UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended June 30, 2019

or

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

For the Transition Period from _____to _____

Commission file number: 000-54329

ORGENESIS INC.

(Exact name of registrant as specified in its charter)

Nevada	**98-0583166**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

20271 Goldenrod Lane
Germantown, MD 20876
(Address of principal executive offices) (zip code)

(480) 659-6404
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbols(s)	Name of each exchange on which registered
Common Stock	ORGS	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	[ ] Accelerated filer	[X]
Non-accelerated filer	[ ] Smaller reporting company	[ ]
(Do not check if a smaller reporting company)	Emerging Growth Company	[ ]

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 [X]

As of August 8, 2019, there were 16,140,962 shares of registrant's common stock outstanding.

ORGENESIS INC.
FORM 10-Q
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2019

TABLE OF CONTENTS

PART I –FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	As of	
	June 30, 2019	**November 30, 2018**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,111	$ 16,064
Restricted cash	544	392
Accounts receivable, net	6,905	4,151
Prepaid expenses and other receivables	1,078	913
GPP receivable, see Note 5	-	6,600
Grants receivable	233	441
Inventory	2,221	1,736
Total current assets	27,092	30,297
NON-CURRENT ASSETS:		
Deposits	622	85
Loans to related party, see Note 5	2,063	1,007
Property and equipment, net	14,295	11,901
Intangible assets, net	15,396	16,700
Operating lease right-of-use assets	9,988	-
Goodwill	15,066	15,165
Other assets	33	292
Total non-current assets	57,346	45,150
TOTAL ASSETS	$ 84,555	$ 75,447

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)

	As of	
	June 30, 2019	**November 30, 2018**
Liabilities and Equity		
CURRENT LIABILITIES:		
Accounts payable	$ 6,786	$ 3,804
Accrued expenses and other payables	1,537	2,060
Employees and related payables	3,311	3,006
Advance payments on account of grant	1,204	1,724
Short-term loans and current maturities of long-term loans	633	647
Contract liabilities	7,355	5,317
Current maturities of long-term finance leases	236	209
Current maturities of operating leases	1,613	-
Current maturities of convertible loans	389	378
Total current liabilities	23,064	17,145
LONG-TERM LIABILITIES:		
Non-current operating leases	7,676	-
Loans payable	1,435	1,662
Convertible loans	8,319	1,038
Retirement benefits obligation	61	265
Deferred taxes	2,082	1,702
Long-term finance leases	589	638
Other long-term liabilities	262	195
Total long-term liabilities	20,424	5,500
TOTAL LIABILITIES	43,488	22,645
COMMITMENTS		
REDEEMABLE NON-CONTROLLING INTEREST	24,313	24,153
EQUITY:		
Common stock of $0.0001 par value, 145,833,334 shares authorized, 16,115,333, 15,540,333 and 14,951,783 shares issued and outstanding as of June 30, 2019, December 31, 2018 and November 30, 2018, respectively	2	1
Additional paid-in capital	94,415	88,082
Receipts on account of shares to be allotted	-	2,253
Accumulated other comprehensive income	373	425
Accumulated deficit	(78,675)	(62,411)
Equity attributable to Orgenesis Inc.	16,115	28,350
Non-controlling interest	639	299
Total equity	16,754	28,649
TOTAL LIABILITIES AND EQUITY	$ 84,555	$ 75,447

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

ORGENESIS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. Dollars in Thousands, Except Share and Loss Per Share Amounts)
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2019	May 31, 2018	June 30, 2019	May 31, 2018
REVENUES	$ 7,757	$ 3,987	$ 15,058	$ 6,623
COST OF REVENUES	4,935	2,195	9,279	3,839
GROSS PROFIT	2,822	1,792	5,779	2,784
RESEARCH AND DEVELOPMENT EXPENSES, net	1,709	788	6,859	1,554
AMORTIZATION OF INTANGIBLE ASSETS	516	445	1,033	881
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	5,883	3,323	11,483	6,667
OTHER INCOME, net	(32)	-	(69)	(316)
OPERATING LOSS	5,254	2,764	13,527	6,002
FINANCIAL (INCOME) EXPENSES, net	53	(587)	193	2,094
SHARE IN NET LOSS OF ASSOCIATED COMPANIES	-	576	-	530
LOSS BEFORE INCOME TAXES	5,307	2,753	13,720	8,626
TAX (INCOME) EXPENSES	518	(277)	555	(673)
NET LOSS	$ 5,825	$ 2,476	$ 14,275	$ 7,953
NET INCOME (LOSS) ATTRIBUTABLE TO NON-CONTROLLING INTERESTS (INCLUDING REDEEMABLE)	(624)	138	(763)	272
NET LOSS ATTRIBUTABLE TO ORGENESIS INC.	$ 5,201	$ 2,614	$ 13,512	$ 8,225
LOSS PER SHARE:				
Basic	$ 0.36	$ 0.20	$ 0.91	$ 0.69
Diluted	$ 0.36	$ 0.20	$ 0.91	$ 0.69
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:				
Basic	16,001,439	13,140,119	15,772,333	11,971,389
Diluted	16,001,439	13,140,119	15,772,333	11,971,389
COMPREHENSIVE LOSS:				
Net loss	$ 5,825	$ 2,476	$ 14,275	$ 7,953
Other comprehensive (income) loss - translation adjustments	(188)	1,056	296	349
Comprehensive loss	$ 5,637	$ 3,532	$ 14,571	$ 8,302
Comprehensive income (loss) attributed to non-controlling interests (including redeemable)	(624)	138	(763)	272
COMPREHENSIVE LOSS ATTRIBUTED TO ORGENESIS INC.	$ 5,013	$ 3,670	$ 13,808	$ 8,574

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	Addi-tional paid-in capital	Receipts on Account of shares to be Allotted	Accumulated Other Comprehen-sive Income (Loss)	Accumu-lated Deficit	Equity Attri-buted to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at January 1, 2019	15,540,333	$ 2	$ 90,597	$ -	$ 669	$ (65,163)	$ 26,105	$ 645	$ 26,750
Changes during the six months ended June 30, 2019:									
Stock-based compensation to employees and directors			1,466				1,466	31	1,497
Stock-based compensation to service providers	50,000	*	467				467		467
Stock based Compensation for JV collaborations (see note 5)	525,000	*	2,641				2,641		2,641
Adjustment to redemption value of redeemable non-controlling interest			(853)				(853)		(853)

Issuance of warrants with respect to convertible loans			97				97		97
Comprehensive loss for the period					(296)	(13,512)	(13,808)	(37)	(13,845)
Balance at June 30, 2019	16,115,333	$ 2	$ 94,415	$ -	$ 373	$ (78,675)	$ 16,115	$ 639	$ 16,754
Balance at December 1, 2017	9,872,659	$ 1	$ 55,334	$ 1,483	$ 1,425	$ (44,120)	$ 14,123	$ -	$ 14,123
Changes during the six months ended May 31, 2018:									
Stock-based compensation to employees and directors			801				801		801
Stock-based compensation to service providers			1,026				1,026		1,026
Issuance of shares and warrant due to conversion of convertible loans	1,341,134	*	7,330				7,330		7,330
Issuance of shares and receipts on account of shares and warrants to be allotted	1,958,806	*	11,218	(1,245)			9,973		9,973

Beneficial conversion feature of convertible loans and Warrants issued			323				323		323
Issuance of Shares due to exercise of warrants	128,077	*	799				799		799
Comprehensive loss for the period					(349)	(8,225)	(8,574)		(8,574)
Balance at May 31, 2018	13,300,676	$ 1	$ 76,831	$ 238	$ 1,076	$ (52,345)	$ 25,801	$ -	$ 25,801
Balance at April 1, 2019	16,102,000	$ 2	$ 94,049	$ -	$ 185	$ (73,474)	$ 20,762	$ 639	$ 21,401
Changes during the three months ended June 30, 2019:									
Stock-based compensation to employees and directors			728				728	11	739
Stock-based compensation to service providers	13,333	*	152				152		152
Adjustment to redemption value of redeemable non-controlling interest			(611)				(611)		(611)
Issuance of warrants with respect to convertible loans			97				97		97

Comprehensive loss for the period					188	(5,201)	(5,013)	(11)	(5,024)
Balance at June 30, 2019	16,115,333	$ 2	$ 94,415	$ -	$ 373	$ (78,675)	$ 16,115	$ 639	$ 16,754

*represent an amount lower than $ 1 thousand

Balance at March 1, 2018	10,273,301	$ 1	$ 61,079	$ 5,997	$ 2,132	$ (49,731)	$ 19,478	$ -	$ 19,478
Changes during the three months ended May 31, 2018:									
Stock-based compensation to employees and directors			415				415		415
Stock-based compensation to service providers		*	322				322		322
Issuance of shares and warrants due to conversion of convertible loans	1,341,134		5,610	(4,148)			1,462		1,462
Issuance of shares and receipts on account of shares and warrants to be allotted	1,558,164		8,607	(1,611)			6,996		6,996
Issuance of shares due to exercise of warrants	128,077		799				799		799

Beneficial conversion feature of convertible loans and warrants issued			(1)				(1)		(1)
Comprehensive loss for the period					(1,056)	(2,614)	(3,670)		(3,670)
Balance at May 31, 2018	13,300,676	$ 1	$ 76,831	$ 238	$ 1,076	$ (52,345)	$ 25,801	$ -	$ 25,801

*represents an amount lower than $ 1 thousand

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

	Six Months Ended	
	June 30, 2019	**May 31, 2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(14,275)	(7,953)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,964	1,827
Stock based compensation for strategic collaborations	2,641	-
Capital gain, net	(5)	-
Share in income of associated company	-	530
Depreciation and amortization expenses	1,907	1,282
Change in fair value of embedded derivatives	-	(490)
Net changes in operating leases	(700)	-
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	58	2,522
Changes in operating assets and liabilities:		
Increase in accounts receivable	(3,678)	(19)
Increase in inventory	(571)	(533)
Increase in other assets	-	(9)
Decrease in related parties, net	(38)	(680)
Effect of exchange differences on inter-company balances	103	-
Decrease (Increase) in prepaid expenses and other accounts receivable	85	(411)
Increase (decrease) in accounts payable	1,803	(1,509)
Decrease in accrued expenses and other payables	(111)	(327)
Increase (decrease) in employee and related payables	62	(654)
Increase in contract liabilities	2,198	1,070
Decrease in advance payments and receivables on account of grant, net	(49)	(878)
Increase (decrease) in deferred taxes	438	(673)
Net cash used in operating activities	(8,168)	(6,905)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in loan to JV with a related party	(1,000)	-
Sale of property and equipment	80	-
Purchase of property and equipment	(2,802)	(2,634)
Investments in associate	-	(345)
Investment in deposits	(225)	-
Net cash used in investing activities	(3,947)	(2,979)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Contingent payment received from redeemable non-controlling interest related to GPP transaction (See Note 5)	6,600	-
Proceeds from issuance of shares and warrants (net of transaction costs)	-	10,773
Proceeds from issuance of convertible loans (net of transaction costs)	7,500	720
Repayment of convertible loans and convertible bonds	-	(177)
Repayment of short and long-term debt	(304)	(213)
Net cash provided by financing activities	13,796	11,103
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	1,681	1,219
EFFECT OF EXCHANGE RATE CHANGES ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(25)	147

CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	14,999	3,518
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	16,655	4,884

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

NOTE 1 – DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc., a Nevada corporation (the "Company"), is a biotechnology company specializing in the development, manufacturing and provision of services in the cell and gene therapy industry. The Company operates through two independent business platforms: (i) a point-of-care ("POCare") cell therapy ("POC") platform and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform, which provides contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business") conducted through its subsidiary, Masthercell Global Inc., a Delaware corporation ("Masthercell Global"). Through the POC platform, the Company's aim is to further the development of Advanced Therapy Medicinal Products ("ATMPs") through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. The Company out-licenses these ATMPs through regional partners to whom the Company also provides regulatory services, pre-clinical studies, intellectual property services, and co-development services (collectively "POC Services") to support their activity in order to reach patients in a point-of-care hospital setting. Currently, the Company's POC Services constitute the entirety of the Company's revenue in the POC platform. Through the CDMO platform, the Company is focused on providing contract manufacturing and development services for biopharmaceutical companies.

