

Orgenesis Inc.
Form 10-Q
October 12, 2018

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

FORM 10-Q

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

For the Quarterly Period Ended August 31, 2018

or

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

For the Transition Period from _____ to _____

Commission file number: 000-54329

ORGENESIS INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or
organization)

98-0583166

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

20271 Goldenrod Lane
Germantown, MD 20876

(Address of principal executive offices) (zip code)

(480) 659-6404

(Registrant's telephone number, including area code)

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

Yes No

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

Yes No

Edgar Filing: Orgenesis Inc. - Form 10-Q

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
(Do not check if a smaller reporting company)		Emerging Growth Company	<input type="checkbox"/>

1

Edgar Filing: Orgenesis Inc. - Form 10-Q

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 12, 2018, there were 15,570,973 shares of registrant's common stock outstanding.

ORGENESIS INC.
FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED AUGUST 31, 2018 AND 2017

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I - FINANCIAL INFORMATION</u>	
<u>ITEM 1 Financial Statements (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets as of August 31, 2018 and November 30, 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended August 31, 2018 and 2017</u>	6
<u>Condensed Consolidated Statements of Changes in Equity for the Nine Months Ended August 31, 2018 and 2017</u>	7
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended August 31, 2018 and 2017</u>	8
<u>Notes to Condensed Consolidated Financial Statements</u>	9
<u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>28</u>
<u>ITEM 3. Quantitative and Qualitative Disclosures about Market Risk</u>	<u>41</u>
<u>ITEM 4. Controls and Procedures</u>	<u>42</u>
<u>PART II - OTHER INFORMATION</u>	
<u>ITEM 1. Legal Proceedings</u>	<u>43</u>
<u>ITEM 1A. Risk Factors</u>	<u>43</u>
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>45</u>
<u>ITEM 3. Defaults Upon Senior Securities</u>	<u>45</u>
<u>ITEM 4. Mine Safety Disclosures</u>	<u>45</u>

<u>ITEM</u> <u>Other Information</u>	<u>45</u>
<u>5.</u>	

<u>ITEM</u> <u>Exhibits</u>	<u>47</u>
<u>6.</u>	

<u>SIGNATURES</u>	<u>48</u>
-------------------	-----------

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

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

	August 31,	November 30,
	2018	2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 16,741	\$ 3,519
Restricted Cash	396	-
Accounts receivable, net	4,154	1,336
Prepaid expenses and other receivables	1,437	841
Receivables from related party	-	691
Grants receivable	267	183
Inventory	1,659	725
Total current assets	24,654	7,295
NON-CURRENT ASSETS:		
Bank deposits	91	-
Call option derivative	-	339
Investments in associates, net	-	1,321
Property and equipment, net	11,056	5,104
Intangible assets, net	17,576	15,051
Goodwill	15,632	10,684
Other assets	287	78
Total non-current assets	44,642	32,577
TOTAL ASSETS	\$ 69,296	\$ 39,872

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

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

	August 31, 2018	November 30, 2017
Liabilities and equity		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,962	\$ 3,914
Accrued expenses and other payables	811	1,435
Employees and related payables	2,312	2,961
Related parties	177	116
Advance payments on account of grant	2,619	1,719
Short-term loans and current maturities of long-term loans	661	378
Deferred income	4,863	3,611
Current maturities of convertible loans	358	2,780
Other	190	-
TOTAL CURRENT LIABILITIES	14,953	16,914
LONG-TERM LIABILITIES:		
Loans payable	\$ 1,800	\$ 2,118
Convertible loans	-	2,415
Retirement benefits obligation	430	6
Deferred taxes	2,979	690
Other	524	-
TOTAL LONG-TERM LIABILITIES	5,733	5,229
TOTAL LIABILITIES	20,686	22,143
COMMITMENTS		
REDEEMABLE NON-CONTROLLING INTEREST	18,646	3,606
EQUITY:		
Common stock of \$0.0001 par value, 145,833,334 shares authorized, 13,620,262 and 9,872,659 shares issued and outstanding as of August 31, 2018 and November 30, 2017, respectively	1	1
Additional paid-in capital	80,889	55,334
Receipts on account of shares to be allotted	5,490	1,483
Accumulated other comprehensive income	660	1,425
Accumulated deficit	(57,415)	(44,120)
Equity attributable to Orgenesis Inc.	29,625	14,123
Non-controlling interests	339	-
TOTAL EQUITY	29,964	14,123
TOTAL LIABILITIES AND EQUITY	\$ 69,296	\$ 39,872

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

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

	Three Months Ended		Nine Months Ended	
	August 31, 2018	August 31, 2017	August 31, 2018	August 31, 2017
REVENUES	\$ 6,230	\$ 2,562	\$ 12,853	\$ 6,712
COST OF REVENUES	3,381	1,867	7,220	4,900
GROSS PROFIT	2,849	695	5,633	1,812
RESEARCH AND DEVELOPMENT EXPENSES, net	1,902	500	3,456	1,906
AMORTIZATION OF INTANGIBLE ASSETS	505	423	1,386	1,201
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	4,008	3,184	10,675	7,887
OTHER INCOME, net	(2,921)	-	(3,237)	-
OPERATING LOSS	645	3,412	6,647	9,182
FINANCIAL EXPENSES (INCOME), net	1,070	(45)	3,164	2,534
SHARE IN LOSSES OF ASSOCIATED COMPANY	202	152	732	348
LOSS BEFORE INCOME TAXES	1,917	3,519	10,543	12,064
TAX EXPENSES	2,353	421	1,680	493
NET LOSS	\$ 4,270	\$ 3,940	\$ 12,223	\$ 12,557
NET INCOME ATTRIBUTABLE TO NON-CONTROLLING INTERESTS (INCLUDING REDEEMABLE)	800	-	1,072	-
NET LOSS ATTRIBUTABLE TO THE COMPANY	\$ 5,070	\$ 3,940	\$ 13,295	\$ 12,557
LOSS PER SHARE:				
Basic	\$ (0.35)	\$ (0.38)	\$ (1.04)	\$ (1.32)
Diluted	\$ (0.35)	\$ (0.40)	\$ (1.04)	\$ (1.34)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE:				
Basic	14,355,430	10,279,180	12,774,802	9,477,211
Diluted	14,355,430	10,385,499	12,774,802	9,503,253

**OTHER COMPREHENSIVE
LOSS:**

Net Loss	\$	4,270	\$	3,940	\$	12,223	\$	12,557
Other Comprehensive (income)								
loss Translation adjustment		416		(1,430)		765		(2,419)
Comprehensive loss		4,686		2,510		12,988		10,138
Net income attributed to non-controlling interests (including redeemable)		800				1,072		

COMPREHENSIVE LOSS**ATTRIBUTED TO ORGENESIS**

INC.	\$	5,486	\$	2,510	\$	14,060	\$	10,138
-------------	----	-------	----	-------	----	--------	----	--------

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

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

Common Stock

	Number	Par Value	Additional Paid-in Capital	Receipts on Account of Share to be Allotted	Accumulated Other Comprehensive Loss	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	C
Balance at December 1, 2016	9,508,068	\$ 1	\$ 45,454	-	\$ (1,205)	\$ (31,753)	\$ 12,497	
Changes during the nine months ended August 31, 2017:								
Stock-based compensation to employees and directors			1,156				1,156	
Stock-based compensation to service providers	79,167	*	1,824				1,824	
Issuance of warrants and beneficial conversion feature of convertible loans			2,550				2,550	
Issuance of shares and receipts on account of shares and warrants to be allotted and cancelation of contingent shares	244,743	*	3,383	852			4,235	
Comprehensive income (loss) for the period					2,419	(12,557)	(10,138)	
Balance at August 31, 2017	9,831,978	\$ 1	\$ 54,367	\$ 852	\$ 1,214	\$ (44,310)	\$ 12,124	
	9,872,659	1	55,334	1,483	1,425	(44,120)	14,123	

**Balance at
December 1,
2017**

**Changes during
the nine months
ended August
31, 2018:**

Stock-based compensation to employees and directors			1,416			1,416
Stock-based compensation to service providers and restricted shares granted to service providers	195,000	*	1,568			1,568
Issuance of warrants and beneficial conversion feature of convertible loans	1,341,134	*	7,330			7,330
Issuance of shares and receipts on account of shares to be allotted related to acquisition of Atvio and CureCell	83,965	*	600	1,853		2,453
Issuance of shares and receipts on account of shares to be allotted	1,990,858	*	13,466	2,154		15,620
Beneficial conversion feature of convertible loans and warrants issued			323			323
Issuance of shares due to exercise of warrants	136,646	*	852			852
Comprehensive income (loss) for					(765)	(13,295)
						(14,060)

the period

Balance at

August 31, 2018	13,620,262 \$	1 \$	80,889 \$	5,490 \$	660 \$	(57,415)\$	29,625 \$
------------------------	---------------	------	-----------	----------	--------	------------	-----------

* represent an amount lower than \$ 1 thousand

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

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

	Nine Months Ended	
	August 31,	August 31,
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (12,223)	\$ (12,557)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,984	2,817
Share in losses of associated company	732	348
Depreciation and amortization expenses	1,833	1,874
Net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date fair value	(4,509)	-
Change in fair value of warrants and embedded derivatives	11	(230)
Change in fair value of convertible bonds	-	(157)
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	2,856	818
Changes in operating assets and liabilities, net of business combination:		
Increase in accounts receivable	(2,818)	(682)
Decrease in related parties, net	(379)	-
Increase in inventory	(848)	(484)
Increase (decrease) in other assets	65	(1)
Increase in prepaid expenses and other accounts receivable	(148)	(818)
Decrease in accounts payable	(1,723)	(1,230)
Increase (decrease) in accrued expenses and other payables	(686)	192
Increase (decrease) in employee and related payables	(820)	554
Increase in deferred income	705	3,268
Increase in advance payments and receivables on account of grant, net	815	2,358
Increase in deferred taxes	1,680	494
Net cash used in operating activities	(12,473)	(3,436)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(4,430)	(639)
Disposals of property and equipment	-	31
Acquisition of CureCell , net of cash acquired (See note 4)	58	-
Acquisition of Atvio , net of cash acquired (See note 4)	245	-
Investments in long term deposit	(92)	-
Investments in associate	-	(835)
Net cash used in investing activities	(4,219)	(1,443)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Short-term line of credit	-	(21)
Proceeds from issuance of shares and warrants (net of transaction costs)	12,666	4,307
Proceeds from issuance of convertible loans (net of transaction costs)	720	4,932

Edgar Filing: Orgenesis Inc. - Form 10-Q

Repayment of convertible loans and convertible bonds	(177)	(3,766)
Proceeds from receipts on account of shares to be allotted	3,626	-
Increase in redeemable non-controlling interests	14,007	-
Repayment of short and long-term debt	(331)	(1,102)
Net cash provided by financing activities	30,511	4,350
NET CHANGE IN CASH AND CASH EQUIVALENTS	13,819	(529)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(201)	400
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,519	891
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 17,137	\$ 762

SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES

Conversion of loans and bonds (including accrued interest) to common stock and warrants	\$ 7,511	\$ 106
Classification of loan receivable into services to be received from CureCell	\$ 813	\$ -

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

ORGENESIS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the Three and Nine Months Ended August 31, 2018 and 2017

NOTE 1 - GENERAL AND BASIS OF PRESENTATION

a. General

Orgenesis Inc., a Nevada corporation (Orgenesis or the Company), is a service and research company in the field of the regenerative medicine industry with a focus on cell therapy development and manufacturing for advanced medicinal products. In addition, the Company is focused on developing novel and proprietary cell therapy trans-differentiation technologies for the treatment of diabetes. The consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries, including those of the Masthercell Global group, a contract development and manufacturing organization, or CDMO, specializing in cell therapy development and manufacturing for advanced medicinal products in the USA, Belgium, Korea and Israel (See Note 4 for explanation that during the third fiscal quarter that the Company gained control of Atvio and CureCell); Orgenesis SPRL (the Belgian Subsidiary), a Belgian-based subsidiary which is engaged in development and manufacturing activities together with clinical development studies in Europe; Orgenesis Maryland Inc. (the U.S. Subsidiary), a Maryland corporation; and Orgenesis Ltd., an Israeli corporation, (the Israeli Subsidiary).

The Company's goal is to industrialize cell therapy for fast, safe and cost-effective production in order to provide rapid therapies for any market around the world through a world-wide network of CDMO joint venture partners. The Company's trans-differentiation technologies for treating diabetes, which will be referred to as the cellular therapy (CT) business, is based on a technology licensed by Tel Hashomer Medical Research (THM) to the Israeli Subsidiary that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and trans-differentiating (converting) them into pancreatic beta cell-like insulin-producing cells.

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

On November 16, 2017, the Company implemented a reverse stock split of its outstanding shares of common stock at a ratio of 1-for-12 shares. The reverse stock split has been reflected in these condensed consolidated financial statements.

On March 13, 2018, the Company's common stock began to be listed and traded on the Nasdaq Capital Market under the symbol ORGS.

