the Closing Date). Interest is calculated at 8% semiannually and is payable, along with the principal on or before December 31, 2014 subject to acceleration for specific events including: (i) if a grant of money to Orgenesis SPRL is not approved by Department De La Gestion Financiere Direction De L analyse Financiere (DGO6) within 90 days after the loan proceeds are advanced; and (ii) if the Company raises, in the aggregate, gross proceeds of more than \$400,000 between the date of the loan and the maturity date, but only to the extent of gross proceeds so raised that are in excess of \$400,000.

Nine Investments may convert all or part of the loan into shares of the Company's common stock at \$0.40 per share. The conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment in the event and in the manner following: (i) if and whenever the Company s common shares at any time outstanding shall be subdivided into a greater or consolidated into a lesser number of common shares, or in case of any capital reorganization or of any reclassification of the capital of the Company or in case of the consolidation, merger or amalgamation of the Company with or into any other company or of the sale of the assets of the Company as or substantially as an entirety or of any other company, the conversion price shall be decreased or increased proportionately; and (ii) in the event the Company issues any shares of common stock or securities

convertible into shares at a price less than the conversion price, the conversion price shall be reduced for any unpaid or unconverted loan amount to the new issuance price.

#### NOTE 6 CONVERTIBLE LOAN AGREEMENTS (cont.)

As consideration for entering into the loan agreement, on June 5, 2014, the Company issued to Nine Investments 500,000 shares of its common stock.

The Company allocated the proceeds from Nine Investments between the shares and the convertible loan based on the relative fair value. In addition, 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 used the fair value of the conversion right derivative as the amount allocated from the proceeds of the convertible loan. The allocation of conversion rights and shares represents a discount to the loan and will be accreted until the expected maturity date of the loan. 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 extended for four months from the original maturity date, or until the end of April 2015.

The table below presents the fair value of the instruments issued as of the Closing Date and the allocation of the proceeds:

	<b>Total Fair</b>	Allocation of
	Value	<b>Proceeds</b>
Loan component	\$ 1,262,000	\$ 746,000
Shares component	250,000	180,000
Embedded derivative component	574,000	574,000
Total	\$ 2,086,000	\$ 1,500,000

The Company estimated the fair value of the embedded derivative by using the Black-Scholes formula for option pricing using the following parameters: Share price \$0.50; Exercise price \$0.40; Volatility 94%; Dividend yield 0; Risk-free interest 0.05% and 80% likelihood for conversion. The bonus shares component was recorded as additional paid-in-capital and the fair value of the embedded derivative component is classified as a financial liability because the conversion price and the number of shares of common stock deliverable upon the conversion of the loan shall be subject to adjustment and will be measured in subsequent periods at fair value with changes in fair value charged to financial expenses or income, net.

#### NOTE 7 SUBSEQUENT EVENTS

#### a. 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 and each of the shareholders of MaSTherCell, which provides for the acquisition by the Company of all of the issued and outstanding shares of the MaSTherCell from the shareholders of the MaSTherCell 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 currently owns 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 MaSTherCell, the Company issued to the shareholders of the MaSTherCell 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.

# ORGENESIS INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the Three Month Period Ended February 28, 2015 (Unaudited)

#### NOTE 7 SUBSEQUENT EVENTS (cont.)

#### **Escrow Agreement**

As of March 2, 2015, the Company and the shareholders and bondholders of the MaSTherCell and Securities Transfer Corporation, the Company s transfer agent, entered into an escrow agreement (the Escrow Agreement) pursuant to which the shareholders of MaSTherCell 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 MaSTherCell 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 MaSTherCell 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 MaSTherCell.

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 MaSTherCell (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 MaSTherCell; 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 MaSTherCell, 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 MaSTherCell, 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 MaSTherCell.

#### NOTE 7 SUBSEQUENT EVENTS (cont.)

#### b. Appointment of Member to Board of Advisors

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. The Company will also grant Prof. Raz 100,000 stock options exercisable at the market price on date of grant. The options will be subject to the Company s stock option plan and will have vesting provisions. Prof. Raz will also be reimbursed for out of pocket expenses incurred for carrying out consulting business. The agreement is for an indefinite period unless terminated by either party with 30 days advance written notice to the other party.

#### c. Nine Investments Limited

As described in Note 6, 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 extended for four months from the original maturity date, or until the end of April 2015.

### 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;

plans to hire industry experts and expand its management team;

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;

beliefs regarding the future of its competitors;

expectation that the demand for its products will eventually increase; and

expectation that it will be able to raise capital when it needs it.