Activities in the POC platform include a multitude of cell therapies, including autoimmune, oncologic, neurologic and metabolic diseases and other indications. The Company plans to provide POC Services to its joint venture ("JV") regional partners, pharmaceutical and biotech companies as well as research institutions and hospitals that have cell therapies in clinical development. The Company believes that each of these customers and collaborations represents a revenue and growth opportunity upon regulatory approval. Furthermore, the Company's trans-differentiation technology 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 pre-clinical animal models that the human derived AIP cells produce insulin in a glucose-sensitive manner. This trans-differentiation technology is licensed by Orgenesis Ltd. (the "Israeli Subsidiary") and is based on the work of Prof. Sarah Ferber, the Company's Chief Science Officer and a researcher at Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") in Israel. The 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.

The Company conducts the POC platform through its wholly-owned subsidiaries. The subsidiaries are as follows:

- United States: Orgenesis Maryland Inc. (the "U.S. Subsidiary") is the center of activity in North America currently focused on technology licensing, therapeutic collaborations and preparation for U.S. clinical trials.
- European Union: Orgenesis SPRL (the "Belgian Subsidiary") is the center of activity in Europe currently focused on process development and preparation of European clinical trials.
- Israel: Orgenesis Ltd. (the "Israeli Subsidiary") is a research and technology center, as well as a provider of regulatory, clinical and pre-clinical services.

The CDMO platform operates through Masthercell Global Inc. ("Masthercell Global"), which currently consists of the following subsidiaries: MaSTherCell S.A ("MaSTherCell") in Belgium, Atvio Biotech Ltd. ("Atvio") in Israel, CureCell Co., Ltd. ("CureCell") in South Korea and Masthercell U.S. LLC in the United States (collectively, the " Masthercell Global Subsidiaries"), having unique know-how and expertise for manufacturing in a multitude of cell types.

The Company operates its CDMO and POC platforms as two separate business segments.

These condensed consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries, including the U.S. Subsidiary, the Belgian Subsidiary, the Israeli Subsidiary, and the Masthercell Global Subsidiaries.

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.

b. Change in Fiscal Year End

On October 22, 2018, the Board of Directors of the Company approved a change in the Company's fiscal year end from November 30 to December 31 of each year. This change to the calendar year reporting cycle became effective on January 1, 2019.

As permitted under SEC rules, prior-period financial statements have not been recast as management believes (i) the six months ended June 30, 2019 are comparable to the six months ended May 31, 2018 and (ii) recasting prior-period results is not practicable or cost justified.

c. Liquidity

As of June 30, 2019, the Company has accumulated losses of approximately $78.7 million. Although the Company is showing positive revenues and gross profit trends on the CDMO platform, the Company expects to incur further losses in the POC platform.

To date, the Company has been funding operations primarily from proceeds raised from private placements of the Company's equity securities, issuance of equity-linked convertible debt and from operating cash flows generated from the POC and CDMO platforms. From January 1, 2019 through June 30, 2019, the Company received proceeds of approximately $13 million in revenues and accounts receivable from customers, $6.6 million from Great Point Partners, LLC and $7.5 million from convertible loans. In addition, from July 1, 2019 through August 8, 2019, the Company received proceeds of approximately $2.6 million in accounts receivable from customers. In May 2019, the Company agreed to a convertible loan with an investor for an aggregate amount of $5 million which has not yet been received (See Note 4).

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and expected level of expenditures for at least 12 months from the date of the issuance of the financial statements, although no assurance can be given that it will not need additional funds prior to such time. Additional funds may be necessary to finance some of the collaborations listed in Note 5. Also, if there are further increases in operating costs in general and administrative expenses for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, the Company will need to seek additional financing. In addition, additional funds may be necessary to finance some of the collaborations listed in Note 5.

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 (the "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 June 30, 2019, and the consolidated statements of comprehensive loss and the changes in equity for the three and six months ended June 30, 2019, and cash flows for the six-month period ended June 30, 2019. The interim results are not necessarily indicative of the results to be expected for the year ending December 31, 2019. 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, 2018.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

The accounting policies adopted are generally consistent with those of the previous financial year except for new policies adopted in the current year as described below.

Recently Issued Accounting Pronouncements- adopted by the Company

ASC 606 - Revenue from Contracts with Customers

On December 1, 2018, the Company adopted the new accounting standard ASC 606, *Revenue from Contracts with Customers* and the related amendments ("New Revenue Standard") to all contracts, using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was immaterial.

Revenue Recognition Prior to the Adoption of the New Revenue Standard

Refer to Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended November 30, 2018, for a summary of our significant accounting policies.

Revenue Recognition Following the Adoption of the New Revenue Standard

The Company's agreements are primarily service contracts that range in duration from a few months to one year. The Company recognizes revenue when control of these services is transferred to the customer for an amount, referred to as the transaction price, which reflects the consideration to which the Company is expected to be entitled in exchange for those goods or services.

A contract with a customer exists only when:

- the parties to the contract have approved it and are committed to perform their respective obligations;
- the Company can identify each party's rights regarding the distinct goods or services to be transferred ("performance obligations");
- the Company can determine the transaction price for the goods or services to be transferred; and
- the contract has commercial substance and it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

For the majority of its contracts, the Company receives non-refundable upfront payments. The Company does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between the time of transfer of the promised goods or services to the customer and the time the customer pays for these goods or services to be generally one year or less. The Company's credit terms to customers are in average between thirty and ninety days.

The Company does not disclose the value of unsatisfied performance obligations for contracts with original expected duration of one year or less.

Disaggregation of Revenue

The following table disaggregates the Company's revenues by major revenue streams.

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Revenue stream:		
Cell process development services	$ 4,060	$ 9,235
Tech transfer services	1,702	3,532
POC Services	962	962
Cell manufacturing services	1,033	1,329
Total	$ 7,757	$ 15,058

Nature of Revenue Streams

The Company operates through two platforms: (i) a point-of-care ("POCare") cell therapy platform ("POC") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform. Through its CDMO platform, the Company is focused on providing contract manufacturing and development services for biopharmaceutical companies. As of the second quarter of 2019, the Company commenced its POC services. However these services do not yet produce significant revenues.

The Company has three main revenue streams from its CDMO platform: cell process development services, tech transfer services, and upon success, cell manufacturing services.

Cell Process Development Services

Revenue recognized under contracts for cell process development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages and milestones are not interrelated or the customer is able to complete the services performed independently or by using competitors of the Company. In other contracts when the above circumstances are not met, the promises are not considered distinct and the contract represents one performance obligation. All performance obligations are satisfied over time, as there is no alternative use to the services it performs, since, in nature, those services are unique to the customer, which retain the ownership of the intellectual property created through the process. Additionally, due to the non-refundable upfront payment the customer pays, together with the payment term and cancellation fine, it has a right to payment (which include a reasonable margin), at all times, for work completed to date, which is enforceable by law.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices. For these contracts, the standalone selling prices are based on the Company's normal pricing practices when sold separately with consideration of market conditions and other factors, including customer demographics and geographic location.

The Company measures the revenue to be recognized over time on a contract by contract basis, determining the use of either a cost-based input method or output method, depending on whichever best depicts the transfer of control over the life of the performance obligation.

Tech Transfer Services

Revenue recognized under contracts for tech transfer services are considered a single performance obligation, as all work packages (including data collection, GMP documentation, validation runs) and milestones are interrelated. Additionally, the customer is unable to complete services of work performed independently or by using competitors of the Company. Revenue is recognized over time using a cost-based based input method where progress on the performance obligation is measured by the proportion of actual costs incurred to the total costs expected to complete the contract.

Cell Manufacturing Services

Revenues from cell manufacturing services represent a single performance obligation which is recognized over time. The progress towards completion will continue to be measured on an output measure based on direct measurement of the value transferred to the customer (units produced).

Significant Judgement and Estimates

The cost-based and output methods of revenue recognition require the Company to make estimates of costs to complete its projects and the percentage of completeness on an ongoing basis. Significant judgment is required to evaluate assumptions related to these estimates. The effect of revisions to estimates related to the transaction price (including variable consideration relating to reimbursement on a cost-plus basis on certain expenses) or costs to complete a project are recorded in the period in which the estimate is revised.

Practical Expedients

As part of ASC 606, the Company has adopted several practical expedients including that the Company's determination that it need not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between when the Company transfers a promised service to the customer and when the customer pays for that service will be one year or less.

Reimbursed Expenses

The Company includes reimbursed expenses in revenues and costs of revenue as the Company is primarily responsible for fulfilling the promise to provide the specified service, including the integration of the related services into a combined output to the customer, which are inseparable from the integrated service. These costs include such items as consumable, reagents, transportation and travel expenses, over which the Company has discretion in establishing prices.

Change Orders

Changes in the scope of work are common and can result in a change in transaction price, equipment used and payment terms. Change orders are evaluated on a contract-by-contract basis to determine if they should be accounted for as a new contract or as part of the existing contract. Generally, services from change orders are not distinct from the original performance obligation. As a result, the effect that the contract modification has on the contract revenue, and measure of progress, is recognized as an adjustment to revenue when they occur.

Costs of Revenue

Costs of revenue include (i) compensation and benefits for billable employees and personnel involved in production, data management and delivery, and the costs of acquiring and processing data for the Company’s information offerings; (ii) costs of staff directly involved with delivering services offerings and engagements; (iii) consumables used for the services; and (iv) other expenses directly related to service contracts such as courier fees, laboratory supplies, professional services and travel expenses.

Contract Assets and Liabilities

Contract assets are mainly comprised of trade receivables net of allowance for doubtful debts, which includes amounts billed and currently due from customers. Contract liabilities are mainly comprised of contract liabilities.

The activity for trade receivables is comprised of:

	Six Months Ended June 30, 2019
Balance as of beginning of period	$ 3,226
Additions	11,653
Collections	(7,960)
Exchange rate differences	(14)
Balance as of end of period	$ 6,905

The activity for contract liabilities is comprised of:

	Six Months Ended June 30, 2019
Balance as of beginning of period	$ 5,175
Adoption of ASC 606:	
Additions	5,018
Realizations	(2,811)
Exchange rate differences	(27)
Balance as of end of period	$ 7,355

ASU 2018-07 Stock based Compensation

In June 2018, the FASB issued ASU 2018-07, “Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” This guidance simplifies the accounting for non-employee share-based payment transactions. The amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods and services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. The standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606, “Revenue from Contracts with Customers.” This standard, adopted as of January 1, 2019, had no material impact on the Company’s consolidated financial statements for the six months ended June 30, 2019.

