

REFINITIV

DELTA REPORT

10-Q

ORGS - ORGENESIS INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

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TOTAL DELTAS 1541

CHANGES 8

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended September 30, 2023

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: 001-38416

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, MD20876

(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 symbol(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 ☒ 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 ☒ 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

☐

Non-accelerated filer

☒

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 ☒

As of November 13, 2023, there were 31,877,063 shares of registrant's common stock outstanding.

ORGENESIS INC.
FORM 10-Q
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022
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PART I –FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

Assets	As of	
	September 30, 2023	December 31, 2022
CURRENT ASSETS:		
Cash and cash equivalents	\$ 55	\$ 5,311
Restricted cash	734	1,058
Accounts receivable, net	71	36,183
Prepaid expenses and other receivables	4,031	958
Receivables from related parties	1,052	-
Convertible loan to related party	2,799	2,688
Inventory	34	120
Total current assets	8,776	46,318
NON-CURRENT ASSETS:		
Deposits	\$ 40	\$ 331
Equity investees	22,509	39
Loans to associates	93	96
Property, plant and equipment, net	1,503	22,834
Intangible assets, net	7,528	9,694
Operating lease right-of-use assets	431	2,304
Goodwill	3,703	8,187
Deferred tax	-	103
Other assets	716	1,022
Total non-current assets	36,523	44,610
TOTAL ASSETS	\$ 45,299	\$ 90,928

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)

Liabilities and Equity	As of	
	September 30, 2023	December 31, 2022
CURRENT LIABILITIES:		
Accounts payable	\$ 4,851	\$ 4,429
Accounts payable related parties	132	-
Accrued expenses and other payables	2,015	2,648
Income tax payable	915	289
Employees and related payables	807	1,860
Other payables related parties	999	-
Advance payments on account of grant	1,376	1,578
Short-term loans	430	-
Current maturities of finance leases	17	60
Current maturities of operating leases	220	542
Current maturities of convertible loans	2,540	4,504
Total current liabilities	14,302	15,910
LONG-TERM LIABILITIES:		
Non-current operating leases	\$ 140	\$ 1,728
Convertible loans	18,394	13,343
Retirement benefits obligation	-	163
Finance leases	8	95
Other long-term liabilities	58	415
Total long-term liabilities	18,600	15,744
TOTAL LIABILITIES	32,902	31,654
REDEEMABLE NON-CONTROLLING INTEREST	\$ -	\$ 30,203
EQUITY:		
Common stock of \$0.0001 par value: Authorized at September 30, 2023 and December 31, 2022: 145,833,334 shares; Issued at September 30, 2023 and December 31, 2022: 30,753,374 and 25,832,322 shares, respectively; Outstanding at September 30, 2023 and December 31, 2022: 30,466,807 and 25,545,755 shares, respectively	3	3
Additional paid-in capital	155,819	150,355
Accumulated other comprehensive income (loss)	71	(270)
Treasury stock 286,567 shares as of September 30, 2023 and December 31, 2022	(1,266)	(1,266)
Accumulated deficit	(142,230)	(121,261)
Equity attributable to Orgenesis Inc.	12,397	27,561
Non-controlling interest	-	1,510
Total equity	12,397	29,071
TOTAL LIABILITIES REDEEMABLE NON-CONTROLLING INTEREST AND EQUITY	\$ 45,299	\$ 90,928

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

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

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenues	\$ 110	\$ 7,841	\$ 14,129	\$ 21,117
Revenues from related party	-	147	-	1,284
Total revenues	110	7,988	14,129	22,401
Cost of revenues	139	983	6,093	2,760
Gross (loss) profit	(29)	7,005	8,036	19,641
Cost of development services and research and development expenses	808	3,683	7,616	18,172
Amortization of intangible assets	153	225	568	686
Selling, general and administrative expenses	1,245	3,104	8,621	8,758
Share in net loss of associated companies	9,518	274	9,517	1,189
Operating loss	11,753	281	18,286	9,164
Other (income), loss net	(2)	2	(4)	(6)
Loss from extinguishment in connection with convertible loan	-	-	283	-
Financial expenses, net	508	1,100	1,807	1,702
Profit from deconsolidation of Octomera (see note 3)	-	-	(411)	-
Loss before income taxes	12,259	1,383	19,961	10,860
Tax expenses	394	25	614	37
Net loss	12,653	1,408	20,575	10,897
Net (loss) income attributable to non-controlling interests (including redeemable)	-	(52)	394	(105)
Net loss attributable to Orgenesis Inc.	\$ 12,653	\$ 1,356	\$ 20,969	\$ 10,792
Loss per share:				
Basic and diluted	\$ 0.43	\$ 0.05	\$ 0.75	\$ 0.43
Weighted average number of shares used in computation of Basic and Diluted loss per share:				
Basic and diluted	29,162,459	25,403,907	27,933,067	24,944,814
Comprehensive loss:				
Net loss	\$ 12,653	\$ 1,408	\$ 20,575	\$ 10,897
Other comprehensive (income) loss - translation adjustments	(9)	556	43	1,033
Release of translation adjustment due to deconsolidation of Octomera	-	-	(384)	-
Comprehensive loss	12,644	1,964	20,234	11,930
Comprehensive (loss) income attributed to non-controlling interests	-	(52)	394	(105)
Comprehensive loss attributed to Orgenesis Inc.	\$ 12,644	\$ 1,912	\$ 20,628	\$ 11,825

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)

	<u>Common Stock</u>			Accumulated			Equity		
	Number	Par Value	Additional Paid-in Capital	Other Comprehensive Income (Loss)	Treasury Shares	Accumulated Deficit	Attributed to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at January 1, 2023	25,545,755	\$ 3	\$ 150,355	\$ (270)	\$ (1,266)	\$ (121,261)	\$ 27,561	\$ 1,510	\$ 29,071
Changes during the nine months ended September 30, 2023:									
Stock-based compensation to employees and directors	-	-	347	-	-	-	347	-	347
Stock-based compensation to service providers	-	-	40	-	-	-	40	-	40
Issuance of shares and warrants net of issuance costs	3,947,368	*	4,341	-	-	-	4,341	-	4,341
Issuance of Shares due to exercise of warrants	973,684	*	-	-	-	-	-	-	-
Issuance of warrants with respect to convertible loans	-	-	449	-	-	-	449	-	449
Extinguishment in connection with convertible loan restructuring	-	-	287	-	-	-	287	-	287
Deconsolidation of Non-controlling Interests	-	-	-	-	-	-	-	(1,421)	(1,421)
Comprehensive income (loss) for the period	-	-	-	341	-	(20,969)	(20,628)	(89)	(20,717)
Balance at September 30, 2023	<u>30,466,807</u>	<u>\$ 3</u>	<u>\$ 155,819</u>	<u>\$ 71</u>	<u>\$ (1,266)</u>	<u>\$ (142,230)</u>	<u>\$ 12,397</u>	<u>\$ -</u>	<u>\$ 12,397</u>

* Represents an amount lower than \$1.

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)

	<u>Common Stock</u>						Equity		
				Accumulated			Attributed		
	Number	Par Value	Additional Paid-in Capital	Other Comprehensive Income (Loss)	Treasury Shares	Accumulated Deficit	to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at January 1, 2022	24,280,799	\$ 3	\$ 145,916	\$ 207	\$ (1,266)	\$ (106,372)	\$ 38,488	\$ 143	\$ 38,631
Changes during the nine months ended September 30, 2022:									
Stock-based compensation to employees and directors	-	-	646	-	-	-	646	-	646
Stock-based compensation to service providers	-	-	48	-	-	-	48	-	48
Exercise of options	510,017	*	6	-	-	-	6	-	6
Issuance of warrants with respect to convertible loans	-	-	574	-	-	-	574	-	574
Issuance of shares	724,999	*	2,175	-	-	-	2,175	-	2,175
Issuance of shares related to acquisition of Mida	29,940	*	100	-	-	-	100	-	100
Comprehensive loss for the period	-	-	-	(1,033)	-	(10,792)	(11,825)	(105)	(11,930)
Balance at September 30, 2022	<u>25,545,755</u>	<u>\$ 3</u>	<u>\$ 149,465</u>	<u>\$ (826)</u>	<u>\$ (1,266)</u>	<u>\$ (117,164)</u>	<u>\$ 30,212</u>	<u>\$ 38</u>	<u>\$ 30,250</u>

* Represents an amount lower than \$1.

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			(Unaudited)						
	Number	Par Value	Additional Paid-in Capital	Accumulated			Equity		Non-Controlling Interest	Total
				Other Comprehensive Income (Loss)	Treasury Shares	Accumulated Deficit	Attributed to Orgenesis Inc.			
Balance at July 1, 2023	28,466,807	\$ 3	\$ 154,743	\$ 62	\$ (1,266)	\$ (129,577)	\$ 23,965	\$ -	\$ 23,965	
Changes during the three months ended September 30, 2023:										
Stock-based compensation to employees and directors	-	-	68	-	-	-	68	-	68	
Stock-based compensation to service providers	-	-	8	-	-	-	8	-	8	
Issuance of shares	2,000,000	*	1,000	-	-	-	1,000	-	1,000	
Comprehensive income (loss) for the period	-	-	-	9	-	(12,653)	(12,644)	-	(12,644)	
Balance at September 30, 2023	30,466,807	\$ 3	\$ 155,819	\$ 71	\$ (1,266)	\$ (142,230)	\$ 12,397	\$ -	\$ 12,397	

* Represents an amount lower than \$1.

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			Receipts on Account of Shares to be Allotted	Accumulated		Equity Attributed			
	Number	Par Value	Additional Paid-in Capital		Other Comprehensive Loss	Treasury Shares	Accumulated Deficit	to Orgenesis Inc.	Non- Controlling Interest	Total
Balance at July 1, 2022	24,820,756	\$ 3	\$ 146,919	\$ 2,175	\$ (270)	\$ (1,266)	\$ (115,808)	\$ 31,753	\$ 90	\$ 31,843
Changes during the three months ended September 30, 2022:										
Stock-based compensation to employees and directors	-	-	183	-	-	-	-	183	-	183
Stock-based compensation to service providers	-	-	11	-	-	-	-	11	-	11
Issuance of warrants with respect to convertible loans	-	-	177	-	-	-	-	177	-	177
Issuance of shares	724,999	*	2,175	(2,175)	-	-	-	-	-	-
Comprehensive loss for the period	-	-	-	-	(556)	-	(1,356)	(1,912)	(52)	(1,964)
Balance at September 30, 2022	25,545,755	\$ 3	\$ 149,465	\$ -	\$ (826)	\$ (1,266)	\$ (117,164)	\$ 30,212	\$ 38	\$ 30,250

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

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

	Nine Months Ended	
	September 30, 2023	September 30, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (20,575)	\$ (10,897)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	387	694
Capital gain, net	-	(5)
Profit from deconsolidation of Octomera	(411)	-
Share in losses of associated companies, net	9,517	1,189
Depreciation and amortization expenses	1,366	1,463
Effect of exchange differences on inter-company balances	129	353
Net changes in operating leases	(82)	(58)
Interest expenses accrued on loans and convertible loans	769	764
Loss from extinguishment in connection with convertible loan restructuring	283	-
Changes in operating assets and liabilities:		
Accounts receivable	(8,076)	(8,838)
Prepaid expenses and other accounts receivable	(1,598)	308
Inventory	(389)	10
Other assets	10	17
Accounts payable	3,925	(1,574)
Accrued expenses and other payables	266	2,379
Employee and related payables	135	32
Deferred taxes liability	9	-
Net cash used in operating activities	\$ (14,335)	\$ (14,163)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Repayment of convertible loan to related party partners	-	538
Increase in loan to associates entities	-	(2,578)
Repayment of loan granted	-	782
Sale of property and equipment	-	71
Purchase of property, plant and equipment	(2,096)	(6,971)
Cash acquired from acquisition of Mida	-	702
Impact to cash resulting from deconsolidation (see note 3)	(973)	-
Investment in Octomera (see note 3)	(543)	-
Investment in long-term deposits	(33)	(2)
Net cash used in investing activities	\$ (3,645)	\$ (7,458)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares due to exercise of options and warrants (net of transaction costs)	4,341	2,181
Proceeds from issuance of convertible loans	5,660	19,150
Proceeds from transaction with redeemable non-controlling interest that do not acquire control of a subsidiary, see note 3	5,000	-
Repayment of convertible loans and convertible bonds	(3,000)	(2,300)
Repayment of short and long-term debt	(33)	(20)
Proceeds from issuance of loans payable	425	-
Grant received in respect of third party	-	1,413
Transfer of the grant received to third party	-	(329)
Net cash provided by financing activities	\$ 12,393	\$ 20,095
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	\$ (5,587)	\$ (1,526)

EFFECT OF EXCHANGE RATE CHANGES ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH				7	19
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD				6,369	5,974
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD				<u>\$ 789</u>	<u>\$ 4,467</u>
SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES					
Right-of-use assets obtained in exchange for new operation lease liabilities	\$	752	\$	432	
Increase (decrease) in accounts payable related to purchase of property, plant and equipment	\$	14	\$	(368)	
Issuance of common stocks for the acquisition of Mida	\$	-	\$	100	
Extinguishment in connection with convertible loan restructuring	\$	287	\$	-	
CASH PAID DURING THE YEAR FOR:					
Interest	\$	785	\$	458	

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

ORGENESIS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the Nine Months Ended September 30, 2023 and 2022
(U.S. Dollars in thousands, except share amounts)
(Unaudited)

NOTE 1 – DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc. (the “Company”) is a global biotech company working to unlock the potential of Cell and Gene Therapies (“CGTs”) in an affordable and accessible format. CGTs can be centered on autologous (using the patient’s own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products (“ATMPs”). The Company is mostly focused on the development of autologous therapies that can be manufactured under processes and systems that are developed for each therapy using a closed and automated approach that is validated for compliant production near the patient for treatment of the patient at the point of care (“POCare”).

In connection with the investment by an affiliate of Metalmark Capital Partners (“Metalmark” or “MM”) in the Company’s subsidiary Octomera LLC (formerly Morgenesi LLC) (“Octomera” or “Morgenesi”) in November 2022 (“the Metalmark Investment”), the Company separated its operations into two operating segments: the operations of Octomera (the “Morgenesi” or “Octomera” segment) and therapies related activities (the “Therapies” segment).

On June 30, 2023, in connection with an additional \$1,000 investment in Octomera, the Company and MM entered into Amendment No. 1 to the Second Amended and Restated Limited Liability Company Agreement (the “LLC Agreement Amendment”) to change the name of Morgenesi to “Octomera LLC” and to amend Morgenesi’s board composition. Pursuant to the LLC Agreement Amendment, the board of managers of Octomera (the “Octomera Board”) will be comprised of five managers, two of which will be appointed by the Company, one of which will be an industry expert appointed by MM, and two of which will be appointed by MM. The change was effective immediately. As a result of the amendment to the composition of the Octomera Board pursuant to the LLC Agreement Amendment described above, the Company deconsolidated Octomera from its consolidated financial statements as of June 30, 2023 (“date of deconsolidation”) and recorded its equity interest in Octomera as an equity method investment, see note 3.

The Company currently owns approximately 75% of Octomera LLC.

These consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries.

The Company’s common stock, par value \$0.0001 per share (the “Common Stock”), is listed and traded on the Nasdaq Capital Market under the symbol “ORGS.” The Company must satisfy Nasdaq’s continued listing requirements, including, among other things, a minimum closing bid price requirement of \$1.00 per share for 30 consecutive business days. Because the Company’s share has traded for 30 consecutive business days below the \$1.00 minimum closing bid price requirement, Nasdaq has sent a deficiency notice to the Company, which was received on September 27, 2023, advising that it has been afforded a “compliance period” of 180 calendar days to regain compliance with the applicable requirements.

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

b. Liquidity

Through September 30, 2023, the Company had an accumulated deficit of \$142,230. For the nine months ended September 30, 2023, the Company incurred negative cash flows from operating activities of \$14,335. The Company's activities have recently been funded primarily by offerings of its equity securities, loans, and convertible loans. There is no assurance that the Company's business will generate sustainable positive cash flows to fund its business operations.

If there are further reductions in revenues or increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, the Company will need to use mitigating actions such as to seek additional financing or postpone expenses that are not based on firm commitments. In addition, in order to fund the Company's operations until such time that the Company can generate sustainable positive cash flows, the Company will need to raise additional funds.

The Company expects its current and projected cash resources and commitments will not be sufficient to meet the Company's obligations for the next 12 months, raising a substantial doubt about the Company's ability to continue as a going concern. Management plans include raising additional capital to fund the Company's operations and to repay the Company's outstanding loans when they become due, as well as exploring additional avenues to increase revenue and reduce capital expenditures. See note 1 a. The Company's ability to fund the completion of its ongoing and planned activities may be substantially dependent upon whether the Company can obtain sufficient funding at acceptable terms. If the Company is unable to raise sufficient additional capital or meet revenue targets, it may have to reduce or eliminate certain activities and reduce its headcount.

The estimation and execution uncertainty regarding the Company's future cash flows and management's judgments and assumptions in estimating these cash flows is a significant estimate. Those assumptions include reasonableness of the forecasted revenue, operating expenses, and uses and sources of cash.

NOTE 2 - BASIS OF PRESENTATION

a. Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all normal and recurring adjustments necessary to fairly state the financial position and results of operations of the Company. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission ("SEC") on March 22, 2023. The year-end balance sheet data was derived from the audited consolidated financial statements as of December 31, 2022, but not all disclosures required by generally accepted accounting principles in the United States ("U.S. GAAP") are included in this Quarterly Report on Form 10-Q.

b. Significant accounting policies

The accounting policies adopted are consistent with those of the previous financial year except as described below:

Use of Estimates in the Preparation of Financial Statements

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, judgments, and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity, the amount of revenues and expenses and the determination of the fair value of the retained interest of equity investment as of the deconsolidation. Actual results could differ from those estimates.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13 “Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments.” This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for Smaller Reporting Companies (SRCs, as defined by the SEC) for the fiscal year beginning on January 1, 2023, including interim periods within that year. The adoption of this guidance did not have a material impact on the Company’s consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08 “Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers”, which requires contract assets and contract liabilities acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606, Revenue from Contracts with Customers. The guidance results in the acquirer recognizing contract assets and contract liabilities at the same amounts recorded by the acquiree. The guidance is to be applied prospectively to acquisitions that occur on or after the effective date. The guidance is currently effective for fiscal years that began after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, including in interim periods, for any financial statements that have not yet been issued. The adoption of this guidance did not have a material impact on the Company’s consolidated financial statements.