Consolidation of CDMO Entities and Strategic Funding

On June 28, 2018, the Company, Masthercell Global Inc. (a newly formed Delaware subsidiary of Orgenesis Inc being the Company that holds the Company's CDMO business (Masthercell Global)), Great Point Partners, LLC, a manager of private equity funds focused on growing small to medium sized health care companies (Great Point), and certain of Great Point's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business. In connection therewith, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company (GPP-II) and an affiliate of Great Point entered into Stock Purchase agreement (the SPA) pursuant to which GPP-II purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the Masthercell Global Preferred Stock), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for cash consideration to be paid into Masthercell Global of up to \$25 million, of which \$13.2 million is subject to certain contingencies described below (the Consideration). Orgenesis holds 622,000 shares of Masthercell Global's Common Stock, representing 62.2% of the issued and outstanding equity share capital of Masthercell Global. An initial cash payment of \$11.8 million of the Consideration was remitted at closing by GPP-II to Masthercell Global. \$1.5 Million of the initial capital contributed to Masthercell Global was used

to reimburse the Investors for their fees and expenses incurred in conjunction with this transaction. The \$1.5 million will reflect the entire fee payable under this transaction (net payment of \$10.3 million). The follow up payment will be in the amount of \$6,600,000 to be made in each of years 2018 and 2019 (the Future Payments), or an aggregate of \$13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis shareholders approve on or before December 31, 2019 certain provisions of the Stockholders Agreement entered into by these parties. None of the future Consideration amounts, if any, will result in an increase in GPP-II's equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing. Notwithstanding the foregoing, GPP-II may, in its sole discretion, elect to pay all or a portion of the future Consideration amounts even if the financial targets described above have not been achieved and the Orgenesis Stockholder Approval has not been obtained.

In connection with the entry into the SPA described above, each of the Company, Masthercell Global and GPP-II entered into the Masthercell Global Inc. Stockholders Agreement (the Stockholders Agreement) providing for certain restrictions on the disposition of Masthercell Global securities, the provisions of certain options and rights with respect to the management and operations of Masthercell Global, certain rights to GPP-II (including, without limitation, a tag along right, drag along right and certain protective provisions). After the earlier of the second anniversary of the closing or certain enumerated circumstances, GPP-II is entitled to effectuate a spinoff of Masthercell Global and the Masthercell Global Subsidiaries (the Spinoff). The Spinoff is required to reflect a market value determined by one of the top ten independent accounting firms in the U.S. selected by GPP, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and the Masthercell Global Subsidiaries of at least \$50 million. In addition, upon certain enumerated events described below, GPP-II is entitled, at its option, to put to the Company (or, at Company's discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global or, alternatively, purchase from the Company its share capital in Masthercell Global at a purchase price equal to the fair market value of such equity holdings provided that the purchase price shall not be greater than three times the price per share of Masthercell Global Preferred Stock paid by GPP-II and shall not be less than the price per share of Masthercell Global Preferred Stock paid by GPP-II. GPP-II may exercise its put or call option upon the occurrence of any of the following: (i) there is an Activist Shareholder of the Company; (ii) the Chief Executive Officer and/or Chairman of the board of directors of the Company resigns or is replaced, removed, or terminated for any reason prior to June 28, 2023; (iii) there is a Change of Control event of the Company; or (iv) the industry expert director appointed to the board of directors of Masthercell Global is removed or replaced (or a new such director is appointed) without the prior written consent of GPP-II. For the purposes of the foregoing, the following definitions shall apply: (A) Activist Shareholder shall mean any Person who acquires shares of capital stock of the Company who either: (x) acquires more than a majority of the voting power of the Company, (y) actively takes over and controls a majority of the board of directors of the Company, or (z) is required to file a Schedule 13D with respect to such Person's ownership of the Company and has described a plan, proposal or intent to take action with respect to exerting significant pressure on the management of or directors of, the Company; and (B) Change of Control shall mean any of: (a) the acquisition, directly or indirectly (in a single transaction or a series of related transactions) by a Person or group of Persons of either (I) a majority of the common stock of the Company (whether by merger, consolidation, stock purchase, tender offer, reorganization, recapitalization or otherwise), or (II) all or substantially all of the assets of the Company and its Subsidiaries (but only if such transaction includes the transfer of Securities held by the Company), (b) if any four (4) of the directors of the Company as of June 28, 2018 are removed or replaced or for any other reason cease to serve as directors of the Company, (c) the filing of a petition in bankruptcy or the commencement of any proceedings under bankruptcy laws by or against the Company, provided that such filing or commencement shall be deemed a Change of Control immediately if filed or commenced by the Company or after sixty (60) days if such filing is initiated by a creditor of the Company and is not dismissed; (d) insolvency of the Company that is not cured by the Company within thirty (30) days; (e) the appointment of a receiver for the Company, provided that such appointment shall constitute an Change of Control immediately if the appointment was consented to by the Company or after sixty (60) days if not consented to by the Company and such appointment is not terminated; or (f) or dissolution of the Company.

The Stockholders Agreement further provides that GPP-II is entitled, at any time, to convert its share capital in Masthercell Global for the Company's common stock in an amount equal to the lesser of (a)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged, divided by (ii) the average closing price per share of Orgenesis Common Stock during the thirty (30) day period ending on the date that GPP-II provides the exchange notice (the Exchange Price) and (b)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged assuming a value of Masthercell Global equal to three and a half (3.5) times the revenue of Masthercell Global during the last twelve (12) complete calendar months immediately prior to the exchange divided by (ii) the Exchange Price; provided, that in no event will (A) the Exchange Price be less than a price per share that would result in Orgenesis having an enterprise value of less than \$250,000,000 and (B) the maximum number of shares of Orgenesis Common Stock to be issued shall not exceed 2,704,247 shares of outstanding Orgenesis Common Stock (representing approximately 19.99% of then outstanding Orgenesis Common Stock), unless Orgenesis obtains shareholder approval for the issuance of such greater amount of shares of Orgenesis

Common Stock in accordance with the rules and regulations of the Nasdaq Stock Market.

Great Point and Masthercell Global entered into an advisory services agreement pursuant to which Great Point is to provide management services to Masthercell Global for which Great Point will be compensated at an annual base compensation equal to the greater of (i) \$250,000 per each 12 month period or (ii) 5% of the EBITDA for such 12 month period, payable in arrears in quarterly installments; provided, that these payments will (A) begin to accrue immediately, but shall not be paid in cash to Great Point until such time as Masthercell Global generates EBITDA of at least \$2,000,000 for any 12 month period or the sale of or change in control of Masthercell Global, and (B) shall not exceed an aggregate annual amount of \$500,000. Such compensation accrues but is not owed to Great Point until the earlier of (i) Masthercell Global generating EBITDA of at least \$2 million for any 12 months period following the date of the agreement or (ii) a Sale of the Company or Change of Control of the Company (as both terms are defined therein).

GPP Securities, LLC, a Delaware limited liability company and an affiliate of Great Point and Masthercell Global entered into a transaction services agreement pursuant to which GPP Securities, LLC is to provide certain brokerage services to Masthercell Global for which GPP Securities LLC will be entitled to a certain Exit Fee and Transaction Fee (as both terms are defined in the agreement), such fees not to be less than 2 percent of the applicable transaction value.

The Company accounted for the investment made by GPP as a redeemable non-controlling interest due to the embedded redemption feature whose settlement is not at the Company discretion.

Corporate Reorganization

Contemporaneous with the execution of the SPA and the Stockholders Agreement, Orgenesis and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which Orgenesis contributed to Masthercell Global assets relating to the CDMO Business (as defined below), including the CDMO subsidiaries (the Corporate Reorganization). For further details see Note 4. Together with MaSTherCell S.A., Atvio and CureCell are directly held subsidiaries under Masthercell Global (collectively, the Masthercell Global Subsidiaries).

Masthercell Global, through the Masthercell Global Subsidiaries, will be engaged in the business of providing manufacturing and development services to third parties related to cell therapy products, and the creation and development of technology, and optimizations in connection with such manufacturing and development services for third parties (the CDMO Business). Under the terms of the Stockholders Agreement, Orgenesis has agreed that so long as it owns equity in Masthercell Global and for two years thereafter it will not engage in the CDMO Business, except through Masthercell Global (but may continue to engage in its other areas of business). In addition, except for certain limited circumstances, each of Orgenesis and GPP-II agreed in the Stockholders Agreement to not recruit or solicit or hire any officer or employee of Masthercell Global that was or is involved in the CDMO Business.

b. Liquidity

As of August 31, 2018, the Company accumulated losses of approximately \$57.4 million. Although the Company is showing positive revenue and gross profit trends in its CDMO business, the Company expects to incur further losses in the CT business.

To date, the Company has been funding operations primarily from the proceeds from private placements of the Company's convertible debt and equity securities and from revenues generated by MaSTherCell S.A. From December 1, 2017 through August 31, 2018, the Company received, through MaSTherCell S.A., proceeds of approximately \$11.5 million in revenues and accounts receivable from customers, and \$16.5 million from the private placement to accredited investors of the Company's equity and equity linked securities and convertible loans and exercise of warrants, out of which \$8.1 million are from the institutional investor with whom the Company entered into definitive agreements in January 2017 for the private placement of units (see also Note 7(a)). In addition, from September 1, 2018 through October 12, 2018, the Company raised \$3.4 million from the private placement referred to above of unsubscribed units under such investor's subscription agreement, and proceeds of approximately \$2.9 million in

accounts receivable from customers of MaSTherCell S.A. See also Note 12.

c. Basis of Presentation

These unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. GAAP, pursuant to the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial statements. Accordingly, they do not contain all information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, the unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of August 31, 2018, and the consolidated statements of comprehensive loss for the three and nine months ended August 31, 2018 and 2017, and the changes in equity and cash flows for the nine-month period ended August 31, 2018 and 2017. The interim results are not necessarily indicative of the results to be expected for the year ending November 30, 2018. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended November 30, 2017.

d. Collaboration and Joint Venture Agreements

Mircod Limited

On June 19, 2018, the Company and Mircod Limited, a company formed under the laws of Cyprus (Mircod) entered into a Collaboration and License Agreement (the Collaboration Agreement) for the research, development and commercialization of potential key technologies related to biological sensing for the Company's clinical development and manufacturing projects (the Development Project). Within 45 days of the execution of the Collaboration Agreement, the parties are to approve a written project development plan outlining each party's responsibilities with respect to the Development Project, and the Company will be funding the projected development costs as outlined in the development plan. Under the terms of the Collaboration Agreement, the Company remitted to Mircod an upfront payment of \$50,000.

Under the Collaboration Agreement, all results of such collaboration (Project Results) shall be jointly owned by Mircod and the Company. The Company was granted an exclusive, worldwide sub licensable license under Mircod's right in such Project Results to use and commercialize Project Results in consideration for a royalty of 5% of Net Sales (as defined in the Collaboration Agreement) of products incorporating Project Results.

Subject to completion of the Development Project, Mircod and the Company are to negotiate and enter into a manufacturing and supply agreement under which Mircod is to manufacture and supply products incorporating the Project Results and, at the Company's request, to provide support and maintenance service for such products. If for whatever reason the parties fail to enter into such manufacturing and supply agreement within 90 days of the completion of the Development Project or if Mircod is unable to perform such services, the Company is entitled to manufacture the products, in which event Mircod will be entitled to a payment of \$80,000 and royalties on Net Sales are to increase to 8% of Net Sales.

HekaBio K.K

On July 10, 2018, the Company and HekaBio K.K. (HB), a corporation organized under the laws of Japan entered into a Joint Venture Agreement (the JVA) pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products (hereinafter the Products) in Japan (the Project). The parties intend to pursue the joint venture through a newly established Japanese company (hereinafter the JV Company) which the Company by itself, or together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB. HB will fund, at its sole expense, all costs associated with obtaining the requisite regulatory approvals for conducting clinical trials, as well as performing all clinical and other testing required for market authorization of the Products in Japan.

Under the JVA, each party may invest up to \$10 million, which may take the form of a loan, if required, as determined by the steering committee. The terms of such investment, if any, will be on terms mutually agreeable to the parties, provided that the minimum pre-money valuation for any such investment shall not be less than \$10 million. Additionally, HB was granted an option to affect an equity investment in the Company of up to \$15 million within the next 12 months on mutually agreeable terms. If such investment is in fact consummated, the Company agreed to invest in the JV Company by way of a convertible loan an amount to HB's pro-rata participating interest in the JV Company, which initially will be at 51%. Such loan may then be converted by the Company into share capital of the JV company at an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million. Under the JVA, the Company can require HB to sell to the Company its participating (including equity) interest in the JV Company in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining JV Company valuation which in no event shall be less than \$10 million.

In addition, under the JVA, the Company shall grant the JV Company an exclusive license to certain intellectual property of the Company as may be required for the JV Company to develop and commercialize the Products in Japan. In consideration of such license, the JV Company shall pay the Company, in addition to other payments, royalties at the rate of 10% of the JV Company's net sales of Products.

It was further agreed that the JV Company shall grant the Company (and its affiliates) a non-exclusive, worldwide (other than Japan), royalty-free and fully paid-up license to use and practice, for any purpose, new inventions, discoveries and intellectual property rights that are generated by and/or on behalf of HB and/or the JV Company in connection with the Project.

All matters pertaining to such license rights shall be governed under a separate license agreement to be entered by and between the Company and the JV Company.

As of August 31, 2018, no activity had begun in the said JV and no investments were made therein.

Image Securities Ltd.

On July 11, 2018, the Company and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Cayman Islands (the "India Partner") entered into a Joint Venture Agreement (the "India JVA") pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products in India (the "Cell Therapy Products"). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products.