ASC 842 - Leases

In February 2016, the FASB issued ASU 2016-02, “Leases”, on the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). ASC 842 supersedes the previous leases standard, ASC 840, “Leases.” The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use ("ROU") asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification.

In July 2018, the FASB issued amendments in ASU 2018-11, which provide another transition method in addition to the existing transition method, by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, and to not apply the new guidance in the comparative periods they present in the financial statements. The guidance is effective for the interim and annual periods beginning on or after December 15, 2018. The Company has elected to apply the standard retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment.

The Company adopted the new leases standard as of January 1, 2019 using the transition method that provides for a cumulative-effect adjustment to retained earnings upon adoption. The consolidated financial statements for the six months ended June 30, 2019 are presented under the new standard, while the comparative period and transition period presented are not adjusted and continue to be reported in accordance with the historical accounting policy. For more information, see Note 8.

NOTE 3 - SEGMENT INFORMATION

The Chief Executive Officer ("CEO") is the Company’s chief operating decision-maker ("CODM"). Management has determined that there are two operating segments, based on the Company's organizational structure, its business activities and information reviewed by the CODM for the purposes of allocating resources and assessing performance.

POC Platform

Through the POC platform, the Company is focused on (i) the development of proprietary cell and gene therapies, including its autologous trans-differentiation technology, (ii) therapeutic collaborations and licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes and (iii) regulatory services, pre-clinical studies, intellectual property services, and co-development services (“POC Services”). Currently, the Company’s POC Services constitute the entirety of the Company’s revenue in the POC platform.

CDMO Platform

The CDMO platform is comprised of a specialization in cell manufacturing and development and includes two types of services to its customers: (i) manufacturing and development services and (ii) cGMP contract manufacturing services. The CDMO platform operates through Masthercell Global, which currently consists of MaSTherCell in Belgium, Atvio in Israel, CureCell in South Korea, and Masthercell U.S. LLC in the United States, each having unique know-how and expertise for manufacturing in a multitude of cell types.

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

Segment data for the six months ended June 30, 2019 is as follows:

	CDMO Platform	POC Platform	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 16,192	$ 962	$ (2,096)	$ 15,058
Cost of revenues	(8,898)	(901)	1,181	(8,618)
Segment gross profit (loss)	7,294	61	(915)	6,440
Research and development				
expenses, net	(293)	(4,291)	932	(3,652)
Operating expenses	(6,482)	(3,373)	(17)	(9,872)
Other income	69			69
Segment operating profit (loss)	$ 588	$ (7,603)		$ (7,015)
Adjustments to presentation of segment Adjusted EBIT:				
Depreciation and amortization	(1,897)	(10)		(1,907)
Segment performance	$ (1,309)	$ (7,613)		$ (8,922)

Reconciliation of segment performance to loss for the six months ended June 30, 2019:

	Six-Months Ended June 30, 2019 (in Thousands)
Segment performance	$ (8,922)
Stock-based compensation	(1,964)
Stock based compensation to First	
Choice	(2,641)
Financial expenses, net	(193)
Loss before income tax	$ (13,720)

Segment data for the six months ended May 31, 2018 is as follows:

	CDMO Platform	POC Platform	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 7,715	$ -	$ (1,092)	$ 6,623
Cost of revenues	(3,918)	-	388	(3,530)
Segment gross profit (loss)	3,797	-	(704)	3,093
Research and development				
expenses, net	-	(1,866)	704	(1,162)
Operating expenses	(2,183)	(2,995)		(5,178)
Other income	316	-		316
Segment operating profit (loss)	$ 1,930	$ (4,861)	$	(2,931)
Adjustments to presentation of segment Adjusted EBIT:				
Depreciation and amortization	(1,240)	(4)		(1,244)
Segment performance	$ 690	$ (4,865)	$	(4,175)

Reconciliation of segment performance to loss for the six months ended May 31, 2018:

	Six-Months Ended May 31, 2018 (in Thousands)
Segment performance	$ (4,175)
Stock-based compensation	(1,827)
Financial expenses, net	(2,094)
Share in losses of associated company	(530)
Loss before income tax	$ (8,626)

Segment data for the three months ended June 30, 2019 is as follows:

	CDMO Platform	POC Platform	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 7,619	$ 962	$ (824)	$ 7,757
Cost of revenues	(4,189)	(901)	483	(4,607)
Segment gross profit (loss)	3,430	61	(341)	3,150
Research and development expenses, net	-	(1,913)	477	(1,436)
Operating expenses	(3,446)	(1,558)	(136)	(5,140)
Other income	32			32
Segment operating profit (loss)	$ 16	$ (3,410)		$ (3,394)
Adjustments to presentation of segment Adjusted EBIT:				
Depreciation and amortization	(964)	(5)		(969)
Segment performance	$ (948)	$ (3,415)		$ (4,363)

Reconciliation of segment performance to loss for the three months ended June 30, 2019:

	Three-Months Ended June 30, 2019 (in Thousands)
Segment performance	$ (4,363)
Stock-based compensation	(891)
Financial expenses, net	(53)
Loss before income tax	$ (5,307)

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

	CDMO Platform	POC Platform	Corporate and Eliminations	Consolidated
	(in thousands)			
Revenues from external customers	$ 4,534	$ -	$ (547)	$ 3,987
Cost of revenues	(2,193)	-	148	(2,045)
Segment gross profit (loss)	2,341	-	(399)	1,942
Research and development expenses, net	-	(979)	399	580
Operating expenses	(1,101)	(1,639)		(2,740)
Other income		-		
Segment operating profit (loss)	$ 1,240	$ (2,618)		$ (1,378)
Adjustments to presentation of segment Adjusted EBIT:				
Depreciation and amortization	(643)	(2)		(645)
Segment performance	$ 597	$ (2,620)		$ (2,023)

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

	Three-Months Ended May 31, 2018 (in Thousands)
Segment performance	$ (2,023)
Stock-based compensation	(741)
Financial expenses, net	587
Share in losses of associated company	(576)
Loss before income tax	$ (2,753)

Geographic, Product and Customer Information

Most of the Company's revenues and long-lived assets are located in Belgium through its subsidiary, MaSTherCell. Net revenues from single customers from the CDMO segment that exceed 10% of total net revenues are:

	Three Months Ended		Six Months Ended	
	June 30, 2019	May 31, 2018	June 30, 2019	May 31, 2018
	(in Thousands)			
Customer A	$ -	$ 896	$ -	$ 1,791
Customer B	$ 2,062	$ 1,300	$ 4,276	$ 2,257
Customer C	$ 563	$ 1,186	$ 1,962	$ 2,157
Customer D	$ 887	$ -	$ 2,194	$ -
Customer E	$ 1,120	$ -	$ 1,887	$ -

NOTE 4– CONVERTIBLE LOANS

0n April 10, 2019, the Company entered into a convertible loan agreement with an offshore investor for an aggregate amount of $500 thousand into the U.S. Subsidiary. The investor, at its option, may convert the outstanding principal amount and accrued interest under this note into shares and three-year warrants to purchase shares of the Company's common stock at a per share exercise price of $7.00; or into shares of the U.S. Subsidiary at a valuation of the U.S. Subsidiary of $50 million.

On May 17, 2019, the Company entered into a private placement subscription agreement with an investor for $5 million. The lender shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share. As of June 30, 2019, the Company had received $5 million in total under this loan agreement.

On June 10 2019, the Company entered into private placement subscription agreements with investors for an aggregate amount of $2 million. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share. As of June 30, 2019, the Company had received $2 million in total under this loan agreement.

In May 2019, the Company had agreed to a 6% convertible loan agreement with an investor for an aggregate amount of $5 million. The lender shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share. As of the date of the filing of this Quarterly Report on Form 10-Q, the loan had not yet been received by the Company.

NOTE 5 – COLLABORATIONS, LICENSE AGREEMENTS AND COMMITMENTS

Consolidation of CDMO Entities and Strategic Funding

As described in Note 10 to the financial statements as of November 30, 2018, in June 2018, the Company, Masthercell Global, and Great Point Partners, LLC, and certain of Great Point's affiliates, entered into a series of definitive strategic agreements intended to finance, strengthen and expand Orgenesis' CDMO business. An initial cash payment of $11.8 million of the consideration was remitted in June 2018 by GPP-II ($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 (net payment of $10.3 million)), with a follow up payment of $6.6 million to be made in each of years 2018 and 2019, or for an aggregate of $13.2 million, if certain conditions are met. Masthercell Global achieved the specified targets in 2018 and as such, Masthercell Global received the first payment of $6.6 million on January 16, 2019.

HekaBio K.K

As described in Note 10 to the financial statements as of November 30, 2018, 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 "HB JVA") and established the joint venture entity Orgenesis K.K., 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").

Effective January 1, 2019, the Company entered into a master service agreement with Orgenesis K.K. whereby the Company, subject to mutually agreed timing and definition of the scope of services, will provide, regulatory services, pre-clinical studies and intellectual property services, as well as POC services and co-development services to Orgenesis K.K.

Apart from the above, there was no material activity with respect to the HB JVA during the six months ended June 30, 2019.

Image Securities Ltd (a Related Party).

As described in Note 10 to the financial statements as of November 30, 2018, on July 11, 2018, the Company 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 form a joint venture entity ("Indian JV Entity") to collaborate in the 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. During February 2019 the Company transferred a further $1 million to the India Partner. As of June 30, 2019, the Company had advanced $2 million in total to the India Partner, reflected in the Company's balance sheet as loan to a related party under non-current assets (held under escrow).

Effective January 1, 2019, the Company entered into a master service agreement for the provision of certain POC services. The first payment of $1 million for these POC Services was received during February of 2019 and was recognized as income received in advance on the Company's balance sheet, of which $556 thousand was recognized as income during the second quarter of 2019. Prior to the establishment of the JV Entity, all activities are being carried out by the India Partner.

Apart from the above, there was no material activity with respect to the Indian JV Entity during the six months ended June 30, 2019.

Collaboration Agreement with Tarus Therapeutics, Inc.