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, any of which may cause the Company's or its industry sactual 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 include, by way of example and not in limitation:

general economic and business conditions;

substantial doubt about its ability to continue as a going concern;

its needs to raise additional funds in the future which may not be available on acceptable terms or at all;

its inability to successfully recruit and retain qualified personnel in order to continue its operations;

its ability to successfully implement its business plan;

conditions in Israel and the surrounding Middle East which may materially adversely affect its Israeli Subsidiary s operations and personnel;

the ability of its Israeli Subsidiary to pay dividends is subject to limitations under Israeli law and dividends paid and loans extended by its Israeli Subsidiary may be subject to taxes;

any probability that Tel Hashomer - Medical Research, Infrastructure and Services Ltd. (  $\,$  THM  $\,$ ) may cancel the License Agreement;

if the Company is unable to successfully acquire, develop or commercialize new products;

its expenditures not resulting in commercially successful products;

third parties claiming that the Company may be infringing their proprietary rights that may prevent the Company from manufacturing and selling some of its products;

the impact of extensive industry regulation, and how that will continue to have a significant impact on its business, especially its product development, manufacturing and distribution capabilities; and

other factors discussed under the section entitled Risk Factors set forth in this Annual Report on Form 10-K for the year ended November 30, 2014.

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

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 ), and Orgenesis Maryland, Inc. (the U.S. Subsidiary ). Unless otherwise specified, all dollar amounts are expressed in United States dollars.

#### Corporate Overview

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.

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.

#### Our Current Business

The Company is developing a technology that it is 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.

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 .

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 development of AIP cells is based on the licensed patents and knowhow of THM and Prof. Ferber. The Company believes that its major competitive advantage is in its cell transformation technology.

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.

The Company intends to grow its business by further developing the technology to a clinical stage. It intends to dedicate most of its capital to research and development with no expectation of revenue from product sales in the foreseeable future.

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#### Recent Corporate Developments

Since the commencement of the year through February 28, 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 us 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 Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the Project). A Cooperation and Project Funding Agreement (CPFA) must be signed for the Project with the BIRD Foundation within three months, or by March 31, 2015.

#### 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 extended for four months from the original maturity date, or until the end of April 2015.

Subsequent Events

#### 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 currently owns 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.

#### **Competitors**

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, Cellforcure SASU, Cell Therapy Catapult Limited and Molmed S.p.A. MaSTherCell's services differ from these companies in two major aspects:

quality and expertise of its services: clients identify the excellence of its facility, quality system, and people as a major differentiating point compared to competitors; and

flexible and tailored approach: MaSTherCell's philosophy is to build a true partnership with its clients and adapt itself 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.

Neither of these differentiating points results in a price premium compared to other CMO s as MaSTherCell operates with a lean organization focused solely on cell therapy.

Finally, 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).

#### Risk factors related to MaSTherCell's Business

#### Risks related to MaSTherCell's financial condition

The Company anticipatse that it will need additional financing in the future to continue its operations; if it is unable to raise additional capital, as and when needed, or on acceptable terms, it may be forced to delay, reduce or eliminate the expansion of its contract development and manufacturing operations.

MaSTherCell's current operating plan will require additional capital to fund, among other things, the operation, enhancement and expansion of its operations to support its customers. The amount and timing of its future capital requirements also will likely depend on many other factors, including:

the cost of expansion of its contract development and manufacturing operations, including but not limited to the costs of expanded facilities, equipment costs, engineering and innovation initiatives and personnel; the opportunity to produce therapies in commercial phases for a customer which will required large production units.

Ultimately, the Company may be unable to raise capital on terms that are acceptable to it, if at all. Our inability to obtain necessary capital or financing to fund its future operating needs could adversely affect its business, results of operations and financial condition.

MaSTherCell has incurred substantial losses and negative cash flow from operations in the past, and expects to continue to incur losses and negative cash flow for the foreseeable future.

MaSTherCell has a limited operating history, limited capital, and limited sources of revenue. Since its inception in 2011 through December 31, 2014, the revenues generated have not been sufficient to cover costs attributable to that business. Based upon current plans, it is expected that MaSTherCell will reach a positive EBITDA in 2015 and will incur operating losses in future periods. This will happen because there are expenses associated with the development, marketing, and sales of its services. As a result, MaSTherCell may not generate significant revenues in the future. Failure to generate significant revenues in near future may cause it to suspend or cease activities. Our ability to achieve and maintain profitability and positive cash flow is dependent upon its ability to generate revenues, manage expenses, and compete successfully with its direct and indirect competitors.