Recently issued accounting pronouncements, not yet adopted

On August 23, the FASB issued guidance requiring a joint venture to initially measure all contributions received upon its formation at fair value. This accounting will largely be consistent with ASC 805, Business Combinations, although there are some specific exceptions. Before the ASU, there was no authoritative guidance in US GAAP that addressed how a joint venture should recognize contributions received. As a result, there has been diversity in practice, with some joint ventures accounting for contributions received at carry over basis and others at fair value. This new guidance is intended to reduce diversity in practice and provide users of the joint venture’s financial statements with more decision-useful information. It may also reduce the amount of basis differences that an investor in a joint venture needs to track. The new guidance should be applied prospectively and is effective for all newly-formed joint venture entities with a formation date on or after January 1, 2025, with early adoption permitted. The adoption of this guidance will not have a material impact on the Company’s consolidated financial statements.

Reclassifications

Certain reclassifications have been made to the prior year’s financial statements to conform to the current year presentation. These reclassifications had no net effect on previously reported results of operations.

NOTE 3 – REDEEMABLE NON-CONTROLLING INTEREST AND DECONSOLIDATION

Additional Investments in Octomera LLC

During 2023, the Company and MM entered into various amendments to the Unit Purchase Agreement, dated November 4, 2022 (the “UPA”). Pursuant to such amendments, MM or the Company as the case may be, agreed to pay certain amounts in exchange for Class A Preferred Units of Octomera to support the continued expansion of Orgenesis’ POCare Services (the “Subsequent Investment”), all as detailed in the table below. In the case of MM investments, the investment amount of the First Future Investment (as defined in the UPA) was reduced by the amount of the Subsequent Investment.

Date	Investing party	Amendment #	Amount	Class A Preferred units obtained
May 5, 2023	MM	1	\$ 5,000	500,000
June 30, 2023	MM	2	\$ 1,000	100,000
August 22, 2023	MM	3	\$ 100	10,000
August 29, 2023	Company	4	\$ 543	54,310
September 6, 2023	MM	5	\$ 100	10,000
September 13, 2023	MM	6	\$ 150	15,000
September 28, 2023	MM	7	\$ 150	15,000
October 12, 2023	Company	8	\$ 117	11,700
November 9, 2023	Company	9	\$ 176	17,600

During October 2023, MM loaned an Octomera subsidiary \$700. The loan bears annual interest of 10% and is due for repayment during April 2024.

As a result of the deconsolidation (see note 1a), the Company recorded a net profit of \$411, representing the difference between the fair value of the retained interest in Octomera and the net assets deconsolidated in the transaction as follows:

Fair value of the retained interest in Octomera	\$	31,442
Net assets deconsolidated		32,551
Other related items deconsolidated, net		(1,520)
Net profit	\$	411

The change in board composition does not constitute a strategic shift from the Company's perspective and therefore the Company did not treat the deconsolidation as a discontinued operation.

Following the Amendment No. 2, the Company accounted for its investment in Octomera according to the equity method in accordance with ASC Topic 323, as it has retained the ability to exercise significant influence but does not control the entity. The Company thus recognized an equity method investment in a total amount of \$31,400 comprised of the assumed fair value of the Octomera shares held by the Company. Following the deconsolidation, the Company recognized related party balances that are disclosed on the face of the Company's balance sheet.

The preliminary allocation of the purchase price ("PPA") to net assets acquired and liability assumed resulted in the recognition of intangible asset of \$6,200 and other net assets of \$25,200. The value assigned to intangible assets is amortized over a period of 10 years and the related amortization will be included under share in net losses (profits) from associated companies. The estimated fair value is preliminary and based on the information that was available as of June 30, 2023.

In evaluating the fair value of the Octomera Equity Investment under the income approach, the Company used a discounted cash flow model of the business, adjusted to the Company's share in the investment. Key assumptions used to determine the estimated fair value included: (a) internal cash flows forecasts for 5 years following the assessment date, including expected revenue growth, costs to produce, operating profit margins and estimated capital needs; (b) an estimated terminal value using a terminal year long-term future growth determined based on the growth prospects of the reporting units; and (c) a discount rate which reflects the weighted average cost of capital adjusted for the relevant risk associated with the Company's reporting unit operations and the uncertainty inherent in the Company's internally developed forecasts. The allocation of the purchase price to the net assets acquired and liabilities assumed resulted in the recognition of other intangible assets, net, which comprised of technology. The useful life of the technology for amortization purposes was determined by considering the period of expected cash flows generated by the assets used to measure the fair value of the intangible assets, adjusted as appropriate for the entity-specific factors including legal, regulatory, contractual, competitive, economic, or other factors that may limit the useful life of intangible assets.

The following table represents the deconsolidated amounts from the Company's Balance Sheet at the date of deconsolidation:

ASSETS:	
Cash and cash equivalents	973
Other current assets	47,217
Non-current assets	29,443
TOTAL ASSETS	77,633
LIABILITIES:	
Current liabilities	6,566
Long-term liabilities	2,313
TOTAL LIABILITIES	8,879
REDEEMABLE NON-CONTROLLING INTEREST	36,203
NET ASSETS DECONSOLIDATED	32,551

NOTE 4 – EQUITY-METHOD INVESTMENTS

As of September 30, 2023, and December 31, 2022, the balances of our equity-method investments were 22,509 and \$39, respectively, and are as follows:

Octomera LLC

The Company currently owns approximately 75% of Octomera LLC.

As of September 30, 2023, the balance of our equity-method investment related to Octomera was approximately \$22,479. Through September 30, 2023, the Company’s share in Octomera’s net loss was \$9,507.

Our equity-method investment in Octomera is considered a significant investee as our proportionate share of its income is greater than 20% of our total net loss. The following table presents summarized results of operations for the three months since the date of deconsolidation:

	Three-Months Ended	
	September 30,	
	2023	
Total revenue	\$	2,704
Gross loss	\$	478
Net loss	\$	11,820

NOTE 5 – SEGMENT INFORMATION

The Octomera operations segment includes mainly POCare Services, while the Therapies segment includes the Company’s therapeutic development operations. The segment information includes all the results of the Octomera segment up to the effective date of deconsolidation.

Because the Company conducted all its operations as one segment prior to the Metalmark Investment, the above changes were reflected through retroactive revision of prior period segment information based on the subsidiaries that were transferred to Octomera. Certain activities of these subsidiaries have changed after they were transferred to the Octomera operations segment.

The Company’s Chief Executive Officer (“CEO”), who is the chief operating decision maker (“CODM”), reviews financial information prepared on a consolidated basis, accompanied by disaggregated information about revenues and contributed profit by the two identified reportable segments to make decisions about resources to be allocated to the segments and assess their performance.

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

Segment data for the nine months ended September 30, 2023 is as follows:

	Octomera	Therapies	Eliminations	Consolidated
Revenues	\$ 16,483	350	\$ (2,704)	\$ 14,129
Cost of revenues*	(6,959)	(531)	1,874	(5,616)
Gross profit	9,524	(181)	(830)	8,513
Cost of development services and research and development expenses*	(6,828)	(2,830)	2,327	(7,331)
Operating expenses*	(13,329)	(4,962)	9,706	(8,585)
Share in net income of associated companies	-	(10)	(9,507)	(9,517)
Other income, net	2	2	-	4
Depreciation and amortization	(1,294)	(589)	517	(1,366)
Loss from extinguishment in connection with convertible loan	-	(283)	-	(283)
Financial Expenses, net	(587)	(1,314)	94	(1,807)
Profit from deconsolidation of Octomera	-	-	411	411
Income (loss) before income taxes	\$ (12,512)	(10,167)	\$ 2,718	\$ (19,961)

* Excluding Depreciation and amortization expenses

Segment data for the nine months ended September 30, 2022 is as follows:

	Octomera	Therapies	Eliminations	Consolidated
Revenues	\$ 20,705	5,908	\$ (5,496)	\$ 21,117
Revenues from related party	1,284	-	-	1,284
Total revenues	21,989	5,908	(5,496)	22,401
Cost of revenues*	(1,988)	(857)	356	(2,489)
Gross profit	20,001	5,051	(5,140)	19,912
Cost of development services and research and development expenses*	(10,791)	(11,209)	4,297	(17,703)
Operating expenses*	(2,822)	(6,742)	843	(8,721)
Share in net income of associated companies	(222)	(967)	-	(1,189)
Other income, net	2	4	-	6
Depreciation and amortization	(685)	(778)	-	(1,463)
Financial Expenses, net	(2,087)	385	-	(1,702)
Income (loss) before income taxes	\$ 3,396	\$ (14,256)	\$ -	\$ (10,860)

* Excluding Depreciation and amortization expenses

Segment data for the three months ended September 30, 2023 is as follows:

	Octomera	Therapies	Eliminations	Consolidated
Revenues	\$ 2,704	110	\$ (2,704)	\$ 110
Cost of revenues*	(1,875)	(133)	1,874	(134)
Gross profit	829	(23)	(830)	(24)
Cost of development services and research and development expenses*	(2,327)	(779)	2,327	(779)
Operating expenses*	(9,706)	(1,241)	9,706	(1,241)
Share in net income of associated companies	-	(11)	(9,507)	(9,518)
Other income	-	2	-	2
Depreciation and amortization	(515)	(193)	517	(191)
Financial Expenses, net	(93)	(508)	93	(508)
Income (loss) before income taxes	\$ (11,812)	(2,753)	\$ 2,306	\$ (12,259)

* Excluding Depreciation, amortization expenses

Segment data for the three months ended September 30, 2022 is as follows:

	Octomera	Therapies	Eliminations	Consolidated
Revenues	\$ 7,756	2,046	\$ (1,961)	\$ 7,841
Revenues from related party	147	-	-	147
Total revenues	7,903	2,046	(1,961)	7,988
Cost of revenues*	(664)	(217)	-	(881)
Gross profit	7,239	1,829	(1,961)	7,107
Cost of development services and research and development expenses*	(4,019)	(1,181)	1,662	(3,538)
Operating expenses*	(1,385)	(2,002)	299	(3,088)
Share in net income of associated companies	(222)	(52)	-	(274)
Other income (loss), net	(1)	(1)	-	(2)
Depreciation and amortization	(288)	(200)	-	(488)
Financial Expenses, net	(836)	(264)	-	(1,100)
Income (loss) before income taxes	\$ 488	\$ (1,871)	\$ -	\$ (1,383)

* Excluding Depreciation, amortization expenses

NOTE 6 – EQUITY

On February 23, 2023, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with certain institutional and accredited investors (the “Purchaser”) relating to the issuance and sale of 1,947,368 shares (the “Shares”) of common stock, par value \$0.0001 per share (the “Common Stock”), and warrants to purchase up to 973,684 shares of Common Stock (the “Warrants”) at a purchase price of \$1.90 per share of Common Stock and accompanying Warrants in a registered direct offering (the “Offering”). The Offering closed on February 27, 2023 (the “Closing Date”).

The Warrants have an exercise price of \$1.90 per share, are exercisable immediately and will expire five years following the date of issuance. The Warrants have an alternate cashless exercise option (beginning on or after the earlier of (a) the thirty-day anniversary of the date of the Purchase Agreement and (b) the date on which the aggregate composite trading volume of Common Stock following the public announcement of the pricing terms exceeds 13,600,000 shares), to receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise and (y) 1.0. The aggregate gross proceeds to the Company from the Offering were \$3,700, before deducting placement agent cash fees equal to 7.0% of the gross proceeds received and other expenses from the Offering payable by the Company. The Company intends to use the net proceeds from the Offering for working capital and general corporate purposes, including the Company’s therapy related activities.

As of September 30, 2023, all of the warrants were exercised using the alternate cashless exercise option described above.

On August 31, 2023, the Company entered into a Securities Purchase Agreement with a certain accredited investor, pursuant to which the Company agreed to issue and sell, in a private placement (the “Offering”), 2,000,000 shares of the Company’s common stock, par value \$0.0001 per share, at a purchase price of \$0.50 per share. The Company received proceeds of \$1,000. The Offering closed on August 31, 2023.

NOTE 7 – LOANS

On July 25, 2023, one of the Company’s subsidiaries received a loan from an offshore investor in the amount of \$175. The loan bears 8% annual interest and is repayable on January 1, 2024.

On August 15, 2023, the Company received a loan from an investor in the amount of \$250. The loan bears 8% annual interest and is repayable on January 1, 2024.

During October 2023, the Company’s subsidiaries received loans in the amount of \$140. The loans bear interest at annual interest rates ranging from 0% to 10%, and are repayable between November 30, 2023 and January 1, 2024.

NOTE 8 – CONVERTIBLE LOANS

Convertible loans outstanding as of September 30, 2023 and December 31, 2022 are as follows:

Principal Amount	Issuance Date (Year)	Current Interest Rate %	Current Maturity (Year)	Current Conversion Price \$
Convertible Loans Outstanding as of September 30, 2023				
\$ 750	2018	10 %	2026	2.50
1,500	2019	10 %	2026	7.00
100	2019	8 %	2023	2.50
5,000	2019	10 %	2026	2.50
100	2020	8 %	2023	7.00
5,000	2022	10 %	2026	2.50
1,150 **	2022	6 %	2023	4.50
5,000	2023	8 %	2026	2.46
660	2023	8 %	2024	*
<u>\$ 19,260</u>				

* See Koligo convertible loan agreement below.

** See note 13.

Convertible Loans Outstanding as of December 31, 2022				
\$ 750	2018	2 %	2023	7.00
1,600	2019	8 %	2024	7.00
5,000	2019	6 %	2023	7.00
100	2020	8 %	2023	7.00
8,000	2022	10 %	2024	2.50
1,150	2022	6 %	2023	4.50
<u>\$ 16,600</u>				

Convertible Loans Entered into in 2023

On January 10, 2023 (the “Effective Date”), the Company entered into the following agreements: (i) a convertible loan agreement (the “NewTech Convertible Loan Agreement”) with NewTech Investment Holdings, LLC (the “NewTech Lender”), pursuant to which the NewTech Lender loaned the Company \$4,000 (the “NewTech Loan Amount”), and (ii) a convertible loan agreement (the “Malik Convertible Loan Agreement”, together with the NewTech Convertible Loan Agreement, the “Convertible Loan Agreements”) with Ariel Malik (the “Malik Lender”, together with the NewTech Lender, the “Lenders”), pursuant to which the Malik Lender loaned the Company \$1,000 (the “Malik Loan Amount”, together with the NewTech Loan Amount, the “Loan Amount”).

The terms of the NewTech Convertible Loan Agreement and the Malik Loan Agreement are identical. Interest is calculated at 8% per annum (based on a 365-day year); provided, that if an Event of Default (as defined in the Convertible Loan Agreements) has occurred and is continuing, the Outstanding Amount (as defined herein) will be calculated at 15.0% per annum. The Loan Amount and all accrued but unpaid interest thereon (collectively, the “Outstanding Amount”) shall either (i) be repaid in cash or (ii) convert to shares of common stock, par value \$0.0001 per share (“Common Stock”), of the Company on the third anniversary of the Effective Date (the “Maturity Date”). The Maturity Date may be extended by the Lender upon the written consent of the Lender. The Outstanding Amount may be prepaid by the Company in whole or in part at any time with the prior approval of the Lender.

At any time prior to or on the Maturity Date, any Lender may provide the Company with written notice to convert all or part of the Outstanding Amount into shares of our Common Stock equal to the quotient obtained by dividing (x) the Outstanding Amount by (y) a price equal to \$2.464 per share (subject to adjustment for certain capital events, such as stock splits) (the “Conversion Price”).

Under the terms of the Convertible Loan Agreements, the Company used the proceeds from the Loan Amount to (i) redeem the loan amount from the previously disclosed Convertible Loan Agreement, dated as of May 19, 2022 between Orgenesis and Ricky Steven Neumann, as amended by the previously disclosed certain Convertible Loan Extension Agreement, dated as of October 23, 2022, by and between Orgenesis and Ricky Steven Neumann, and (ii) for general corporate purposes. Pursuant to the terms, the Company repaid said loan upon receipt of the Loan Amount.

In connection with such loan, the Company agreed to issue the NewTech Lender warrants representing the right to purchase 405,844 shares of Common Stock, at an exercise price of \$2.50 per share and the Malik Lender warrants representing the right to purchase 101,461 shares of Common Stock, at an exercise price of \$2.50 per share. Such Warrants will be exercisable at any time beginning six months and one day after closing and ending 36 months after the closing date.

Koligo Convertible Loan

On March 27, 2023, the Company’s subsidiary Koligo Therapeutics Inc. (“Borrower”), entered into a convertible loan agreement (the “Convertible Loan Agreement”) with Yehuda Nir (the “Lender,” and together with the Borrower, the “Parties”), pursuant to which the Lender agreed to loan the Borrower up to \$5,000 (the “Loan Amount”). Interest is calculated at 8% per annum (based on a 365-day year) and is payable, along with the principal, on or before January 1, 2024 (the “Maturity Date”). The Maturity Date may be extended by the Lender in the Lender’s sole and absolute discretion and any such extension(s) shall be in writing signed by the Parties. The Loan Amount may be prepaid by the Borrower in whole or in part at any time with the prior written approval of the Lender.

If prior to December 31, 2023, the Borrower issues equity securities (“Equity Securities”) in a transaction or series of related transactions resulting in aggregate gross proceeds to the Borrower of at least \$5,000 (excluding conversion of the Loan Amount) (a “Qualified Financing”), then the outstanding principal amount of the Loan Amount, and any and all accrued but unpaid interest thereon (collectively, the “Outstanding Amount”), will automatically convert into such Equity Securities issued pursuant to the Qualified Financing at a price per share equal to fifty percent (50%) of the price per share paid for each share of the Equity Securities purchased for cash by the investors in the Qualified Financing (the “Mandatory Conversion”). The per share price for the Mandatory Conversion shall be calculated on a fully diluted basis (including equity underlying all outstanding options, warrants, and other convertible securities, but excluding the Equity Securities issuable upon the Mandatory Conversion).