On February 27, 2019, the Company and Tarus Therapeutics Inc., a Delaware corporation, ("Tarus") entered into a Collaboration Agreement (the "Tarus Agreement") for the collaboration in the funding, development and commercialization of certain technologies, products and patents of Tarus in the areas of therapeutics for cancer and other diseases in the field of cell therapies and their combination with checkpoint inhibitors comprised of Adenosine Receptor Antagonists. Under the terms of the Tarus Agreement and subject to final due diligence and approved financing of the Company, the Company and/or one or more qualified investors (the "Investors") shall advance to Tarus a convertible loan in an amount of not less than $1,750 thousand and up to $3,000 thousand (the "Loan Agreement"). As of the date of the filing of the Quarterly Report on Form 10-Q, the loan agreements have not been concluded, nor has any financing been made to Tarus. As part of such Loan Agreement, and subject to approval by the board of directors of the Company, the Investors shall have the right, within two years of the date of the Loan Agreement, to convert the outstanding convertible loan into either (i) shares of Tarus at a price per share based on a pre- money valuation of $12,500 thousand or (ii) shares of the Company's common stock at a price per share set in accordance with an approved financing of the Company, with such terms as approved by the Company in its sole discretion. Further, as part of the Loan Agreement, the Company shall advance to Tarus up to $500,000 within fourteen days of execution of the Loan Agreement. Subject to the closing of the Loan Agreement, the Company and/or the Investors shall have an option, exercisable by sending written notice to Tarus at any time through the second anniversary of the closing of the Loan Agreement, to invest additional funds in an amount of up to $1,250 thousand and not less than $500,000 in Tarus. The Company will also have the right to appoint and/or replace one member of board of directors of Tarus. Upon and subject to the execution of a definitive development and manufacturing agreement between the Company and Tarus("Manufacturing and Supply Agreement"), the Company, or one or more of its affiliates, shall manufacture and supply to Tarus licensees, assignees of interest all requirements for all cell therapy elements of any combination therapy incorporating the technology of Tarus. Following the conclusion of the clinical development stage of each product emanating from the technology of Tarus, the cell therapy component of any such product borne out of the technology of Tarus shall be exclusively supplied by the Company under the Manufacturing and Supply Agreement. If the Company and Tarus fail to sign such Manufacturing and Supply Agreement for any given Tarus product, Tarus shall pay the Company an amount equal to four percent of gross revenues derived by Tarus from Tarus products.

Apart from the above, there was no activity in the Tarus collaboration.

Theracell Advanced Biotechnology

On February 14, 2019, the Company and Theracell Advanced Biotechnology ("Theracell"), a corporation organized under the laws of Greece, entered into a Joint Venture Agreement (the "JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products (hereinafter, the "Company Products") in Greece, Turkey, Cyprus and Balkan countries (the "Territory") and the clinical development and commercialization of Theracell's products (hereinafter, the "Theracell Products") worldwide (the "Project"). The parties intend to pursue the Project through a joint venture ("JV") by forming a JV entity (the "Greek JV Entity"). Until the Greek JV Entity is formed, all JV activities are being carried out by Theracell. The Company by itself, or together with a designee, will hold a 50% participating interest in the Greek JV Entity, with the remaining 50% participating interest being held by Theracell or its affiliate following the parties' contributions to the Greek JV Entity as set forth under the JVA. The Greek JV Entity will have a steering committee that will act as the board of directors of the Greek JV Entity and shall be composed of a total of five members, with two members appointed by each party and one industry expert.

Under the JVA, each party shall be responsible for providing up to $10 million in funding, of which $5 million shall be provided in the form of in-kind contributions. Each party shall also have the right to invest up to an additional $10 million, if such financing is determined to be necessary by the steering committee of the Greek JV Entity or if a party wishes to maintain its pro rata participating interest upon a future financing round in the Greek JV Entity ("Additional Investment"). The terms of such Additional Investment, if any, will be on terms mutually agreeable to the parties, provided that the minimum pre-money valuation for any such Additional Investment shall be at least $20 million. Any Additional Investment by a Party may lead to dilution of the other Party's participating interest unless such other party provides the requisite investment to maintain its participating percentage within two (2) years of such Additional Investment.

Under the JVA, the Company can require Theracell to sell to the Company its entire participating interest in the Greek JV Entity in consideration for the issuance of the Company's Common Stock based on an agreed upon formula for determining the Greek JV Entity's valuation, which shall be the higher of (i) $20 million, (ii) two times the revenues of the Greek JV Entity, (iii) four times the EBITDA of the Greek JV Entity or (iv) the valuation of the Greek JV Entity in its last Additional Investment round. If the parties decide to sell the Greek JV Entity, they will mutually agree upon the terms of such sale.

Under the JVA, the Company shall, subject to fulfilment of Theracell's obligations under the JVA, grant the Greek JV Entity an exclusive license to certain intellectual property of the Company as may be required for the Greek JV Entity to develop and commercialize the Company Products in the Territory. In consideration for such license, the Greek JV Entity shall pay the Company, royalties at the rate of 15% of the Greek JV Entity's net sales of Company Products in the Territory.

In addition, under the JVA, Theracell shall, subject to fulfillment of the Company's obligations under the JVA, grant the Greek JV Entity an exclusive license to certain intellectual property of Theracell as may be required for the Greek JV Entity to develop and commercialize the Theracell Products globally. In consideration of such license, the Greek JV Entity shall pay Theracell, in addition to other payments, royalties at the rate of 15% of the Greek JV Entity's worldwide net sales of Theracell Products.

Any new intellectual property discovered in connection with the development undertaken by the Greek JV Entity shall belong to the Greek JV Entity and such intellectual property will be licensed to the Company on a non-exclusive, worldwide (other than the Territory, as defined in the JVA), royalty free basis.

On February 14, 2019, the Company entered into a master service agreement with Theracell whereby the Company, subject to mutually agreed timing and definition of the scope of services, will provide regulatory services, pre-clinical studies, intellectual property services, GMP process translation services and co-development services to Theracell during 2019. During the 6-month period ended June 30, 2019, the Company recognized POC service revenue in the amount of $406 thousand.

During June 2019, the Company transferred $300,000 to Theracell. Prior to the establishment of the JV Entity, all activities were being carried out by Theracell.

Apart from the above, there was no material activity under the Theracell JVA.

First Choice International Company, Inc.

On March 12, 2019, the Company and First Choice International Company, Inc., ("First Choice"), a corporation organized under the laws of Delaware entered into a Joint Venture Agreement (the "Panama JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products (hereinafter the "Company Products") in Panama and certain other Latin American countries as agreed by the parties (the "Territory") and the clinical development and commercialization of First Choice's products (hereinafter the "First Choice Products") worldwide (other than in the Territory) (the "Project"). The parties intend to pursue the Project through a joint venture ("Panama JV") by forming a JV entity ("Panama JV Entity"). Until the Panama JV Entity is formed, all Panama JV activities will be carried out by First Choice within the Territory. Upon formation of the Panama JV Entity, the Company by itself, or together with a designee, will hold a 50% participating interest in the Panama JV Entity, with the remaining 50% participating interest being held by First Choice or its affiliate or partner. The Panama JV Entity will have a steering committee that will act as the board of directors of the Panama JV Entity and shall be composed of five members, with two members appointed by each party and one industry expert.

Under the Panama JVA, each party shall endeavor to provide up to $5 million in funding for development, either through investment instruments or in-kind contributions within the first three (3) years of the Panama JV. Each party shall also have the right to invest additional funds in the Panama JV Entity (which such investment(s) may also be in the form of a convertible loan), if such financing is determined to be necessary by the steering committee of the Panama JV Entity or to maintain such Party's pro-rata share of the Panama JV Entity ("Additional Investment").

In order to compensate First Choice for the Panama JV activities that First Choice has already completed prior to the Panama JVA, the Company paid First Choice $50,000 and will thereafter pay an additional $50,000. In addition, it has issued to First Choice 375,000 shares of Common Stock and will issue another 150,000 shares of Common Stock in September of 2019. These payments and the value of Common Stock issued in the amount of $2.6 million were charged to research and development expenses in the quarter ended June 30, 2019 under ASC 730-10-50 and ASC 20-50.

Each of the Company and First Choice shall provide strategic guidance to the Panama JV Entity and the Company shall provide hospital (management) services to the Panama JV Entity, among other POC Services as shall be set forth in a master service agreement to be negotiated in good faith and entered into by the parties.

Under the Panama JVA, the Company can require First Choice to sell to the Company its participating interest in the JV Entity in consideration for the issuance of the Company's Common Stock by dividing an agreed upon Panama JV Entity valuation by the weighted average price of the Company's Common Stock during the three (3) trading day preceding the closing of such sale. The Panama JV Entity valuation will be the higher of (i) two times the revenues of the Panama JV Entity, (ii) four times the EBITDA of the Panama JV Entity or (iv) the valuation of the Panama JV Entity in its last Additional Investment round. If the parties decide to sell the Panama JV Entity, they will mutually agree on the terms of such sale.

Under the Panama JVA, the Company shall, subject to fulfilment of First Choice's obligations under the Panama JVA, grant the Panama JV Entity an exclusive license to certain intellectual property of the Company as may be required for the Panama JV Entity to develop and commercialize the Company Products in the Territory, subject to minimum sales obligations. In consideration of such license, the Panama JV Entity shall pay the Company royalties at the rate of 15% of the Panama JV Entity net sales of Company Products sold in the Territory.

In addition, under the Panama JVA, First Choice shall, subject to fulfilment of the Company's obligations under the Panama JVA, grant the Panama JV Entity an exclusive license to certain intellectual property of First Choice as may be required for the Panama JV Entity to develop and commercialize the First Choice Products globally. In consideration of such license, the Panama JV Entity shall pay First Choice, royalties at the rate of 15% of the Panama JV Entity's worldwide net sales of First Choice Products. Additionally, and for separate consideration to the Company, First Choice shall be granted a limited, non-exclusive license to certain Company owned rights relating to the Human Papilloma Virus.

Any new inventions discovered during the development with respect to the JV shall belong to the Panama JV Entity and will be licensed to the Company on a non-exclusive, worldwide (other than the Territory), royalty free basis.

At the request of either party, the parties shall discuss between them in good faith the terms upon which a party may convert its participating interests in the Panama JV Entity into streaming royalties based on Panama JV Entity's revenues.

Apart from the above, there was no activity in the Panama JVA.

Cure Therapeutics Collaboration Agreement

As described in Note 10 to the financial statements as of November 30, 2018, on May 7, 2018, the Company and Cure Therapeutics entered into a collaboration agreement for the development of therapies based on liver and NK cells. An amount of $930 thousand was charged during the six months ended June 30, 2019. As of June 30, 2019, the development project has not been completed. As part of the agreement, Cure Therapeutics has subcontracted development and contract manufacturing activities to CureCell. An amount of $350 thousand was recognized during the six months ended June 30, 2019.

KinerjaPay Corp

On May 6, 2019 (the "Effective Date"), the Company and KinerjaPay Corp., a Delaware corporation, entered into a Joint Venture Agreement (the "Singapore JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products in Singapore (the "Territory") and the introduction of KinerjaPay products to be offered for sale by the Company globally outside the Territory. The parties intend to pursue the joint venture through a newly established company (hereinafter the "Singapore JV Entity"), which the Company by itself, or together with a designee, will hold a 51% participating interest therein, with the remaining 49% participating interest being held by KinerjaPay Corp.

Under the Singapore JVA, each party shall endeavor to provide the Singapore JV Entity up to $5 million within three (3) years of the Singapore JVA. Funding may be provided in part in the form of convertible loans, in-kind contributions, including intellectual property, and services related to advancement of the Singapore JV Entity. The Company's in-kind contribution may be in the form of 250,000 shares of the Company's restricted stock, issuable to KinerjaPay or KinerjaPay designated third party (instead of to the Singapore JV Entity) on the Effective Date and to be held in escrow by the Company to be released to KinerjaPay in return for services to be provided by KinerjaPay or KinerjaPay designated third party as will be mutually agreed between the parties.

Under the Singapore JVA, the Company can require KinerjaPay to sell to the Company its participating interest in the Singapore JV Entity in consideration for the issuance of the Company's common stock based on an agreed upon formula for determining Singapore JV Company valuation.

Apart from the above, there was no activity in the Singapore JV.