Risks related to the Company s contract (process and assay) development and manufacturing business

Cell therapy is in its early stages, it is still a developing field and a significant global market for its third party manufacturing services at MaSTherCell may never emerge.

Cell therapy is in its early stages and is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace, making difficult their own funding to enable them to continue their business. At MaSTherCell, the current market and its existing contracts principally consist of providing consulting and manufacturing of cell and tissue-based therapeutic products in clinical trials. The number of people who may use cell or tissue-based therapies and thus the demand for stem cell processing services is difficult to forecast. If cell therapies under development by its customers to treat disease are not proven effective, demonstrate unacceptable risks or side effects or, where required, fail to receive regulatory approval, its business will be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved products in the United States, Asia and in Europe. Ultimately, its success in developing its contract development and manufacturing business depends on the development and growth of a broad and profitable global market for cell- and tissue-based therapies and services and its ability to capture a share of this market through MaSTherCell.

# MaSTherCell's revenues may vary dramatically from period to period making it difficult to forecast future results.

The nature and duration of MaSTherCell's contracts with customers often involve regular renegotiation of the scope, level and price of the services it is providing. If its customers reduce the level of their spending on research and development or marketing or are unsuccessful in attaining or retaining product sales due to market conditions, reimbursement issues or other factors, its results of operations may be materially impacted. In addition, other factors, including the rate of enrollment for clinical studies, will directly impact the level and timing of the products and services the Company delivers. As such, the levels of its revenues and profitability can fluctuate significantly from one period to another and it can be difficult to forecast the level of future revenues with any certainty.

The loss of one or more of MaSTherCell s major clients or a decline in demand from one or more of these clients could harm MaSTherCell s business.

MaSTherCell has a few major clients that together account for a large percentage of the total revenues earned. There can be no assurance that such clients will continue to use MaSTherCell s services at the same level or at all. A reduction or delay in the use of MaSTherCell s services, including reductions or delays due to market, economic or competitive conditions, could have a material adverse effect on MaSTherCell s business, operating results and financial condition.

# MaSTherCell has a finite manufacturing capacity, which could inhibit the long-term growth prospects of this business.

MaSTherCell currently provides services and produces materials for clinical trials at its existing manufacturing facilities in Gosselies (Belgium), which it has designed and operated to be compliant with cGMP requirements. While the Company believes these facilities provide it with sufficient capacity to meet expected near term demand, it is possible that the demand for its services and products could exceed its existing manufacturing capacity. It may become necessary or desirable for it to expand its manufacturing capabilities for cell therapy services and products in the future, which may require it to invest significant amounts of capital and to obtain regulatory approvals. In this regard, the Company is reviewing opportunities for expansion to both commercial level and international manufacturing capabilities. If it is unable to meet rising demand for products and services on a timely basis or unable to maintain cGMP compliance standards, then it is likely that its clients and potential clients will elect to obtain the products and services from competitors, which could materially and adversely affect the level of its revenues and its prospects for growth.

# MaSTherCell s business is subject to risks associated with a single manufacturing facility.

MaSTherCell s contract manufacturing services are dependent upon a single facility located in Gosselies (Belgium). A catastrophic loss of the use of all or a portion of MaSTherCell s manufacturing facility due to accident, fire, explosion, labor issues, weather conditions, other natural disaster or otherwise, whether short or long-term, could have a material adverse effect on MaSTherCell s customer relationships and financial results.

# If MaSTherCell loses electrical power at its manufacturing facility, its business operations may be adversely affected.

MaSTherCell owns a back-up generator allowing it to provide for its manufacturing power consumption needs for a few hours. However, if MaSTherCell loses electrical power at its manufacturing facility for more than a few hours, MaSTherCell would be unable to continue its manufacturing operations for an extended period of time because MaSTherCell does not own any other back-up power source large enough to provide for its manufacturing power consumption needs. Additionally, MaSTherCell does not have an alternative manufacturing location. Therefore, a significant disruption in MaSTherCell s manufacturing operations could materially and adversely affect its business operations during an extended period of power outage.

# The Company has a limited marketing staff and budget for its MaSTherCell operations, which could limit its ability to grow this business.