The Parties agreed that the Lender shall have the option to assign \$1,500 of the Loan Amount due to the Lender under that certain convertible loan agreement between the Lender and the Company dated April 21, 2022, as amended, (collectively the “Original Loan”), to the Borrower (the “Loan Assignment”). The terms of the Loan Assignment will be the same as under the Original Loan, including a maturity date of January 31, 2026 and an annual interest rate of 10%. The Loan Assignment will be subject to the Mandatory Conversion as described above. As of the date of the issue of these financial statements, said assignment has not occurred.

Under the terms of the Koligo Convertible Loan Agreement, the Borrower agreed to use the Loan Amount to fund working capital and ongoing operations and for no other purposes unless the Lender agrees in writing. As of September 30, 2023, Koligo received \$660 under the Koligo Convertible Loan Agreement.

On September 29, 2023, Borrower entered into another convertible loan agreement (the “Sai Convertible Loan Agreement”) with Sai Traders (the “Lender,” and together with the Borrower, the “Parties”), pursuant to which the Lender agreed to loan the Borrower up to \$25,000 (the “Sai Convertible Loan”). The Sai Convertible Loan shall consist of an Initial Installment of \$1,500 (“Initial Installment”), and at the election of the Borrower thereafter while the Sai Convertible Loan remains outstanding, Borrower may issue up to an additional \$23,500 (“Subsequent Installments”). The Sai Convertible loan bears transaction costs of 8%. Interest is calculated at 10% per annum (based on a 365-day year) of all outstanding principal borrowings and is payable, along with the principal (collectively the “Outstanding Amount”), on or before December 1, 2027 (the “Maturity Date”). The Loan Amount may be prepaid by the Borrower in whole or in part at any time without penalty.

Under the terms of the Sai Convertible Loan Agreement, at the option of the Lender at the Maturity Date or any time prior, the Outstanding Amount may be convertible, in whole or in part, into the number of shares of Common Stock of the Company equal to the quotient obtained by dividing (x) the Outstanding Amount by (y) the Conversion Price. The “Initial Installment Conversion Price” for the Outstanding Amount relating to the Initial Installment shall be a price per share of Common Stock equal to \$2.50. The “Subsequent Installment Conversion Price” for the Outstanding Amount relating to the Subsequent Installment(s) shall be a price per share of Common Stock equal to \$3.50. Lender agrees that it shall not deliver a notice of conversion that upon effect results in the holder to beneficially own more than 19.99% of the then outstanding shares of Company’s Common Stock. Lender may elect to, instead of the conversion of the Outstanding Amount into Common shares of Company, convert the entire Outstanding Amount into the securities of Borrower pursuant to a the first issuance of equity of the Borrower under which the Borrower raises at least \$5,000 in gross proceeds (“Qualified Financing”) at a price per share equal to 75% of the price per share paid for each share of the equity securities purchased for cash by the investors in such a Qualified Financing. In the event of the Borrower being listed on a public securities exchange, Lender shall have the option to convert the Outstanding Amount at a 25% premium to the volume weighted average price of the Borrower’s equity over the preceding five (5) days as reported by Bloomberg (“5-Day VWAP”), provided that any such conversion shall not result in the Lender to beneficially own more than 19.99% of the then beneficial shares of the Borrower. In the event of an acquisition of the Borrower (“Acquisition”), prior to the closing of such acquisition, Lender shall have the option to convert the Outstanding Amount into equity securities of the Borrower at a price equivalent to seventy five percent (75%) of the price paid by such buyer to acquire the Borrower.

As of September 30, 2023, and as of the date of this report, the Initial Installment was not received, and was therefore not reflected in the Consolidated Balance sheet of September 30, 2023.

Extension of Existing Loan Agreements

On January 12, 2023, the Company entered into (i) a Convertible Credit Line and Unsecured Convertible Note Extension #2 Agreement with Yosef Dotan (the “Dotan Extension Agreement”), (ii) a Convertible Credit Line Extension Agreement with Aharon Lukach (the “Lukach Extension Agreement”) and (iii) a Convertible Loans and Unsecured Convertible Notes Extension #2 Agreement with Yehuda Nir (the “Nir Extension Agreement”), each which extended the maturity date of the convertible loans under their respective loan agreements (as described below) to January 31, 2026. The aggregate principal amount of loans extended was \$12,000 and the interest rate on the extended loans varied between 2% and 10%. In consideration for the extensions, (i) the interest rate on such principal amount of such loans was increased to 10% per annum commencing on February 1, 2023 (except for the Nir Convertible Loan Agreement dated as of April 12, 2022, which already had a 10% per annum interest rate), (ii) the conversion price of the loans was reduced from \$7.00 to \$2.50 (except for the Nir Convertible Loan Agreement dated as of April 12, 2022, which already had a \$2.50 conversion price), (iii) the exercise price of the warrants issuable upon conversion of the 2% Notes and the Nir Convertible Loan Agreement dated as of May 17, 2019 was reduced to \$2.50 per share and the term of such warrants was extended to January 31, 2026.

The Dotan Extension Agreement related to a Convertible Credit Line Agreement dated as of October 3, 2019, as amended, of which \$750 principal amount plus interest is outstanding as of September 30, 2023, and 2% Notes purchased from the Company on November 3, 2018, of which \$250 principal amount plus interest is outstanding. Based on its analysis, the Company concluded that the change in terms referred to Convertible Credit Line Agreement and the 2% Notes should be accounted for as a modification and an extinguishment respectively.

The Lukach Extension Agreement related to a Convertible Credit Line Agreement dated as of October 3, 2019, as amended, of which \$750 principal amount plus interest is outstanding as of September 30, 2023. Based on its analysis, the Company concluded that the change in terms referred to above should be accounted for as a modification.

The Nir Extension Agreement related to 2% Notes purchased from the Company on November 3, 2018, as amended, of which \$500 principal amount plus interest is outstanding as of September 30, 2023, a Convertible Loan Agreement dated as of May 17, 2019, of which \$5,000 principal amount plus interest is outstanding, and a Convertible Loan Agreement dated as of April 12, 2022, as amended, of which \$5,000 principal amount plus interest is outstanding. Based on its analysis, the Company concluded that the change in terms referred to the 2% Notes and Convertible Loan Agreement should be accounted for as an extinguishment and a modification respectively.

NOTE 9 – 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, 2023 to September 30, 2023:

	<u>No. of Options Granted</u>	<u>Exercise Price</u>	<u>Vesting Period</u>	<u>Fair Value at Grant</u>	<u>Expiration Period</u>
			Quarterly over a period of two years		
Employees	253,500	\$ 0.74		\$ 128	10 years

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

	<u>During the Period from January 1, 2023 to September 30, 2023</u>
Value of one common share	\$0.58-\$1.36
Dividend yield	0 %
Expected stock price volatility	70%-78 %
Risk free interest rate	3.91%-4.28 %
Expected term (years)	5.56-6.06

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, 2023 to September 30, 2023:

	<u>No. of Options Granted</u>	<u>Exercise Price</u>	<u>Vesting Period</u>	<u>Fair Value at Grant</u>	<u>Expiration Period</u>
			Annually over a period of five years		
Non-employees	8,335	\$ 1.36		\$ 9	10 years

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

	During the Period from January 1, 2023 to September 30, 2023	
Value of one common share	\$	1.36
Dividend yield		0 %
Expected stock price volatility		80 %
Risk free interest rate		4.07 %
Expected term (years)		10

NOTE 10 – LOSS PER SHARE

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

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Basic and diluted:				
Net loss attributable to Orgenesis Inc.	\$ 12,653	\$ 1,356	\$ 20,969	\$ 10,792
Weighted average number of common shares outstanding	29,162,459	25,403,907	27,933,067	24,944,814
Net loss per share	\$ 0.43	\$ 0.05	\$ 0.75	\$ 0.43

For the nine months ended September 30, 2023 and September 30, 2022, 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 7,929,275 shares underlying outstanding options and warrants and 7,139,018 shares upon conversion of convertible loans for the nine months ended September 30, 2023, because the effect of their inclusion in the computation would be antidilutive. Diluted loss per share does not include 7,963,476 shares underlying outstanding options and warrants and 7,213,348 shares upon conversion of convertible loans for the three months ended September 30, 2023, because the effect of their inclusion in the computation would be antidilutive.

Diluted loss per share does not include 6,481,221 shares underlying outstanding options and warrants and 2,327,590 shares upon conversion of convertible loans for the nine months ended September 30, 2022, because the effect of their inclusion in the computation would be antidilutive. Diluted loss per share does not include 7,040,592 shares underlying outstanding options and warrants and 3,118,868 shares upon conversion of convertible loans for the three months ended September 30, 2022, because the effect of their inclusion in the computation would be antidilutive.

NOTE 11 – REVENUES

Disaggregation of Revenue

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

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue stream:				
POC development services	\$ -	\$ 1,118	\$ -	\$ 13,716
Cell process development services and hospital services	110	4,438	8,598	5,837
POC cell processing	-	2,432	5,531	2,848
Total	\$ 110	\$ 7,988	\$ 14,129	\$ 22,401

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A breakdown of the revenues per customer constituted at least 10% of revenues is as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue earned:				
Customer A (United States)	\$ -	\$ -	\$ 3,415	\$ -
Customer B (United States)	\$ -	\$ -	\$ 2,572	\$ -
Customer C (Greece)	\$ -	\$ 3,401	\$ 2,022	\$ 6,058
Customer D (United States)	\$ -	\$ 669	\$ 3,605	\$ 4,398
Customer E (Korea)	\$ -	\$ 283	\$ -	\$ 3,708
Customer F (United Arab Emirates)	\$ -	\$ 1,254	\$ -	\$ 3,508

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.

The activity for trade receivables is comprised of:

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Balance as of beginning of period	\$ 36,183	\$ 1
Elimination of acquisition receivables	-	(
Additions	14,167	2
Collections	(6,090)	(1
Exchange rate differences	(73)	
Deconsolidation of Octomera	(44,116)	
Balance as of end of period	\$ 71	\$ 2

* The activity of the related party included in the trade receivables activity above is comprised of:

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Balance as of beginning of period		\$
Additions		
Collections		(
Balance as of end of period		\$

The activity for contract liabilities is comprised of:

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Balance as of beginning of period	\$ 70	\$
Additions	156	
Deconsolidation of Octomera	(106)	
Balance as of end of period	\$ 120	\$

NOTE 12 – OTHER SIGNIFICANT TRANSACTIONS AND AGREEMENTS DURING THE NINE MONTHS ENDED SEPTEMBER 30, 2023

In January 2023, the Company entered into updated joint venture (JV) agreements (JVAs) with Theracell Advanced Biotechnology SA, Broaden Bioscience and Technology Corp, Image Securities FZC, Cure Therapeutics, and Med Centre for Gene and Cell Therapy FZ-LLC and assigned certain rights and obligations under its JVAs to Texas Advanced Therapies LLC, a Delaware Limited Liability company (“Texas AT”) not related to the Company. Texas AT will receive the Company’s option to require the incorporation of the JV entity, Company’s share in the JV Entity, if and when the latter are incorporated, an option to invest additional funding in the JV Entity, and board and veto rights on certain critical decisions in the JV Entity. The Company has retained the call option to acquire the JV partner’s share in the JVE, to receive a royalty and a right to conclude the Manufacturing and Service Agreement with the JV entity. Pursuant to the JVAs, the Company will no longer be entitled to the additional share of fifteen percent of the JVE’s GAAP profit after tax granted as per the previous version of the JVAs. The Company also has no further obligation to provide any additional funding to the JV entities. As of September 30, 2023, no JV entities were incorporated pursuant to the JVAs.

On July 25, 2023, the Company and Mircod LLC (“Mircod”) entered into a settlement and release agreement pursuant to which they agreed to terminate the joint venture and loan agreement between themselves. Also, pursuant to the agreement, Mircod agreed to deliver all the related deliverables to the Company, and the Company agreed to pay Mircod consideration in the amount of \$1,000, of which half will be paid in cash, and one half in Orgenesis shares, upon receipt of the deliverables. As of September 30, 2023, Mircod invoiced the Company \$300 in respect of deliverables that it claims were delivered and this amount is included in accounts payable.

On July 25, 2023, the Company, a Sub-licensee, and the equity interest owner of that Sub-licensee (“Sub-licensee Owner”), entered into agreements whereby:

- 1) the Company sub-licensed certain of its therapies to Sub-licensee in return for royalties on future sales and payments upon the successful completion of certain milestones;
- 2) subject to the fulfilment certain conditions and milestones, none of which have been fulfilled to date, the Sub-licensee Owner granted the Company a call option to purchase his interests in Sub-licensee at a valuation to be determined by a third-party valuation firm of not less than \$8,000 unless agreed otherwise by the parties to the option; and
- 3) subject to the fulfilment of certain conditions and milestones, none of which have been fulfilled to date, the Sub-licensee Owner was granted a put option to cause the Company to purchase his equity interest in Sub-licensee at a valuation to be determined by a third-party valuation firm of not less than \$8,000 unless agreed otherwise by the parties to the option.

The Company has received \$120 from Sub-licensee as an advance on account of future license fees. No milestones have been completed to date.

On September 14, 2023, the Company informed Yeda Research and Development Company Limited of its intention to terminate the license and research agreement entered into during 2022. The termination will take effect on November 13, 2023.

NOTE 13 – LEGAL PROCEEDINGS

On January 18, 2022, a complaint (the “Complaint”) was filed in the Tel Aviv District Court (the “Court”) against the Company, Orgenesis LTD (“the Israeli Subsidiary”), Prof. Sarah Ferber, Vered Caplan and Dr. Efrat Asa Kunik (collectively, the “defendants”) by plaintiffs the State of Israel, as the owner of Chaim Sheba Medical Center at Tel Hashomer (“Sheba”), and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (collectively, the “plaintiffs”). In the Complaint, the plaintiffs are seeking that the Court issue a declaratory remedy whereby the defendants are required to pay royalties to the plaintiffs at the rate of 7% of the sales and 24% of any and all revenues in consideration for sublicenses related to any product, service or process that contain know-how and technology of Sheba and any and all know-how and technology either developed or supervised by Prof. Ferber in the field of cell therapy, including in the category of the point-of-care platform and any and all services and products in relation to the defendants’ CDMO activity. In addition, the plaintiffs seek that the defendants provide financial statements and pay NIS 10,000 to the plaintiffs due to the royalty provisions of the license agreement, dated February 2, 2012, between the Israeli subsidiary and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (the “License Agreement”). The Complaint alleges that the Company and the Israeli subsidiary used know-how and technology of Sheba and know-how and technology either developed or supervised by Prof. Ferber while employed by Sheba in the field of cell therapy, including in the category of the point-of-care platform and the services and products in relation to the defendants’ CDMO activity and are entitled to the payment of certain royalties pursuant to the terms of the License Agreement. The defendants have filed their statements of defense responding to this Complaint, the Plaintiffs filed their response and the parties are now conducting disclosure proceedings in accordance with Israel’s civil regulations. Since a material loss is not considered probable, no provision was made in the financial statements.

It has been brought to the Company’s attention, that, on September 6, 2023, a claim (the “Claim”) was filed in the Tel Aviv District Court (the “Court”) against the Company, the Israeli Subsidiary, Octomera LLC, Orgenesis Biotech Israel LTD, Theracell Laboratories Private Company, and Vered Caplan (collectively, the “defendants”) by Ehud Almon (Plaintiff) for certain finders’ fees and / or royalties related to sales made by an Octomera subsidiary to a Greek entity in the amount of \$896 and also for other means of compensation. The Claim has yet to be legally delivered to the defendants. Since a material loss is not considered probable, no provision was made in the financial statements.

On October 26, 2023, a complaint was filed in the Supreme Court of the State of New York by plaintiffs Southern Israel Bridging Fund Two LP and Mr. Amir Hasidim, against the Company, seeking the payment of \$1,150 together with interest in the amount of 6%. The said amount is based on a Convertible Loan Agreement dated May 17, 2022, which provided for a loan amount of \$5,000 under which the Company was only allowed to borrow \$1,150 from the plaintiffs. Notwithstanding the Convertible Loan Agreement, on August 21, 2023, Company sent the plaintiffs an offset notice in light of the plaintiffs’ breach of obligations under the Convertible Loan Agreement and the damages caused to the Company as a result of said breach. Accordingly, the Company disputes whether it owes plaintiffs the amount sought in the Complaint.

NOTE 14 – SUBSEQUENT EVENTS

Recent developments

The Company conducts certain of its operations in the State of Israel and some of our business and operations may be affected by economic, political, geopolitical and military conditions in Israel. In October 2023, Hamas terrorists infiltrated Israel’s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel’s border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel’s security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict. The current war military operations may affect certain of the Company’s activities, business and operations although it is currently not possible to predict such effect.

Registered Direct Offering

On November 8, 2023, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with an institutional investor named therein (the “Investor”), pursuant to which the Company agreed to issue and sell, in a registered direct offering by the Company directly to the Investor (the “Offering”), (i) 1,410,256 shares (the “Shares”) of common stock, par value \$0.0001 per share, of the Company (“Common Stock”), and (ii) warrants exercisable for 1,410,256 shares of Common Stock (the “Warrants” and, together with the Shares, the “Securities”). The combined offering price for each Share and accompanying Warrant was \$0.78. The Warrants will be exercisable immediately following the date of issuance and may be exercised for a period of five years from the initial exercisability date at an exercise price of \$0.78 per share. The exercise prices and numbers of shares of Common Stock issuable upon exercise of the Warrants will be subject to adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Company’s Common Stock.

The Offering closed on November 9, 2023, and the Company received net proceeds of approximately \$943 after deducting placement agent’s fees and estimated offering expenses payable by the Company.

Equity Line of Credit

On November 8, 2023, the Company also agreed to enter into an Equity Line of Credit Agreement (the “ELOC Agreement”) with the Investor pursuant to which the Company may sell and issue to the Investor, and the Investor is obligated to purchase from the Company, up to \$25,000 of its Common Stock, from time to time over a 24-month period, provided that certain conditions are met. In connection with the ELOC Agreement, the Company agreed that it shall be prohibited from entering into any variable, reset, or otherwise adjustable equity or equity-linked transactions during the term of the ELOC Agreement. The Company also agreed to issue to the Investor warrants exercisable for 750,000 shares of Common Stock at an exercise price of \$0.01 per share if the ELOC Agreement is not closed by February 6, 2024.