Grants

In December 2018, the Belgian subsidiary received the approval of a new grant from the Walloon Region for financial support of a maximum of Euro 317 thousand ($350 thousand in USD) in a program for the development of gene-therapy research for diabetes 1 treatment. The program is planned to start in 2019 for a 2-year period until 2021. In the first quarter of 2019, the Belgian subsidiary received an advance payment of grant in the amount of Euro 80 thousand ($90 thousand in USD).

In February 2019, the Israeli subsidiary and a Canadian partner received the approval of a new grant from the Canada-Israel Industrial Research and Development Foundation for financial support in a program for pre-clinical development of insulin producing cells using advanced gene delivery platforms. In terms of the grant, the Israeli subsidiary can receive support of up to 100 Thousand Canadian Dollars ($75 Thousand in USD). The program is planned to start in 2019 for a 2-year period until 2021.

See Note 8 regarding Lease commitments.

NOTE 6 – STOCK BASED COMPENSATION

a. Options Granted to employees

The table below summarizes the terms of options for the purchase of shares in the Company granted to employees during the period from January 1, 2019 to June 30, 2019:

	No. of Options Granted	Exercise Price	Vesting Period	Fair Value at Grant (in thousands)	Expiration Period
Employees	77,000	$ 4.5-5.07	Quarterly over a period of 2 years commencing in July 1, 2019	$ 272	10 years

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

	During the Period from January 1, 2019 to June 30, 2019
Value of one common share	$ 4.5-5.07
Dividend yield	0%
Expected stock price volatility	87%-88%
Risk free interest rate	2.25%-2.47%
Expected term (years)	5.56

b. Options Granted to non-employees

The table below summarizes all the options for the purchase of shares in the Company granted to consultants and service providers during the period from January 1, 2019 to June 30, 2019:

	No. of Options Granted	Exercise Price	Vesting Period	Fair Value at Grant (in thousands)	Expiration Period
Non-employees	10,000	$ 4.5-$5.07	20% immediately and the rest over a period of 4 year on an annual basis and quarterly over a period of 2 years	$ 42	10 years

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

	During the Period from January 1, 2019 to June 30, 2019
Value of one common share	$ 4.5-5.07
Dividend yield	0%
Expected stock price volatility	91%-92%
Risk free interest rate	2.42%-2.62%
Expected term (years)	10

c. Shares and Warrants for the purchase of shares in the Company granted to non-employees

During December 2018, the Company issued to consultants 2,858 warrants, each exercisable at $7.00 per share for six years. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was $8 thousand.

In December 2018, the Company entered into an investor relation services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to issue the consultant 10,000 shares of restricted common stock, of which the first 2,500 shares vested on the signing date, and 7,500 shares are to vest monthly over 3 months commencing January 2019. As of June 30, 2019, 10,000 shares were fully vested. The fair value of the shares was $51 thousand using the fair value of the shares on the vesting dates. $37 thousand was recognized during the six months ended June 30, 2019.

In December 2018, the Company entered into a separate investor relations services, marketing and related services agreement. Under the terms of the agreement, the Company agreed to issue the consultant 40,000 shares of restricted common stock, of which the first 6,667 shares vested on the signing date, and 33,333 shares vested monthly over five months commencing January 2019. As of June 30, 2019, 40,000 shares are vested. The fair value of the shares was $200 thousand using the fair value of the shares at the vesting dates. $163 thousand was recognized during the six months ended June 30, 2019.

d. Options Granted to employees of Masthercell Global for the purchase of shares in Masthercell Global

The rows below summarize the terms of options granted to employees of Masthercell Global Inc. during the six months ended June 30, 2019:

	No. of Options Granted	Exercise Price	Vesting Period	Fair Value at Grant (in thousands)	Expiration Period
Employees	77,000	$ 4.91	Over 5 years Approximately 56% of the options are perfomance based 2019	$ 272	10 years

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

	January 1, 2019 to June 30, 2019
Value of one common share	$ 12.28*
Dividend yield	0%
Expected stock price volatility	69%**
Risk free interest rate	2.78%
Expected term (years)	7

* Based on Masthercell Global valuation
** Based on comparable companies

NOTE 7 – LOSS PER SHARE

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

	Three Months Ended		Six Months Ended	
	June 30, 2019	May 31, 2018	June 30, 2019	May 31, 2018
	(in thousands, except per share data)			
Basic:				
Net loss attributable to Orgenesis Inc.	$ 5,201	$ 2,614	$ 13,512	$ 8,225
Adjustment of redeemable non-controlling interest to redemption amount	611	-	853	-
Net loss attributable to Orgenesis Inc. for loss per share	5,812	2,614	14,365	8,225
Weighted average number of common shares outstanding	16,001,439	13,140,119	15,772,333	11,971,389
Loss per common share	$ 0.36	$ 0.20	$ 0.91	$ 0.69
Diluted:				
Net loss attributable to Orgenesis Inc. for loss per share	5,812	2,614	14,365	8,225
Weighted average number of shares used in the computation of basic and diluted loss per share	16,001,439	13,140,119	15,772,333	11,971,389
Loss per common share	$ 0.36	$ 0.20	$ 0.91	$ 0.69

For the six months ended June 30, 2019, all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive. Diluted loss per share does not include 8,947,131 shares underlying outstanding options and warrants and 1,116,979 shares upon conversion of convertible loans for the six months ended May 31, 2018, because the effect of their inclusion in the computation would be anti-dilutive.

NOTE 8 – LEASES

As of January 1, 2019, the Company adopted ASU No. 2016-02, "Leases (Topic 842)," which requires leases with durations greater than twelve months to be recognized on the balance sheet. The Company adopted the standard using the modified retrospective approach with an effective date as of the beginning of our fiscal year, January 1, 2019. The total impact of the adoption of this standard at January 1, 2019 is an increase of assets and liabilities in the amount of $3,226 thousand. Prior year financial statements were not recast under the new standard and, therefore, those amounts are not presented below. The Company elected the package of transition provisions available for expired or existing contracts, which allowed us to carryforward our historical assessments of (1) whether contracts are or contain leases, (2) lease classification and (3) initial direct costs.

The Company leases research and development facilities, equipment, offices and cars under finance and operating leases. For leases with terms greater than 12 months, the Company record the related asset and obligation at the present value of lease payments over the term. Many of the leases include rental escalation clauses, renewal options and/or termination options that are factored into the determination of lease payments when appropriate.

The Company's leases do not provide a readily determinable implicit rate. Therefore, the Company estimated the incremental borrowing rate to discount the lease payments based on information available at lease commencement.

Research and Development facilities

The Company leases space for its CDMO facilities and research and development facilities in Belgium, Israel, South Korea and the United States of America under five lease agreements of operating leases. The leasing contracts are for a period of 3-15 years.

Equipment

The Company leases laboratory equipment in Belgium under several agreements of finance leases. The equipment is the basic material for our new production center (such as incubator, laminar flow and bio-reactor). Each leasing contract is valid for a term of 5 years.

Offices

The Company leases space for offices in Belgium, Korea, Israel and the United States of America under operating leases. The leasing contracts are valid for terms of 1.5 - 16 years. These contracts are considered as operational leasing and under operating lease right-of-use assets.

Cars

The Company leases cars. Each leasing contract is valid for a term of 4 years. These contracts are considered as operational leasing and operating lease right-of-use assets.

Lease Position

The table below presents the lease-related assets and liabilities recorded on the balance sheet.

		June 30, 2019
Assets		
Operating Leases		
Operating lease right-of-use assets	$	9,988
Finance Leases		
Property and equipment, gross	$	1,070
Accumulated depreciation		(143)
Property and equipment, net		927
Liabilities		

Current liabilities	
Current maturities of operating leases	(1,613)
Current maturities of long-term finance leases	(236)
Long-term liabilities	
Non-current operating leases	(7,676)
Long-term finance leases	(589)
Weighted Average Remaining Lease Term	
Operating leases	10.7 years
Finance leases	3.2 years
Weighted Average Discount Rate	
Operating leases	5.7%
Finance leases	4.7%

Lease Costs

The table below presents certain information related to lease costs and finance and operating leases during the six months ended June 30, 2019.

	Six-Months Ended June 30, 2019
Operating lease cost:	$ 1,010
Finance lease cost:	
Amortization of leased assets	110
Interest on lease liabilities	12
Total finance lease cost	$ 122

The table below presents certain information related to lease costs and finance and operating leases during the three months ended June 30, 2019:

	Three-Months Ended June 30, 2019
Operating lease cost:	$ 686
Finance lease cost:	
Amortization of leased assets	41
Interest on lease liabilities	-
Total finance lease cost	$ 41

The table below presents supplemental cash flow information related to leases during the six months ended June 30, 2019:

	Six Months Ended June 30, 2019 (in Thousands)
Cash paid for amounts included in the measurement of leases liabilities:	
Operating cash flows from operating leases	$ 1,717
Operating cash flows from finance leases	121
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases, net	$ 7,906
Finance leases	

Undiscounted Cash Flows

The table below reconciles the undiscounted cash flows for each of the first five years and total of the remaining years to the finance lease liabilities and operating lease liabilities recorded on the balance sheet.

	Operating Leases	Finance Leases
Year ended December 31,		
Remaining months 2019	$ 1,076	$ 197
2020	1,729	394
2021	1,315	209
2022	1,242	174
2023	1,098	108
Thereafter	9,082	-
Total minimum lease payments	15,542	1,082
Less: amount of lease payments representing interest	(6,254)	(257)
Present value of future minimum lease payments	9,288	825
Less: Current leases obligations	(1,613)	(236)
Long-term leases obligations	$ 7,675	$ 589

Future minimum lease payments as of November 30, 2018

Future minimum lease commitments under non-cancelable operating lease agreements are as follows:

2019	$ 783
2020	626
2021 and thereafter	3,504
Total	$ 4,913

Future minimum lease payments as of December 31, 2018

No material change in the month ended December 31, 2018

Lease facilities in the United States

During January 2019, Masthercell U.S., LLC executed a lease agreement for production facilities in the United States. Under the terms of the agreement, Masthercell U.S., LLC leased approximately 32,011 square feet for 180 months. Masthercell U.S., LLC advanced $1.6 million on account of a security deposit, tenant improvement allowance and prepaid base rent.

Lease facilities in Belgium

In March 2019, Masthercell announced plans to establish a new, state-of-the-art production site in the Gosselies Biopark in Belgium, designed to manufacture late-stage and commercially approved cell and gene therapy products. In connection with this announcement, the Company signed a lease agreement for a 61,354 square foot building.

NOTE 9 – SUBSEQUENT EVENTS

On August 7, 2019, the Company, Masthercell Global and GPP-II entered into a Transfer Agreement, pursuant to which Masthercell Global transferred to the Company, for nominal consideration, all of Masthercell Global's right, title and interest in Atvio Biotech Ltd. and CureCell Co., Ltd., which were previously transferred to Masthercell Global in connection with the strategic transaction with GPP consummated in June 2018.