The degree of market acceptance of its products and services depends upon a number of factors, including the strength of its sales and marketing support. If its marketing is not effective, its ability to generate revenues could be significantly impaired. The newness of the industry and capital constraints provide challenges to its marketing and sales activities at MaSTherCell, and the failure to attract a sufficient base of customers will affect its ability to increase its revenues and operate profitably.

# The logistics associated with the distribution of materials produced by MaSTherCell for third parties and for the Company are significant, complex and expensive and may negatively impact its ability to generate and meet future demand for its products and improve profitability.

Current cell therapy products and product candidates, have a limited shelf life, in certain instances limited to less than 12 hours. Thus, it is necessary to minimize the amount of time between when the cell product is extracted from a patient, arrives at the Company s facility for processing, and is returned for infusion in the patient. To do so, the Company needs cell therapy facilities to be located in major population centers in which patients are likely to be located and within close proximity of major airports. In the future, it may be necessary to build new facilities, which

would require a significant commitment of capital and may not then be available to the Company. Even if the Company is able to establish such new facilities, it may experience challenges in ensuring that they are compliant with cGMP standards, EMEA requirements, and/or applicable state or local regulations. It cannot be certain that it would be able to recoup the costs of establishing a facility in a given market. Given these risks, it could choose not to expand its cell processing and manufacturing services into new geographic markets that will limit its future growth prospects.

Product liability and uninsured risks may adversely affect MaSTherCell s continuing operations and damage its reputation.

MaSTherCell operates in an industry susceptible to significant product liability claims. MaSTherCell may be liable if it manufactures any product that causes injury, illness, or death. In addition, product liability claims may be brought against MaSTherCell s clients, in which case MaSTherCell s clients or others may seek contribution from MaSTherCell if they incur any loss or expenses related to such claims. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. The defense of such claims may be costly and time-consuming, and could divert the attention of MaSTherCell s management and technical personnel.

A breakdown or breach of MaSTherCell s information technology systems could subject MaSTherCell to liability or interrupt the operation of its business.

MaSTherCell relies upon its information technology systems and infrastructure for its business. The size and complexity of MaSTherCell s computer systems make it potentially vulnerable to breakdown and unauthorized intrusion. MaSTherCell could also experience a business interruption, theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber attacks, which may compromise MaSTherCell s system infrastructure or lead to data leakage, either internally or at MaSTherCell s third-party providers.

Similarly, data privacy breaches by those who access MaSTherCell s systems may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to MaSTherCell or its employees, clients or other business partners, may be exposed to unauthorized persons or to the public. There can be no assurance that MaSTherCell s efforts to protect its data and information technology systems will prevent breakdowns or breaches in MaSTherCell s systems that could adversely affect its business and result in financial and reputational harm to MaSTherCell.

#### Risks Related to Our Market

The Company faces competition from established as well as other emerging companies, which could divert clients to its competitors, result in pricing pressure and significantly reduce its revenue.

The Company expects existing competitors and new entrants to CDMO market to constantly revise and improve their business models in response to challenges from competing businesses, including the Company s. Some of its competitors and potential competitors have significantly greater resources than the Company. Increased competition may result in pricing pressure for the Company in terms of the prices it is able to negotiate to receive from a client. If the Company cannot compete successfully against its competitors, its ability to grow its business and achieve profitability could be impaired.

#### **Management**

MaSTherCell s management team has extensive experience in domestic and internationally regulated cellular therapy development, including contract research, development and manufacturing across a broad range of science, technologies, and process operations. Team members are recognized and credentialed experts in all aspects of clinical and product development, characterization, manufacturing, delivery, and use, of cellular products and have extensive experience designing, validating, and operating cGMP cell therapy manufacturing facilities.

# **Employees**

MaSTherCell has approximately 29 full-time employees. Most of MaSTherCell's senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies.

# **Facilities**

MaSTherCell s offices and facilities are located on the second, third and fourth floors of the Itech Incubator II Building in Gosselies (Belgium). The company operates a 860 square meter area in this building based on two long-term lease agreements. The facility features four independent production suites, each composed of two rooms. The layout of the suites allows for parallel production and has been designed to reduce cross contamination risk to the lowest possible limit. Also, as the suites are independent (separated HVAC), it is possible to perform maintenance (or even decontamination) of a suite without impeding ongoing activities in the other suites. The plant also features a technology transfer / development lab, a quality control lab, a warehouse and all necessary office spaces. The construction of the facilities was completed in October 2012. In September 2013, the plant received the cGMP manufacturing authorization for production of advanced medicinal therapeutic products (ATMP) after extensive audits by the Belgian Drug Agency (AFMPS).