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 December 31, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 22, 2023. 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. Other factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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," "our Company" or "Orgenesis" refer to Orgenesis Inc., a Nevada corporation, and our majority or wholly-owned subsidiaries or subsidiaries of Octomera LLC (whose name was changed on June 30, 2023, from Morgogenesis LLC), Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"); Orgenesis Belgium SRL, a Belgian-based entity (the "Belgian Subsidiary"); Orgenesis Services SRL, a Belgian-based entity ("Orgenesis Services SRL"); Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"); Orgenesis Maryland LLC (formerly Orgenesis Maryland Inc.), a Maryland limited liability company (the "U.S. Subsidiary"); Orgenesis Switzerland Sarl, (the "Swiss Subsidiary"); Orgenesis Biotech Israel Ltd. ("OBI"); Koligo Therapeutics Inc., a Kentucky corporation ("Koligo"); Tissue Genesis International LLC ("Tissue Genesis") a Texas limited liability company; Orgenesis Germany GmbH (the "German Subsidiary"); Orgenesis CA, Inc. (the "California Subsidiary"); Mida Biotech BV (the "Dutch Subsidiary") which was purchased in 2022; Orgenesis Australia PTY LTD (the "Australian Subsidiary"); Orgenesis Italy SRL (the "Italian Subsidiary"); Theracell Laboratories Private Company ("Theracell Laboratories"), a Greek company; Orgenesis Austria GmbH, an Austrian company; ORGS POC CA Inc., a Delaware company incorporated in 2023; and Octomera LLC, a Delaware limited liability company ("Morgogenesis" or "Octomera").

Corporate Overview

We are a global biotech company working to unlock the potential of CGTs in an affordable and accessible format. CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products, or ATMPs. We are mostly focused on the development of autologous therapies that can be manufactured under processes and systems that are developed for each therapy using a closed and automated approach that is validated for compliant production near the patient for treatment of the patient at the point of care, or POCare. This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients, ultimately limiting the number of patients that can have access to, or can afford, these therapies.

To achieve these goals, we have developed a collaborative worldwide network of research institutes and hospitals who are engaged in the POCare model, or our POCare Network, and a pipeline of licensed POCare advanced therapies that can be processed and produced under such closed and automated processes and systems, or POCare Therapies. We are developing our pipeline of advanced therapies and with the goal of entering into out-licensing agreements for these therapies. Our cellular therapies, though defined as drug products, conceptually differ from other drug modalities in that they are based on reprogramming of cells sourced from the patient or from a donor. In most cases, they are individually produced per patient in a highly sterile and controlled environment, and their efficacy is optimized when administered a short time following production as fresh product.

To advance the execution of our goal of bringing such therapies to market, we have designed and built our POCare Platform - a scalable infrastructure of technology and services that ensures a central quality system, replicability and standardization of infrastructure and equipment, and centralized monitoring and data management. The platform is constructed on POCare Centers that serve as hubs that locally implement our quality system, Good Manufacturing Practices, training procedures, quality control testing, incoming supply of materials and oversee the actual production in the Organogenesis Mobile Processing Units & Labs, or OMPULs.

In connection with the investment by an affiliate of Metalmark Capital Partners ("Metalmark" or "MM") in November 2022, we separated our operations into two operating segments: the operations of Octomera LLC (the "Morgensis" segment which we have renamed the "Octomera" segment following the change of name of Morgensis LLC to Octomera LLC) and therapies related activities (the "Therapies" segment). Prior to that, we conducted all our operations as one single segment. The Octomera segment includes mainly POCare Services and includes the results of the subsidiaries transferred to Octomera and all of the operations of Octomera LLC. The Therapies segment includes our therapeutic development operations. The segment information presented in note 3 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q reflects the results of the subsidiaries that were transferred to Octomera.

On June 30, 2023, in connection with an additional \$1 million investment in Octomera, we and MM entered into Amendment No. 1 to the Second Amended and Restated Limited Liability Company Agreement (the "LLC Agreement Amendment") to change the name of Morgensis to "Octomera LLC" and to amend Octomera's board composition. Pursuant to the LLC Agreement Amendment, the board of managers of Octomera (the "Octomera Board") will be comprised of five managers, two of which will be appointed by us, one of which will be an industry expert appointed by MM, and two of which will be appointed by MM. However, as a result of the amendment to the composition of the Octomera Board pursuant to the LLC Agreement Amendment described above, we deconsolidated Octomera from our consolidated financial statements as of June 30, 2023 (the "effective date of deconsolidation") and recorded our equity interest in Octomera as an equity method investment.

We currently own approximately 75% of Octomera LLC.

Therapies segment (POCare Therapies)

While the biotech industry struggles to determine the best way to lower cost of goods and enable CGTs to scale, the scientific community continues to advance and push the development of such therapies to new heights. Clinicians and researchers are excited by all the new tools (new generations of industrial viruses, big data analysis for genetic and molecular data) and technologies (CRISPR, mRNA, etc.) available, often at a low cost, to perform advanced research in small labs. Most new therapies arise from academic institutes or small spinouts from such institutes. Though such research efforts may manage to progress into a clinical stage, utilizing lab based or hospital-based production solutions they lack the resources to continue the development of such drugs to market approval.

Historically, drug/therapeutic development has required investments of hundreds of millions of dollars to be successful. One significant cause for the high cost is that each therapy often requires unique production facilities and technologies that must be subcontracted or built. Further the cost of production during the clinical stage is extremely expensive, and the cost of the clinical trial itself is very high. Given these financial restraints, researchers and institutes hope to out-license their therapeutic products to large biotech companies or spin-out new companies and raise large fundraising rounds. However, in many cases they lack the resources and the capability to de-risk their therapeutic candidates enough to be attractive for such fundings or partnership.

Our POCare Network is an alternative to the traditional pathway of drug development. We collaborate with academic institutions and entities that have been spun out from such institutions. We are in close contact with researchers who are experts in the field of the drug and also partners with leading hospitals and research institutes. Based on such collaborations, we enter into in-licensing agreements with relevant institutions for promising therapies with the aim of adapting them to a point-of-care setting through regional or strategic biological partnerships. Based on the results of the collaboration, we are then able to out-license our own therapeutic developments, as well as those therapies developed from in-licensing agreements to out-licensing partners at preferred geographical regions.

The ability to produce these products at low cost allows for an expedited development process, and the partnership with hospitals around the globe enables joint grants and lower cost of clinical development. The POCare Therapies division reviews many therapies available for out licensing and select the ones which they believe have the highest market potential, can benefit the most from a point of care approach and have the highest chance of clinical success. It assesses such issues by utilizing its global POCare Network and its internal knowhow accumulated over a decade of involvement in the field. The goal of this in-licensing is to quickly adapt such therapies to a point-of-care approach through regional partnerships, and to out-license the products for market approval in preferred geographical regions. This approach lowers overall development cost, through minimizing pre-clinical development costs incurred by us, and through receiving of the additional funding from grants and/or payments by regional partners.

Our therapies development subsidiaries are:

- Koligo Therapeutics, Inc., a Kentucky corporation, which is a regenerative medicine company, specializing in developing personalized cell therapies. It is currently focused on commercializing its metabolic pipeline via the POCare Network throughout the United States and in international markets.
 - Organesis CA, Inc. a Delaware corporation, which is currently focused on development of technologies and therapies in California.
 - Organesis Belgium SRL which is currently focused on product development. Since its incorporation, the subsidiary has been awarded grants in excess of 18,000 Euro from the Walloon region for several projects (DGO6 grants).
 - Organesis Switzerland Sarl, which is currently focused on providing group management services.
 - MIDA Biotech BV, which is currently focused on research and development activities, was granted a 4,000 Euro grant under the European Innovation Council Pathfinder Challenge Program which supports cutting-edge science and technology. The grant is for technologies enabling the production of autologous induced pluripotent stem cells (iPSCs) using microfluidic technologies and artificial intelligence (AI).
- Organesis Italy SRL which is currently focused on R&D activities.
- Organesis Ltd., an Israeli subsidiary which is focused on R&D and a provider of R&D management services for out licenced products. Israel is a hub for biotech research and pioneers in this field.
 - Organesis Austria GmbH, an Austrian subsidiary, which is focused on R&D activities.

Octomera segment (mainly POCare Services)

Octomera LLC (“Octomera” or “Morgenesis”) is responsible for most of our POCare services platform. The POCare Services platform is utilized by parties such as biotech companies and hospitals for the supply of their products. Octomera’s services include adapting the process to the platform and supplying the products, or POCare Services. These are services for third party companies and for CGTs that are not necessarily based on our POCare Therapies. POCare services that we and our affiliated entities perform include:

- Process development of therapies, process adaptation, and optimization inside the OMPULs, or “OMPULization”;
- Adaptation of automation and closed systems to serviced therapies;
- Incorporation of the serviced therapies compliant with GMP in the OMPULs that we design and build;
- Tech transfers and training of local teams for the serviced therapies at the POCare Centers;
- Processing and supply of the therapies and required supplies under GMP conditions within our POCare Network, including required quality control testing; and
- Contract Research Organization services for clinical trials.

The POCare Services are performed in decentralized hubs that provide harmonized and standardized services to customers, or POCare Centers. We are working to expand the number and scope of our POCare Centers with the intention of providing an efficient and scalable pathway for CGT therapies to reach patients rapidly at lowered costs. Our POCare Services are designed to allow rapid capacity expansion while integrating new technologies to bring together patients, doctors and industry partners with a goal of achieving standardized, regulated clinical development and production of therapies.

POCare Services Operations Subsidiaries

We conduct our core POCare operations through Octomera (of which we currently own approximately 75%) and which was a consolidated subsidiary of the Company until June 30, 2023. The Octomera subsidiaries which are all wholly owned except as otherwise stated below (collectively, the “Subsidiaries”) include:

- Organesis Maryland LLC, which is the center of POCare Services activity in North America and is currently focused on setting up and providing POCare Services and cell-processing services to the POCare Network.
- Tissue Genesis International LLC, a Texas limited liability company currently focused on development of our technologies and therapies.
- Organesis Services SRL, which is currently focused on expanding our POCare Network in Belgium.
- Organesis Germany GmbH, which is currently focused on providing CRO services to the POCare Network.
- Organesis Korea Co. Ltd., which is a provider of cell-processing and pre-clinical services in Korea. Octomera owns 94.12% of the Korean Subsidiary.
- Organesis Biotech Israel Ltd., which is a provider of process development and cell-processing services in Israel.
- Organesis Australia PTY LTD, which was transferred to Octomera in January 2023 and is currently focused on the development of our POC Network in Australia.
- Theracell Laboratories private company (“Theracell Labs”), a Greek company currently focused on expanding our POCare Network.
- ORGS POC CA Inc, incorporated in 2023, which is currently focussed on expanding our POCare Network in California.

During 2023, we and MM invested \$836 thousand and \$ 6.5 million respectively into Octomera in exchange for Octomera preferred shares.

Developments During the Nine Months Ended September 30, 2023

In January 2023, we entered into updated joint venture (JV) agreements (the “JVAs”) with Theracell Advanced Biotechnology SA, Broaden Bioscience and Technology Corp, Image Securities FZC, Cure Therapeutics, and Med Centre for Gene and Cell Therapy FZ-LLC and assigned certain rights and obligations under its JVAs to Texas Advanced Therapies LLC, a Delaware Limited Liability company (“Texas AT”) not related to us. Texas AT will receive our option to require the incorporation of the JV Entity, our share in the JV Entity if and when the latter are incorporated, an option to invest additional funding in the JV Entity, and board and veto rights on certain critical decisions in the JV Entity. We have retained the call option to acquire the JV partner’s share in the JVE, to receive a royalty and a right to conclude the Manufacturing and Service Agreement with the JV entity. We have no further obligation to provide any additional funding to the JV entities. As of September 30, 2023, no JV entities were incorporated as per the JVAs.

On January 10, 2023 (“Effective Date”), we entered into convertible loan agreements (the “CLAs”) with lenders pursuant to which we received convertible loans totaling \$5 million. Interest on the CLAs is calculated at 8% per annum (based on a 365-day year); provided, that if an Event of Default (as defined in the Convertible Loan Agreements) has occurred and is continuing, the Outstanding Amount (as defined herein) will be calculated at 15.0% per annum. The Loan Amount and all accrued but unpaid interest thereon (collectively, the “Outstanding Amount”) shall either (i) be repaid in cash or (ii) convert to shares of our common stock, par value \$0.0001 per share (“Common Stock”), on the third anniversary of the Effective Date (the “Maturity Date”). At any time prior to or on the Maturity Date, Lender may provide us with written notice to convert all or part of the Outstanding Amount into shares of our Common Stock equal to the quotient obtained by dividing (x) the Outstanding Amount by (y) a price equal to \$2.464 per share (subject to adjustment for certain capital events, such as stock splits) (the “Conversion Price”).

Under the terms of the CLAs, we may use the proceeds from the Loan Amount to (i) redeem the loan amount from the previously disclosed Convertible Loan Agreement, dated as of May 19, 2022 between Orgenesis and Ricky Steven Neumann, as amended by the previously disclosed certain Convertible Loan Extension Agreement, dated as of October 23, 2022, by and between Orgenesis and Ricky Steven Neumann, and (ii) for general corporate purposes. Pursuant to the terms, we repaid said loan upon receipt of the Loan Amount. In connection with the CLAs, we agreed to issue Lender warrants representing the right to purchase 507,305 shares of our Common Stock, at an exercise price of \$2.50 per share.

On February 23, 2023, we entered into a securities purchase agreement with certain institutional and accredited investors relating to the issuance and sale of 1,947,368 shares of common stock, par value \$0.0001 per share and warrants to purchase up to 973,684 shares of Common Stock at a purchase price of \$1.90 per share of Common Stock and accompanying Warrants in a registered direct offering. The offering closed on February 27, 2023 and the Company received approximately \$3.7 million, before deducting the placement agent’s cash fee equal to 7% of the proceeds. The Company intends to use the net proceeds from the Offering for working capital and general corporate purposes, including the Company’s therapy related activities. The offering was made pursuant to an effective registration statement on Form S-3 (Registration Statement No. 333-254806), as previously filed with and declared effective by the Securities and Exchange Commission (the “SEC”) on April 7, 2021, a base prospectus included as part of the registration statement, and a final prospectus supplement filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

On March 27, 2023, our subsidiary Koligo Therapeutics Inc. (“Borrower”), entered into a convertible loan agreement (the “Convertible Loan Agreement”) with Yehuda Nir (the “Lender,”), pursuant to which the Lender agreed to loan the Borrower up to \$5 million (the “Loan Amount”). Interest is calculated at 8% per annum (based on a 365-day year) and is payable, along with the principal, on or before January 1, 2024.

If prior to December 31, 2023, the Borrower issues equity securities (“Equity Securities”) in a transaction or series of related transactions resulting in aggregate gross proceeds to the Borrower of at least \$5,000 (excluding conversion of the Loan Amount) (a “Qualified Financing”), then the outstanding principal amount of the Loan Amount, and any and all accrued but unpaid interest thereon, will automatically convert into such Equity Securities issued pursuant to the Qualified Financing at a price per share equal to fifty percent (50%) of the price per share paid for each share of the Equity Securities purchased for cash by the investors in the Qualified Financing.

As of September 30, 2023, we borrowed \$660 thousand pursuant to the Convertible Loan Agreement.

On July 25, 2023, our Israeli Subsidiary received a loan from an offshore investor in the amount of \$175 thousand. The loan bears 8% annual interest and is repayable on January 1, 2024.

On August 15, 2023, we received a loan from an investor in the amount of \$250 thousand. The loan bears 8% annual interest and is repayable on January 1, 2024.

On August 31, 2023, we entered into a Securities Purchase Agreement with a certain accredited investor, pursuant to which we agreed to issue and sell, in a private placement (the “Offering”), 2,000,000 shares of our common stock, par value \$0.0001 per share, at a purchase price of \$0.50 per share. We received gross proceeds of \$1 million before deducting related offering expenses. The Offering closed on August 31, 2023.

On September 29, 2023, Borrower entered into another convertible loan agreement (the “Sai Convertible Loan Agreement”) with Sai Traders (the “Lender,” and together with the Borrower, the “Parties”), pursuant to which the Lender agreed to loan the Borrower up to \$25 million (the “Sai Convertible Loan”). The Sai Convertible Loan shall consist of an Initial Installment of \$1.5 million (“Initial Installment”), and at the election of the Borrower thereafter while the Sai Convertible Loan remains outstanding, Borrower may issue up to an additional \$23.5 million (“Subsequent Installments”). The Sai Convertible loan bears transaction costs of 8%. Interest is calculated at 10% per annum (based on a 365-day year) of all outstanding principal borrowings and is payable, along with the principal (collectively the “Outstanding Amount”), on or before December 1, 2027 (the “Maturity Date”). The Loan Amount may be prepaid by the Borrower in whole or in part at any time without penalty.

Under the terms of the Sai Convertible Loan Agreement, at the option of the Lender at the Maturity Date or any time prior, the Outstanding Amount may be convertible, in whole or in part, into the number of shares of Common Stock of the Company equal to the quotient obtained by dividing (x) the Outstanding Amount by (y) the Conversion Price. The “Initial Installment Conversion Price” for the Outstanding Amount relating to the Initial Installment shall be a price per share of Common Stock equal to \$2.50. The “Subsequent Installment Conversion Price” for the Outstanding Amount relating to the Subsequent Installment(s) shall be a price per share of Common Stock equal to \$3.50. Lender agrees that it shall not deliver a notice of conversion that upon effect results in the holder to beneficially own more than 19.99% of the then outstanding shares of Company’s Common Stock. Lender may elect to, instead of the conversion of the Outstanding Amount into Common shares of Company, convert the entire Outstanding Amount into the securities of Borrower pursuant to a the first issuance of equity of the Borrower under which the Borrower raises at least \$5 million in gross proceeds (“Qualified Financing”) at a price per share equal to 75% of the price per share paid for each share of the equity securities purchased for cash by the investors in such a Qualified Financing. In the event of the Borrower being listed on a public securities exchange, Lender shall have the option to convert the Outstanding Amount at a 25% premium to the volume weighted average price of the Borrower’s equity over the preceding five (5) days as reported by Bloomberg (“5-Day VWAP”), provided that any such conversion shall not result in the Lender to beneficially own more than 19.99% of the then beneficial shares of the Borrower. In the event of an acquisition of the Borrower (“Acquisition”), prior to the closing of such acquisition, Lender shall have the option to convert the Outstanding Amount into equity securities of the Borrower at a price equivalent to seventy five percent (75%) of the price paid by such buyer to acquire the Borrower.