The India JVA becomes effective upon the consummation of an equity investment by the India partner in the Company of \$5 million within 15 days of the execution of the India JVA through the purchase of units of Orgenesis securities at a per unit purchase price payable into the Company of \$6.24, with each unit comprised of one share of the Company and three-year warrant for the acquisition of an additional common share at a per share exercise price of \$6.24. Subject to the consummation of such equity investment in the Company, the Company is to advance to the JV Company a convertible loan in the amount of \$5 million. The loan is convertible into equity capital of the JV Company at an agreed upon formula for determining JV Company valuation. The investment in the Company by the India Partner would be the consummation of the previously disclosed private placement subscription agreement entered into in December 2016 between the Company and an affiliate of the India Partner pursuant to which the closing of such subscription agreement was by the terms thereof delayed until terms comprising the India JV were mutually agreed to.

Under the India JVA, the India Partner agreed to invest in the JV \$10 million within 12 months of the incorporation of the JV Company. If for whatever reason such investment is not made by the India Partner within such time, then Orgenesis is authorized to convert its above-referenced loan into 50% of the equity capital of the JV Company on a

fully diluted basis, provided that if the pre-money valuation of the JV Company is then independently determined to be less than \$5 million, then such conversion to be effected in the basis of such valuation.

As of August 31, 2018, no activity had begun in the said JV and no investments were made therein.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies adopted are consistent with those of the previous financial year, except as noted below regarding the adoption of new accounting pronouncements.

Recently Issued Accounting Pronouncements- adopted by the Company

1) In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a Consensus of the FASB Emerging Issues Task Force) (ASU 2016-18), which requires entities to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for annual reporting periods (including interim periods within those annual reporting periods) beginning after December 15, 2017. The Company adopted this standard as of beginning of 2018. The Company did not have restricted cash in the previously presented period. Therefore, there is no impact for the new adoption on previously reported periods.

2) In July 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815)", ("ASU 2017-11"). This update was issued to address complexities in accounting for certain equity-linked financial instruments containing down round features. The amendment changes the classification analysis of these financial instruments (or embedded features) so that equity classification is no longer precluded. The amendments in ASU 2017-11 are effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company elected to early adopt the standard effective September 1, 2017, retrospectively. Following is the result of the adoption on the Company's condensed consolidated financial statements previously reported:

Shareholders' Equity

	As reported Previously	August 31, 2017 Impact of adoption In thousands	As revised
Additional paid-in capital	\$ 50,518	\$ 3,849	\$ 54,367
Accumulated deficit	\$ (41,345)	\$ (2,965)	\$ (44,310)
Total equity	\$ 11,251	\$ 873	\$ 12,124

Statement of Comprehensive Loss

	Nine months ended August 31, 2017			Three months ended August 31, 2017		
	As reported Previously	Impact of adoption	As revised	As reported Previously	Impact of adoption	As revised
	In thousands					
Financial expenses (income),	\$ 1,488	\$ 1,046	\$ 2,534	\$ (2,032)	\$ 1,987	\$ (45)

Edgar Filing: Orgenesis Inc. - Form 10-Q

net												
Loss												
before												
income												
taxes	\$	11,018	\$	1,046	\$	12,064	\$	1,532	\$	1,987	\$	3,519
Net loss	\$	11,511	\$	1,046	\$	12,557	\$	1,953	\$	1,987	\$	3,940

14

NOTE 3 - SEGMENT INFORMATION

The Chief Executive Officer ("CEO") is the Company's chief operating decision-maker ("CODM").

Based on the Company's organizational structure, its business activities and information reviewed by the CODM for the purposes of allocating resources and assessing performance, management has determined that there are two operating segments.

CDMO

The CDMO activity is comprised of a specialization in cell therapy development for advanced therapeutic products and is comprised of two types of services to its customers: (i) process and assay development services and (ii) cGMP contract manufacturing services. The CDMO activities include the operations of Masthercell Global since the Corporate Reorganization (which includes the operations of CureCell and Atvio from the same date) and MaSTherCell prior to the Corporate Reorganization. As of the date of acquisition of CureCell and Atvio their activity is included in this segment.

CT Business

The CT Business activity is based on our technology that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and differentiating (converting) them into pancreatic beta cell-like insulin producing cells for patients with Type 1 Diabetes. This segment is comprised of all entities aside from Masthercell Global, CureCell and Atvio.

The CODM does not review assets by segment, therefore the measure of assets has not been disclosed for each segment.

Segment data for the nine months ended August 31, 2018 is as follows:

	CDMO	CT	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	\$ 15,807	\$ 83	\$ (3,037)	\$ 12,853*
Cost of revenues	(7,826)	-	927	(6,899)
Segment gross profit (loss)	7,981	83	(2,110)	5,954
Research and development expenses, net	(245)	(4,764)	2,110	(2,899)
Operating expenses	(3,895)	(4,448)		(8,343)
Other income	228	-		228
Segment operating profit (loss)	4,069	(9,129)	-	(5,060)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(1,807)	(7)		
Segment performance	2,262	(9,136)		

* The Company's revenues consist of: \$9,493 from services and \$3,360 from goods sold.

Reconciliation of segment performance to loss for the nine months ended August 31, 2018:

	Nine months Ended August 31, 2018 in thousands
Segment performance	(6,874)
Stock-based compensation	(2,782)
Financial expenses, net	(3,164)
Net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date fair value	4,509
Transaction expenses related to GPP agreement	(1,500)
Share in losses of associated companies	(732)
Loss before income tax	\$ (10,543)

Edgar Filing: Orgenesis Inc. - Form 10-Q

Segment data for the three months ended August 31, 2018 is as follows:

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 8,092	\$ 83	\$ (1,945)	\$ 6,230*
Cost of revenues	(3,908)	-	539	(3,369)
Segment gross profit (loss)	4,184	83	(1,406)	2,861
Research and development expenses, net	(245)	(2,898)	1,406	(1,737)
Operating expenses	(1,712)	(1,453)		(3,165)
Other expenses	(88)	-		(88)
Segment operating profit (loss)	2,139	(4,268)	-	(2,129)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization	(567)	(3)		
Segment performance	1,572	(4,271)		

* The Company's revenues consist of: \$4,473 from services and \$1,757 from goods sold.

Reconciliation of segment performance to loss for the three months ended August 31, 2018:

	Three Months Ended August 31, 2018 in thousands
Segment performance	(2,699)
Stock-based compensation	(955)
Financial expenses, net	(1,070)
Share in losses of associated companies	(202)
Net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date fair value	4,509
Transaction expenses related to GPP agreement	(1,500)
Loss before income tax	\$ (1,917)

Segment data for the nine months ended August 31, 2017 is as follows:

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Revenues from external customers	\$ 7,705	\$ -	\$ (993)	\$ 6,712
Cost of revenues	(4,358)		403	(3,955)
Segment gross profit (loss)	3,347		(590)	2,757
Research and development expenses, net		(1,932)	590	(1,342)
Operating expenses	(916)	(6,060)		(6,976)
Segment operating profit (loss)	2,431	(7,992)	-	(5,561)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization expenses	(2,145)	(7)		
Segment Performance	286	(7,999)		

Reconciliation of segment performance to loss for the nine months ended August 31, 2017:

**Nine Months
Ended
August 31,
2017
in thousands**

Segment performance	(7,713)
Stock-based compensation	(1,469)
Financial expenses, net	(2,534)
Share in losses of associated companies	(348)
Loss before income tax	(12,064)

Segment data for the three months ended August 31, 2017 is as follows:

	CDMO	CT	Corporate and Eliminations (in thousands)	Consolidated
Net revenues from external customers	\$ 2,956		(394)	2,562
Cost of revenues	(1,439)		95	(1,344)
Segment gross profit (loss)	1,517		(299)	1,218
Research and development expenses, net		(688)	299	(389)
Operating expenses	(1,641)	(1,272)		(2,913)
Segment operating profit (loss)	(124)	(1,960)	-	(2,084)
Adjustments to presentation of segment				
Adjusted EBIT				
Depreciation and amortization expense	(945)			
Segment Performance	(1,069)	(1,960)		

Reconciliation of segment performance to loss for the three months ended August 31, 2017:

	Three Months Ended August 31, 2017
	in thousands
Segment performance	(3,029)
Stock-based compensation	(383)
Financial expenses, net	45
Share in losses of associated companies	(152)
Loss before income tax	(3,519)

17

Geographic, Product and Customer Information

Substantially all the Company's revenues and long-lived assets are in Belgium and South Korea. Net revenues from single customers from the CDMO segment that exceed 10% of total net revenues are:

	Nine Months Ended		Three Months Ended	
	August 31, 2018	August 31, 2017	August 31, 2018	August 31, 2017
	(in thousands)			
Customer A \$	2,339	\$ 852	\$ -	\$ 2,813
Customer B \$	3,922	\$ -	\$ 1,651	\$ -
Customer C \$	3,109	\$ 809	\$ 956	\$ 1,904
Customer D \$	-	\$ 679	\$ -	\$ 1,637
Customer E \$	-	\$ -	\$ 1,100	\$ -
Customer F \$	-	\$ -	\$ 784	\$ -

NOTE 4 EXERCISE OF CALL OPTIONS OF CURECELL AND ATVIO*Description of the Transactions*

Contemporaneous with the execution of the SPA and the Masthercell Global Stockholders Agreement (as described above), the Company and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which Company contributed to Masthercell Global the Orgenesis' assets relating to the CDMO business, including the CDMO subsidiaries. In furtherance thereof, Masthercell Global, as Orgenesis' assignee, acquired all of the issued and outstanding share capital of Atvio, the Company's Israel based CDMO partner since August 2016, and 94.2% of the share capital of CureCell, the Company's Korea based CDMO partner since March 2016. Orgenesis exercised the "call option" to which it was entitled under the joint venture agreements with each of these entities to purchase from the former shareholders their equity holding. The consideration for the outstanding share equity in each of Atvio and CureCell consisted solely of Company Common Stock. In respect of the acquisition of Atvio, the Company issued to the former Atvio shareholders an aggregate of 83,964 shares of Company Common Stock. In respect of the acquisition of CureCell, the Company will issue according to valuation to the former CureCell shareholders an aggregate of 202,846 shares of Company Common Stock. Together with MaSTherCell S.A., Atvio and CureCell are directly held subsidiaries under Masthercell Global.

CureCell and Atvio are customer-oriented CDMO companies specializing in cell therapy development for advanced medicinal products.

The exercise of the call options of CureCell and Atvio, pursuant to which the Company obtained effective control over such entities, was accounted for as a business combination. The results of operations of CureCell and Atvio have been included in the Company's condensed consolidated statements of operations starting from June 28, 2018, the date on which the Company obtained effective control of CureCell and Atvio. The revenues from operations of CureCell and Atvio for the period from June 28, 2018, the acquisition date, to August 31, 2018 was approximately \$784 thousands and \$41 thousands, respectively.

Fair Value of Consideration Transferred

The Company accounted for the exercise of the call options of CureCell and Atvio as a business combination under the acquisition method of accounting.

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

<u>CureCell</u>	
Total assets acquired:	
Cash and cash equivalents	\$ 58
Property and equipment, net	1,104
Inventory	148
Other assets	300
Other Intangible assets (a)	3,933
Goodwill (b)	3,950
Total assets	9,493
Total liabilities assumed:	
Deferred income from the company and others	1,945
Deferred tax	80
Fair value of convertible loan from the company	892
Non-controlling interests	299
Other liabilities	1,487
Total liabilities	4,703
Total consideration transferred	\$ 4,790
Fair value according of shares issued	
	1,853
Acquisition date fair value of previously held equity interest	2,937
Total consideration transferred	\$ 4,790

(a) The allocation of the purchase price to the net assets acquired and liabilities assumed resulted in the recognition of other intangible assets which comprised of: Customer Relationships of \$859 and Know How of \$3,074. These other intangible assets have a useful life of 10 and 12 years, respectively. The useful life of the other intangible assets for amortization purposes was determined considering the period of expected cash flows generated by the assets used to measure the fair value of the intangible assets adjusted as appropriate for the entity-specific factors, including legal, regulatory, contractual, competitive, economic or other factors that may limit the useful life of intangible assets.

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

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

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

Atvio

The total consideration of Atvio of \$890 thousand was attributed mainly to goodwill.

The Company's purchase price allocation for both companies are preliminary. The fair values of acquired assets and liabilities may be further adjusted as additional information becomes available during the measurement period.

Additional information may become available subsequently and may result in changes in the values allocated to various assets and liabilities includes, but is not limited to, any changes in the values allocated to tangible and identified intangible assets acquired and liabilities assumed during the measurement period and may result in material adjustments to goodwill.

NOTE 5 CONVERTIBLE LOAN AGREEMENTS

(a) During the nine months ended August 31, 2018, the Company entered into several unsecured convertible loan agreements with accredited or offshore investors for an aggregate amount of \$720 thousand. The loans bear an annual interest rate of 6% and mature in six months or two years from the closing date, unless earlier converted subject to the terms defined in the agreements.

The loans provide that the entire principal amount and accrued interest convert into a Unit, consisting of one share of Common Stock and one three-year warrant exercisable into an additional share of common stock at a per share exercise price of \$6.24. In addition, the Company issued to certain investors 40,064 three-year warrants to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24.

Since the closing price of the Company's publicly traded stock is greater than the effective conversion price on the closing date, the conversion feature is considered "beneficial" to the holders and equal to \$193 thousand. The difference is treated as issued equity and reduces the carrying value of the host debt; the discount is accreted as deemed interest on the debt. The transaction costs for were approximately \$89 thousand, out of which \$31 thousand are stock-based compensation due to issuance of warrants (See also Note 8(c)). Through August 31, 2018, all convertible loans were converted. See additional information in Note 5b.

