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, 2021

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, MD 20876
(Address of principal executive offices) (Zip Code)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ 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 4, 2021, there were 24,275,276 shares of registrant’s common stock outstanding

ORGENESIS INC.
FORM 10-Q
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

TABLE OF CONTENTS

ITEM 1. FINANCIAL STATEMENTS

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

	As of	
	September 30, 2021	**December 31, 2020**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,917	$ 44,923
Restricted cash	487	645
Accounts receivable, net *	15,950	3,085
Prepaid expenses and other receivables	1,667	1,070
Convertible loan to related party	3,018	-
Grants receivable	169	169
Inventory	133	185
Total current assets	36,341	50,077
NON-CURRENT ASSETS:		
Deposits	$ 358	$ 296
Investments in associates, net	397	175
Property, plant and equipment, net	5,706	3,073
Intangible assets, net	12,064	13,023
Operating lease right-of-use assets	1,122	1,474
Goodwill	8,414	8,745
Other assets	802	821
Total non-current assets	28,863	27,607
TOTAL ASSETS	$ 65,204	$ 77,684

* Including related party in the amount of $1,069 thousand and $744 thousand as of September 30, 2021 and as of December 31, 2020, respectively.

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

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

	As of	
	September 30, 2021	**December 31, 2020**
Liabilities and Equity		
CURRENT LIABILITIES:		
Accounts payable	$ 3,056	$ 8,649
Accrued expenses and other payables	2,474	792
Income tax payable	74	7
Employees and related payables	1,919	1,463
Advance payments on account of grant	1,108	692
Short-term loans and current maturities of long-term loans	-	145
Contract liabilities	59	59
Current maturities of finance leases	18	19
Current maturities of operating leases	476	485
Current maturities of convertible loans	4,382	3,974
Total current liabilities	13,566	16,285
LONG-TERM LIABILITIES:		
Non-current operating leases	$ 665	$ 1,020
Convertible loans	7,277	7,200
Retirement benefits obligation	98	74
Non-current finance leases	47	64
Other long-term liabilities	290	313
Total long-term liabilities	8,377	8,671
TOTAL LIABILITIES	21,943	24,956
EQUITY:		
Common stock, par value $0.0001 per share, 145,833,334 shares authorized, 24,537,366 and 24,223,093 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	145,338	140,397
Accumulated other comprehensive income	290	748
Treasury stock 262,090 and 55,309 shares as of September 30, 2021 and December 31, 2020, respectively	(1,159)	(250)
Accumulated deficit	(101,356)	(88,319)
Equity attributable to Orgenesis Inc.	43,116	52,579
Non-controlling interest	145	149
Total equity	43,261	52,728
TOTAL LIABILITIES AND EQUITY	$ 65,204	$ 77,684

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

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

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenues	$ 7,606	$ 1,450	$ 25,656	$ 4,305
Revenues from related party	1,070	279	2,954	1,051
Total revenues	8,676	1,729	28,610	5,356
Cost of services and other research and development expenses	10,007	6,951	25,861	36,787
Amortization of intangible assets	236	87	713	258
Selling, general and administrative expenses	6,092	4,042	11,961	11,171
Other income, net	(3)	(5)	(31)	(9)
Operating loss	7,656	9,346	9,894	42,851
Financial expenses, net *	2,410	238	3,049	904
Share in net loss of associated companies	18	-	33	-
Loss from continuing operations before income taxes	10,084	9,584	12,976	43,755
Tax expenses (income)	67	(18)	65	(53)
Net loss from continuing operations	10,151	9,566	13,041	43,702
Net income from discontinued operations, net of tax	-	(7,132)	-	(90,318)
Net loss (income)	10,151	2,434	13,041	(46,616)
Net loss (income) attributable to non-controlling interests from continuing operations	8	(7)	(4)	(40)
Net income attributable to non-controlling interests from discontinued operations	-	-	-	(492)
Net loss (income) attributable to Orgenesis Inc.	$ 10,159	$ 2,427	$ 13,037	$ (47,148)
Loss (Earnings) per share:				
Basic and diluted from continuing operations	$ 0.42	$ 0.43	$ 0.54	$ 2.13
Basic and diluted from discontinued operations	$ -	$ (0.32)	$ -	$ (4.69)
Basic and diluted	$ 0.42	$ 0.11	$ 0.54	$ (2.56)
Weighted average number of shares used in computation of Basic and Diluted loss (earnings) per share:				
Basic and diluted	24,275,276	22,094,470	24,278,292	20,469,470
Comprehensive loss (income):				
Net loss from continuing operations	$ 10,151	$ 9,566	$ 13,041	$ 43,702
Net income from discontinued operations, net of tax	-	(7,132)	-	(90,318)
Other comprehensive loss (income)- translation adjustments	229	(282)	458	115
Release of translation adjustment due to sale of subsidiary	-	-	-	(194)
Comprehensive loss (income)	10,380	2,152	13,499	(46,695)
Comprehensive (loss) income attributed to non-controlling interests from continuing operations	8	(7)	(4)	(40)
Comprehensive income attributed to non-controlling interests from discontinued operations	-	-	-	(492)
Comprehensive loss (income) attributed to Orgenesis Inc.	$ 10,388	$ 2,145	$ 13,495	$ (47,227)