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

Forward-Looking Statements

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Quarterly Report on Form 10-Q, as well as our Annual Report on Form 10-K for the fiscal year ended November 30, 2018, as filed with the Securities and Exchange Commission (the "SEC") on February 13, 2019. Certain statements made in this discussion are "forward-looking statements" within the meaning of 27A of the Securities Act of 1933, as amended (the "Securities Act"), 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 the 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," "forecast," "future," "intend," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" or the negative of these terms and similar 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" or "Orgenesis" 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 (the "Maryland Subsidiary"), and Cell Therapy Holdings S.A. Masthercell Global's subsidiaries include MaSTherCell S.A ("MaSTherCell"), a Belgian-based subsidiary and a Contract Development and Manufacturing Organization ("CDMO") specializing in cell therapy development and manufacturing for advanced medicinal products, Masthercell U.S., LLC, a U.S.-based CDMO, Atvio Biotech Ltd. ("Atvio"), an Israeli-based CDMO, and CureCell Co. Ltd. ("CureCell"), a Korea-based CDMO.

Corporate Overview

We are a biotechnology company specializing in the development, manufacturing and provision of technologies and services in the cell and gene therapy industry. We operate through two platforms: (i) a point-of-care ("POCare") cell therapy platform ("POC") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform conducted through our subsidiary, Masthercell Global. Through our POC platform, our aim is to further the development of Advanced Therapy Medicinal Products ("ATMPs") through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. We out-license these ATMPs through regional partners to whom we also provide regulatory services, pre-clinical studies, intellectual property services, and co-development services (collectively, "POC Services") to support their activity in order to reach patients in a point-of-care hospital setting. Through our CDMO platform, we are focused on providing contract manufacturing and development services for biopharmaceutical companies.

Activities in our POC platform include a multitude of cell therapies, including autoimmune, oncologic, neurologic and metabolic diseases and other indications. We plan to provide POC Services to our joint venture ("JV") regional partners, pharmaceutical and biotech companies as well as research institutions and hospitals that have cell therapies in clinical development. We believe that each of these customers and collaborations represents a revenue and growth opportunity upon regulatory approval. Furthermore, our trans-differentiation technology 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 pre-clinical 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 Scientific Officer and a researcher at Tel Hashomer Medical Center 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. With respect to these technologies, we own or have exclusive rights to twelve (12) United States and thirteen (13) foreign issued patents, six (6) pending applications in the United States, thirty-two (32) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Israel, Japan, South Korea, Mexico, and Singapore, and five (5) international Patent Cooperation Treaty ("PCT") patent applications. These patents and applications relate, among others, to (1) the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis, and (2) scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, trans-differentiation, and transplantation in the treatment of autoimmune diseases, including diabetes. In June 2019, the United States Food & Drug Administration ("FDA") granted us the Orphan Drug designation for our Autologous Insulin Producing ("AIP") cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy ("TP") due to chronic pancreatitis ("CP").

Our CDMO platform operates through Masthercell Global, which currently consists of the following subsidiaries: MaSTherCell in Belgium, Atvio in Israel and CureCell in South Korea and MaSTherCell U.S., LLC in the United States, each having unique know-how and expertise for manufacturing in a multitude of cell types. As part of our United States ("U.S.") activity, we are setting 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 of 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 more cost-effective way. Masthercell Global strives to provide services that are all compliant with Good Manufacturing Practice, or GMP, requirements, ensuring identity, purity, stability, potency and robustness of cell therapy products for clinical Phase I, II, III and through commercialization.

We operate our POC and CDMO platforms units as two separate business segments.

POC Platform

Our therapeutic development efforts in our cell therapy business are focused on advancing breakthrough scientific achievements in the field of autologous therapies which have a curative potential. We base our development on therapeutic collaborations and in-licensing with other pre-clinical and clinical-stage biopharma companies as well as direct collaboration with research and healthcare institutes. We are engaging in therapeutic collaborations and in-licensing with other academic centers and research centers in order to pursue emerging technologies of other ATMPs in cell and gene therapy in such areas as cell-based immunotherapies, metabolic diseases, neurodegenerative diseases and tissue regeneration. Each of these customers and collaborations represents a growth opportunity and future revenue potential as we out-license these ATMPs through regional partners to whom we also provide regulatory, pre-clinical and training services to support their activity in order to reach patients in a POC point-of-care hospital setting.

POC Subsidiaries and Collaboration Agreements

We intend to devote significant resources to process development and manufacturing in order to optimize the safety and efficacy of our future product candidates, as well as our cost of goods and time to market. Our goal is to carefully manage our fixed cost structure, maximize optionality, and drive long-term cost of goods as low as possible.

The subsidiaries related to this business are as follows:

- United States: Orgenesis Maryland Inc. – This is the center of activity for North America currently focusedon technology licensing, therapeutic collaborations and preparation for U.S. clinical trials.
- European Union: Orgenesis SPRL – This is the center of activity for Europe, currently focused on processdevelopment and preparation of European clinical trials.
- Israel: Orgenesis Ltd. – This is a research and technology center, as well as a provider of regulatory, clinicaland pre-clinical services.

We have embarked on a strategy of collaborative arrangements with strategically situated third parties around the world. We believe that these parties have the expertise, experience and strategic location to advance our POC therapy business.

POC Revenue Model

Through analysis of the cell therapy landscape, we are introducing a novel POCare therapy business model with our goal of bringing autologous therapies in a cost-effective, high-quality and scalable manner to patients. We are establishing and positioning our POC platform in order to bring POCare therapies to patients in a scalable way via a network of leading healthcare facilities active in autologous cell therapy product development, including facilities in India, Germany, Austria, Greece, the U.S., Panama, Singapore, Korea and Japan.

Our unique understanding of industry needs allows us to offer our clients a range of technologies and processes that potentially generate revenues. Regulatory assistance and joint ventures with local partners who bring strong regional networks through (1) joint venture partnerships with local hospitals utilizing hospital networks for clinical development of therapies, (2) a global network of supply, (3) harmonized quality systems, (4) the provision of a comprehensive portfolio of ATMPs to hospitals via continuous in-licensing of autologous therapies from academia and research institutes, and (4) out-licensing hospital and academic-based therapies.

This may include:

- Development Services: Industrial manufacturing know-how to the cell and gene therapy arena, thus reducingcost of goods and facilitating regulatory scrutiny, higher automation level required to increase process robustness and reduce attrition rates, biological assay development, assay validation and assay optimization;
- Sub-Licensing Fees: Innovative technologies such as scaffolds and IoT sensors and closed systembioreactors that allow autologous cell manufacturing in lower grade clean rooms; and
- POC Services: Regulatory services, pre-clinical studies, intellectual property services, and co-developmentservices

Our aim is to provide a pathway to bring ATMPs in the cell and gene therapy industry from research to patients worldwide through our POCare network. We define POCare cell and gene therapy as a process of collecting, processing and administering cells within the patient care environment, namely through academic partnerships in a hospital setting. We believe this approach is an attractive proposition for personalized medicine because POCare therapy facilitates the development of technologies through our strategic partnerships and utilizes closed systems that have 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 POC business strategy is currently limited to early stage development to overcome certain industry challenges, we intend to continue developing a global POCare network, with the goal of developing ATMPs, and namely autologous cell therapies, via joint ventures with partners who bring strong regional networks. Such networks include partnerships with local hospitals which allows us to engage in continuous in-licensing of, namely, 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 consider the following to be the four pillars in order to advance our POC business strategy:

- Innovation: This leverages our unique know-how and expertise for industrial processes, operational excellence, process development and optimization, quality control assays development, quality management systems and regulatory expertise.
- Systems: We are developing cell production cGMP systems utilizing sensor technology and AI-based systems for biological production, closed system devices for processing cells, proprietary virus/ media technologies and partnerships with key system providers.
- Cell and Gene Products: We intend to grow our internal asset pipeline consisting of our unique portfolio of immuno-oncology related technologies, MSC and liver-based therapies and secretome-based therapies.
- Distribution: Our plan is to enable the industrialization, commercialization and distribution of POCare systems in major hospitals and key geographies, including Europe, Asia, North America, and South America.

CDMO Platform

Companies developing cell therapies need to make a decision early on in their approach to the transition from the lab to the clinic regarding the process development and manufacturing of the cells necessary for their respective therapeutic treatments. Of the companies active in this market, only a small number have developed their own GMP manufacturing facilities due to the high costs and expertise required to develop these processes. In addition to the limitations imposed by a limited number of trained personnel and high infrastructure/operational costs, the industry faces a need for custom innovative process development and manufacturing solutions. Due to the complexity and diversity of the industry, such solutions are often customized to the particular needs of a company and, accordingly, a multidisciplinary team of engineers, cell therapy experts, cGMP and regulatory experts is required. Such a unique group of experts can exist only in an organization that both specializes in developing characterization assays and solutions and manufactures cell therapies.

The complexity of manufacturing individual cell therapy treatments poses a fundamental challenge for cell therapy-based companies as they enter the field. This complexity potentially casts a spotlight on improved cGMP, large-scale manufacturing processes, such as the services provided by Masthercell Global. Manufacturing and delivery can be more complex in cell therapy products than for a typical drug. In the U.S., only a few dozen specialized hospitals are currently qualified to provide CAR T treatments, which require retrieving, processing and then returning immune cells to the patient, all done under strict cGMP, as well as monitoring and treating side effects. These factors provide real incentives for cell therapy companies to seek third-party partners, or contract manufacturers, who possess technical, manufacturing, and regulatory expertise in cell therapy development and manufacturing such as cell therapy CDMOs like MaSTherCell. Additionally, establishing a manufacturing facility for cell therapy requires specific expertise and significant capital which can delay the clinical trials by at least two years. As companies are looking to expedite their market approval, utilization of a CDMO can result in faster time to market and overall lower expenditure.

Integration of development and manufacturing and logistics services through Masthercell Global (and its subsidiaries) provide the basis for generating a recurring revenue stream, as well as carefully managing our fixed cost structure to maximize optionality and drive down production cost. We believe that Masthercell Global is also beneficial for our own manufacturing needs and provides us, and our customers, with enhanced control of material supply for both clinical trials and the commercial market.

Our CDMO Growth Strategy

In light of the globalization of the industry in general and the therapeutics industry in particular, adding to that the high cost of reaching the market, developers of cell therapies see themselves as global organizations and build their models on global markets. As cell therapies are based on living cells, they are limited in their ability to be centrally manufactured. An additional challenge for globalization is the fact that the regulatory requirements for the therapies is not harmonized between jurisdictions, presenting additional operational challenges.

We have leveraged the recognized quality expertise and experience in cell process development and manufacturing of our Belgian subsidiary, MaSTherCell S.A., to first-class entities in Israel and Korea and to build a global CDMO in the cell therapy development and manufacturing area. We believe that cell therapy companies need to be global in order to truly succeed. We target the international manufacturing market as a key priority through joint-venture agreements that provide development capabilities, along with manufacturing facilities and experienced staff.

The main revenue drivers of our growth strategy on a global reach are the number of batches and the number of patients per manufacturing batch. These parameters vary along the development cycle of the new treatments (starting from as few as 20 patients in Phase I to thousands of patients when reaching commercialization). When a client reaches the commercial stage, their demand for manufacturing substantially increases, while barriers preventing the client from switching to another manufacturing organization remain extremely high. The difficulty in transferring CDMOs is a function of the tech transfer of such complex manufacturing processes being extremely lengthy, requiring many months of training highly specialized employees, while also possibly requiring new regulatory approvals. Therefore, we believe we are well positioned to continue expanding our revenue for the following reasons:

(1) A higher number of companies in later phases of clinical trials and soon potentially in commercial phases;
(2) Therapy companies requiring higher manufacturing abilities concurrent with a global reach; and
(3) An increasing need for the manufacturing scalability provided by a CDMO.