(b) During the nine months ended August 31, 2018, holders of approximately \$7.7 million in principal and accrued interest of convertible loans converted these outstanding amounts, into units of the Company's securities at a deemed per unit conversion price of \$6.24, with each unit comprised of: (i) one share of the Company's Common Stock and (ii) one warrant, exercisable for a period of three years from the date of conversion, for an additional share of Common Stock, at a per share exercise price of \$6.24. As a result of these conversions, the holders are entitled to 1,240,972 shares of Common Stock and three-year warrants for an additional 1,240,972 shares of common stock at a per share exercise price of \$6.24.

The Company allocated the converted amounts based on the fair value of the warrants and the shares. The table below presents the converted amounts of the proceeds as of the closing date:

	Proceeds allocation (in thousands)
Warrants component	\$ 3,037
Shares component	4,706
Total	\$ 7,743

The fair value of these warrants determined using a Black-Scholes model based on the following assumptions:

	Nine Months Ended August 31, 2018
Value of one common share	\$7.61 - \$13.85
Dividend yield	0%
Expected stock price volatility	94.12%-90.6%
Risk free interest rate	2.43%-2.29%
Expected term (years)	3

These loans had beneficial conversion features ("BCF"). Therefore, the Company recognized the unamortized BCF as of the conversion date as interest expenses.

(c) During the nine months ended August 31, 2018, holders of approximately \$805 thousand in principal and accrued interest of a convertible loans outstanding from November 2014 and December 2016 converted their outstanding amounts, into shares of the Company's common stock at a deemed conversion price of \$4.80 and \$6.24 per share. As a result of this conversion, the Company issued 137,765 shares of common stock.

These loans had beneficial conversion features ("BCF"). Therefore, the Company recognized the unamortized BCF as of the conversion date as interest expenses.

(d) In March 2018, a former Israel-based consultant exercised warrants issued in November 2016 to purchase shares of the Company's Common Stock. A related party of such consultant submitted at the same time notice of its intention to convert into shares of the Company's common stock the principal amount and accrued interest of approximately \$396 thousand outstanding under a loan originally advanced to the Company in November 2016. The exercise price of the warrants and conversion price were fixed at \$0.52 per share (pre-reverse stock split implemented by the Company in November 2017). There is a significant disagreement between the Company and these two entities as to the number of shares of Common Stock issuable to these entities, and they contend that the number of shares of Common Stock issuable to them should not consider the reverse stock split. The Company rejects these contentions in their entirety and, based on the advice of specially retained counsel, believes that these claims are without legal merit and not made in good faith. The Company intends to vigorously defend its interests and pursue other avenues of legal address. Through its counsel, the Company has advised these entities that unless they withdraw their request within a specified period, the Company will cancel the above referenced agreements and these parties' right to receive any shares of the Company's Common Stock. In April 2018, the Company withdrew the agreements and deposited the principal amount and accrued interest of the loan in an escrow account presented as restricted cash in the balance sheet as of August 31, 2018.

NOTE 6 COMMITMENTS

"MSA" with Adva Biotechnology Ltd.

On January 28, 2018, the Company and Adva Biotechnology Ltd. (Adva), entered into a Master Services Agreement (MSA), under which the Company and/or its affiliates are to provide certain services relating to development of products to Adva, as may be agreed between the parties from time to time. Under the MSA, the Company undertook to provide Adva with in kind funding in the form of materials and services having an aggregate value of \$749,900 at the Company's own cost in accordance with a project schedule and related mutually acceptable project budget. The Company entered into agreement with Atvio Biotech Ltd, its Israeli-based joint venture, to fulfill its obligations pursuant this MSA. As of August 31, 2018, the Company incurred a total expense of \$282 thousand.

In consideration for and subject to the fulfillment by the Company of such in-kind funding commitment, Adva agreed that upon completion of the development of the products, the Company and/or its affiliates and Adva shall enter into a supply agreement pursuant to which for a period of eight (8) years following execution of such supply agreement, the Company and/or its affiliates (as applicable) is entitled (on a non-exclusive basis) to purchase the products from Adva at a specified discount pricing from their then standard pricing. The Company and/or its affiliates were also granted a non-exclusive worldwide right to distribute such products, directly or through any of their respective contract development and manufacturing organization (CDMO) service centers during such term. The MSA shall remain in effect for 10 years unless earlier terminated in accordance with its terms.

Grants

On December 18, 2017, MaSTherCell S.A. (MaSTherCell), as coordinator of the Icone project with a consortium of private and public searchers, received the approval of a new grant from the Walloon Region with a direct financial support of Euro 1 million (\$1.2 million) in a program for development of iPS-derived Cortical Neurons. The program started in 2017 for a 4-year period until 2021. After two years, project partners will decide to continue the program

upon pre-defined scientific milestone achievements. During the nine months ended August 31, 2018, MaSTherCell received an advance payment of Euro 0.6 million (\$0.7 million).

NOTE 7 EQUITY*Financings*

a) In January 2017, the Company entered into definitive agreements with an institutional investor for the private placement of 2,564,115 units of the Company's securities for aggregate subscription proceeds to the Company of \$16 million at \$6.24 price per unit. Each unit is comprised of one share of the Company's Common Stock and a warrant, exercisable over a three-years period from the date of issuance, to purchase one additional share of Common Stock at a per share exercise price of \$6.24. The subscription proceeds were payable on a periodic basis through September 2018. The Company subsequently agreed to delay the payments until October 15, 2018. Each periodic payment of subscription proceeds will be evidenced by the Company's standard securities subscription agreement.

In July 2018, the Company entered into definitive agreements with assignees of the aforementioned institutional investor whereby these assignees remitted \$4.6 million in respect of the units available under the original subscription agreement that have not been subscribed for, entitling such investors to 702,307 units, with each unit being comprised of (i) one share of the Company's common stock and (ii) one three-year warrant to purchase up to an additional one share of the Company's common stock at a per share exercise price of \$6.24.

During the nine months ended August 31, 2018 the investor and the assignees remitted to the Company \$8,065 thousand, and the Company issued 1,263,204 shares of the Company's Common Stock and three-year warrants to purchase up to an additional 1,263,204 shares of the Company's Common Stock at a per share exercise price of \$6.24.

The Company allocated the proceeds based on the fair value of the warrants and the shares. The table below presents the allocation of the proceeds as of the closing date:

	Proceeds Allocation (in thousands)
Warrants component	\$ 2,923
Shares component	5,142
Total	\$ 8,065

The fair value of these warrants determined using a Black-Scholes Model based on the following assumptions:

	Nine Months Ended August 31, 2018
Value of one common share	\$6.5-\$14.68
Dividend yield	0%
Expected stock price volatility	90.6%-93.8%
Risk free interest rate	1.99%-2.73%
Expected term (years)	3

The transaction costs were approximately \$328 thousand, out of which \$121 thousand are stock-based compensation due to issuance of warrants and shares. See also 8(c).

As of August 31, 2018, the Company has received a total of \$12.6 million out of the committed \$16 million subscription proceeds.

b) During the nine months ended August 31, 2018, the Company entered into definitive agreements with accredited and other qualified investors relating to a private placement of 1,237,642 units. Each unit is comprised of (i) one share of the Company's common stock and (ii) three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24, for aggregate proceeds to the Company of approximately \$7.7 million.

The Company allocated the proceeds based on the fair value of the warrants and the shares. The table below presents the allocation of the proceeds as of the closing date:

	Proceeds Allocation (in thousands)
Warrants component	\$ 2,813
Shares component	4,910
Total	\$ 7,723

The transaction costs were approximately \$349 thousand, out of which \$125 thousand are stock-based compensation due to issuance of warrants. See also 8(c).

NOTE 8 STOCK BASED COMPENSATION

a. Options Granted to employees

Below is a table summarizing the terms of options granted to employees during the nine months ended August 31, 2018:

	No. of options granted	Exercise price	Vesting period	Fair Value at grant (in thousands)	Expiration period
Employee	50,000	\$ 4.42	Quarterly over a period of 1 year	\$ 163	10 years
Employees	30,500	\$ 8.91	Quarterly over a period of 2 years	\$ 192	10 years
Employee	250,000	\$ 8.36	Semi-annual over a period of 1 year	\$ 1,488	10 years
MaSTherCell's employees	70,300	\$ 8.43	Quarterly over a period of 2 years	\$ 464	10 years
MaSTherCell's employees	123,550	\$ 8.43	Quarterly over a period of 4 years	\$ 925	10 years

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

	Nine Months Ended August 31, 2018
Value of one common share	\$4.42 - \$8.85

Edgar Filing: Orgenesis Inc. - Form 10-Q

Dividend yield	0%
Expected stock price volatility	97%-91%
Risk free interest rate	2.96%-2.11%
Expected term (years)	5-7

b. Options Granted to non-employees

Below is a table summarizing all the options granted to consultants and service providers during the nine months ended August 31, 2018:

	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employee	5,200	4.42	Over six months	\$ 36	10 years
Non-employee	13,725	\$ 4.42,8.34	Immediately	\$ 82	10 years
Non-employee	8,333	\$ 8.43	Annual over a period of 5 year	\$ 57	10 years

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

	Nine Months Ended August 31, 2018
Value of one common share	\$8.3,\$4.42
Dividend yield	0%
Expected stock price volatility	91%-98%
Risk free interest rate	\$2.33-\$2.83
Expected term (years)	4.5-10

c. Shares and Warrants Granted to non-employees

- 1) During the nine months ended August 31, 2018, the Company granted to several consultants 50,938 warrants with each exercisable at \$6.24 to \$15.41 per share for three years as a success fee with respect to the issuance of the convertible loans and part of the private placement. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was \$248 thousand.
- 2) In December 2017, the Company entered into investor relations services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to grant the consultant 100,000 shares of restricted common stock, out of which the first 25,000 shares will vest after 30 days from the signing date, and 75,000 shares are to vest monthly over 15 months commencing February 2018. As of August 31, 2018, 60,000 shares were vested. The fair value of the shares as of the date of grant was \$738 thousand.
- 3) In December 2017, the Company entered into an investor relations services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to grant the consultant 95,000 shares of restricted common stock, of which the first 25,000 shares will vest after 30 days from the signing date, and 70,000 shares are to vest monthly over 14 months commencing February 2018. As of August 31, 2018, 60,000 shares were vested. The fair value of the shares as of the date of grant was \$701 thousand.
- 4) In January 2018, the Company entered into a consulting agreement with a financial advisor for a period of one year. Under the terms of the agreement, the consultant was entitled to receive \$60 thousand and 19,000 units of the Company securities. Each unit is comprised of (i) one share of the Company's common stock and (ii) a three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24. The fair value of the units as of the date of grant was \$171 thousand, out of which \$62 thousand reflect the fair value of the warrants using the Black-Scholes valuation model. In July 2018, the board approved an additional issuance of 6,629 shares and three-year warrants to purchase up to 6,629 shares of the Company's Common Stock at a per share exercise price of \$6.24. The fair value of the units as of the date of grant was \$88 thousand.
- 5) During the nine months ended August 31, 2018, investors exercised 136,646 warrants into 136,646 shares of the Company's Common Stock, for aggregate proceeds of \$853 thousand.
- 6) On July 6, 2018, the Compensation Committee approved the issuance of 13,558 warrants to two consultants to purchase 13,558 shares of Common Stock, exercisable at a per share exercise price of \$11.19.

NOTE 9 LOSS PER SHARE

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

	Three Months Ended August 31,		Nine Months Ended August 31,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Basic:				
Loss for the period	\$ 5,070	\$ 3,940	\$ 13,295	\$ 12,557
Weighted average number of common shares outstanding	14,355,430	10,279,180	12,774,802	9,477,211
Loss per common share	\$ (0.35)	\$ (0.38)	\$ (1.04)	\$ (1.32)
Diluted:				
Loss for the period	\$ 5,070	\$ 3,940	\$ 13,295	\$ 12,557
Changes in fair value of embedded derivative and interest expense on convertible loans	-	238	-	137
Loss for the period	\$ 5,070	\$ 4,178	\$ 13,295	\$ 12,694
Weighted average number of shares used in the computation of basic and diluted loss per share	14,355,430	10,279,180	12,774,802	9,477,211
Number of dilutive shares related to convertible loans	-	106,319	-	26,042
Weighted average number of common shares outstanding	14,355,430	10,385,499	12,774,802	9,503,253
Loss per common share	\$ (0.35)	\$ (0.40)	\$ (1.04)	\$ (1.34)

Diluted loss per share does not include 7,919,874 shares underlying outstanding options and warrants and 201,557 shares upon conversion of convertible notes for the nine months ended August 31, 2018, because the effect of their inclusion in the computation would be anti-dilutive.

Diluted loss per share does not include 4,375,856 shares underlying outstanding options and warrants and 2,462,598 shares upon conversion of convertible notes for the three and nine months ended August 31, 2017, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 10 - FAIR VALUE PRESENTATION

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

Edgar Filing: Orgenesis Inc. - Form 10-Q

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable inputs that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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

Edgar Filing: Orgenesis Inc. - Form 10-Q

As of August 31, 2018, and November 30, 2017, the Company's assets and liabilities that are measured at fair value and classified as level 3 fair value are as follows (in thousands):

	August 31, 2018	November 30, 2017
	<u>Level 3</u>	<u>Level 3</u>
Embedded derivatives convertible loans*(1)	\$ -	\$ 37
Call/Put option derivatives	\$ -	\$ (339)

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

(1) The fair value is determined by using a Black-Scholes Model.