* Including loss from extinguishment in connection with convertible loan restructuring in the amount of $ 1,865 thousand for the three and nine months ended September 30, 2021. See Note5.

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

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

	Common Stock								
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Treasury Shares	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at January 1, 2021	24,167,784	$ 3	$ 140,397	$ 748	$ (250)	$ (88,319)	$ 52,579	$ 149	$ 52,728
Changes during the nine months ended September 30, 2021:									
Stock-based compensation to employees and directors	-	-	876	-	-	-	876	-	876
Stock-based compensation to service providers	-	*	305	-	-	-	305	-	305
Exercise of options	8,750	-	50	-	-	-	50	-	50
Extinguishment in connection with convertible loan restructuring	-	-	1,848	-	-	-	1,848	-	1,848
Issuance of Shares due to exercise of warrants	305,523	*	1,862	-	-	-	1,862	-	1,862
Repurchase of treasury stock	(206,781)	-	-	-	(909)	-	(909)	-	(909)
Comprehensive loss for the period	-	-	-	(458)	-	(13,037)	(13,495)	(4)	(13,499)
Balance at September 30, 2021	24,275,276	$ 3	$ 145,338	$ 290	$ (1,159)	$ (101,356)	$ 43,116	$ 145	$ 43,261

* Represents an amount lower than $1 thousand.

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

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

	Common Stock							
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at January 1, 2020	16,140,962	$ 2	$ 94,691	$ 213	$ (89,429)	$ 5,477	$ 601	$ 6,078
Changes during the nine months ended September 30, 2020:								
Stock-based compensation to employees and directors	-	-	1,178	-	-	1,178	-	1,178
Stock-based compensation to service providers	**270,174	*	1,090	-	-	1,090	-	1,090
Stock-based compensation for Tamir purchase agreement	3,400,000	*	17,748	-	-	17,748	-	17,748
Exercise of options	83,334	*	300	-	-	300	-	300
Beneficial conversion feature of convertible loans	-	-	42	-	-	42	-	42
Issuance of shares and warrants	2,200,000	*	8,438	-	-	8,438	-	8,438
Sale of subsidiaries	-	-	-	-	-	-	(413)	(413)
Adjustment to redemption value of redeemable non-controlling interest	-	-	5,160	-	-	5,160	-	5,160
Comprehensive (income) loss for the period	-	-	-	79	47,148	47,227	(40)	47,187
Balance at September 30, 2020	**22,094,470	$ 2	$ 128,647	$ 292	$ (42,281)	$ 86,660	$ 148	$86,808

* Represents an amount lower than $1 thousand.
** Out of which 82,500 shares have additional restrictions on transfer until services have been provided.