Recent Developments During the Three Months Ended June 30, 2019s

Sponsored Research and Exclusive License Agreement with Columbia University

Effective April 2, 2019, the Company and The Trustees of Columbia University in the City of New York, a New York corporation, (“Columbia”) entered into a Sponsored Research Agreement (the “SRA”) whereby the Company will provide financial support for studying the utility of serological tumor marker for tumor dynamics monitoring. Under the terms of the SRA, the Company shall pay $300,000 per year for three years, or for a total of $900,000, with payments of $150,000 due every six months.

Effective April 2, 2019, the Company and Columbia entered into an Exclusive License Agreement (the “Columbia License Agreement”) whereby Columbia granted to the Company an exclusive license to discover, develop, manufacture and sell product in the field of cancer therapy. In consideration of the licenses granted under the Columbia License Agreement, the Company shall pay to Columbia (i) a royalty of 5% of net sales of any patented product sold and (ii) 2.5% of net sales of other products.

IRB Approval for Liver Cell Collection

On April 29, 2019, the Company received Institutional Review Board ("IRB") approval to collect liver biopsies from patients at Rambam Medical Center located in Haifa, Israel for a planned study to confirm the suitability of liver cells for personalized cell replacement therapy for patients with insulin-dependent diabetes resulting from total or partial pancreatectomy. The liver cells are intended to be bio-banked for potential future clinical use.

The goal of the proposed study, entitled “Collection of Human Liver Biopsy and Whole Blood Samples from Type 1 Diabetes Mellitus (T1DM), Total or Partial Pancreatectomy Patients for Potential use as an Autologous Source for Insulin Producing Cells in Future Clinical Studies,” is to confirm the suitability of the liver cells for personalized cell replacement therapy, as well as eligibility of patients to participate in a future clinical study, as defined by successful AIP cell production from their own liver biopsy. The secondary objective of the study is to evaluate patients' immune response to AIPs based on the patient’s blood samples and followed by subcutaneous implantation into the patients' arm which would represent the first human trial. The Company has developed a novel technology based on technology licensed from Tel Hashomer Medical Research Infrastructure and Services Ltd., utilizing liver cells as a source for AIP cells as replacement therapy for islet transplantation.

During the study, liver samples will be collected and then processed and stored in specialized, clinical grade, tissue banks for potential clinical use. The propagated cells will be maintained in a tissue bank and are intended to be utilized in a future clinical study, in which the cells will be transdifferentiated and administered back to the patients as a potential treatment. This personalized autologous process will be performed under our POCare model in which the patient liver samples are processed, cryopreserved and potentially re-injected, all in the medical center under clinical grade/GMP level conditions.

Joint Venture Agreement with KinerjaPay Corp.

Effective May 6, 2019, the Company and KinerjaPay Corp., a Delaware corporation entered into a Joint Venture Agreement (the "Singapore JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of the Company's products in Singapore and the introduction of KinerjaPay products which will be offered for sale by the Company globally outside Singapore. The parties intend to pursue the joint venture through a newly established company (hereinafter the "JV Company") which the Company by itself, or together with a designee, will hold a 51% participating interest therein, with the remaining 49% participating interest being held by KinerjaPay Corp.

Under the JVA, each party may invest up to $5 million. Funding may be provided in part in the form of convertible loans, in-kind contributions, including Intellectual Property ("IP"), and services related to advancement of the JV. The Company's in-kind contribution may be in the form of 250,000 shares of the Company's restricted stock, issuable to KinerjaPay or KinerjaPay designated third party (instead of to the JV Entity) on the Effective Date and to be held in escrow by the Company to be released to KinerjaPay in accordance with terms and conditions in return for services to be provided by KinerjaPay or KinerjaPay designated third party as will be mutually agreed between the Parties.

Under the JVA, the Company can require KinerjaPay 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.

Joint Venture Agreement with SBH Sciences, Inc.

On May 15, 2019, the Company entered into a Joint Venture Agreement with SBH Sciences, Inc., a Massachusetts corporation, ("SBH") for the establishment of a joint venture with SBH for the purpose of collaborating in the field of gene and cell therapy development, process and services of bio-exosome therapy products and services in the areas of diabetes, liver cells and skin applications, including wound healing (the "SBH JV Agreement"). Under the terms of the SBH JV Agreement, a joint venture entity shall be formed as an LLC in the State of Delaware, with participating interests equally held by the Company and SBH (the "JV Entity"). The SBH JV Agreement requires that SBH and the Company shall each contribute $250,000 to the JV Entity for the purpose of carrying out the initial development activities relating to (i) a development hub for in vitro assays design, development and optimization of standard operating procedures in order to demonstrate product safety, identity, purity, content and potency for cell-based product quality control, as required by regulatory agencies and (ii) novel therapies/assays in the gene and cell therapy field. Further to the Company's and SBH's cash contributions to the SBH JV, SBH and the Company shall make an in-kind contribution toward the development activities valued at $250,000 for (i) SBH to create and manage a certified facility, know-how related to assay development, contribution of a human cell-line bank, the provision of a fully equipped in vitro cell culture lab, the establishment and training and performance of developed assays and for (ii) the Company to identify potential business development and revenue opportunities, regulation and intellectual property consulting, assay development as required for GMP manufacturing, budget and work planning and control testing. The board of directors of the SBH JV shall be comprised of three directors with one appointed by SBH and two appointed by the Company. All intellectual property conceived or developed resulting from the business of the SBH JV, that is not SBH's or the Company's background intellectual property, shall be owned exclusively by the JV Entity, although the Company shall be granted the right to exclusively license any intellectual property arriving from the development activities of the JV Entity, or exclusively distribute products based thereon.

FDA Approval for Orphan Drug Designation for AIP Cells

On June 11, 2019, the FDA granted Orphan Drug Designation for the Company's AIP cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy ("TP") due to chronic pancreatitis. The incidence of diabetes following TP is 100%, resulting in immediate and lifelong insulin-dependence with the loss of both endogenous insulin secretion and that of the counter-regulatory hormone, glucagon. Glycemic control after TP is notoriously difficult with conventional insulin therapy due to complete insulin dependence and loss of glucagon-dependent counter-regulation. Patients with this condition experience both severe hyperglycemic and hypoglycemic episodes.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 to the Three Months Ended May 31, 2018

Our financial results for the three months ended June 30, 2019 are summarized as follows in comparison to the three months ended May 31, 2018:

	Three Months Ended June 30, 2019	Three Months Ended May 31, 2018
	(in thousands)	
Revenues	$ 7,757	$ 3,987
Cost of sales	4,935	2,195
Research and development expenses, net	1,709	788
Amortization of intangible assets	516	445
Selling, general and administrative expenses	5,883	3,323
Share in losses of associated company	-	576
Financial expense (income), net	53	(587)
Other income, net	(32)	-
Loss before income taxes	$ 5,307	$ 2,753

Revenues

	Three Months Ended June 30, 2019	Three Months Ended May 31, 2018
	(in thousands)	
Services	$ 6,068	$ 2,993
Goods	1,689	994
Total	$ 7,757	$ 3,987

Our revenues were derived from sales made by our subsidiary Masthercell Global and its subsidiaries (mainly MaSTherCell S.A.) and from POC Services to our Indian and Greek collaborations.

Our revenues for the three months ended June 30, 2019 were $7,757 thousand, as compared to $3,987 thousand for the three months ended May 31, 2018, representing an increase of 95%. The increase in revenues is attributable to (i) increased service fees generated by MaSTherCell, resulting primarily from the extension of existing customer service contracts with biotech clients, as well as from revenues generated from existing manufacturing agreements as MaSTherCell was able to accept the additional contracts following its expansion of laboratory capacity, (ii) revenues from contracts from CureCell and Atvio which were not consolidated in the three months ended May 31, 2018 (see Note 5), and (iii) from revenues of $962 thousand generated from POC Services.

Expenses

Cost of Revenues

	Three Months Ended June 30, 2019	Three Months Ended May 31, 2018
	(in thousands)	
Salaries and related expenses	$ 1,948	$ 975
Stock-based compensation	67	-
Professional fees and consulting services	279	-
Raw materials	2,203	992
Depreciation and amortization expenses, net	261	169
Other expenses	177	59
	$ 4,935	$ 2,195

Cost of revenues for the three months ended June 30, 2019 were $4,935 thousand, as compared to $2,195 thousand for the three months ended May 31, 2018, representing an increase of 125%. The increase is primarily attributed to the following: (i) an increase in salaries and related expenses primarily attributable to an increase in head-count in the production and development departments and (ii) an increase in raw materials used due to the growth in the volume of the services provided by MaSTherCell, as well as from revenues generated from existing manufacturing agreements.

Research and Development Expenses

	Three Months Ended June 30, 2019	Three Months Ended May 31, 2018
	(in thousands)	
Salaries and related expenses	$ 690	$ 365
Stock-based compensation	133	157
Professional fees and consulting services	42	253
Lab expenses	666	149
Depreciation expenses, net	140	(4)
Other research and development expenses	388	108
Less – grant	(350)	(240)
Total	$ 1,709	$ 788

Research and development expenses for the three months ended June 30, 2019 were $1,709 thousand, as compared to $788 thousand for the three months ended May 31, 2018, representing an increase of 117%. The increase is primarily attributable to an increase in salaries and related expenses and lab expenses primarily attributable to an increase in clinical operation activities in the U.S., Israel and Belgium, and new therapeutics projects. This was partially offset by the reallocation of several R&D employees and contractors to the production and development departments.

Selling, General and Administrative Expenses

	Three Months Ended June 30, 2019	Three Months Ended May 31, 2018
	(in thousands)	
Salaries and related expenses	$ 2,059	$ 1,101
Stock-based compensation	691	580

Accounting and legal fees	584	597
Professional fees	759	210
Rent and related expenses	940	296
Business development	490	356
Other general and administrative expenses	360	183
Total	$ 5,883	$ 3,323

Selling, general and administrative expenses for the three months ended June 30, 2019 were $5,883 thousand, as compared to $3,323 thousand for the three months ended May 31, 2018, representing an increase of 77%. The increase is primarily attributable to increased salaries and related expenses as a result of increased commercial activity, facility expansion and additional personnel appointments particularly in Masthercell Global, additional sales and support staff at MaSTherCell S.A. In addition, salaries and related expenses of CureCell and Atvio not previously consolidated, as well as rent and related expenses for additional space for new production areas at MaSTherCell LLC and MaSTherCell S.A. contributed to the increase (See Note 8).

Financial (Income) Expenses, net

	Three Months Ended June 30, 2019	Three Months Ended May 31, 2018
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	$ -	$ (606)
Interest expense on convertible loans and loans	46	177
Foreign exchange loss, net	(3)	(167)
Other expenses	10	9
Total	$ 53	$ (587)

Financial (income) expenses, net for the three months ended June 30, 2019 were $53 thousand, as compared to $(587) thousand for the three months ended May 31, 2018 In the three months ended May 31, 2018, finance income was incurred in the valuation of the fair value of the put option of Atvio. Said option was exercised in June 2018 (see Note 5).