As of September 30, 2023 and the date of this report, the Initial Installment was not received, and was therefore not reflected in the Consolidated Balance sheet of September 30, 2023.

During October 2023, certain of our subsidiaries borrowed an aggregate of \$140 thousand at annual interest rates varying between 0% and 10%. The loans are repayable between November 30, 2023 and January 1, 2024.

Results of Operations

The results of our operations include all of the results of Octomera LLC and its subsidiaries (the Octomera segment) up to the effective date of deconsolidation.

Comparison of the Three Months Ended September 30, 2023 to the Three Months Ended September 30, 2022.

The following table presents our results of operations for the three months ended September 30, 2023 and 2022 (dollars in thousands in the table and discussion thereafter):

	Three-Months Ended	
	September 30, 2023	September 30, 2022
Revenues	\$ 110	\$ 7,988
Revenues from related party	-	-
Total revenues	110	7,988
Cost of revenues	139	983
Gross profit	(29)	7,849
Cost of development services and research and development expenses	808	808
Amortization of intangible assets	153	153
Selling, general and administrative expenses	1,245	1,245
Share in net loss of associated company	9,518	9,518
Operating loss	11,753	11,753
Other income, net	(2)	(2)
Financial expenses, net	508	508
Loss before income taxes	12,259	12,259
Tax expense	394	394
Net loss	\$ 12,653	\$ 12,653

Revenues

During the three months ended September 30, 2023, we recognized revenue in the amount of \$110, as compared to \$7,988 during the three months ended September 30, 2022, representing a decrease of 99%. This was attributable to the deconsolidation of Octomera as of June 30, 2023. The majority of our revenues are from Octomera.

During the three months ended September 30, 2023, the Octomera segment recognized revenue in the amount of \$2,704, as compared to \$7,903 during the three months ended September 30, 2022, representing a decrease of 66%. This was mainly attributable to performance obligations not having been completed during the three months ended September 30, 2023 in cell processing and cell process development contracts, and which are expected to be completed in the fourth quarter of 2023.

Expenses**Cost of Revenues**

	Three-Months Ended	
	September 30, 2023	September 30, 2022
Salaries and related expenses	\$ 94	\$ 386
Stock-based compensation	1	1
Professional fees and consulting services	4	244
Raw materials	5	117
Depreciation expenses, net	5	102
Other expenses	30	133
Total	\$ 139	\$ 983

Cost of revenues for the three months ended September 30, 2023 were \$139, as compared to \$983 for the three months ended September 30, 2022, representing a decrease of 86%. This was attributable to the deconsolidation of Octomera at June 30, 2023. The majority of our cost of revenues are from Octomera.

In the Octomera segment, cost of revenues for the three months ended September 30, 2023 were \$1,875 as compared to \$664 for the three months ended September 30, 2022, representing an increase of 182%. The increase was due to increased costs, including additional salaries, professional fees, raw materials and depreciation expenses incurred mainly related to higher costs of revenues of process development and POC cell processing.

Cost of Development Services and Research and Development Expenses

	Three-Months Ended	
	September 30, 2023	September 30, 2022
Salaries and related expenses	\$ 669	\$
Stock-based compensation	24	
Subcontracting, professional and consulting services	(38)	
Lab expenses	22	
Depreciation expenses, net	29	
Other research and development expenses	171	
Less – grant	(69)	
Total	<u>\$ 808</u>	<u>\$</u>

Cost of development services and research and development for the three months ended September 30, 2023 were \$808, as compared to \$3,683 for the three months ended September 30, 2022, representing a decrease of 78%. This was mainly attributable to the deconsolidation of Octomera at June 30, 2023. Cost of development services and research and development declined in both the Octomera and Therapies segments because costs that were related to POC development services were no longer required due to the conclusion of the POC development revenue contracts, and our decision to reduce subcontracting, professional and consulting service fees, and other research and development expenses.

Selling, General and Administrative Expenses

	Three-Months Ended	
	September 30, 2023	September 30, 2022
Salaries and related expenses	\$ 259	\$
Stock-based compensation	53	
Accounting and legal fees	460	
Professional fees	134	
Rent and related expenses	13	
Business development	60	
Depreciation expenses, net	4	
Other general and administrative expenses	262	
Total	<u>\$ 1,245</u>	<u>\$</u>

Selling, general and administrative expenses for the three months ended September 30, 2023 were \$1,245, as compared to \$3,104 for the three months ended September 30, 2022, representing a decrease of 60%. The decrease in selling, general and administrative expenses in the three months ended September 30, 2023 compared to the three months ended September 30, 2022 is primarily attributable to the deconsolidation of Octomera as of June 30, 2023.

In the Octomera segment, selling, general and administrative expense (excluding depreciation) for the three months ended September 30, 2023 were \$9,706 as compared to \$1,385 for the three months ended September 30, 2022, representing an increase of 601%. The increase was mainly as a result of an increase in an allowance for doubtful debts.

Share in Net Loss of Associated Company

Share in net loss of associated company for the three months ended September 30, 2023 was \$9,518, as compared to \$274 for the three months ended September 30, 2022, representing an increase of 3,374%. The increase in share in net loss of associated company in the three months ended September 30, 2023 compared to the three months ended September 30, 2022 is primarily attributable to credit losses in the period resulting from higher than previously expected credit losses related to a group of customers that are significantly overdue in Octomera.

Financial Expenses, net

	Three-Months Ended	
	September 30, 2023	September 30, 2022
Interest expense on convertible loans and loans	\$ 575	\$
Foreign exchange loss (income), net	(69)	
Other expenses (income)	2	
Total	\$ 508	\$

Financial expenses, net for the three months ended September 30, 2023 were \$508, as compared to \$1,100 for the three months ended September 30, 2022, representing a decrease of 54%. The decrease was mainly due to foreign exchange losses incurred in the three months ended September 30, 2022 in the Octomera segment.

Comparison of the Nine Months Ended September 30, 2023 to the Nine Months Ended September 30, 2022.

The following table presents our results of operations for the nine months ended September 30, 2023 and 2022 (dollars in thousands in the table and discussion thereafter):

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Revenues	\$ 14,129	\$ 22,401
Revenues from related party	-	
Total revenue	14,129	22,401
Cost of revenues	6,093	
Gross profit	8,036	22,401
Cost of development services and research and development expenses	7,616	11,000
Amortization of intangible assets	568	
Selling, general and administrative expenses	8,621	
Share in net loss of associated company	9,517	
Operating loss	18,286	
Other income, net	(4)	
Loss from extinguishment in connection with convertible loan	283	
Financial expenses, net	1,807	
Profit from deconsolidation of Octomera	(411)	
Loss before income taxes	19,961	11,000
Tax expense	614	
Net loss	\$ 20,575	\$ 11,000

Revenues

Our revenues for the nine months ended September 30, 2023 were \$14,129, as compared to \$22,401 for the nine months ended September 30, 2022, representing a decrease of 37%. This was attributable to the deconsolidation of Octomera at June 30, 2023. The majority of our revenues are from Octomera and were included in our revenues until the date of deconsolidation.

During the nine months ended September 30, 2023, the Octomera segment recognized revenue in the amount of \$16,483, as compared to \$21,989 during the nine months ended September 30, 2022, representing a decrease of 25%. This was mainly attributable to our not having completed certain performance obligations in cell processing and process development contracts, which we expect to complete in the fourth quarter of 2023.

Expenses

Cost of Revenues

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Salaries and related expenses	\$ 2,298	\$
Stock-based compensation	4	
Professional fees and consulting services	1,882	
Raw materials	715	
Depreciation expenses, net	477	
Other expenses	717	
Total	\$ 6,093	\$

Cost of revenues for the nine months ended September 30, 2023 were \$6,093, as compared to \$2,760 for the nine months ended September 30, 2022, representing an increase of 121%. The increase was due to increased costs including additional salaries, professional fees, raw materials and depreciation expenses incurred as a result of increased process development and cell processing revenues mainly in the Octomera segment, which were incurred mainly until the date of deconsolidation.

Cost of Development Services and Research and Development Expenses

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Salaries and related expenses	\$ 4,153	\$
Stock-based compensation	187	
Subcontracting, professional and consulting services	1,563	
Lab expenses	326	
Depreciation expenses, net	285	
Other research and development expenses	1,312	
Less – grant	(210)	
Total	\$ 7,616	\$ 1

Cost of development services and research and development for the nine months ended September 30, 2023 were \$7,616, as compared to \$18,172 for the nine months ended September 30, 2022, representing a decrease of 58%. The decrease was mainly attributable to the deconsolidation of the Octomera segment at June 30, 2023, and our decision to reduce investing in subcontracting, professional and consulting service fees and other research and development expenses this year.

Selling, General and Administrative Expenses

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Salaries and related expenses	\$ 2,520	\$
Stock-based compensation	197	
Accounting and legal fees	2,804	
Professional fees	1,020	
Rent and related expenses	127	
Business development	421	
Depreciation expenses, net	36	
Other general and administrative expenses	1,496	
Total	\$ 8,621	\$

Selling, general and administrative expenses for the nine months ended September 30, 2023 were \$8,621, as compared to \$8,758 for the nine months ended September 30, 2022, representing a decrease of 2%. The decrease was mainly as a result of the deconsolidation of Octomera as of June 30, 2023.

In the Octomera segment, selling, general and administrative expense (excluding depreciation) for the nine months ended September 30, 2023 were \$13,329 as compared to \$2,822 for the nine months ended September 30, 2022, representing an increase of 372%. The increase was mainly as a result of increases in salaries and related expenses, professional fees, and other general and administrative expenses as a result of ramped up activities, and an increase in an allowance for doubtful debts.

Share in Net Loss of Associated Company

Share in net loss of associated company for the nine months ended September 30, 2023 was \$9,517, as compared to \$1,189 for the three months ended September 30, 2022, representing an increase of 700%. The increase in Share in net loss of associated company in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 is primarily attributable to credit losses in the three months ended September 30, 2023 resulting from higher than previously expected credit losses related to a group of customers that are significantly overdue in Octomera.

Financial Expenses, net

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Interest expense on convertible loans and loans	\$ 1,629	\$ 1,629
Foreign exchange loss, net	173	173
Other expenses (income)	5	5
Total	<u>\$ 1,807</u>	<u>\$ 1,807</u>

Financial expenses, net for the nine months ended September 30, 2023 were \$1,807, as compared to \$1,702 for the nine months ended September 30, 2022, representing an increase of 6%.

Working Capital

(dollars in thousands)

	As of	
	September 30, 2023	December 31, 2022
Current assets	\$ 8,776	\$ 9,118
Current liabilities	14,302	14,302
Working capital	<u>\$ (5,526)</u>	<u>\$ (5,184)</u>

Current assets decreased by \$37,542 between December 31, 2022 and September 30, 2023 due mainly to the deconsolidation of Octomera. The majority of cash and cash equivalents, restricted cash, and accounts receivable at December 31, 2023 were part of Octomera. Prepaid expenses and other receivables increased by \$3,073 from December 31, 2022 to September 30, 2023 mainly as a result of prepayments in development contracts. Receivables from related parties in the amount of \$1,052 are receivables from Octomera subsidiaries, that were consolidated at December 31, 2022 and not at September 30, 2023.

Current liabilities decreased by \$1,608 between December 31, 2022 and September 30, 2023 primarily as a result of the deconsolidation of Octomera. Accounts payable not related to Octomera increased as a result of a shortage of funds. Other payables related parties in the amount of \$132 are payables to Octomera subsidiaries, that were consolidated at December 31, 2022 and not at September 30, 2023. Short-term and current maturities of convertible loans increased by \$430 for representing an increase of \$430 mainly as a result new loans taken.

Liquidity and Financial Condition

(dollars in thousands)

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Net loss	\$ (20,575)	\$ (14,163)
Net cash used in operating activities	(14,335)	(14,163)
Net cash used in investing activities	(3,645)	(7,458)
Net cash provided by financing activities	12,393	20,095
Decrease in cash and cash equivalents	\$ (5,587)	\$ (15,626)

During the nine months ended September 30, 2023, we funded our operations from existing funds, and equity and loan financings.

Net cash used in operating activities for the nine months ended September 30, 2023 was approximately \$14,335, as compared to net cash used in operating activities of approximately \$14,163 for the nine months ended September 30, 2022. This is mainly attributable to:

- An increase in the share of losses of associated companies in the amount of \$8,328 mainly related to an increase in the provision for doubtful debts in Octomera.
- The deconsolidation of Octomera. The majority of accounts receivable and inventory as at December 31, 2023 were part of Octomera.
- An increase in prepaid expenses and other accounts receivable in the amount of \$1,906 mainly as a result of prepayments of development contracts.
- An increase in accounts payable not related to Octomera, as a result of our not having sufficient funds to pay vendors.

Net cash used in investing activities for the nine months ended September 30, 2023 was approximately \$3,645, as compared to net cash used in investing activities of approximately \$7,458 for the nine months ended September 30, 2022. The decrease was mainly due to loans granted to associated entities last year not granted this year, reduced investments in OMPULs, and the deconsolidation of Octomera.

Net cash provided by financing activities for the nine months ended September 30, 2023 was approximately \$12,393, as compared to net cash provided by financing activities of approximately \$20,095 for the nine months ended September 30, 2022. During the nine months ended September 30, 2023 we raised equity investments in the net amount of \$4,341 (see Note 4), raised proceeds from loans in the amount of \$5,660 (see Note 5), raised proceeds from MM in the amount of \$5,000 see note 3 and repaid convertible loans in the amount of \$3,000 (see Note 5).

Liquidity & Capital Resources Outlook

Our activities have recently been funded primarily by offerings of our equity securities, loans, and convertible loans. There is no assurance that our business will generate sustainable positive cash flows to fund our business operations.

If there are further reductions in revenues or increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, we will need to use mitigating actions such as to seek additional financing or postpone expenses that are not based on firm commitments. In addition, in order to fund our operations until such time that we can generate sustainable positive cash flows, we will need to raise additional funds.

We expect that our current and projected cash resources and commitments will not be sufficient to meet our obligations for the next 12 months, raising a substantial doubt about our ability to continue as a going concern. Our management plans include raising additional capital to fund our operations and to repay our outstanding loans when they become due, as well as exploring additional avenues to increase revenue and reduce capital expenditures. Our ability to fund the completion of our ongoing and planned activities may be substantially dependent upon whether we can obtain sufficient funding at acceptable terms. If we are unable to raise sufficient additional capital or meet revenue targets, we may have to reduce or eliminate certain activities and reduce our headcount.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our 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 September 30, 2023 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

Information regarding legal proceedings is available in Note 13 to the condensed consolidated financial statements in this Report.

Except as described above, we are not involved in any pending material legal proceedings.

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 our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 22, 2023, 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. Except as set forth below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2022. The Company's business, operating results and financial condition could be adversely affected due to any of those risks.

We may fail to comply with the continued listing requirements of the Nasdaq Capital Market, such that our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on the Nasdaq Capital Market. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price requirement of \$1.00 per share for 30 consecutive business days (the "Minimum Bid Price Requirement"). If a company trades for 30 consecutive business days below the \$1.00 minimum closing bid price requirement, Nasdaq will send a deficiency notice to the company advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements. We received such notice on September 27, 2023 and thus risk delisting unless we are able to regain compliance in a timely fashion.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until March 25, 2024, to regain compliance with the Minimum Bid Price Requirement. Compliance can be achieved automatically and without further action if the closing bid price of our stock is at or above \$1.00 for a minimum of 10 consecutive business days at any time during the 180-day compliance period, in which case Nasdaq will notify us of our compliance and the matter will be closed. If, however, we do not achieve compliance with the Minimum Bid Price Requirement by March 25, 2024, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period. There can be no assurance that we will regain compliance with the Minimum Bid Price Requirement, that we will maintain compliant with other Nasdaq listing requirements or that we will be granted a second compliance period.

A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

We conduct certain of our operations in Israel. Conditions in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect certain of our operations.

Because we conduct certain operations in the State of Israel, some of our business and operations may be affected by economic, political, geopolitical and military conditions in Israel. In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict.

Any hostilities involving Israel, or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect certain of our operations and results of operations and could make it more difficult for us to raise capital. The conflict in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. There have been travel advisories imposed relating to travel to Israel, and restriction on travel, or delays and disruptions as related to imports and exports may be imposed in the future. Additionally, certain members of our management and employees are located and reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Several of our employees are subject to military service in the IDF and have been, or may be, called to serve. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt certain of our business and operations, among others.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits required by Item 601 of Regulation S-K

No.	Description
(10)	Material Contracts
10.1	Securities Purchase Agreement, dated August 31, 2023, by and among the Company and a certain investor.
10.2	Convertible Loan Agreement dated September 29, 2023, by and among the Borrower and Sai Traders.
(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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* 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: November 13, 2023

/s/ Elliot Maltz

Elliot Maltz

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: November 13, 2023

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Exhibit 10.1

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (“Agreement”) is made as of August 31, 2023 (the “Effective Date”), by and among Orgenesis Inc., a Nevada corporation (the “Company”), and each of those persons and entities, severally and not jointly, listed as a Purchaser on the Schedule of Purchasers attached as Exhibit A hereto (the “Schedule of Purchasers”). Such persons and entities are hereinafter collectively referred to herein as “Purchasers” and each individually as a “Purchaser.”

AGREEMENT

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Company and each Purchaser (severally and not jointly) hereby agree as follows:

SECTION 1.

AUTHORIZATION OF SALE OF SHARES

The Company has authorized the sale and issuance of 2,000,000 shares (the “Shares”) of its common stock, par value \$0.0001 per share (the “Common Stock”), on the terms and subject to the conditions set forth in this Agreement. The shares of Common Stock sold hereunder at the Closing (as defined below) shall be referred to as the “Shares.”

SECTION 2.