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

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

	Common Stock								
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Treasury Shares	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at July 1, 2021	24,275,276	$ 3	$ 143,197	$ 519	$ (1,159)	$ (91,197)	$ 51,363	$ 137	$ 51,500
Changes during the three months ended September 30, 2021:									
Stock-based compensation to employees and directors	-	-	264	-	-	-	264	-	264
Stock-based compensation to service providers	-	-	29	-	-	-	29	-	29
Extinguishment in connection with convertible loan restructuring	-	-	1,848	-	-	-	1,848	-	1,848
Comprehensive income (loss) for the period	-	-	-	(229)	-	(10,159)	(10,388)	8	(10,380)
Balance at September 30, 2021	24,275,276	$ 3	$ 145,338	$ 290	$ (1,159)	$ (101,356)	$ 43,116	$ 145	$ 43,261

* Represents an amount lower than $1 thousand.

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

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

	Common Stock							
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non-Controlling Interest	Total
Balance at July 1, 2020	22,094,470	$ 2	$ 128,076	$ 10	$ (39,854)	$ 88,234	$ 155	$88,389
Changes during the three months ended September 30, 2020:								
Stock-based compensation to employees and directors	-	-	268	-	-	268	-	268
Stock-based compensation to service providers	-	-	303	-	-	303	-	303
Comprehensive income (loss) for the period	-	-	-	282	(2,427)	(2,145)	(7)	(2,152)
Balance at September 30, 2020	**22,094,470	$ 2	$ 128,647	$ 292	$ (42,281)	$ 86,660	$ 148	$86,808

** Out of which 82,500 shares have additional restrictions on transfer until services have been provided.

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, 2021	**September 30, 2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (13,041)	$ 46,616
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,181	2,268
Stock-based compensation for Tamir Purchase Agreement	-	17,048
Capital loss, net	18	14
Gain on disposal of subsidiaries	-	(96,960)
Share in losses of associated company	33	-
Depreciation and amortization expenses	1,384	1,004
Effect of exchange differences on inter-company balances	333	171
Net changes in operating leases	(12)	4
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	449	397
Loss from extinguishment in connection with convertible loan restructuring	1,865	-
Changes in operating assets and liabilities:		
Increase in accounts receivable	(12,947)	(2,569)
Decrease (increase) in inventory	41	(96)
Increase in other assets	(14)	(136)
Increase in prepaid expenses and other accounts receivable	(645)	(1,358)
Decrease in accounts payable	(5,634)	(2,882)
Increase in accrued expenses and other payables	1,759	4,528
Increase (decrease) in employee and related payables	504	(536)
Decrease in contract liabilities	-	(63)
Change in advance payments and receivables on account of grant, net	324	(186)
Decrease in deferred taxes liability	-	(83)
Net cash used in operating activities	$ (24,402)	$ (32,819)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in loan to JV with a related party	-	(500)
Investment in convertible loan to related party	(3,000)	-
Sale of property, plant and equipment	-	4
Purchase of property, plant and equipment	(3,360)	(1,292)
Proceed from sale of subsidiaries	-	105,634
Investment in associated company	(263)	-
Investment in deposits	(21)	-
Repayment from deposits	-	19
Net cash provided by (used in) investing activities	$ (6,644)	$ 103,865
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repurchase of treasury stock	(909)	-
Proceeds from issuance of shares and warrants (net of transaction costs)	1,912	8,738
Proceeds from issuance of convertible loans (net of transaction costs)	-	250
Repayment of convertible loans and convertible bonds	-	(2,400)
Repayment of short and long-term debt	(14)	(438)
Net cash provided by financing activities	$ 989	$ 6,150
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	$ (30,057)	$ 77,196
EFFECT OF EXCHANGE RATE CHANGES ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(107)	(13)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	45,568	12,041
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD (*)	$ 15,404	$ 89,224

SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES				
Finance leases of property, plant and equipment	$	-	$	365
Right-of-use assets obtained in exchange for new operating lease liabilities, net	$	-	$	653
Purchase of property, plant and equipment change included in accounts payable	$	75	$	286
Acquisition of other asset	$	-	$	700
Extinguishment in connection with convertible loan restructuring	$	1,848	$	-

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

(*) See Note 3 for information regarding the discontinued operations.