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

The table below sets forth a summary of the changes in the fair value of the Company's financial liabilities classified as Level 3 for the nine months ended August 31, 2018:

	<u>Embedded Derivatives</u>	<u>Put Option Derivative</u>
Balance at beginning of the period	\$ 37	\$ (339)
Repayment	(14)	-
Changes in fair value during the period	(23)	49
Option disposal (See Note 4)	-	290
Balance at end of the period	\$ -	\$ -

(*) There were no transfers to Level 3 during the nine months ended August 31, 2018.

The table below sets forth a summary of the changes in the fair value of the Company's financial assets and liabilities classified as Level 3 for the year ended November 30, 2017:

	<u>Embedded Derivatives</u>	<u>Convertible Bonds</u>	<u>Put Option Derivative</u>
Balance at beginning of the year	\$ 240	\$ 1,818	\$ 273
Repayment	(876)	(1,827)	-
Changes in fair value during the period	662	22	(612)
Translation adjustments	11	(13)	-
Balance at end of the year	\$ 37	\$ -	\$ (339)

(*) There were no transfers to Level 3 during the twelve months ended November 30, 2017.

NOTE 11 OTHER INCOME - NET

Includes net gain on remeasurement of previously equity interest in Atvio and CureCell to acquisition date fair value in the amount of \$4,509 and transaction costs related to GPP agreement in the amount of \$1.5 million.

NOTE 12 - SUBSEQUENT EVENTS

In October 2018, the Company raised \$3.4 million from the institutional investor referred to in Note 7 entitling such investor to 550,481 shares of Common Stock and three-year warrants for an additional 550,481 shares. Following this remittance and those referred to in Note 7, the Company has received, as of October 12, 2018, a total of \$16 million out of the committed \$16 million subscription proceeds under such agreement.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains may contain forward-looking statements within the meaning of 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used herein, the words anticipate, believe, estimate, expect, future, intend, plan, or the negative of these terms or expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this report.

Unless otherwise indicated or the context requires otherwise, the words we, us, our, the Company or our Company refer to Orgenesis Inc., a Nevada corporation, and its majority-owned subsidiary, Masthercell Global Inc., a Delaware corporation (Masthercell Global), and Orgenesis SPRL, a Belgian-based entity which is engaged in development and manufacturing activities, together with clinical development studies in Europe (the Belgian Subsidiary), and its wholly-owned subsidiaries Orgenesis Ltd., an Israeli corporation (the Israeli Subsidiary), Orgenesis Maryland Inc., a Maryland corporation, and Cell Therapy Holdings S.A. Masthercell Global's wholly-owned subsidiaries include MaSTherCell S.A (MaSTherCell), a Belgian-based subsidiary and a contract development and manufacturing organization, or CDMO, specialized in cell therapy development and manufacturing for advanced medicinal products; Atvio Biotech Ltd. (Atvio), an Israeli-based CDMO, and CureCell Co. Ltd. (CureCell), a Korea-based CDMO.

Corporate Overview

We are a vertically integrated service and research company in the regenerative medicine industry with a focus on cell and gene therapy development and manufacturing. Our Company operates through two platforms including (i) a Cell Therapy (CT) development platform and (ii) a Contract Development and Manufacturing Organization (CDMO) platform. Through our CT development platform, we are focused on the development of proprietary cell therapies, including our autologous trans-differentiation technology and therapeutic collaborations and licensing with other pre-clinical and clinical-stage biopharma companies and research and healthcare institutes. Through our CDMO

platform, we are focused on manufacturing and development services for other biopharma companies.

Activities in our CT platform include our Company's trans-differentiation technology that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver or other tissues and transdifferentiating them into pancreatic beta cell-like Autologous Insulin Producing (AIP) cells for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases. This technology, which has yet to be proven in human clinical trials, has shown in relevant animal models that the human derived AIP cells produce insulin in a glucose-sensitive manner. This trans-differentiation technology is licensed by our Israeli Subsidiary and is based on the work of Prof. Sarah Ferber, our Chief Science Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. (THM) in Israel. Our development plan calls for conducting additional pre-clinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating human clinical trials. Furthermore, through our CT platform, we are engaging in therapeutic collaborations and licensing with other academic centers and research centers in order to pursue emerging technologies of other cell therapy products in such areas as cell-based immunotherapies, cardiovascular diseases, neurodegenerative diseases and tissue regeneration. With respect to our trans-differentiation technology, we own or have exclusive rights to four (4) United States and seven (7) foreign issued patents, three (3) pending applications in the United States, eleven (11) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and one (1) international PCT patent application, relating to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β -cell phenotype and function, and their use in the treatment of degenerative pancreatic disorders including diabetes, pancreatic cancer, and pancreatitis.

Our CDMO platform operates through Masthercell Global, which currently consists of MaSTherCell in Belgium, Atvio in Israel and our subsidiaries in South Korea and in the United States, each having unique knowhow and expertise for manufacturing in a multitude of cell types. As part of our U.S. activity, we intend to also set up a CDMO facility in the United States. We believe that, in-order to provide the optimal service to our customers, we need to have a global presence. We target the international market as a key priority through our network of facilities that provide development, manufacturing and logistics services, utilizing our advanced quality management system and experienced staff. All these capabilities offered to third-parties are utilized for our internal development projects, with the goal of allowing us to be able to bring new products to patients faster and in a cost-effective way. Masthercell Global strives to provide services that are all compliant with GMP requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical phase I, II, III and through commercialization.

Business Strategy

Our aim is to utilize our know-how and intellectual property in order to bring new autologous cell therapies to patients by leveraging and evolving our expertise toward point-of-care (POCare) cell therapies. We define POCare cell therapy as a process of collecting, processing and administering cells within the patient care setting, without the need to transfer the cells to be manufactured at a centralized facility. We believe the approach of decentralized manufacturing is an attractive proposition for personalized medicine because a POCare approach based on utilizing closed systems has the potential of reducing the required grade of clean room facilities, thus substantially reducing manufacturing costs. Furthermore, cell transportation, which is a high-risk and costly aspect of the supply chain, could be minimized or eliminated.

While our POCare strategy is currently limited to early stage development, we intend to continue developing a global POCare network, with the goal of developing autologous cell therapies with regional partners. We believe that we will reduce costs by leveraging our joint ventures with local partners who bring strong regional networks. Such networks include partnerships with local hospitals which allows us to engage in continuous in-licensing of autologous therapies from academia and research institutes, co-development of hospital and academic-based therapies, and utilization of hospital networks for clinical development of therapies.

We intend to leverage our following capabilities in order to advance our POCare strategy:

- industrial manufacturing know-how and biological assay development;

integration of higher automation levels resulting in significantly lower cell production costs; providing ingredients (assays, viruses, etc.) and technology components (e.g. sensors); implementation of manufacturing automation enabling closed systems; and a harmonized quality system.

We operate our CDMO and the CT platforms as two separate business segments.

Revenue Model

Companies developing cell therapies need to decide early on in their approach to the transition from the lab to the clinic regarding the manufacturing and production of the cells necessary for their respective treatments. Of the companies active in this market, only a small number have established their own GMP manufacturing facilities due to the high costs and expertise required to develop and maintain such production centers. In addition to the limitations imposed by a limited number of trained personnel and high infrastructure/operational costs, we believe that the industry faces a need for custom innovative process development and manufacturing solutions. In this context, we have grown total revenue from \$6.4 million in our fiscal year November 30, 2016 to \$10.1 million for fiscal year November 30, 2017 and from \$6.7 million for the nine months ended August 31, 2017 to \$12.9 million for the nine months ended August 31, 2018. The increased revenues derive from an increase in the volume of the services provided by our CDMO segment, mainly from our Belgian-based subsidiary, MaSTherCell, through its customer service contracts with existing customers and the entry into new customer service contracts with leading biotech companies, as well as from revenues generated from existing manufacturing agreements.

Recent Significant Developments

Funding from SFPI

On November 15, 2017, we, MaSTherCell and the Belgian Sovereign Funds Société Fédérale de Participations et d'Investissement (SFPI) entered into a Subscription and Shareholders Agreement (the Agreement) pursuant to which SFPI completed an equity investment in MaSTherCell in the aggregate amount of €5million (approximately \$5.9 million), for approximately 16.7% of MaSTherCell. Following the SFPI investment in MaSTherCell, in November 2017, MaSTherCell announced the expansion by 600m² of its facility in Belgium with a dedicated, late-stage clinical and commercial cGMP unit, anticipated to be operational by the fourth quarter of 2018. This new expansion enables MaSTherCell to augment its commercial capabilities in Europe with five state-of-the-art advanced manufacturing units and extended GMP-accredited quality control (QC) laboratories. On June 13, 2018, SPFI has paid into MaSTherCell S.A. the balance of Euro 1.9 million (approximately \$2.3 million).

Collaboration Agreements/Joint Ventures

On June 19, 2018, we and Mircod Limited, a company formed under the laws of Cyprus (Mircod) entered into a Collaboration and License Agreement for the research, development and commercialization of potential key technologies related to biological sensing for our clinical development and manufacturing projects (the Development Project). Within 45 days of the execution of the Collaboration Agreement, the parties are to approve a written project development plan outlining each party's responsibilities with respect to the Development Project, and we will be funding the projected development costs as outlined in the development plan. Under the terms of the Collaboration Agreement, we remitted to Mircod an upfront payment of \$50,000.

On July 10, 2018, we and HekaBio K.K., a corporation organized under the laws of Japan (HB) entered into a Joint Venture Agreement (the JVA) pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products (hereinafter the Products) in Japan (the Project). The parties intend to pursue the joint venture through a newly established Japanese company (hereinafter the JV Company) which the Company by itself, or together with a designee, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by HB. HB will fund, at its sole expense, all costs associated with obtaining the requisite regulatory approvals for conducting clinical trials, as well as performing all clinical and other testing required for market authorization of the Products in Japan.

In addition, under the JVA, the Company shall grant the JV Company an exclusive license to certain intellectual property of the Company as may be required for the JV Company to develop and commercialize the Products in Japan. In consideration of such license, the JV Company shall pay the Company, in addition to other payments, royalties at the rate of 10% of the JV Company's net sales of Products.

It was further agreed that the JV Company shall grant the Company (and its affiliates) a non-exclusive, worldwide (other than Japan), royalty-free and fully paid-up license to use and practice, for any purpose, new inventions, discoveries and intellectual property rights that are generated by and/or on behalf of HB and/or the JV Company in connection with the Project.

All matters pertaining to such license rights shall be governed under a separate license agreement to be entered by and between the Company and the JV Company.

On July 11, 2018, we and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Cayman Islands (*India Partner*) entered into a Joint Venture Agreement (the *India JVA*) pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products in India (the *Cell Therapy Products*). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products.

The India JVA becomes effective upon the consummation of an equity investment by the India partner in the Company of \$5 million through the purchase of units of Orgenesis securities at a per unit purchase price payable into the Company of \$6.24, with each unit comprised of one share of Company common stock and three-year common stock purchase warrant for an additional share of common stock at a per share exercise price of \$6.24.

On August 2, 2018, we entered into a research and license agreement (the *Research and License Agreement*) with B.G. Negev Technologies and Applications Ltd. and the National Institute for Biotechnology in the Negev Ltd., both affiliates of Ben-Gurion University of the Negev (both herein, the *BG Entities*), pursuant to which, *inter alia*, we and the BG Entities agreed to collaborate in carrying out projects for the purpose of developing and commercializing a novel alginate scaffold technology for cell transplantation, with an initial focus on autoimmune diseases, as set forth under the Research and License Agreement (the *Projects*). Intellectual property rights created through the joint efforts of us and the BG Entities under the Projects, in accordance with the terms set forth under the Research and License Agreement, shall be jointly owned by us and the BG Entities in equal (50%-50%) shares (the *Joint IP*). In addition, under the Research and License Agreement, the BG Entities granted us an exclusive, worldwide, royalty-bearing license to make, develop and commercialize BG Entities' rights in and to the BG Entities' background intellectual property, the Project results, certain patents (as set forth under the Research and License Agreement) and the Joint IP, as well as products which are covered by any of the foregoing (*Licensed Products*), in the field of treatment of autoimmune diseases, including, use of islets to treat diabetes. In consideration of such license, we are required to pay the BG Entities, in addition to other payments, royalties at the rate of 4% of net sales actually received by us and/or any of our affiliates and sublicensees with respect to the commercialization of the Licensed Products, provided that such royalty rate shall be reduced to (i) 2.5%, in the event that the relevant Licensed Product is solely covered by or incorporates Joint IP (and not any other intellectual property rights), or (ii) 2%, in the event that the relevant Licensed Product is not covered by a valid claim under a patent or a pending patent application or not protected under any applicable statutory protections (as set forth under the Research and License Agreement). In addition to such royalty payments, we are also required to pay the BG Entities an amount equal to 15%-20% depending on the clinical trial stage, of income received by us from any sublicensee (which amount may be reduced in accordance with the terms and conditions set forth under the Research and License Agreement), milestone-related payments as well as an annual license fee in the amount of US\$ 100,000.