# Results of Operations

Comparison of the Three Months Ended February 28, 2015 to the Three Months Ended February 28, 2014

#### Revenue

The Company has not earned any revenues since its inception and it does not anticipate earning revenues in the near future.

#### **Expenses**

The Company s expenses for the three months ended February 28, 2015 are summarized as follows in comparison to its expenses for three months ended February 28, 2014:

	Three Months Ended February 28,			
		2015		2014
Research and development expenses	\$	175,617	\$	605,111
General and administration expenses		659,091		512,109
Financial income, net		(44,498)		(407,906)
Loss	\$	790,210	\$	709,314

#### **Research and Development Expenses**

	Three Months Ended February 28,			
		2015		2014
Salaries and related expenses	\$	118,473	\$	164,591
Stock-based compensation		41,372		242,133
Professional fees and consulting services		122,867		182,795
Lab expenses		62,862		31,540
Other research and development expenses		35,823		(15,948)
Less - grant		(205,780)		-
Total	\$	175,617	\$	605,111

The decrease in salaries and related expenses and in stock based compensation in the three months ended February 28, 2015, compared to the same period last year is mainly due to lower compensation expense for certain executives that are no longer under the employ of the Company and stock-compensation expense. The grant deduction is due to a grant approved from DGO6 in the Belgian Subsidiary and a grant approved from TEDCO in the U.S. Subsidiary for the Company s research and development activities during 2014 and 2015.

# **General and Administrative Expenses**

	Three Months Ended February 28,			
		2015		2014
Salaries and related expenses	\$	114,472	\$	45,739
Stock-based compensation		207,009		208,853
Accounting and legal fees		186,929		97,956
Professional fees		82,417		66,850
Business development		13,435		54,527
Other general and administrative expenses		54,829		38,184
Total	\$	659,091	\$	512,109

The increase in salaries and related expenses for the three months ended February 28, 2015, compared to the same period last year is due to the current year having higher employee compensation cost for a number of employees and consultants. In addition, there was an increase in legal and accounting fees due to the various material transactions that occurred, namely the acquisition of MaSTherCell.

# Financial Income, Net

	Three Months Ended February 28,			
		2015		2014
Decrease in fair value of warrants and embedded derivative	\$	(182,954)	\$	(419,774)
Interest expense on convertible loans		116,105		6,722
Foreign exchange loss, net		18,656		3,688
Bank commissions, net		3,695		1,458
Total	\$	(44,498)	\$	(407,906)

The increase in interest expense in the three months ended February 28, 2015, compared to the same period last year is mainly attributable to additional convertible loans received during 2014 and that were still accruing interest during the three month period, including the main convertible loan received equal to \$1,500,000. The decrease in fair value of the warrants and embedded derivative is a non-cash metric that is based on the Company s share price as of the measurement date and that reflects the issuance of beneficial warrants that were granted during 2014. Due to a decrease in the Company s shares price during the period, the expense decreased.

Liquidity and Financial Condition

#### **Working Capital Deficiency**

	February 28,		November 30,	
		2015		2014
Current assets	\$	1,201,900	\$	2,229,526
Current liabilities		4,437,754		4,663,320
Working Capital Deficiency	\$	(3,235,854)	\$	(2,433,794)

The decrease in current assets is mainly due to a decrease in the Company s cash that was used during the three-month period ending February 28, 2015 to fund research and development expenses and to the decrease of the receivables on account of grant due to the Company s receipt of approximately 1.2 million euro from DG06. This was partially offset by an increase in prepaid expenses during the period mainly due to an advance payment to MaSTherCell. The decrease in current liabilities was mainly due to a decrease in accounts payable from an advance payment to a vendor and to accrued expenses and employee and related party payables. This was partially offset by advance payment on account of grant from DG06.

#### **Cash Flows**

	Three Months Ended February 28,			
		2015		2014
Net loss		(790,210)		(709,314)
Net cash used in operating activities		(640,569)		(500,016)
Net cash used in investing activities		(11,668)		(1,055)
Net cash provided by (used in) financing activities		(14,084)		687,625
Increase (decrease) in cash and cash equivalents	\$	(666,321)	\$	186,554

Net loss for the three months ended February 28, 2015 of \$790,210 increased slightly from the comparable period last year as a result of an increase in retirement benefits obligation and an increase in financial expense. This was offset mainly by a decrease in stock-based compensation related expense from options granted to employees and a change in the fair value of warrants during the period, as compared to the same period last year.