NOTE 1 – DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc., a Nevada corporation, 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 ("ATMP"). The Company mostly focusses on autologous therapies, with processes and systems that are developed for each therapy using a closed and automated processing system approach that is validated for compliant production near the patient for treatment of the patient at the point of care ("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, the Company has developed a Point of Care Platform ("POCare Platform") comprised of three enabling components: (i) a pipeline of licensed POCare advanced therapies that are designed to be processed and produced, (ii) automated closed POCare technology systems, and (iii) a collaborative worldwide network of POCare research institutes and hospitals ("POCare Network"). The POCare Platform relies, in particular, on the development of its own production capacity to ensure that therapies are accessible at the point of treatment (the "POCare Center"). These POCare Centers are based on a global approach and local adaptation with replication and expansion. Global harmonization is ensured by a central quality system, replicability of infrastructure and equipment becoming commodities and centralized monitoring and data management. The Company is working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. The workflow of a POCare Center is designed to allow rapid capacities expansion meanwhile integrating new technologies as the Company also draws on extensive medical expertise to identify promising new autologous therapies to leverage within the POCare Platform either via ownership or licensing.

The POCare Network brings together patients, doctors and industry partners with a goal of achieving harmonized, regulated clinical development and production of POCare advanced therapies.

The Company has worked to develop and validate POCare technologies that can be combined within mobile production units for advanced therapies. The Company has made significant investments in the development of several types of Orgenesis Mobile Processing Units and Labs ("OMPULs") with the expectation of use and/or distribution through the Company's POCare Network and/or partners, collaborators, and joint ventures. As of the date of this report, the OMPULs are still in the development stage.

OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved advanced therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The OMPUL design delivers a potential industrial solution for the Company to deliver CGTs to practically any clinical institution at the point of care.

Until December 31, 2019, the Company operated the POCare Platform as one of its two separate business segments.

The Company's other business segment was a Contract Development and Manufacturing Organization ("CDMO") platform, providing contract manufacturing and development services for biopharmaceutical companies (the "CDMO Business"). The CDMO platform was historically operated mainly through majority-owned Masthercell Global (which consisted mainly of the following two subsidiaries: MaSTherCell S.A. in Belgium and Masthercell U.S., LLC in the United States (collectively, "Masthercell")). In February 2020, the Company sold its entire equity interests in Masthercell Global Inc. (the "Masthercell Business"), which comprised the majority of the Company's CDMO Business, to Catalent Pharma Solutions, Inc. (the "Masthercell Sale"). The Company determined that the Masthercell Business ("Discontinued Operations") met the criteria to be classified as a discontinued operations as of the first quarter of 2020. The Discontinued Operations includes the vast majority of the previous CDMO Business (See Note 3).

The Company has continued to grow its infrastructure and expand its processing sites into new markets and jurisdictions. In addition, the Company has continued investing manpower and financial resources to focus on developing, manufacturing and rolling out several types of OMPULs to be used and/or distributed through the Company's POCare Network and/or partners, collaborators, and joint ventures.

The Chief Executive Officer is the Company's chief operating decision-maker who reviews financial information prepared on a consolidated basis. Effective from the first quarter of 2020, all of the Company's continuing operations are in one segment, being the point-of-care business via our POCare Platform. Therefore, no segment information has been presented.

The Company currently conducts its core CGT business operations through itself and its subsidiaries which are all wholly-owned except as otherwise stated (collectively, the "Subsidiaries"). The Subsidiaries are as follows:

- United States: Orgenesis Maryland Inc. (the "U.S. Subsidiary") is the center of activity in North America currently focused on setting up of the POCare Network.

- Koligo Therapeutics Inc. ("Koligo") is a Kentucky corporation that was acquired in 2020 and is currently focused on developing the POCare Network and advanced therapies.

- European Union: Orgenesis Belgium SRL (the "Belgian Subsidiary") and Orgenesis Germany GmbH (incorporated in 2021), (the "German subsidiary") are currently focused on process development and preparation of European clinical trials.