Consolidation of CDMO Entities and Strategic Funding

On June 28, 2018, the Company, Masthercell Global Inc., a Delaware company and a newly formed subsidiary of the Company that holds our business relating to the third party contract manufacturing for cell therapy companies (CDMO) (*Masthercell Global*), Great Point Partners, LLC, a manager of private equity funds focused on growing small to medium sized health care companies (*Great Point*), and certain of Great Point's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business. In

connection therewith, the Company, Masthercell Global and GPP-II Masthercell, LLC, a Delaware limited liability company (GPP-II) and an affiliate of Great Point entered into Stock Purchase agreement (the SPA) pursuant to which GPP-II purchased 378,000 shares of newly designated Series A Preferred Stock of Masthercell Global (the Masthercell Global Preferred Stock), representing 37.8% of the issued and outstanding share capital of Masthercell Global, for cash consideration to be paid into Masthercell Global of up to \$25 million, subject to certain adjustments (the Consideration). Orgenesis holds 622,000 shares of Masthercell Global s Common Stock, representing 62.2% of the issued and outstanding equity share capital of Masthercell Global. An initial cash payment of \$11.8 million of the Consideration was remitted at closing, with a follow up payment of \$6,600,000 to be made in each of years 2018 and 2019 (the Future Payments), or an aggregate of \$13.2 million, if (a) Masthercell Global achieves specified EBITDA and revenues targets during each of these years, and (b) the Orgenesis shareholders approve certain provisions of the Stockholders Agreement referred to below on or before December 31, 2019. None of the future Consideration amounts, if any, will result in an increase in GPP-II s equity holdings in Masthercell Global beyond the 378,000 shares of Series A Preferred Stock issued to GPP-II at closing. The proceeds of the investment will be used to fund the activities of Masthercell Global and its consolidated subsidiaries. Notwithstanding the foregoing, GPP-II may, in its sole discretion, elect to pay all or a portion of the future Consideration amounts even if the financial targets described above have not been achieved and the Orgenesis Stockholder Approval has not been obtained.

In connection with the entry into the SPA described above, each of the Company, Masthercell Global and GPP-II entered into the Masthercell Global Inc. Stockholders Agreement (the Stockholders Agreement) providing for certain restrictions on the disposition of Masthercell Global securities, the provisions of certain options and rights with respect to the management and operations of Masthercell Global, certain favorable, preferential rights to GPP-II (including, without limitation, a tag right, drag right and certain protective provisions), a right to exchange the Masthercell Global Preferred Stock for shares of Orgenesis common stock and certain other rights and obligations. In addition, after the earlier of the second anniversary of the closing or certain enumerated circumstances, GPP-II is entitled to effectuate a spinoff of Masthercell Global and the Masthercell Global Subsidiaries (the Spinoff). The Spinoff is required to reflect a market value determined by one of the top ten independent accounting firms in the U.S. selected by GPP, provided that under certain conditions, such market valuation shall reflect a valuation of Masthercell Global and the Masthercell Global Subsidiaries of at least \$50 million. In addition, upon certain enumerated events as described below, GPP-II is entitled, at its option, to put to the Company (or, at Company s discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global or, alternatively, purchase from the Company its share capital in Masthercell Global at a purchase price equal to the fair market value of such equity holdings as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II, provided that the purchase price shall not be greater than three times the price per share of Masthercell Global Preferred Stock paid by GPP-II and shall not be less than the price per share of Masthercell Global Preferred Stock paid by GPP-II . GPP-II may exercise its put or call option upon the occurrence of any of the following: (i) there is an Activist Shareholder of the Company; (ii) the Chief Executive Officer and/or Chairman of the board of directors of the Company resigns or is replaced, removed, or terminated for any reason prior to June 28, 2023; (iii) there is a Change of Control event of the Company; or (iv) the industry expert director appointed to the board of directors of Masthercell Global is removed or replaced (or a new such director is appointed) without the prior written consent of GPP-II. For the purposes of the foregoing, the following definitions shall apply: (A) Activist Shareholder shall mean any Person who acquires shares of capital stock of the Company who either: (x) acquires more than a majority of the voting power of the Company, (y) actively takes over and controls a majority of the board of directors of the Company, or (z) is required to file a Schedule 13D with respect to such Person s ownership of the Company and has described a plan, proposal or intent to take action with respect to exerting significant pressure on the management of or directors of, the Company; and (B) Change of Control shall mean any of: (a) the acquisition, directly or indirectly (in a single transaction or a series of related transactions) by a Person or group of Persons of either (I) a majority of the common stock of the Company (whether by merger, consolidation, stock purchase, tender offer, reorganization, recapitalization or otherwise), or (II) all or substantially all of the assets of the Company and its Subsidiaries (but only if such transaction includes the transfer of Securities held by the Company), (b) if any four (4) of the directors of the Company as of June 28, 2018 are removed or replaced or for any other reason cease to serve as directors of the Company, (c) the filing of a petition in bankruptcy or the commencement of any proceedings under bankruptcy laws by or against the Company, provided that such filing or commencement shall be deemed a Change of Control immediately if filed or commenced by the Company or after sixty (60) days if such filing is initiated by a creditor of the Company and is not dismissed; (d) insolvency of the Company that is not cured by the Company within thirty (30) days; (e) the appointment of a receiver for the Company, provided that such appointment shall constitute an Change of Control immediately if the appointment was consented to by the Company or after sixty (60) days if not consented to by the Company and such appointment is not terminated; or (f) or dissolution of the Company .

The Stockholders' Agreement further provides that GPP-II is entitled, at any time, to convert its share capital in Masthercell Global for the Company's common stock in an amount equal to the lesser of (a)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged, as determined by one of the top ten independent accounting firms in the U.S. selected by GPP-II and the Company, divided by (ii) the average closing price per share of Orgenesis Common Stock during the thirty (30) day period ending on the date that GPP-II provides the exchange notice (the Exchange Price) and (b)(i) the fair market value of GPP-II's shares of Masthercell Global Preferred Stock to be exchanged assuming a value of Masthercell Global equal to three and a half (3.5) times the revenue of Masthercell Global during the last twelve (12) complete calendar months immediately prior to the exchange divided by (ii) the Exchange Price; provided, that in no event will (A) the Exchange Price be less than a price per share that would result in Orgenesis having an enterprise value of less than \$250,000,000 and (B) the maximum number of shares of Orgenesis Common Stock to be issued shall not exceed 2,704,247 shares of outstanding Orgenesis Common Stock (representing approximately 19.99% of then outstanding Orgenesis Common Stock), unless Orgenesis obtains shareholder approval for the issuance of such greater amount of shares of Orgenesis Common Stock in accordance with the rules and regulations of the Nasdaq Stock Market.

Great Point and Masthercell Global entered into an advisory services agreement pursuant to which Great Point is to provide management services to Masthercell Global for which Great Point will be compensated at an annual base compensation equal to the greater of (i) \$250,000 per each 12 month period or (ii) 5% of the EBITDA for such 12 month period, payable in arrears in quarterly installments; provided, that these payments will (A) begin to accrue immediately, but shall not be paid in cash to Great Point until such time as Masthercell Global generates EBITDA of at least \$2,000,000 for any 12 month period or the sale of or change in control of Masthercell Global, and (B) shall not exceed an aggregate annual amount of \$500,000. Such compensation accrues but is not owed to Great Point until the earlier of (i) Masthercell Global generating EBITDA of at least \$2 million for any 12 months period following the date of the agreement or (ii) a Sale of the Company or Change of Control of the Company (as both terms are defined therein).

GPP Securities, LLC, a Delaware limited liability company and an affiliate of Great Point and Masthercell Global entered into a transaction services agreement pursuant to which GPP Securities, LLC is to provide certain brokerage services to Masthercell Global for which GPP Securities LLC will be entitled to a certain Exit Fee and Transaction Fee (as both terms are defined in the agreement), such fees not to be less than 2 percent of the applicable transaction value.

Corporate Reorganization

Contemporaneous with the execution of the SPA and the Stockholders' Agreement, Orgenesis and Masthercell Global entered into a Contribution, Assignment and Assumption Agreement pursuant to which Orgenesis contributed to Masthercell Global the Orgenesis' assets relating to the CDMO Business (as defined below), including the CDMO subsidiaries (the "Corporate Reorganization"). In furtherance thereof, Masthercell Global, as Orgenesis' assignee, acquired all of the issued and outstanding share capital of Atvio, the Company's Israel based CDMO partner since May 2016, and 94.2% of the share capital of CureCell, the Company's Korea based CDMO partner since March 2016. Orgenesis exercised the "call option" to which it was entitled under the joint venture agreements with each of these entities to purchase from the former shareholders their equity holding. The consideration for the outstanding share equity in each of Atvio and CureCell consisted solely of Orgenesis Common Stock. In respect of the acquisition of Atvio, Orgenesis Inc. issued to the former Atvio shareholders an aggregate of 84,085 shares of Orgenesis Common Stock. In respect of the acquisition of CureCell, Orgenesis Inc. issued to the former CureCell shareholders an aggregate of 202,846 shares of Orgenesis Common Stock subject to a third-party valuation. Together with MaSTherCell S.A., Atvio and CureCell are directly held subsidiaries under Masthercell Global (collectively, the "Masthercell Global Subsidiaries").

Masthercell Global, through the Masthercell Global Subsidiaries, will be engaged in the business of providing manufacturing and development services to third parties related to cell therapy products, and the creation and

development of technology, and optimizations in connection with such manufacturing and development services for third parties (the CDMO Business). Under the terms of the Stockholders Agreement, Orgenesis has agreed that so long as it owns equity in Masthercell Global and for two years thereafter it will not engage in the CDMO Business, except through Masthercell Global (but may continue to engage in its other areas of business). In addition, except for certain limited circumstances, each of Orgenesis and GPP-II agreed in the Stockholders Agreement to not recruit or solicit or hire any officer or employee of Masthercell Global that was or is involved in the CDMO Business.

We intend, through our direct subsidiaries, to continue to engage in the manufacturing, researching, marketing, developing, selling and commercializing (either alone or jointly with third parties) products that are not directly related to the CDMO business, including, joint ventures, collaboration, partnership or similar arrangement with a third party.

Results of Operations

Comparison of the Three Months Ended August 31, 2018 to the Three Months Ended August 31, 2017

Our financial results for the three months ended August 31, 2018 are summarized as follows in comparison to the three months ended August 31, 2017:

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Revenues	\$ 6,230	\$ 2,562
Cost of sales	3,381	1,867
Research and development expenses, net	1,902	500
Amortization of intangible assets	505	423
Selling, general and administrative expenses	4,008	3,184
Other income	(2,921)	-
Share in losses of associated company	202	152
Financial expense (income), net	1,070	(45)
Loss before income taxes	\$ 1,917	\$ 3,519

Revenues

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Services	\$ 4,473	\$ 2,015
Goods	1,757	547
Total	\$ 6,230	\$ 2,562

All of our revenues were derived from the CDMO segment, most of which were generated from our Belgian Subsidiary, MaSTherCell S.A. We believe that revenue diversification by source in the CDMO segment, together with a leading position in immunotherapy and, in particular, CAR T-cell therapy development and manufacturing, strengthen MaSTherCell's resilience in the industry.

Our revenues for the three months ended August 31, 2018 were \$6,230 thousand, as compared to \$2,562 thousand for the corresponding period in 2017, representing an increase of 143%. The increase in revenues for the three months ended August 31, 2018 compared to the corresponding period in 2017 is attributable to an increase in the projects provided by MaSTherCell, resulting primarily from the extension of existing customer service contracts with biotechnology clients, as well as from revenues generated from existing manufacturing agreements.

In March 2018, MaSTherCell entered into an agreement with ZELLUNA Immunotherapy to develop and manufacture TCR adoptive cell therapy platform for which MaSTherCell has recognized revenue of approximately \$515 thousand during the three months ended August 31, 2018.

In April 2018, MaSTherCell entered into an agreement with a U.S. customer to manufacture autologous TIL therapies for which MaSTherCell has recognized revenue of approximately \$1.1 million during the three months ended August 31, 2018.

In addition, we acquired all the issued and outstanding share capital of Atvio, our Israel based CDMO partner since August 2016, and 94.2% of the share capital of CureCell, our Korea based CDMO partner since March 2016, which are reflected in the increase in our revenues from services provided of \$823 thousand during the three months ended August 31, 2018.

Expenses

Cost of Revenues

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 1,568	\$ 515
Stock-based compensation	28	-
Professional fees and consulting services	98	(90)
Raw materials	1,504	832
Depreciation and amortization expenses, net	(36)	522
Other expenses	219	88
	\$ 3,381	\$ 1,867

Cost of revenues for the three months ended August 31, 2018 were \$3,381 thousand, as compared to \$1,867 thousand, during the same period in 2017, representing an increase of 81%. The increase for the three months ended in August 31, 2018 as compared to the corresponding period in 2017 is primarily attributed to the following:

- (i) An increase of \$672 thousand in raw materials due to the growth in the volume of the services provided by MaSTherCell, as well as from revenues generated from existing and new manufacturing agreements.
- (ii) An increase in salaries and related expenses primarily attributable to an increase of 79% in personnel in our production and development department. This increase is attributable to the increase of our operations.
- (iii) A decrease in the Depreciation and amortization expenses due to change in the amortization in 2018 due to the change in valuations' rules over property and equipment.

Research and Development Expenses

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 846	\$ 321
Stock-based compensation	106	112
Professional fees and consulting services	(167)	(7)
Lab expenses	1,063	329
Depreciation expenses, net	82	-
Other research and development expenses	138	14
Less grant	(166)	(269)
Total	\$ 1,902	\$ 500

Research and development expenses for the three months ended August 31, 2018 were \$1,902 thousand, as compared to \$500 thousand for the same period in 2017, representing an increase of 280%. The increase in research and development expenses in the three months ended August 31, 2018 is primarily attributable to (i) an increase in lab expenses in the amount of \$734 thousand, representing an increase of 223%, as a result of an increase in new therapeutic development in the U.S. and (ii) an increase of \$525 thousand, representing an increase of 164%, of Salaries and related expenses, mostly attributed to the DGO6 project.