AGREEMENT TO SELL AND PURCHASE THE SHARES

2.1 **Sale of Shares.** At the Closing (as defined in Section 3.1), the Company will sell to each Purchaser, and each Purchaser will purchase from the Company, the number of Shares set forth opposite such Purchaser’s name on the Schedule of Purchasers at a purchase price of \$0.50 per Share. The aggregate purchase price for the Shares purchased by each Purchaser is set forth opposite such Purchaser’s name on the Schedule of Purchasers. The parties acknowledge that each Purchaser is entitled to nominate one or more nominees to subscribe for Shares under this Agreement with the consent of the Company not to be unreasonably withheld, and in this event, all references to the Purchaser under this Agreement shall be a reference to the Purchaser’s nominee(s).

2.2 **Separate Agreement.** Each Purchaser shall severally, and not jointly, be liable for only the purchase of the Shares that appear on the Schedule of Purchasers that relate to such Purchaser. The Company’s agreement with each of the Purchasers is a separate agreement, and the sale of Shares to each of the Purchasers is a separate sale. The obligations of each Purchaser hereunder are expressly not conditioned on the purchase by any or all of the other Purchasers of the Shares such other Purchasers have agreed to purchase.

SECTION 3

CLOSING AND DELIVERY

3.1 **Closing.** The closing of the purchase and sale of the Shares (which Shares are set forth in the Schedule of Purchasers) pursuant to this Agreement (the “Closing”) shall be held on August 31, 2023 at the offices of Mintz, Levin, Cohn, Glovsky and Popeo, P.C., 666 Third Avenue, New York, NY 10017, or on such other date and place as may be agreed to by the Company and the Purchasers. At or prior to the Closing, each Purchaser shall execute any related agreements or other documents required to be executed hereunder, dated as of the date of the Closing (the “Closing Date”).

3.2 **Issuance of the Shares at the Closing.** At the Closing, the Company shall issue or deliver to each Purchaser evidence of a book entry position evidencing the Shares purchased by such Purchaser hereunder, registered in the name of such Purchaser, or in such nominee name(s) as designated by such Purchaser, representing the number of Shares to be purchased by such Purchaser at such Closing as set forth in the Schedule of Purchasers against payment of the purchase price for such Shares. The name(s) in which the Shares are to be issued to each Purchaser are set forth in the Purchaser Questionnaire and the Selling Stockholder Notice and Questionnaire in the form attached hereto as Appendix I and II (the “Purchaser Questionnaire” and the “Selling Stockholder Questionnaire”, respectively), as completed by each Purchaser, which shall be provided to the Company no later than the Closing Date.

SECTION 4

REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY

Except as set forth on the Schedule of Exceptions delivered to the Purchasers concurrently with the execution of this Agreement (the “Schedule of Exceptions”) or as otherwise described in the SEC Documents (as defined below), which disclosures qualify these representations and warranties in their entirety, the Company hereby represents and warrants as of the date hereof to, and covenants with, the Purchasers as follows:

4.1 Subsidiaries. The Company's Subsidiaries (as defined below) are listed its Annual Report on Form 10-K for the year ended December 31, 2022 and updated on its Quarterly Report on Form 10-Q for the six months ended June 30, 2023. The Company owns, directly or indirectly, all of the capital stock or comparable equity interests of each Subsidiary free and clear of any and all liens, charges, claims, encumbrances, security interests, rights of first refusal, preemptive rights or other restrictions of any kind (collectively, "**Liens**"), and all the issued and outstanding shares of capital stock or comparable equity interest of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. "**Subsidiary**" means any entity in which the Company, directly or indirectly, owns sufficient capital stock or holds a sufficient equity or similar interest such that it is consolidated with the Company in the financial statements of the Company.

4.2 Organization and Standing. The Company and each of its Subsidiaries (i) has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation or organization (as applicable), with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as presently conducted or proposed to be conducted in the SEC Documents, and (ii) is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except in the case of clause (ii) above, to the extent that the failure to be so qualified or be in good standing would not reasonably be expected to result in (i) a material adverse effect on the validity or enforceability of this Agreement, (ii) a material adverse effect on the condition (financial or otherwise), results of operations, business, prospects or properties of the Company and its Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect its obligations under this Agreement (any of (i), (ii) or (iii)) (a "**Material Adverse Effect**").

4.3 Corporate Power; Authorization. The Company has all requisite corporate power and authority, and has taken all requisite corporate action, to execute and deliver this Agreement, , sell and issue the Shares and carry out and perform all of its obligations under this Agreement. This Agreement constitutes the legal, valid and binding obligation of the Company, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting the enforcement of creditors' rights generally, and (ii) as limited by equitable principles generally, including any specific performance.

4.4 Issuance and Delivery of the Shares. The Shares have been duly authorized and, when issued and paid for in compliance with the provisions of this Agreement, will be validly issued, fully paid and nonassessable. Assuming the accuracy of the representations made by each Purchaser in Section 5, the offer and issuance by the Company of the Shares is exempt from registration under the Securities Act.

4.5 SEC Documents; Financial Statements. The Company has filed in a timely manner all documents that the Company was required to file with the Securities and Exchange Commission (the "**Commission**") under Sections 13, 14(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), since January 1, 2021 (collectively with all exhibits, schedules and annexes thereto, the "**SEC Documents**"). As of their respective filing dates (or, if amended prior to the date of this Agreement, when amended), all SEC Documents complied in all material respects with the requirements of the Exchange Act and the rules and regulations of the Commission promulgated thereunder. None of the SEC Documents as of their respective dates contained any untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they were made, not misleading. The consolidated financial statements of the Company included in the SEC Documents (the "**Financial Statements**") present fairly the consolidated financial condition, results of operations and cash flows of the Company and its Subsidiaries, taken as a whole, as of the dates and for the periods indicated, comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing and have been prepared in conformity with generally accepted accounting principles ("**GAAP**") applied on a consistent basis throughout the periods involved (except as otherwise noted therein). Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, who have certified certain financial statements of the Company delivered their report with respect to the audited consolidated financial statements and schedules included in the SEC Documents, are independent registered public accountants with respect to the Company within the meaning of the Exchange Act and the applicable published rules and regulations thereunder.

4.6 Capitalization. The authorized capital stock of the Company consists of 145,833,334 shares of Common Stock. As of the Effective Date, there are 28,753,374 shares of Common Stock outstanding, of which no shares are owned by the Company. There are no other shares of any other class or series of capital stock of the Company issued or outstanding. The Company has no capital stock reserved for issuance, except that, as of June 30, 2023, there are (i) 4,000,000 shares of Common Stock reserved for issuance pursuant to the Company's equity incentive plans, of which 3,510,767 shares are issuable upon the exercise of stock options outstanding on the date hereof, , and (ii) no shares of Common Stock reserved for issuance upon the vesting of restricted stock units. As of June 30, 2023, there were outstanding warrants to purchase 6,883,210 shares of Common Stock. As of June 30, 2023, there were outstanding convertible debentures to purchase 8,120,331 shares of Common Stock. There are no bonds, debentures, notes or other indebtedness having general voting rights (or convertible into securities having such rights) ("**Voting Debt**") of the Company issued and outstanding. The issuance of Common Stock or other securities pursuant to any provision of this Agreement will not give rise to any preemptive rights or rights of first refusal on behalf of any Person (as defined below) or result in the triggering of any anti-dilution rights, and the Company is not otherwise subject to any preemptive rights or rights of first refusal on behalf of any Person or any anti-dilution rights. There are no agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the Securities Act. "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

4.7 Litigation. No action, suit, proceeding, inquiry or investigation brought by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries or their respective properties is pending or, to the best knowledge of the Company, threatened that would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business; and the aggregate of all pending legal or governmental proceedings to which the Company or any of its subsidiaries is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect.

4.8 Governmental Consents. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, or local governmental authority on the part of the Company or any of its Subsidiaries is required in connection with the consummation of the transactions contemplated by this Agreement except for (a) the filing of a Form D with the Commission under the Securities Act and compliance with the securities and blue sky laws in the states and other jurisdictions in which shares of Common Stock are offered and/or sold, which compliance will be effected in accordance with such laws, and (b) the filing of a Notification Form: Listing of Additional Shares with the Nasdaq Capital Market ("**Nasdaq**") for the listing of the Shares .

4.9 No Default or Consents. Neither the execution, delivery or performance of this Agreement by the Company nor the consummation of any of the transactions contemplated thereby (including, without limitation, the issuance and sale by the Company of the Shares) will conflict with, result in a breach or violation of, or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, (i) the charter or by-laws of the Company or any of its Subsidiaries, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company or any of its Subsidiaries is a party or bound or to which its or their property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company or any of its Subsidiaries of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its Subsidiaries or any of their respective properties, except in the case of clauses (ii) and (iii) above, for any conflict, breach or violation of, or imposition that would not, individually or in the aggregate, have or reasonably be expected to have a Material Adverse Effect.

4.10 No Material Adverse Change. Since June 30, 2023, there have not been any changes in the authorized capital, assets, liabilities, financial condition, business, Material Contracts (as defined below) or operations of the Company from that reflected in the Financial Statements except changes in the ordinary course of business which have not had or would not reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

4.11 No General Solicitation. Neither the Company nor any Person acting on its behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D promulgated under the Securities Act) in connection with the offer or sale of the Shares.

4.12 No Integrated Offering. Neither of the Company or any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any Company security, under circumstances that would adversely affect reliance by the Company on Regulation D, Regulation S or Section 4(a)(2) of the Securities Act or require registration of any of the Shares under the Securities Act or cause this offering of the Shares to be integrated with prior offerings by the Company for purposes of the Securities Act.

4.13 Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including, without limitation, Section 402 relating to loans.

4.14 Intellectual Property. The Company and its Subsidiaries collectively own, possess, license or have other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the "Intellectual Property") which cover its products and are necessary for the conduct of the Company's and its Subsidiaries' business, taken as a whole, as now conducted or as proposed in the SEC Documents to be conducted (the "Company Intellectual Property") except to the extent that the failure to do so would not reasonably be expected to have a Material Adverse Effect on the Company. To the knowledge of the Company, there is no infringement by third parties of any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any valid patent, trademark, copyright, trade secret or other proprietary rights of others. The Company is not aware of any material facts required to be disclosed to the U.S. Patent and Trademark Office ("USPTO") which have not been disclosed to the USPTO and which would preclude the grant of a material patent in connection with any patent application of the Company Intellectual Property or could form the basis of a finding of invalidity with respect to any material issued patents of the Company Intellectual Property, except to the extent that the failure to do so would not reasonably be expected to have a Material Adverse Effect on the Company.

4.15 Compliance with Nasdaq Continued Listing Requirements. The Company is in compliance with applicable Nasdaq continued listing requirements. There are no proceedings pending or, to the Company's knowledge, threatened against the Company relating to the continued listing of the Common Stock on Nasdaq and the Company has not received any notice of, nor to the Company's knowledge is there any reasonable basis for, the delisting of the Common Stock from Nasdaq.

4.16 Disclosure. The Company understands and confirms that the Purchasers will rely on the foregoing representations in effecting transactions in securities of the Company. To the knowledge of the executive officers of the Company, all due diligence materials regarding the Company, its business and the transactions contemplated hereby, furnished by or on behalf of the Company to each Purchaser upon its request are, when taken together with the SEC Documents and the Schedule of Exceptions, true and correct in all material respects and do not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading.

4.17 Contracts. Each franchise, contract or other document of a character required to be described in the SEC Documents or to be filed as an exhibit to the SEC Documents that have been filed prior to date hereof under the Securities Act and the rules and regulations promulgated thereunder (collectively, the "Material Contracts") is so described or filed.

4.18 Properties and Assets. The Company and its Subsidiaries own or lease all such properties as are necessary to the conduct of its operations as presently conducted.

4.19 Compliance. Except as (A) set forth herein or (B) would not (1) have or reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect or (2) materially and adversely affect the validity or enforceability of, or the authority or the ability of the Company to perform its obligations under, this Agreement: (i) the Company and each of its Subsidiaries are in compliance with statutes, laws, ordinances, rules and regulations applicable to the Company and its Subsidiaries, including without limitation for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company or any of its Subsidiaries or out-licensed by the Company or any of its Subsidiaries (a "Company Product"), including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., the Public Health Service Act, 42 U.S.C. § 262, similar laws of other governmental entities and the regulations promulgated pursuant to such laws (collectively, "Applicable Laws"); (ii) the Company and each of its Subsidiaries possess all licenses, certificates, approvals, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or for the ownership of their respective properties or the conduct of their respective businesses, including without limitation as it relates to a Company Product and as described in the SEC Documents (collectively, "Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iii) neither the Company nor any of its Subsidiaries has received any written notice of adverse finding or warning letter from the U.S. Food and Drug Administration (the "FDA") or any other governmental entity alleging or asserting noncompliance with any Applicable Laws or

Authorizations relating to a Company Product; (iv) neither the Company nor any of its Subsidiaries has received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental entity or third party alleging that any Company Product, operation or activity related to a Company Product is in violation of any Applicable Laws or Authorizations or has any knowledge that any such governmental entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) neither the Company nor any of its Subsidiaries has received written notice that any governmental entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such governmental entity has threatened or is considering such action with respect to a Company Product; and (vi) the Company and each of its Subsidiaries have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). Neither the Company nor any of its Subsidiaries, directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental entity.

4.20 Taxes. The Company and each of its Subsidiaries has filed all material tax returns that are required to be filed or has requested extensions thereof. All such tax returns are correct and complete in all material respects for the periods to which such tax returns relate, and the Company and each of its Subsidiaries has paid all taxes required to be paid by them and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not have or reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.21 Transfer Taxes. There are no transfer taxes or other similar fees or charges under Federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Shares.

4.22 Investment Company. The Company is not and, after giving effect to the offering and sale of the Shares, will not be an “investment company” as defined in the Investment Company Act of 1940, as amended.

4.23 Insurance. The Company and each of its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are reasonable and customary in the business in which it is engaged; all policies of insurance and fidelity or surety bonds insuring the Company and each of its Subsidiaries or their respective businesses, assets, employees, officers and directors are in full force and effect; the Company and each of its Subsidiaries is in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company or any of its Subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any of its Subsidiaries has been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.24 Price of Common Stock. The Company has not taken, directly or indirectly, any action designed to cause or result in, or that has constituted or that might reasonably be expected to constitute the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Shares.

4.25 Governmental Permits, Etc. The Company and each of its Subsidiaries possess all licenses, certificates, permits and other authorizations issued by all applicable authorities necessary to conduct their respective businesses, and neither the Company nor any of its Subsidiaries has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.26 Internal Control over Financial Reporting; Sarbanes-Oxley Matters. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company’s internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) are effective 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 and the Company has no material weakness in its internal controls over financial reporting. The Company maintains “disclosure controls and procedures” (as such term is defined in Rule 13a-15(e) under the Exchange Act); such disclosure controls and procedures are effective.

4.27 Foreign Corrupt Practices. Neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, any director, officer, agent, or employee of the Company, has taken any action, directly or indirectly, that is in violation or would result in a violation by the Company or such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the “FCPA”), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA.

4.28 Labor. No labor problem or dispute with the employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors, that could have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.29 ERISA. None of the following events has occurred or exists: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the United States Employee Retirement Income Security Act of 1974, as amended (“ERISA”), and the regulations and published interpretations thereunder with respect to a Plan that is required to be funded, determined without regard to any waiver of such obligations or

extension of any amortization period; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company that could have a Material Adverse Effect; (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company that would reasonably be expected to have a Material Adverse Effect. None of the following events has occurred or is reasonably likely to occur: (i) a material increase in the aggregate amount of contributions required to be made to all Plans (as defined below) in the current fiscal year of the Company compared to the amount of such contributions made in the most recently completed fiscal year of the Company; (ii) a material increase in the “accumulated post-retirement benefit obligations” (within the meaning of Statement of Financial Accounting Standards 106) of the Company compared to the amount of such obligations in the most recently completed fiscal year of the Company; (iii) any event or condition giving rise to a liability under Title IV of ERISA that could have a Material Adverse Effect; or (iv) the filing of a claim by one or more employees or former employees of the Company related to their employment that could have a Material Adverse Effect. For purposes of this paragraph, the term “Plan” means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company may have any liability.

4.30 Environmental Laws. The Company and each of its Subsidiaries (i) are in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (“Environmental Laws”), (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business and (iii) have not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the aggregate, have or reasonably be expected to have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business. Neither the Company nor any of its Subsidiaries has been named as a “potentially responsible party” under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

4.31 Money Laundering Laws. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Money Laundering Laws”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

4.32 OFAC. Neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, any director, officer, agent or employee of the Company or any of its Subsidiaries (i) is currently subject to any sanctions administered or imposed by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Treasury Department, the U.S. Department of State, or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, or the United Kingdom (including sanctions administered or controlled by Her Majesty’s Treasury) (collectively, “Sanctions” and such persons, “Sanction Persons”) or (ii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person in any manner that will result in a violation of any economic Sanctions by, or could result in the imposition of Sanctions against, any person (including any person participating in the offering, whether as advisor, investor or otherwise). Neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, any director, officer, agent, or employee of the Company or any of its Subsidiaries, is a person that is, or is 50% or more owned or otherwise controlled by a person that is: (i) the subject of any Sanctions; or (ii) located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (including without limitation Cuba, Iran, North Korea, Sudan, and Syria) (collectively, “Sanctioned Countries” and each, a “Sanctioned Country”). Neither the Company nor any of its Subsidiaries has engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding three years, nor does the Company or its Subsidiaries have any plans to engage in any dealings or transactions with Sanctioned Persons, or with or in Sanctioned Countries.

SECTION 5.

REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PURCHASERS.

5.1 Each Purchaser, severally and not jointly, represents and warrants to and covenants with the Company that:

(a) Such Purchaser (if an entity) is a validly existing corporation, limited partnership or limited liability company and has all requisite corporate, partnership or limited liability company power and authority to enter into and consummate the transactions contemplated by this Agreement and to carry out its obligations hereunder and thereunder, and to invest in the Shares pursuant to this Agreement.