Comparison of the Six Months Ended June 30, 2019 to the Six Months Ended May 31, 2018

Our financial results for the six months ended June 30, 2019 are summarized as follows in comparison to the six months ended May 31, 2018:

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Revenues	$ 15,058	$ 6,623
Cost of sales	9,279	3,839
Research and development expenses, net	6,859	1,554
Amortization of intangible assets	1,033	881
Selling, general and administrative expenses	11,483	6,667
Share in losses of associated company	-	530
Financial expense, net	193	2,094
Other income, net	(69)	(316)
Loss before income taxes	$ 13,720	$ 8,626

Revenues

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Services	$ 11,163	$ 5,019
Goods	3,895	1,604
Total	$ 15,058	$ 6,623

Our revenues for the six months ended June 30, 2019 were $15,058 thousand, as compared to $6,623 thousand for the six months ended May 31, 2018, representing an increase of 127%. The increase in revenues is attributable to (i) increased service fees generated by MaSTherCell, resulting primarily from the extension of existing customer service contracts with biotech clients, as well as from revenues generated from existing manufacturing agreements - MaSTherCell was able to accept the additional contracts following its expansion of laboratory capacity (ii) revenues from contracts from CureCell and Atvio which were not consolidated in the three months ended May 31, 2018 (see Note 5), and (iii) from revenues of $962 thousand generated from POC Services.

Expenses

Cost of Revenues

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Salaries and related expenses	$ 3,635	$ 1,742
Stock-based compensation	106	-
Professional fees and consulting services	281	-
Raw materials	4,421	1,643
Depreciation and amortization expenses, net	555	328
Other expenses	281	126
	$ 9,279	$ 3,839

Cost of revenues for the six months ended June 30, 2019 were $9,279 thousand, as compared to $3,839 thousand for the six months ended May 31, 2018, representing an increase of 142%. The increase is primarily attributed to the following: (i) an increase in salaries and related expenses primarily attributable to an increase in head-count in the production and development departments and (ii) an increase in raw materials used due to the growth in the volume of the services provided by MaSTherCell, as well as from revenues generated from existing manufacturing agreements.

Research and Development Expenses

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Salaries and related expenses	$ 1,523	$ 651
Stock-based compensation	299	339
Professional fees and consulting services	546	440
Lab expenses	1,478	310
JV Collaboration (See Note 5)	2,741	-
Depreciation expenses, net	266	54
Other research and development expenses	643	119
Less – grant	(637)	(359)
Total	$ 6,859	$ 1,554

Research and development expenses for the six months ended June 30, 2019 were $6,859 thousand, as compared to $1,554 thousand for the six months ended May 31, 2018, representing an increase of 341%. The increase is primarily attributable to an increase in salaries and related expenses, professional fees and lab expenses, mainly attributable to an increase of clinical operation activities in the U.S., Israel and Belgium, and new therapeutics projects, as well as JV collaborations (see Note 5). This was partially offset by the reallocation of several R&D employees and contractors to the production and development departments.

Selling, General and Administrative Expenses

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Salaries and related expenses	$ 3,867	$ 1,903
Stock-based compensation	1,560	1,488
Accounting and legal fees	1,343	925
Professional fees	1,496	974
Rent and related expenses	1,313	576
Business development	1,101	665
Other general and administrative expenses	803	136
Total	$ 11,483	$ 6,667

Selling, general and administrative expenses for the six months ended June 30, 2019 were $11,483 thousand, as compared to $6,667 thousand for the six months ended May 31, 2018, representing an increase of 72%. The increase is primarily attributable to increased commercial activity, facility expansion and additional personnel, particularly in Masthercell Global, additional sales and support staff at MaSTherCell S.A. In addition, salaries and related expenses of CureCell and Atvio not previously consolidated and increased rent and related expenses for additional space for new production areas at MaSTherCell LLC and MaSTherCell SA contributed to the increase (See Note 8).

Financial Expenses, net

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Changes in fair value financial liabilities and assets measured at fair value	$ -	$ (489)
Interest expense on convertible loans and loans	91	2,659
Foreign exchange loss, net	83	(94)
Other expenses	19	18
Total	$ 193	$ 2,094

Financial expenses, net, for the six months ended June 30, 2019 were $193 thousand, as compared to $2,094 thousand for the six months ended May 31, 2018, representing a decrease of 91%. The decrease is mainly attributable to a decrease of interest expenses on convertible loans and other loans which were converted to equity during the six months ended June 30, 2019. In the six months ended May 31, 2018, finance charges were incurred in the valuation of the fair value of the put option of Atvio. Said option was exercised in June 2018 (see Note 5).

Working Capital

	June 30, 2019	November 30, 2018
	(in thousands)	
Current assets	$ 27,092	$ 30,297
Current liabilities	(23,064)	(17,145)
Working capital	$ 4,028	$ 13,152

Current assets decreased by $3,205 thousand between November 30, 2018 and June 30, 2019. The GPP receivable was received in January 2019. Accounts receivable increased as a result of increased sales.

Current liabilities increased by $5,919 thousand between November 30, 2018 and June 30, 2019. The increase was primarily attributable to an increase of (i) $2,459 thousand in Accounts payable and Accrued expenses, (ii) $2,038 thousand in contract liabilities (see Note 2), and (iii) $1,613 thousand of current maturities of operating leases.

Liquidity and Financial Condition

	Six Months Ended June 30, 2019	Six Months Ended May 31, 2018
	(in thousands)	
Net loss	$ 14,275	$ 7,953
Net cash used in operating activities	(8,168)	(6,905)
Net cash used in investing activities	(3,947)	(2,979)
Net cash provided by financing activities	13,796	11,103
Increase in cash and cash equivalents	$ 1,681	$ 1,219

Since inception, we have funded our operations primarily through the sale of equity securities and convertible notes, and, more recently, through revenue generated from the activities of the MaSTherCell Global subsidiaries. At June 30, 2019, we had a working capital surplus of $4,028 thousand, including cash and cash equivalents of $16,655 thousand.

Net cash used in operating activities was approximately $8,168 thousand for the six months ended June 30, 2019, as compared with net cash used in operating activities of $6,905 thousand for the six months ended May 31, 2018. We successfully expanded our global activity of the CDMO division at our subsidiary MaSTherCell, thereby increasing gross profit and generating cash to help pay our ongoing operating expenses.

Net cash used in investing activities for the six months ended June 30, 2019 was approximately $3,947 thousand, as compared with approximately $2,979 thousand for the six months ended May 31, 2018.

During the six months ended June 30, 2019, our financing activities consisted of receipts of convertible loans of $7.5 million (see Note 4) and proceeds in the amount of $6.6 million received from Great Point Partners, LLC pursuant to the strategic agreement between the Company, Masthercell Global, and Great Point Partners, LLC (see Note 5). During the six months ended May 31, 2018, our financing activities consisted of proceeds in the amount of $11.1 million.

Liquidity & Capital Resources Outlook

We believe that our business plan will provide sufficient liquidity to fund operating needs for the next 12 months. Additional funds may be necessary to finance some of the collaborations listed in Note 5. However, there are factors that can impact our ability to continue to fund our operating needs, including:

- Our ability to expand sales volume, which is highly dependent on implementing our growth strategy;
- Restrictions on our ability to continue receiving government funding and grants for our POC platform;
- 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.

In the six months ended June 30, 2019, we received $7.500 million from convertible loans, proceeds of approximately $13 million in revenues and accounts receivable from customers and $6.600 million from the proceeds received from the strategic investor Great Point Partners, LLC.

From July 1, 2019 to the date of this report, we received proceeds of approximately $2.6 million in revenues and accounts receivable from customers.

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

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation and subject to the foregoing, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, the design and operation of our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2019 that have materially affected, or that 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, 2018, as filed with the SEC on February 13, 2019, in addition to other information contained in our 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.

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

As of November 30, 2018, during the period from December 1, 2018 to June 30, 2019, the Company entered into a convertible loan agreement with an offshore investor for an aggregate amount of $250 thousand. The loan bears an annual interest rate of 2% and matures in three years unless converted earlier. The investor, at its option, may convert the outstanding principal amount and accrued interest under this note into a total of 35,714 shares and 35,714 three years warrants to purchase up to an additional 35,714 shares of the Company's common stock at a per share exercise price of $7. During the first two years, the investor also has the right to convert the outstanding principal amount and accrued interest of the convertible notes instead into shares of capital stock of either Hemogenyx-Cell S.A. or Immugenyx, LLC according under the relevant note agreement, subsidiaries of Hemogenyx Pharmaceuticals Plc, at a price per share based on a pre-money valuation of Hemogenyx-Cell S.A. or Immugenyx, LLC of $12 million and $8 million, respectively, pursuant to the collaboration agreement with Hemogenyx Pharmaceuticals Plc and Immugenyx, LLC.

On April 10, 2019, the Company entered into a convertible loan agreement with an offshore investor for an aggregate amount of $500 thousand into the U.S. Subsidiary. The investor, at its option, may convert the outstanding principal amount and accrued interest under this note into shares and three-year warrants to purchase shares of the Company's common stock at a per share exercise price of $7.00; or into shares of the U.S. Subsidiary at a valuation of the U.S. Subsidiary of $50 million.

On May 17, 2019, the Company entered into a private placement subscription agreement with an investor for $5 million. The lender shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share. As of June 30, 2019, the Company had received $5 million in total under this subscription agreement.

On June 10 2019, the Company entered into a private placement subscription agreement with investors for an aggregate amount of $2 million. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share. As of June 30, 2019, the Company had received $2 million in total under this subscription agreement.

In May 2019, the Company had agreed to a 6% convertible loan agreement with an investor for an aggregate amount of $5 million. The lender shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share. As of the date of the filing of this Quarterly Report on Form 10-Q, the loan had not been received by the Company.

The above issuances of warrants did not involve any underwriters, underwriting discounts or any public offering. The Company relied upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Act") by virtue of Section 4(a)(2) thereof and/or Regulation D promulgated by the SEC under the Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits required by Item 601 of Regulation S-K

No.	Description
(31)	**Rule 13a-14(a)/15d-14(a) Certification**
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
(32)	**Section 1350 Certification**
32.1*	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2*	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
(101)*	**Interactive Data Files**
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* *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: August 8, 2019

/s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: August 8, 2019

Exhibit 31.1

ORGENESIS INC.
CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vered Caplan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 of Orgenesis Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to the us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on the our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By:

/s/ Vered Caplan
Vered Caplan
President & Chief Executive Officer
(Principal Executive Officer)
Date: August 8, 2019

Exhibit 31.2

ORGENESIS INC.
CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neil Reithinger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 of Orgenesis Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to the us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By:

/s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: August 8, 2019

Exhibit 32.1

ORGENESIS INC.
CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Vered Caplan, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Quarterly Report on Form 10-Q of Orgenesis Inc. for the quarter ended June 30, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) Information contained in the Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Orgenesis Inc.

By:

/s/ Vered Caplan
Vered Caplan
President & Chief Executive Officer
(Principal Executive Officer)
Date: August 8, 2019

Exhibit 32.2

ORGENESIS INC.
CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Neil Reithinger, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Quarterly Report on Form 10-Q of Orgenesis Inc. for the quarter ended June 30, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) Information contained in the Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Orgenesis Inc.

By:

/s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: August 8, 2019