Selling, General and Administrative Expenses

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 1,096	\$ 716
Stock-based compensation	846	270
Accounting and legal fees	615	427
Professional fees	730	843
Rent and related expenses	328	320
Business development	222	286
Expenses related to a joint venture	-	263
Other general and administrative expenses	171	59
Total	\$ 4,008	\$ 3,184

Selling, general and administrative expenses for the three months ended August 31, 2018 were \$4,008 thousand, as compared to \$3,184 thousand for the same period in 2017, representing an increase of 26%. The increase in selling, general and administrative expenses in the three months ended August 31, 2018 compared to the same period in 2017 is primarily attributable to the following: (i) an increase in salaries as result of additional managerial positions, as well as an internal transformation program implemented in MaSTherCell in the second quarter of 2017 to evolve from an organization based on projects to a matrix organization supported by transversal departments focusing on value creation; and (ii) an increase of Stock-based compensation as a result of options granted to the CEO and certain employees. As part of the internal transformation program, managers position has been opened and filled by new employees either from internal appointment from the laboratories managers positions or from external new employees such as SG&A departments where several new staff members have joined in order to develop and strengthen the internal structure and SG&A departments.

Financial Expenses, net

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	\$ 681	\$ (362)
Stock-based compensation related to warrants granted to bondholder	-	(275)
Interest expense on convertible loans and loans	127	301
Foreign exchange loss, net	153	289
Other expenses	109	2
Total	\$ 1,070	\$ (45)

Financial expenses, net for the three months ended August 31, 2018, increased by 1,115\$ thousand, compared to the same period in 2017. The increase in financial expenses is mainly attributable to the change in fair value of the put options of Atvio of \$681 thousand.

Tax expenses

	Three Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Tax expenses	2,353	421
Total	\$ 2,353	\$ 421

Tax expenses for the three months ended August 31, 2018 increased by \$1,932 thousand, compared to the same period in 2017. The increase in tax expenses is mainly due to a decrease in deferred taxes related to carryforward losses in MaSTherCell. This followed a Belgian tax reform bill approved in December 2017, as well as increased taxable income at Masthercell.

Comparison of the Nine Months Ended August 31, 2018 to the Nine Months Ended August 31, 2017

Our financial results for the nine months ended August 31, 2018 are summarized as follows in comparison to the nine months ended August 31, 2017:

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Revenues	\$ 12,853	\$ 6,712
Cost of sales	7,220	4,900
Research and development expenses, net	3,456	1,906
Amortization of intangible assets	1,386	1,201
Selling, general and administrative expenses	10,675	7,887
Share in losses of associated company	732	348
Financial expense, net	3,164	2,534
Other income	(3,237)	-
Loss before income taxes	\$ 10,543	\$ 12,064

Revenues

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Services	\$ 9,493	\$ 5,600
Goods	3,360	1,112
Total	\$ 12,853	\$ 6,712

Our revenues for the nine months ended August 31, 2018 were \$12,853 thousand, as compared to \$6,712 thousand for the corresponding period in 2017, representing an increase of 91%. The increase in revenues for the nine months ended August 31, 2018 compared to the corresponding period in 2017 is attributable to an increase of \$2.9 million in the volume of the services provided by MaSTherCell, resulting primarily from the extension of existing customer service contracts with biotechnology clients, as well as from revenues generated from existing manufacturing agreements.

In March 2018, MaSTherCell entered into an agreement with ZELLUNA Immunotherapy to develop and manufacture TCR adoptive cell therapy platform for which MaSTherCell has recognized revenue of approximately \$515 thousand during the three months ended August 31, 2018.

In April 2018, MaSTherCell entered into an agreement with a US customer to manufacture autologous TIL therapies for which MaSTherCell has recognized revenue of approximately \$1.1 million during the three months ended August 31, 2018.

In addition, we acquired all the issued and outstanding share capital of Atvio, our Israel based CDMO partner since August 2016, and 94.2% of the share capital of CureCell, our Korea based CDMO partner since March 2016, which reflected an increase in our revenues for services provided of \$823 thousand during the three months ended August 31, 2018.

ExpensesCost of Revenues

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 3,309	\$ 2,050
Stock-based compensation	28	-
Professional fees and consulting services	98	83
Raw materials	3,147	1,588
Depreciation and amortization expenses, net	293	944
Other expenses	345	235
	\$ 7,220	4,900

Cost of revenues for the nine months ended August 31, 2018 were \$7,220 thousand, as compared to \$4,900 thousand, during the same period in 2017, representing an increase of 47%. The increase for the nine months ended August 31, 2018 as compared to the corresponding period in 2017 is primarily attributed to the following: (i) an increase in salaries and related expenses primarily attributable to an increase in personnel of MaSTherCell's production, quality control and quality assurance departments in order to respond to the acquisitions of new projects and services agreement and salaries and related expenses of \$740 thousand related to Atvio and CureCell; and (ii) an increase of \$1,559 in raw materials due to an increase in the volume of the services provided by MaSTherCell, as well as from revenues generated from existing manufacturing agreements.

Research and Development Expenses

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 1,497	\$ 872
Stock-based compensation	446	564
Professional fees and consulting services	273	103
Lab expenses	1,373	881
Depreciation expenses, net	136	-
Other research and development expenses	256	109
Less grant	(525)	(623)
Total	\$ 3,456	\$ 1,906

Research and development expenses for the nine months ended August 31, 2018 were \$3,456 thousand, as compared to \$1,906 thousand for the same period in 2017, representing an increase of 81%. The increase in lab expenses in the nine months ended August 31, 2018 is primarily attributable to an increase in new therapeutic development in the U.S. and an increase in salaries and related expenses of approximately \$625, mostly attributed to the DGO6 project.

Selling, General and Administrative Expenses

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Salaries and related expenses	\$ 2,999	\$ 1,774
Stock-based compensation	2,333	902
Accounting and legal fees	1,540	1,281
Professional fees	1,704	1,568
Rent and related expenses	905	624

Edgar Filing: Orgenesis Inc. - Form 10-Q

Business development	887	546
Expenses related to a joint venture	-	865
Other general and administrative expenses	307	327
Total	\$ 10,675	\$ 7,887

38

Selling, general and administrative expenses for the nine months ended August 31, 2018 were \$10,675 thousand, as compared to \$7,887 thousand for the same period in 2017, representing an increase of 35.3%. The increase in selling, general and administrative expenses in the nine-month period in 2018 compared to the same period in 2017 is primarily attributable to the following: (i) an increase of \$1,225 thousand in salaries and related expenses primarily attributable to an increase in salaries as result of additional managerial positions as well as an internal transformation program implemented in MaSTherCell in the second quarter of 2017 to evolve from an organization based on projects to a matrix organization supported by transversal departments focusing on value creation; (ii) an increase of \$1,431 thousand in non-cash stock-based compensation mainly resulting from grants of options to consultants and key personnel during the nine months of 2018; and (iii) a general increase in our expenses related to Atvio and CureCell.

Financial Expenses, net

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	\$ 48	\$ (297)
Stock-based compensation related to warrants granted to bondholder and shares and units granted to creditor	-	1,349
Interest expense on convertible loans and loans	2,934	987
Foreign exchange loss, net	55	483
Other expenses	127	12
Total	\$ 3,164	\$ 2,534

Financial expenses, net for the nine months ended August 31, 2018, increased by 24.8%, or \$630 thousand, compared to the same period in 2017. The decrease in financial expenses is mainly attributable to the following: (i) an increase of \$345 thousand in the fair value of the put option of Atvio; (ii) an increase in interest expenses on convertible loans due to recognition of the unrecognized discount related to a beneficial conversion feature as additional interest expenses upon conversion of convertible loans; (iii) a decrease of \$1,349 thousand due to stock-based compensation related to warrants granted to bondholder and shares and units granted to creditor.

Tax Expenses

	Nine Months Ended August 31,	
	<u>2018</u>	<u>2017</u>
	(in thousands)	
Tax expenses	1,680	493
Total	\$ 1,680	\$ 493

Tax expenses for the nine months ended August 31, 2018, increased by \$1,187 thousand, compared to the same period in 2017. The increase in tax expenses is mainly due to a decrease in deferred taxes related to carryforward losses in MaSTherCell. This followed a Belgian tax reform bill approved in December 2017, as well as increased taxable income at Masthercell.

Working Capital

	August 31, 2018		November 30, 2017
		(in thousands)	
Current assets	\$ 24,654	\$	7,295
Current liabilities	14,953		16,914
Working capital (deficiency)	\$ 9,701	\$	(9,619)

Current assets increased by \$17,359 thousand, which was primarily attributable to the following: (i) an increase in cash and cash equivalents due to proceeds from private placements of debt and equity securities, initial cash payment of \$10.3 million from GPP-II to our subsidiary, Masthercell Global and an increase of \$303 thousand due to the acquisition of CureCell and Atvio; (ii) an increase in inventory and accounts receivable due to the acquisition of CureCell and higher sales of MaSTherCell.

Current liabilities decreased by \$1,961 thousand, which was primarily attributable to (i) a decrease of \$2.4 million in current maturities of convertible loans due to the conversion of the outstanding amounts on these loans into units of shares of common stock and warrants in the nine months ended in August 31, 2018; (ii) an increase in deferred revenues of \$1.3 million due to the increases sales of MaSTherCell; (iii) a decrease of \$1,576 thousand in accounts payable and accrued expenses and other payables mainly as a result of new payment schedule processes and payment of debts to service providers during the nine months ended August 31, 2018.

Liquidity and Capital Resources

	Nine Months Ended August 31,	
	2018	2017
	(in thousands)	
Net loss	\$ (12,223)	\$ (12,557)
Net cash used in operating activities	(12,473)	(3,436)
Net cash used in investing activities	(4,219)	(1,443)
Net cash provided by financing activities	30,511	4,350
Increase (decrease) in cash and cash equivalents	\$ 13,819	\$ (529)

Since inception, we have funded our operations primarily through private placements and debt instruments and through revenues generated from the activities of MaSTherCell, our Belgian Subsidiary. As of August 31, 2018, we had positive working capital of \$9.7 million, including cash and cash equivalents and restricted cash of \$17.1 million.

Net cash used in operating activities was approximately \$12.5 million for the nine months ended August 31, 2018, as compared with net cash used in operating activities of approximately \$3.4 million for the same period in 2017. We expanded our pre-clinical studies in the U.S., Israel, Belgium and South Korea. The increase reflects management's focus on moving our trans-differentiation technology with first indication in Type 1 Diabetes to the next stage towards clinical trials. We also expanded our global activity of the CDMO business with Masthercell Global, while maintaining the same level of cash used in operating activities as a result of the increased revenues at our subsidiaries MaSTherCell, CureCell and Atvio, thereby increasing gross profit and generating cash to pay our ongoing operating expenses. Additionally, we improved payment terms to our service providers.

Net cash used in investing activities for the nine months ended August 31, 2018 was approximately \$4.2 million, as compared with approximately \$1.4 million for the same period in 2017. Net cash used in investing activities was primarily for additions to fixed assets at our subsidiaries, MaSTherCell and CureCell.

During the nine months ended August 31, 2018, our financing activities consisted of (i) proceeds from private placements of our equity securities and exercise of equity-linked instruments in the net amount of approximately \$16.5 million through the issuance of 1,766,369 restricted shares of common stock and additional 1,638,292 three-year warrants exercisable at a per share exercise price of \$6.24 and (ii) proceeds of \$720 thousand from the issuance of convertible loans from July 2016 to January 2018. Through August 31, 2018, these convertible loans were converted into units of the Company's securities, consisting of 116,296 shares of common stock and warrants to purchase 116,296 shares of common stock at a per share exercise price of \$6.24.

Liquidity and Capital Resources Outlook

We believe that our business plan will provide sufficient liquidity to fund our operating needs for the next 12 months. However, there are factors that can impact our ability continue to fund our operating needs, including:

- our ability to expand sales volume, which is highly dependent on implementing our growth strategy in Masthercell Global;
- restrictions on our ability to continue receiving government funding for our CT business;
- additional CDMO expansion into other regions that we may decide to undertake; and
- the need for us to continue to invest in operating activities to remain competitive or acquire other businesses and technologies and to complement our products, expand the breadth of our business, enhance our technical capabilities or otherwise offer growth opportunities.

If we cannot effectively manage these factors, we may need to raise additional capital before such date to fund our operating needs.

From December 1, 2017 to the date of this report on Form 10-Q, we raised an aggregate of \$20 million in private placements of our equity and equity-linked securities and convertible loans.

For the nine months ended August 31, 2018, we had been funding operations primarily from the proceeds from private placements of our convertible debt and equity securities and from revenues generated by MaSTherCell. From December 2017 through August 2018, we received, through MaSTherCell, proceeds of approximately \$11.5 million in revenues and accounts receivable from customers and \$16.5 million from the private placement to accredited investors of our equity and equity-linked securities and convertible loans.

The equity investment in November 2017 by SFPI in MaSTherCell of €5 million (approximately \$5.9 million), which includes the conversion of €1 million in an outstanding loan by SFPI to MaSTherCell, will cover costs associated with an expansion of MaSTherCell's manufacturing and production capabilities.