The increase in net cash used in operating activities during the three month period February 28, 2015, compared to the same period last year is mainly related to the decrease in accounts payable, accrued expenses and employee and related party payables and prepaid expenses. These amounts were offset by an increase in payable and receivable on account of grant due to grants the Company received in the Company s Belgian and U.S Subsidiaries. The decrease in cash provided by financing activities in the three month period ended February 28, 2015, compared to the same period last year is due to no capital raising activity during the period.

# 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 February 28, 2015 of \$16,969,286, as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the twelve months following February 28, 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 regulations 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 February 28, 2015 to be as follows:

Research and development	\$ 4,300,000
Manufacturing and scale-up	2,700,000
General and administrative	1,600,000
Total	\$ 8,600,000

As more fully described in Note 7 to the financial statements herein, on November 6, 2014, the Company entered into a share exchange agreement with MaSTherCell and each of the shareholders of MaSTherCell, which provides for the acquisition by the Company of all of the issued and outstanding shares of MaSTherCell from the shareholders of MaSTherCell in exchange for the issuance of \$24,593,000 in value of shares of common stock in the capital of the Company. MaSTherCell SA and Cell Therapy Holding SA are private limited liability companies incorporated in Belgium, are generating limited revenue and are not profitable. 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 once acquired by us.

# 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 us 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 us 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

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.

In addition, in June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, Development Stage Entities (Topic 915), Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation ( ASU 2014-10 ). The amendments in ASU 2014-10 remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from accounting principles generally accepted in the United States of America (U.S. GAAP). In addition, the amendments eliminate the requirements for development stage entities to: (i) present inception-to-date information in the statements of income, cash flows, and shareholder equity; (ii) label the financial statements as those of a development stage entity; (iii) disclose a description of the development stage activities in which the entity is engaged; and (iv) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The presentation and disclosure requirements in Accounting Standard Codification ( ASC ) Topic 915, Development Stage Entities are no longer required for interim and annual reporting periods beginning after December 15, 2014. The revised consolidation standards will take effect in annual periods beginning after December 15, 2015, however, early adoption is permitted. The Company has elected to early adopt the provisions of ASU No. 2014-10 for its unaudited condensed consolidated financial statements that are included in this quarterly report.

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. Currently, there is no guidance under U.S. GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern or to provide related footnote disclosures. The amendments in this Update provide that guidance. In doing so, the amendments should 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 February 28, 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.

# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable

#### ITEM 4. CONTROLS AND PROCEDURES

#### Disclosure Controls and Procedures

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

# Management s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over the Company s financial reporting. In order to evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002. Our management, with the participation of the Company s principal executive officer and principal financial officer has conducted an assessment, including testing, using the criteria in Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation. Based on this evaluation, the Company s management concluded its internal control over financial reporting was not effective as of February 28, 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.

The Company plans to take steps to enhance and improve the design of its internal control over financial reporting. During the period covered by this quarterly report on Form 10-Q, the Company has not been able to remediate the material weaknesses identified above. To remediate such weaknesses, the Company plans to implement the following changes during its fiscal year ending November 30, 2015:

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

The remediation efforts set out in (i) is largely dependent upon the Company securing additional financing to cover the costs of implementing the changes required. If the Company is 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 the 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.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company s internal control over financial reporting during the three months ended February 28, 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 Company s annual report on Form 10-K for the fiscal year ended November 30, 2014 filed with the SEC on February 19, 2015, in addition to other information contained in that annual report 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:

No.	Description
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 Organesis 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)

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# 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\* Certification Statement of the Chief Executive Officer pursuant to Section 302 of the SarbanesOxley Act of 2002
- 31.2\* Certification Statement of the Chief Financial Officer pursuant to Section 302 of the SarbanesOxley Act of 2002
- 32.1\* Certification Statement of the Chief Executive Officer pursuant to Section 906 of the SarbanesOxley Act of 2002
- 32.2\* Certification Statement of the Chief Financial Officer pursuant to Section 906 of the SarbanesOxley Act of 2002
- 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)
- Ompensation 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.

<sup>\*</sup>Filed herewith

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# **ORGENESIS INC.**

By:

/s/ Vered Caplan
Vered Caplan
President, Chief Executive Officer, and Chairperson of the Board
(Principal Executive Officer)
Date: April 14, 2015

/s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)

Date: April 14, 2015