(b) Such Purchaser acknowledges that it can bear the economic risk and complete loss of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby. Such Investor has had an opportunity to receive, review and understand all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the offering of the Shares, and has conducted and completed its own independent due diligence. Such Purchaser acknowledges that the Company has made available the SEC Documents. Based on the information such Purchaser has deemed appropriate, and without reliance upon any placement agent, it has independently made its own analysis and decision to enter into this Agreement. Such Purchaser is relying exclusively on its own sources of information, investment analysis and due diligence (including professional advice it deems appropriate) with respect to the execution, delivery and performance of this Agreement, the Shares and the business, condition (financial and otherwise), management, operations, properties and prospects of the Company, including but not limited to all business, legal, regulatory, accounting, credit and tax matters.

(c) The Shares to be received by such Purchaser hereunder will be acquired for such Purchaser’s own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act, and such Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act without prejudice, however, to such Purchaser’s right at all times to sell or otherwise dispose of all or any part of such Shares in compliance with applicable federal and state securities laws. Such Purchaser is not a broker-dealer registered with the Commission under the Exchange Act or an entity engaged in a business that would require it to be so registered. Such Purchaser understands that the Shares are characterized as “restricted securities” under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. Such Purchaser will not, directly or indirectly, offer, sell, pledge,

transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the securities purchased hereunder except in compliance with the Securities Act, applicable blue sky laws, and the rules and regulations promulgated thereunder.

(d) Such Purchaser is an “accredited investor” within the meaning of Rule 501(a) under the Securities Act. Such Purchaser has determined based on its own independent review and such professional advice as it deems appropriate that its purchase of the Shares and participation in the transactions contemplated by this Agreement (i) are fully consistent with its financial needs, objectives and condition, (ii) comply and are fully consistent with all investment policies, guidelines and other restrictions applicable to such Purchaser, (iii) have been duly authorized and approved by all necessary action, (iv) do not and will not violate or constitute a default under such Purchaser’s charter, by-laws or other constituent document or under any law, rule, regulation, agreement or other obligation by which such Purchaser is bound and (v) are a fit, proper and suitable investment for such Purchaser, notwithstanding the substantial risks inherent in investing in or holding the Shares.

(e) The execution, delivery and performance by such Purchaser of this Agreement to which such Purchaser is a party have been duly authorized and each has been duly executed and when delivered will constitute the valid and legally binding obligation of such Purchaser, enforceable against such Purchaser in accordance with their respective terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability relating to or affecting creditors’ rights generally.

(f) Purchaser is not a broker or dealer registered pursuant to Section 15 of the Exchange Act (a “registered broker-dealer”) and is not affiliated with a registered broker dealer. Purchaser is not party to any agreement for distribution of any of the Shares.

(g) Purchaser shall have completed and delivered to the Company no later than the Closing Date, the Purchaser Questionnaire and the answers to the Purchaser Questionnaire are true and correct in all material respects as of the date of this Agreement and will be true and correct as of the Closing Date;

(h) Such Purchaser understands that no United States federal or state agency, or similar agency of any other country, has reviewed, approved, passed upon, or made any recommendation or endorsement of the Company or the purchase of the Shares.

(i) Such Purchaser has no present intent to effect a “change of control” of the Company as such term is understood under the rules promulgated pursuant to Section 13(d) of the Exchange Act.

(j) Such Purchaser has not taken any of the actions set forth in, and is not subject to, the disqualification provisions of Rule 506(d)(1) of the Securities Act.

(k) Such Purchaser did not learn of the investment in the Shares as a result of any general solicitation or general advertising.

(l) Such Purchaser’s residence (if an individual) or offices in which its investment decision with respect to the Shares was made (if an entity) are located at the address immediately below such Purchaser’s in the Schedule of Purchasers.

5.2 Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include the location and/or reservation of borrowable shares of Common Stock) (“Short Sales”), of the securities of the Company during the period commencing as of the time that such Purchaser was first contacted by the Company or any other person regarding the transactions contemplated hereby and ending immediately prior to the Effective Date. Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to the identification of the availability of, or securing of, available shares to borrow in order to effect Short Sales or similar transactions in the future.

5.3 Purchaser understands that nothing in this Agreement or any other materials presented to Purchaser in connection with the purchase and sale of the Shares constitutes legal, tax or investment advice. Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

5.4 Legends.

(a) Purchaser understands that, until such time as the Shares have been sold pursuant to a registration statement or the Shares may be sold pursuant to Rule 144 under the Securities Act (“Rule 144”) without any restriction as to the number of securities as of a particular date that can then be immediately sold, the book entry notations evidencing the Shares may bear one or more legends in substantially the following form and substance:

“THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE REOFFERED, SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, HYPOTHECATED OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION WHICH IS EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, IN EACH CASE IN ACCORDANCE WITH ALL APPLICABLE SECURITIES LAWS, AND IN THE CASE OF A TRANSACTION EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO IT THAT SUCH TRANSACTION DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS.”

(b) The Company agrees that at such time as such legend is no longer required under this Section, it will, no later than three business days following the delivery by a Purchaser to the Company or the Company’s transfer agent of a certificate representing Shares and if such Shares are certificated, issued with a restrictive legend, together with such representations and covenants of such Purchaser or such Purchaser’s executing broker as the Company may reasonably require in connection therewith, deliver or cause to be delivered to such Purchaser a book entry position representing such shares that is free from any legend referring to the Securities Act. The Company shall not make any notation on its records or give instructions to any transfer agent of the Company that enlarge the restrictions on transfer set forth in this Section. Certificates for Shares subject to legend removal hereunder shall be transmitted by the transfer agent of the Company to the Purchasers by crediting the account of such Purchaser’s prime broker with the Depository Trust Company. All costs and expenses related to the removal of the legends and the reissuance of any Shares shall be borne by the Company.

(c) The Company shall cause the restrictive legend set forth in this section above to be removed by the Company’s transfer agent and the Company shall issue a certificate or book entry position without such restrictive legend or any other restrictive legend to the holder of the applicable shares upon which it is stamped or issue to such holder by electronic delivery with the applicable balance account at the Depository Trust Company (“DTC”) or in

physical certificated shares, if appropriate, if (i) such Shares are registered for resale under the Securities Act (provided that, if the Purchaser is selling pursuant to an effective registration statement registering the Shares for resale, the Purchaser agrees to only sell such Shares during such time that such registration statement is effective and such Purchaser is not aware or has not been notified by the Company that such registration statement has been withdrawn or suspended, and only as permitted by such registration statement); (ii) such Shares are sold or transferred pursuant to Rule 144 (if the transferor is not an affiliate of the Company); or (iii) such Shares are eligible for sale without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions. Subject to receipt of such representations, and covenants as are contemplated hereby, following Rule 144 becoming available for the resale of the Shares, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to the Shares and without volume or manner-of-sale restrictions, the Company shall issue to the Company's transfer agent the instructions with respect to legend removal consistent with this Section and shall cause such transfer agent to remove such legend. Any fees (with respect to the transfer agent, the Company's counsel or otherwise) associated with the issuance of such opinion or the removal of such legend shall be borne by the Company; provided, however, that the Purchaser shall be responsible for the costs of the Purchaser's counsel and advisors.

5.5 Restricted Securities. Purchaser understands that the Shares are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such Shares may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, such Purchaser represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

5.6 Exculpation Among Purchasers. Purchaser acknowledges that it is not relying upon any other Purchaser, or any officer, director, employee, agent, partner, member or affiliate of any such other Purchaser, in making its investment or decision to invest in the Company. Purchaser agrees that neither any Purchaser nor the respective controlling Persons, officers, directors, partners, agents, or employees of any Purchaser shall be liable to any other Purchaser for any action heretofore taken or omitted to be taken by any of them in connection with the purchase of the Shares.

SECTION 6.

CONDITIONS TO COMPANY'S OBLIGATIONS AT THE CLOSING

The Company's obligation to complete the sale and issuance of the Shares and deliver Shares to each Purchaser, individually, as set forth in the Schedule of Purchasers at the Closing shall be subject to the following conditions to the extent not waived by the Company:

6.1 Receipt of Payment. The Company shall have received payment, by wire transfer of immediately available funds, in the full amount of the purchase price for the number of Shares being purchased by such Purchaser at the Closing as set forth in the Schedule of Purchasers.

6.2 Representations and Warranties. The representations and warranties made by the Purchasers in Section 5 hereof shall be true and correct in all material respects when made, and shall be true and correct in all material respects on the Closing Date with the same force and effect as if they had been made on and as of said date. The Purchaser shall have performed in all material respects all obligations and covenants herein required to be performed by them on or prior to the Closing Date.

SECTION 7.

CONDITIONS TO PURCHASERS' OBLIGATIONS AT THE CLOSING.

Each Purchaser's obligation to accept delivery of the Shares and to pay for the Shares shall be subject to the following conditions to the extent not waived by such Purchaser:

7.1 Representations and Warranties Correct. The representations and warranties made by the Company in Section 4 hereof shall be true and correct in all material respects as of, and as if made on, the date of this Agreement and as of the Closing Date, except to the extent any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct as of such earlier date. The Company shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

7.2 Certificate. Each Purchaser shall have received a certificate signed by the Chief Executive Officer or the Chief Financial Officer of the Company to the effect that the representations and warranties of the Company in Section 4 hereof are true and correct in all material respects as of, and as if made on, the date of this Agreement and as of the Closing Date and that the Company has satisfied in all material respects all of the conditions set forth in this Section 7.

7.3 Good Standing. The Company is validly existing as a corporation in good standing under the laws of Nevada.

7.4 Nasdaq Approval. The Company shall have filed with Nasdaq a Notification Form: Listing of Additional Shares for the listing of the Shares.

7.5 Judgments. No judgment, writ, order, injunction, award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining or preventing the consummation of the transactions contemplated hereby.

7.6 Stop Orders. No stop order or suspension of trading shall have been imposed by the Nasdaq Capital Market, the Commission or any other governmental regulatory body with respect to public trading in the Common Stock.

SECTION 8.

TERMINATION OF OBLIGATIONS TO EFFECT CLOSING; EFFECTS.

8.1 The obligations of the Company, on the one hand, and the Purchasers, on the other hand, to effect the Closing shall terminate as follows:

(a) upon the mutual written consent of the Company and Purchasers that agreed to purchase a majority of the Shares to be issued and sold pursuant to this Agreement;

(b) by the Company if any of the conditions set forth in Section 6 shall have become incapable of fulfillment, and shall not have been waived by the Company; or

(c) by a Purchaser (with respect to itself only) if any of the conditions set forth in Section 7 shall have become incapable of fulfillment or have not occurred on or before the fifth Business Day following the Effective Date, and shall not have been waived by such Purchaser. "Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

8.2 Nothing in this Section 8 shall be deemed to release any party from any liability for any breach by such party of the terms and provisions of this Agreement or to impair the right of any party to compel specific performance by any other party of its obligations under this Agreement.

SECTION 9.

BROKER'S FEES.

The Company and each Purchaser (severally and not jointly) hereby represent that there are no broker or finders fees payable and no brokers or finders entitled to compensation in connection with the sale of the Shares, and shall indemnify each other for any such fees for which they are responsible.

SECTION 10.

ADDITIONAL AGREEMENTS OF THE PARTIES.

10.1 Nasdaq Listing. The Company will use commercially reasonable efforts to continue the listing and trading of its Common Stock on Nasdaq and, in accordance, therewith, will use commercially reasonable efforts to comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of such market or exchange, as applicable.

10.2 Access to Information. From the date hereof until the Closing, the Company will make reasonably available to the Purchasers' representatives, consultants and their respective counsels for inspection, such information and documents as the Purchasers reasonably request, and will make available at reasonable times and to a reasonable extent officers and employees of the Company to discuss the business and affairs of the Company.

10.3 [Reserved].

10.4 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Shares and to provide a copy thereof, promptly upon request of any Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to the Purchaser at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

10.5 Integration. The Company shall not, and shall use its commercially reasonable efforts to ensure that no affiliate of the Company shall, sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that will be integrated with the offer or sale of the Shares in a manner that would require the registration under the Securities Act of the sale of the Shares to the Purchasers, or that will be integrated with the offer or sale of the Shares for purposes of the rules and regulations of any trading market such that it would require stockholder approval prior to the closing of such other transaction unless stockholder approval is obtained before the closing of such subsequent transaction.

10.6 Short Sales and Confidentiality After the Date Hereof. Each Purchaser covenants that neither it nor any affiliates acting on its behalf or pursuant to any understanding with it will execute any Short Sales during the period from the date hereof until the earlier of such time as (i) after the transactions contemplated by this Agreement are first publicly announced or (ii) this Agreement is terminated in full. Each Purchaser covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company, such Purchaser will maintain the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Each Purchaser understands and acknowledges that the Commission currently takes the position that coverage of short sales of shares of the Common Stock "against the box" prior to effectiveness of a resale registration statement with securities included in such registration statement would be a violation of Section 5 of the Securities Act, as set forth in Item 239.10 of the Securities Act Compliance and Disclosure Interpretations compiled by the Office of Chief Counsel, Division of Corporation Finance.

10.7 Securities Laws Disclosure; Publicity. The Company will issue a press release disclosing the material terms of the transactions contemplated hereby prior to the opening of trading on Nasdaq on the trading day immediately following the Effective Date. On or before the fourth trading day immediately following the execution of this Agreement, the Company will file a Current Report on Form 8-K (the "8-K") with the Commission describing the terms of this Agreement (and including as exhibits to such Current Report on Form 8-K the agreements required to be filed in connection therewith). Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any public filing with the Commission or any regulatory agency or Nasdaq, without the prior written consent of such Purchaser, which consent shall not be unreasonably withheld, conditioned or delayed, except: (a) as required by federal securities law in connection with (i) any registration statement filed by the Company and (ii) the filing of the final Agreement with the Commission; (b) the filing of a Form D with the Commission under the Securities Act and (c) to the extent such disclosure is required by law or Nasdaq regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (c).

SECTION 11.

INDEMNIFICATION.

11.1 Indemnification by the Company. The Company agrees to indemnify and hold harmless each of the Purchasers, each of its directors and officers and each Person, if any, who controls any Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act) (each, an "Indemnified Party"), against any losses, claims, damages, liabilities or expenses, joint or several, to which such Indemnified Party may become subject under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based in whole or in part on any inaccuracy in the representations and warranties of the Company contained in this Agreement or any failure of the Company to perform its obligations hereunder, and will reimburse each Indemnified Party for legal and other expenses reasonably incurred as such expenses are reasonably incurred by such Indemnified Party in connection with investigating, defending, settling, compromising or paying such loss, claim, damage, liability, expense or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon (i) the failure of such Indemnified Party to comply with the covenants and agreements contained in Section 6 above respecting sale of the Shares, or (ii) the inaccuracy of any representations made by such Indemnified Party herein.

11.2 Indemnification by Purchasers. Each Purchaser shall severally, and not jointly, indemnify and hold harmless the other Purchasers and the Company, each of its directors, and each

Person, if any, who controls the Company within the meaning of the Securities Act, against any losses, claims, damages, liabilities or expenses to which the Company, each of its directors or each of its controlling Persons may become subject, under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Purchaser) insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based upon (i) any failure by such Purchaser to comply with the covenants and agreements contained in Sections 5 and 10.6 above respecting the sale of the Shares unless such failure by such Purchaser is directly caused by the Company's failure to provide written notice of a Suspension

to such Purchaser or (ii) the inaccuracy of any representation made by such Purchaser herein, in each case to the extent, and will reimburse the Company, each of its directors, and each of its controlling Persons for any legal and other expense reasonably incurred, as such expenses are reasonably incurred by the Company, each of its directors, and each of its controlling Persons in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. No Purchaser shall be liable for the indemnification obligations of any other Purchaser.

SECTION 12.

NOTICES.

All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed facsimile or electronic mail, or mailed by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, and shall be deemed given when so sent in the case of facsimile or electronic mail transmission, or when so received in the case of mail or courier, and addressed as follows:

if to the Company, to:

Orgenesis Inc.

20271 Goldenrod Lane

Germantown, Maryland 20876

Attention: Eliot Maltz, CFO Facsimile: (480) 659-6407

with a copy (which shall not constitute notice) to:

Pearl Cohen Zedek Latzer Baratz, LLP

7 Times Square

New York, New York 10036

Attention: Mark Cohen, Esq.

Facsimile: (646) 878-0801

and

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C

666 Third Avenue

New York, New York 10017

Attention: Jeffrey Schultz, Esq.

Facsimile: (212) 983-3115

or to such other person, at such other place or in such manner as one party shall designate to other party in writing; and if to the Purchasers, at the address as set forth in Exhibit A or at such other address or addresses as may have been furnished to the Company in writing.

SECTION 13.

MISCELLANEOUS.

13.1 Payment of Fees and Expenses. Each of the Company and the Purchasers shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

13.2 Waivers and Amendments. Neither this Agreement nor any provision hereof may be changed, waived, discharged, terminated, modified or amended except upon the written consent of the Company and holders of at least a majority of the Shares.

13.3 Replacement of Shares. If the Shares are certificated and any certificate or instrument evidencing any Shares is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof, or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company and the Company's transfer agent of such loss, theft or destruction and the execution by the holder thereof of a customary lost certificate affidavit of that fact and an agreement to indemnify and hold harmless the Company and the Company's transfer agent for any losses in connection therewith or, if required by the transfer agent, a bond in such form and amount as is required by the transfer agent. The applicants for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs associated with the issuance of such replacement Shares. If a replacement certificate or instrument evidencing any Shares is requested due to a mutilation thereof, the Company may require delivery of such mutilated certificate or instrument as a condition precedent to any issuance of a replacement.

13.4 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser under this Agreement. Nothing contained herein and no action taken by any Purchaser pursuant hereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group, or are deemed affiliates (as such term is defined under the Exchange Act) with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser shall be entitled to independently protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose.

13.5 Governing Law; Submission to Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the County of New York, in the State of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the County of New York, in the State of New York, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of this Agreement), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby

irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law.

13.6 **Successors and Assigns.** Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto. This Agreement, or any rights or obligations hereunder, may not be assigned by any party without the prior written consent of the other parties; provided that each Purchaser may assign its rights and obligations hereunder to an affiliate of such Purchaser without the prior written consent of the Company or any other Purchaser.

13.7 **Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

13.8 **Severability.** In case any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

13.9 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

13.10 **Entire Agreement.** This Agreement and other documents delivered pursuant hereto, including the exhibits and the Schedule of Exceptions, constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof.