We believe that the investment consummated in June 2018 by an affiliate of Great Point in our newly formed subsidiary, Masthercell Global, which included an initial gross payment amount of \$11.8 million and, subject to meeting certain specified financial targets and other conditions over the course of 2018 and 2019, an additional \$13.2 million, should cover the costs associated with the current business plan of Masthercell Global

From September 1 through October 15, 2018, we raised \$3.4 million from the institutional investor with whom we entered into definitive agreements in January 2017 for the private placement of units of our securities for aggregate subscription proceeds to us of \$16 million payable through August 2018.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of August 31, 2018, we conducted an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"). The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods and that such disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of August 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at reasonable assurance level due to a material weakness in internal control over financial reporting, as further described below.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As disclosed in Item 9A of our Annual Report on Form 10-K for the year ended November 30, 2017, our management concluded that our internal control over financial reporting was not effective at November 30, 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The limitation of our internal control over financial reporting was due to the applied risk-based approach which is indicative of many small companies with limited number of staff in corporate functions implying:

- (i) Improved but insufficient segregation of duties with control objectives; and
- (ii) Insufficient controls over period end financial disclosure and reporting processes.

Our management believes the weaknesses identified above have not had any material effect on our financial results.

We are committed to maintaining a strong internal control environment and believe that our remediation efforts specified in Item 9A of our Annual Report on Form 10-K for the year ended November 30, 2017 represent significant improvements in our control environment. We expect that our remediation efforts will continue through the end of 2018 and into 2019, although the material weakness will not be considered remediated until the applicable internal controls operate for a sufficient period, and management has concluded, through testing, that these controls are operating effectively.

From the beginning of the third quarter of 2018, management introduced internal control and review procedures including the hiring of a Sarbanes and Oxley (SOX) expert in order to remediate the material weaknesses in internal controls referred to above.

Changes in Internal Control Over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes.

Except for the material weakness and associated remediation plan, during the quarter ended August 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We know of no material pending legal proceedings to which the Company or its subsidiaries are a party or of which any of its properties, or the properties of its subsidiaries, are the subject. In addition, we do not know of any such proceedings contemplated by any governmental authorities.

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

ITEM 1A. RISK FACTORS

An investment in the Company's common stock involves a number of very significant risks. You should carefully consider the risk factors included in the Risk Factors section of the Annual Report on Form 10-K for the year ended November 30, 2017, as filed with the Securities & Exchange Commission on February 28, 2018, in addition to other information contained in those reports and in this quarterly report in evaluating the Company and its business before purchasing shares of our common stock. The Company's business, operating results and financial condition could be adversely affected due to any of those risks.

In addition, since the filing of our Annual Report on Form 10-K for the year ended November 30, 2017, we have identified the following additional risk actors:

Our subsidiary, Masthercell Global, may not receive the future payments pursuant to the Stock Purchase Agreement with GPP-II.

The purchase price for the Masthercell Global Preferred Stock was up to \$25 million, subject to certain adjustments, of which \$11.8 million was paid in cash at closing. The Stock Purchase Agreement also requires GPP-II to make up to two additional payments to Masthercell Global if certain specified EBITDA (as defined in the Stock Purchase Agreement) and revenue targets are satisfied by Masthercell Global during each of years 2018 and 2019. For each of those fiscal years in which such specified EBITDA and revenue targets are satisfied by Masthercell Global, GPP-II will be obligated to pay an additional \$6.6 million, subject to adjustment, to Masthercell Global shortly after the end of that fiscal year. To earn such contingent payment for the 2018 fiscal year, Masthercell Global must (i) during the twelve month period ending on or prior to December 31, 2018, generate Net Revenue equal to or greater than €14,100,000 and EBITDA equal to or greater than €1,800,000, and (ii) by December 31, 2018, obtain stockholder approval of the Stockholders' Agreement Terms in accordance with law and in a manner that will ensure that GPP-II is able to exercise its rights under the Stockholders' Agreement without any further action or approval by GPP-II, us, our stockholders, or any other person, which includes the stockholder approval sought in our proxy statement for our annual meeting of stockholders (Proper Approval). To earn such contingent payment for the 2019 fiscal year, Masthercell Global must (i) during the twelve-month period ending on or prior to December 31, 2019, generate Net Revenue equal to or greater than €19,100,000 and EBITDA equal to or greater than €3,900,000, and (ii) by December 31, 2019, obtain Proper Approval, if not already obtained. Accordingly, if our stockholders do not approve the Stockholders' Agreement Terms and do not meet the applicable Net Revenue and EBITDA targets, Masthercell Global will not be eligible to receive the future payments. In addition, in such event, GPP-II will obtain the right to put to us (or, at our discretion, to Masthercell Global if Masthercell Global shall then have the funds available to consummate the transaction) its shares in Masthercell Global.

GPP-II may force the sale of Masthercell Global which may result in GPP-II receiving a greater value than the Company and its shareholders.

At any time following the earlier to occur of (i) after June 28, 2020 or (ii) Masthercell Global's failure to generate positive EBITDA for any twelve (12) month period as determined on a quarterly basis prior to June 28, 2020 or its failure to generate at least \$1,000,000 of EBITDA during any such twelve (12) month period after June 28, 2020 (collectively, a Material Underperformance Event), GPP-II has the right, in its sole discretion, to approve and force the sale of Masthercell Global. While we have the right of first refusal with respect to acquiring Masthercell Global in the entirety, if GPP-II elects to exercise such a right, if we are not in the position to do so, GPP-II may cause the sale of Masthercell Global to any third party on terms GPP-II approves on an arm's length basis and subject to the receipt of a fairness opinion. If this occurs, we are contractually obligated to approve such a sale and execute any documents as required by GPP-II. We must also share in any costs and expenses relating to such a sale on a pro rata basis. Based on this, there may be a situation where GPP-II approves a sale that is more valuable or beneficial to GPP-II than to our Company and our shareholders, and we will not be able to prevent such a transaction. A sale of Masthercell Global could have impacts to the CDMO activities of Orgenesis as conducted through Masthercell Global and to Orgenesis overall value as a whole.

GPP-II may, under certain circumstances, assume control of the Board of Directors of our subsidiary, Masthercell Global, which would result in our inability to control and direct the activities of such subsidiary.

Currently, the Board of Directors of Masthercell Global is comprised of seven (7) directors, four (4) of whom are appointed by us (one of whom must be an industry expert (the Industry Expert Director)) and three (3) of whom are appointed by GPP-II. In the event the Industry Expert Director is removed or replaced without the prior written approval of GPP-II, or a Material Underperformance Event has occurred after June 28, 2020, GPP-II has the right to increase the size of the Board of Directors of Masthercell Global and appoint additional directors to fill such vacancies so that GPP-II appointments represent a majority of the directors. If this were to occur, GPP-II would control the Board of Directors of Masthercell Global and will be entitled to direct its activities and approve any transactions of Masthercell Global, even if such transactions provide greater value to GPP-II than they do to Orgenesis and its stockholders. This lack of control could diminish the value of Masthercell Global as it relates to Orgenesis' overall activity and significantly impact CDMO activities of Orgenesis as conducted through Masthercell Global.

GPP-II has the right to buy our shares in Masthercell Global upon the occurrence of certain events resulting in Orgenesis not holding any shares in Masthercell Global.

GPP-II has the right to purchase all of the shares of stock we hold in Masthercell Global if any of the following occurs: (i) there is an Activist Shareholder (as defined in the Stockholders' Agreement) of the Company; (ii) the Chief Executive Officer and/or Chairman of the Board of Directors of Orgenesis is replaced prior to June 28, 2023; (iii) there is a Change of Control (as defined in the Stockholders' Agreement) of Orgenesis; or (iv) the Industry Expert Director is removed or replaced without the prior written consent of GPP-II. If any of these events occur, GPP-II, upon notice to Orgenesis, can force Orgenesis to sell all of the securities it holds in Masthercell Global to GPP-II based upon a valuation of Masthercell Global to be determined by one of the top ten (10) independent third-party accounting firms in the United States with experience in performing valuations as selected by GPP-II. This right of GPP-II expires if GPP-II fails to exercise this right within three (3) years from the first occurrence of any of the events listed above. In the event GPP-II does exercise its right following the occurrence of any such event, Orgenesis shall cease to be a stockholder of Masthercell Global and will no longer derive any benefits from this subsidiary or its activities. This would also affect the CDMO activities being conducted by Orgenesis through Masthercell Global.

GPP-II has the right to effectuate a spin-off of our subsidiary, Masthercell Global

In addition to the other rights GPP-II has obtained under the Stockholders' Agreement, GPP-II also has the right to effectuate a spin-off of Masthercell Global upon the earlier to occur of: (i) any of the four events listed in the section above or (ii) ninety (90) days after GPP-II provides Orgenesis of its intent to exercise this right provided that such notice cannot be delivered by GPP-II before June 28, 2020. Such a spin-off would be based on a valuation of Masthercell Global as determined in accordance with the terms of the Stockholders' Agreement. If such a spin-off was

to occur, Masthercell Global would no longer be a subsidiary of Orgenesis and Orgenesis would not receive the benefits or value of such a subsidiary. This would also affect the CDMO activities being conducted by Orgenesis through Masthercell Global.

If GPP-II opts to exchange its Masthercell Global Preferred Stock for shares of our common stock, we could potentially issue a substantial number of shares of our common stock to GPP-II, which may result in significant dilution to our existing stockholders.

The Stockholders Agreement provides that GPP-II is entitled, at any time, to convert its share capital in Masthercell Global for our common stock (such exchange option being the Stock Exchange Option). Under the Stock Exchange Option, GPP-II is entitled to exchange the Masthercell Global Preferred Stock for our common stock based on an exchange price (as defined in the Stockholders Agreement) that is not currently known. If GPP-II opts to exchange its Masthercell Global Preferred Stock for shares of our common stock, we could potentially issue a substantial number of shares of our common stock to GPP-II. The common stock issuable to GPP-II upon exchange of the Masthercell Global Preferred Stock for our common stock could have a depressive effect on the market price of our common stock by increasing the number of shares of common stock outstanding. Such downward pressure could encourage short sales by certain investors, which could place further downward pressure on the price of the common stock. Accordingly, the number of shares of outstanding common stock may increase significantly and the ownership interests and proportionate voting power of the existing stockholders may be significantly diluted.

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

The following paragraph sets forth certain information with respect to all securities sold by us during the three months ended August 31, 2018 without registration under the Securities Act:

During the three months ended August 31, 2018, we entered into definitive agreements with accredited and other qualified investors relating to a private placement of 862,263 units. Each unit is comprised of (i) one share of the Company's common stock and (ii) three-year warrant to purchase up to an additional one share of the Company's Common Stock at a per share exercise price of \$6.24, for aggregate proceeds to the Company of approximately \$5.6 million.

These securities were not registered under the Securities Act of 1933, as amended (the "Securities Act"), but qualified for exemption under Section 4(a)(2) of the Securities Act and Regulation S promulgated thereunder. The securities were exempt from registration under Section 4(a)(2) of the Securities Act and Regulation S because the issuance of such securities by the Company did not involve a "public offering," as defined in Section 4(a)(2) of the Securities Act, the Investor's representations that it is not a U.S. Person as that term is defined in Rule 902(k) of Regulation S, and that it is acquiring the securities for its own account for investment purposes and not as nominee or agent, and not with a view to the resale or distribution thereof, and that the investor understands that the securities may not be sold or otherwise disposed of without registration under the Securities Act and any applicable state securities laws, or an applicable exemption therefrom.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

In October 2018, the Company raised \$3.4 million from the institutional investor referred to in Note 7 entitling such investor to 550,481 shares of Common Stock and three-year warrants for an additional 550,481 shares. Following this remittance and those referred to in Note 7, the Company has received, as of October 12, 2018, a total of \$16 million out of the committed \$16 million subscription proceeds under such agreement.

The issuance of shares of Orgenesis common stock to these investors will be made in reliance on one or more exemptions or exclusions from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), including Section 4(a)(2) of the Securities Act, Regulation D promulgated under the Securities Act, and Regulation S promulgated under the Securities Act, and the exemption from qualification under applicable state securities laws.

ITEM 6. EXHIBITS

No.	Description
(10)	Material Agreements
<u>10.1*</u>	<u>Collaboration and License Agreement, dated as of June 18, 2018, between Orgenesis Inc. and Mircod Limited</u>
(31)	Rule 13a-14(a)/15d-14(a) Certification
<u>31.1*</u>	<u>Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002</u>
<u>31.2*</u>	<u>Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002</u>
(32)	Section 1350 Certification
<u>32.1*</u>	<u>Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002</u>
<u>32.2*</u>	<u>Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002</u>
(101)*	Interactive Data Files
<u>101.INS</u>	<u>XBRL Instance Document</u>
<u>101.SCH</u>	<u>XBRL Taxonomy Extension Schema Document</u>
<u>101.CAL</u>	<u>XBRL Taxonomy Extension Calculation Linkbase Document</u>
<u>101.DEF</u>	<u>XBRL Taxonomy Extension Definition Linkbase Document</u>
<u>101.LAB</u>	<u>XBRL Taxonomy Extension Label Linkbase Document</u>
<u>101.PRE</u>	<u>XBRL Taxonomy Extension Presentation Linkbase Document</u>

* Filed herewith.

SIGNATURES

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

ORGENESIS INC.

By:

/s/ Vered Caplan

Vered Caplan

President & Chief Executive Officer

(Principal Executive Officer)

Date: October 12, 2018

/s/ Neil Reithinger

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting
Officer)

Date: October 12, 2018