13.11 **Survival.** The representations, warranties, covenants and agreements made in this Agreement shall survive any investigation made by the Company or the Purchasers and the Closing.

[signature pages follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

ORGENESIS INC.

By: /s/ Vered Caplan

Name: Vered Caplan

Title: CEO

PURCHASERS:

PURCHASER

/s/ Jacob Safier

Jacob Safier

EXHIBIT A

Name and Address	Number of Shares	Aggregate Purchase Price of Shares
Jacob Safier	2,000,000	\$ 1,000,000
TOTAL	2,000,000	\$ 1,000,000

APPENDIX I
PURCHASER QUESTIONNAIRE

Exhibit 10.2

CONVERTIBLE LOAN AGREEMENT

THIS CONVERTIBLE LOAN AGREEMENT (this “**Agreement**”) is made as of the 29th day of September, 2023 (“**Effective Date**”), by and between Sai Traders, having an address at 3rd Floor, ALTIUS, 1, OLYMPIA TECHNOLOGY PARK, Guindy, SIDCO Industrial Estate, Chennai, Tamil Nadu 600032 (“**Lender**”), and **Koligo Therapeutics, Inc.**, a Kentucky corporation., of 2113 State Street New Albany, IN 47150 and wholly-owned subsidiary of Orgenesis Inc. (“**Borrower**”) (Lender, together with Borrower, each a “**Party**” and together, the “**Parties**”).

WHEREAS, Lender desires to provide financing by way of a loan to the Borrower to be used by the Borrower for working capital and ongoing operations, and the Borrower desires to receive such financing to be used by the Borrower for working capital and ongoing operations;

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein contained, and other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Funding.** Lender will provide financing in form of a convertible loan under the terms of this Agreement in the amount of up to Twenty Five Million US Dollars (\$25,000,000) (the “**Convertible Loan**”) in accordance with the terms hereof. The Borrower shall accept such funding and shall use the proceeds for working capital and on-going operations. The Convertible Notes shall consist of an Initial Installment of One Million Five Hundred US Dollars (\$1,500,000) (“**Initial Installment**”), and at the election of the Borrower thereafter while the Convertible Notes remain outstanding, Borrower may issue up to Twenty Three Million Five Hundred US Dollars (\$23,500,000) in an additional Convertible Loan (“**Subsequent Installments**”).

2. Loan; Closing.

(a) **Terms of Loan.** The Lender shall lend the Convertible Loan to the Borrower, and the Borrower shall borrow the Convertible Loan from the Lender. The Convertible Loan or parts thereof of principal outstanding at any time shall bear simple interest at the rate of **ten percent (10%)** per annum (based upon a 365-day year). Unless otherwise converted into equity pursuant to the terms of this Agreement, all outstanding principal borrowings of the Convertible Loan, and all accrued but unpaid interest thereon (collectively, the “**Outstanding Amount**”), shall become due and payable on December 1, 2027 (the “**Maturity Date**”) without any action required from the Lender. If requested by the Borrower, the Maturity Date may be extended by the Lender in the Lender’s sole and absolute discretion and any such extension(s) shall be in writing signed by both Parties. The Outstanding Amount under this Convertible Loan may be prepaid by the Borrower in whole or in part at any time without penalty.

(b) **The Closing.** At the closing of the Initial Installment, and any and each Subsequent Installment, the Lender and the Borrower shall each deliver a fully executed version of this Agreement to the other Party (the “**Closing**”). Within 2 days after the Closing, the Lender shall transfer the Convertible Loan by wire to the bank account of the Borrower in accordance with wiring instructions provided by the Borrower to the Lender prior to the Closing and detailed below in Section 10(g).

3. **Use of Proceeds.** The Borrower shall use the Convertible Loan to fund the working capital and ongoing operations (“**Purpose**”). Borrower may also be subject to a three percent (3%) fee on each such transfer or proceeds from Lender to Borrower (“**Transfer Fee**”).

4. Events of Default.

(a) The following shall constitute events of default (each an “Event of Default”):

i. filing of a petition in bankruptcy or the commencement of any proceedings under any bankruptcy laws by or against the Borrower, which filing or proceeding is not dismissed within ninety (90) days after the filing or commencement thereof, or if the Borrower shall completely cease or suspend the conduct of its usual business or if the Borrower shall become, , insolvent and admits in writing that it is unable to pay its debts or liabilities as they fall due;

ii. breaches any material covenant by the Borrower (other than a payment covenant) which is not cured within 30 days of receipt of written notice of such breach;

iii. an order, judgment or decree shall be entered, without the application, approval or consent of the Borrower by any court of competent jurisdiction, approving a petition seeking reorganization of the Borrower or appointing a receiver, trustee or liquidator of the Borrower or of all or a substantial part of its assets, and such order, judgment or decree shall continue unstayed and in effect for any period of ninety (90) consecutive days;

iv. Borrower fails to repay principal when due or interest and such failure continues for ten business days of the Borrower’s receipt of written notice from the Lender; and

v. Borrower breaches any representation or warranty under this Agreement in any material respect.

(b) If, at any time, an Event of Default shall occur, all obligations under this Agreement shall become immediately due and payable without presentment, demand or protest, all of which are hereby waived by the Borrower.

5. **Representations and Warranties.** The Borrower represents and warrants to the Lender (and to the extent identified below, the Lender represents and warrants to the Borrower) as follows:

(a) The Borrower is duly formed, validly existing and in good standing under the laws of Kentucky. The Borrower has full power and authority to consummate the transactions contemplated hereunder, and the consummation of such transactions and the performance of this Agreement by the Borrower does not violate the provisions of any applicable law, and will not result in any material breach of, or constitute a material default under any agreement or instrument to which the Borrower is a party or under which the Borrower is bound.

(b) The execution and performance of this Agreement by the Borrower has been duly authorized by all necessary actions. This Agreement has been duly executed and delivered by the Borrower and the Lender and this Agreement is the legal, valid, and binding obligation of the Borrower and the Lender, and is fully enforceable against the Borrower and the Lender according to its terms.

(c) All of the shares of the Borrower after its establishment to be issued to the Lender upon the conversion of the amounts outstanding of the Convertible Loan shall be, when issued, duly authorized, validly issued, fully paid, non-assessable free and clear of all liens, pledges, security interests, charges and encumbrances.

(d) There is no existing lien, encumbrance, security interest, indebtedness, mortgage or third-party rights of any kind that are, or could be, ranked senior in nature to the amounts outstanding of the Convertible Loan other than any lien arising by operation of law.

(e) The securities and shares of Common Stock of Organogenesis Inc. issuable upon conversion hereunder are being acquired for the Lender’s own account, not as nominee or agent, and not with a view to, or for resale in connection with, any distribution or public offering thereof within the meaning of the 1933 Act.

(f) The Lender has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in connection with the transactions contemplated in this Agreement. Such Lender has, in connection with its decision to purchase the securities hereunder, relied only upon the representations and warranties contained herein. Further, each Lender has had such opportunity to obtain additional information and to ask questions of, and receive answers from, the Borrower, concerning the terms and conditions of the investment and the business and affairs of the Borrower, as such Lender considers necessary in order to form an investment decision.

(g) The Lender is an “accredited investor” as such term is defined in Rule 501(a) of the rules and regulations promulgated under the 1933 Act. The Lender is not purchasing the securities hereunder as a result of any advertisement, article, notice or other communication regarding the securities published in any newspaper, magazine or similar media or broadcast over the television or radio or presented at any seminar or any other general solicitation or general advertisement.

6. Conversion.

(a) At the option of the Lender, at the Maturity Date or at any time and from time to time, the Outstanding Amount shall be convertible, in whole or in part, into the number of shares of Common Stock of Orgenesis Inc., the parent company of Koligo Therapeutics Inc., equal to the quotient obtained by dividing (x) the Outstanding Amount by (y) the Conversion Price. The “**Initial Installment Conversion Price**” for the Outstanding Amount relating to the Initial Installment shall be a price per share of Common Stock equal to \$2.50; subject to proportional adjustment in the event of a Common Stock share-split. The “**Subsequent Installment Conversion Price**” for the Outstanding Amount relating to the Subsequent Installment(s) shall be a price per share of Common Stock equal to \$3.50; subject to proportional adjustment in the event of a Common Stock share-split. The Lender may effect one or more conversions by delivering to the Borrower a written notice (each, a “**Notice of Conversion**”), specifying therein the Outstanding Amount and accrued interest, if any, to be converted, and the date on which such conversion shall be effected (such date, the “**Conversion Date**”). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion is deemed delivered hereunder. Following the applicable Conversion Date, a Conversion completed pursuant to this Section 2(a)(i) shall have the effect of reducing the Outstanding Amount in amount equal to the Convertible Loan set forth in the corresponding Notice of Conversion. Lender agrees that it shall not deliver a Notice of that upon effect results in the holder to beneficially own more than 19.99% of the then outstanding shares of Orgenesis Inc. Common Stock. For the avoidance of doubt, the Borrower may reject or modify, upon mutual agreement of Borrower and Lender, a Notice of Conversion duly delivered by the Lender if such conversion would result in the Lender to beneficially own more than 19.99% of the then outstanding shares of Orgenesis Inc. Common Stock. The Parties shall maintain records showing the total Outstanding Amount converted and the date of each such Conversion.

(b) Lender may elect to, instead of the conversion of the Outstanding Amount as per section 6(a) into Common shares of Orgenesis Inc., convert the entire Outstanding Amount into the securities of Borrower pursuant to a the first issuance of equity of the Borrower under which the Borrower raises at least \$5,000,000 in gross proceeds (“**Qualified Financing**”) at a price per share equal to seventy five percent (75%) of the price per share paid for each share of the equity securities purchased for cash by the investors in such a Qualified Financing. The equity issued upon said conversion shall have all preferential and associated rights with the highest class of equity issued in such Qualified Financing. In the event of the Borrower being listed on a public securities exchange, Lender shall have the option to submit a Notice of Conversion to convert the Outstanding Amount at a 25% premium to the volume weighted average price of the Borrower’s equity over the preceding five (5) days as reported by Bloomberg (“**5-Day VWAP**”), provided that any such conversion shall not result in the Lender to beneficially own more than 19.99% of the then beneficial shares of the Borrower. In the event of an acquisition of the Borrower (“**Acquisition**”), prior to the closing of such acquisition, Lender shall have the option to convert outstanding principal and accrued interest into equity securities of the Borrower at a price equivalent to seventy five percent (75%) of the price paid by such buyer to acquire the Borrower. Borrower shall provide notice to Lender in anticipation of such Qualified Financing at least five (5) days prior to the closing of such Qualified Financing or Acquisition.

(c) Upon the conversion pursuant to Section 6(a) above, the rights of repayment of the Outstanding Amount shall be extinguished, and the Lender shall surrender this Agreement. As soon as practicable the Borrower into whose shares the Outstanding Amount is converted, shall issue and deliver to the Lender a capital contribution certificate.

(d) The shares issued upon conversion of the Outstanding Amount, free from preemptive rights or any other actual contingent purchase rights of persons other than the Lender.

(e) The conversion of the Outstanding Amount into equities shall be made without charge to the Lender for any documentary stamp or similar taxes upon conversion.

(f) The Lender understands that the securities of Borrower or shares of Common Stock of Orgenesis Inc., as applicable, issuable upon conversion of the Outstanding Amount will be “restricted securities” within the meaning of Rule 144 under the Securities Act of 1933, as amended (the “**1933 Act**”) and may not be sold, pledged, assigned or transferred and must be held indefinitely in the absence of (i) an effective registration statement under the 1933 Act and applicable state securities laws with respect thereto or (ii) an available exemption from, or in a transaction not subject to, the registration requirements of the 1933 Act as evidenced by an opinion of counsel satisfactory to the Borrower that such registration is not required. The certificates for the securities of Borrower or shares of Common Stock of Orgenesis Inc., as applicable, issuable upon conversion of the Outstanding Amount shall bear the following or similar legend (in addition to such other restrictive legends as are required or deemed advisable under any applicable law or any other agreement to which the Borrower is a party):

“THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), OR UNDER THE SECURITIES LAWS OF ANY STATES. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE SOLD, DISTRIBUTED, OFFERED, PLEDGED, ENCUMBERED, ASSIGNED OR OTHERWISE TRANSFERRED EXCEPT AS PERMITTED UNDER THE SECURITIES ACT AND THE APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION, AN AVAILABLE EXEMPTION THEREFROM, OR A TRANSACTION NOT SUBJECT TO THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT OR UNDER THE SECURITIES LAWS OF ANY STATES. UNLESS SOLD PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT, THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE SECURITIES ACT AND ANY APPLICABLE STATE SECURITIES LAWS.”

(g) The Lender consents to the Borrower making a notation on its records or giving instructions to any transfer agent of the securities of Borrower or shares of Common Stock of Orgenesis Inc. in order to implement the restrictions on transfer set forth and described herein.

7. Waiver; Non-Negotiable. The Borrower, for itself and each of its legal representatives, hereby waives presentment for payment, demand, right of setoff, notice of nonpayment, notice of dishonor, protest of any dishonor, notice of protest and protest of this Agreement, and all other notices in connection with the delivery, acceptance, performance, default or enforcement of the obligations under this Agreement. This Agreement is non-negotiable.

8. No Security Interest. At all times, the Outstanding Amount shall rank, and shall be deemed, senior to any and all indebtedness of the Borrower unless otherwise subordinated by the Lender in writing in the Lender's sole and absolute discretion. The Borrower hereby agree, covenant and undertake not to permit any indebtedness, lien, encumbrance, mortgage or third party right of any kind to become senior to the Outstanding Amount other than any lien arising by operation of law and in the ordinary course of business.

9. Further Assurances. The Parties shall perform such further acts and execute such further documents as may reasonably be necessary to carry out and give full effect to the provisions of this Agreement.

10. Miscellaneous.

(a) Entire Agreement; Amendments. This Agreement constitutes the entire understanding of the Parties hereto with respect to the subject matter hereof and supersedes all prior written and oral understandings of such parties with regard thereto. This Agreement may be modified, amended, or any term hereof waived with the written consent of the Borrower and the Lender. Any amendment effected in accordance with this Section 10(a) shall be binding upon all Parties and their respective successors and assignees.

(b) Governing Law; Jurisdiction. This Agreement shall be governed by and construed according to the laws of the State of New York without regard to the conflict of laws provisions thereof. Any dispute arising under or in relation to this Agreement shall be resolved by arbitration administered by the American Arbitration Association with the International Arbitration Rules of the American Arbitration Association for the time being in force on the commencing date of the arbitration. The place of the arbitration is the New York City. The tribunal shall be composed of one arbitrator mutually acceptable to the Parties, or barring such acceptance, by the American Arbitration Association. The language of the arbitration shall be English.

(c) Notices. All notices and other communications required or permitted hereunder to be given to a Party to this Agreement shall be in writing and shall be telecopied or mailed by registered or certified mail, postage prepaid, or otherwise delivered by hand or by messenger. Any notice sent in accordance with this Agreement shall be effective (i) if mailed, seven (7) business days after mailing to the address set forth each Party's signature below, (ii) if sent by messenger, upon delivery, and (iii) if sent via email, upon transmission and electronic confirmation of receipt or (if transmitted and received on a non-business day) on the first business day following transmission and electronic confirmation of receipt. Additionally, a copy of each notice sent or delivered to Borrower (which does not constitute a notice) shall be sent or delivered to Mark Cohen, Pearl Cohen Zedek Latzer LLP, Times Square Tower, 7 Times Square, 19th Floor, New York, NY 10036.

(d) Assignment; Waiver. This Agreement may not be assigned by the Borrower without the prior written consent of the Lender. The Lender may not assign this Agreement without the prior written consent of the Borrower. This Agreement shall be binding upon the successors, assigns and representatives of each Party. No delay or omission to exercise any right, power, or remedy accruing to any Party upon any breach or default under this Agreement, shall be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, either under this Agreement or by law or otherwise afforded to any of the Parties, shall be cumulative and not alternative.

(e) Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be excluded from this Agreement and the remainder of this Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Agreement shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

(g) No-Short. Lender acknowledges and agrees that Lender, including any of its affiliates, has never engaged in any short-selling, arbitrage, derivative or hedging transaction with the respect to the Common Stock of Orgenesis Inc. Lender further agrees it shall not engage in any short-selling, arbitrage, derivative or hedging transaction with the respect to the Common Stock of Orgenesis Inc. while this Agreement is outstanding.

(h) If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be excluded from this Agreement and the remainder of this Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Agreement shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction.

(i) Borrower bank account wire instructions:

Account Name: Koligo Therapeutics Inc.

Account number: 619955930

ABA Routing: 021000021

Swift Code: CHASUS33

Bank: JPMorgan Chase

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have executed this Loan Agreement as of the date first above written.

LENDER

SAI TRADERS

By: _____

Name: Nithya Rajendiran

Address:

3rd Floor, ALTIUS, 1,

OLYMPIA TECHNOLOGY

PARK, Guindy, SIDCO

Industrial Estate, Chennai,

Tamil Nadu 600032

THE BORROWER

KOLIGO THERAPEUTICS INC.

By: _____

Name: Vered Caplan

Title: Chief Executive

Officer Address:

[Signature page to the Convertible Loan Agreement between Koligo Therapeutics Inc. and Lender]

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 September 30, 2023 March 31, 2024 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 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 operations 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: _____

By:

/s/ Vered Caplan

Vered Caplan

President & Chief Executive Officer

(Principal Executive Officer)

Date: November 13, 2023 May 20, 2024

Exhibit 31.2

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

I, Elliot Maltz, Victor Miller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024 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 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 operations 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:

By:

/s/ Elliot Maltz Victor Miller

Elliot Maltz Victor Miller

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: November 13, 2023 May 20, 2024

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 September 30, 2023 March 31, 2024 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:

By:

/s/ Vered Caplan

Vered Caplan

President & Chief Executive Officer

(Principal Executive Officer)

Date: November 13, 2023 May 20, 2024

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

The undersigned, Elliot Maltz, Victor Miller, 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 September 30, 2023 March 31, 2024 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:

By:

/s/ Elliot Maltz Victor Miller

Elliot Maltz Victor Miller

Chief Financial Officer, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

Date: November 13, 2023 May 20, 2024

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