- Orgenesis Switzerland Sarl (the "Swiss Subsidiary") incorporated in 2020 is currently focused on providing management services to the Company.

- Israel: Orgenesis Ltd. (the "Israeli Subsidiary") is a provider of regulatory, clinical and pre-clinical services in Israel, and Orgenesis Biotech Israel Ltd. ("OBI") is a provider of cell-processing services in Israel.

- Korea: Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"), is a provider of processing and pre-clinical services in Korea. The Company owns 94.12% of the Korean Subsidiary.

These condensed consolidated financial statements include the accounts of Orgenesis Inc. and its subsidiaries (and in 2020 includes the Discontinued Operations).

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."

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

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and expected level of expenditures for at least 12 months from the date of the issuance of these financial statements, although no assurance can be given that it will not need additional funds prior to such time. If there are material further increases in operating costs for facilities expansion or investments required to fund the Company's collaborations, research and development, commercial and clinical activity, or decreases in revenues from customers, the Company will need to seek additional financing . In addition, in order to fund the Company's operations until such time that the Company can generate sustainable positive cashflows, the Company may need to raise additional funds.

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, 2020, as filed with the Securities and Exchange Commission ("SEC"). The year-end balance sheet data was derived from the audited consolidated financial statements as of December 31, 2020, but not all disclosures required by generally accepted accounting principles in the United States ("U.S. GAAP") are included.

b. Significant accounting policies

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

POC Development Services

Revenue recognized under contracts for POC development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages are not interrelated or the customer is able to complete the services performed.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices.

The Company recognizes revenue when, or as, it satisfies a performance obligation. At contract inception, the Company determines whether the services are transferred over time or at a point in time. Performance obligations that have no alternative use and that the Company has the right to payment for performance completed to date at all times during the contract term, are recognized over time. All other performance obligations are recognized as revenues by the company at a point of time (upon completion). In addition, during 2021, the Company started providing support services to its customers. These revenues are recognized as and when the services are provided because the customer simultaneously receives and consumes the benefits provided.

Also included in POC development services is Hospital supplies revenue which is derived principally from the sale or lease of products and the performance of services to hospitals or other medical providers. Revenue is earned and recognized when product and services are received by the customer.

Recently issued accounting pronouncements, not yet adopted

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). The guidance is effective for the Company on January 1, 2022. The Company is currently evaluating the impact of adopting this standard.

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 determining whether an acquisition is a business combination or a purchase of asset. Actual results could differ from those estimates.

The full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We examined the impact of COVID-19 on our financial statements, and although there is currently no major impact, there may be changes to those estimates in future periods. Actual results may differ from these estimates.

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.

Revision of Previously Reported Consolidated Financial Statements

In connection with the preparation of the company's consolidated financial statements for the fiscal year ended December 31, 2020, the Company identified an immaterial error originating in the first quarter of 2020 related to the gain calculation on the sale of Masthercell. The Company did not adjust the gain calculation for the reversal of previously-recorded accretion adjustments to the carrying amount of the Redeemable Non-Controlling Interest (NCI) in the amount of $5,574. The Company has revised its financial statements presented herein for the nine months ended September 30, 2020, respectively, to correct the error. The revision resulted in an increase to additional paid-in capital and a decrease in net income from discontinued operations, net of tax. There is no impact on net loss from continuing operations or earning per share. In addition, there is no impact on the Company's balance sheet or statement of cash flows.

The following table summarizes the impact of the revision on additional paid-in capital and net income from discontinued operations, net of tax, for the nine months ended September 30, 2020:

	As reported	Adjustment	As revised
		(in thousands)	
Net income from discontinued operations, net of tax	$ 95,892	$ (5,574)	$ 90,318
Additional paid-in capital	123,073	5,574	128,647

NOTE 3 – DISCONTINUED OPERATIONS

On February 2, 2020, the Company completed the Masthercell Sale and determined that the Masthercell Business met the criteria to be classified as a discontinued operations.

The financial results of the Masthercell Business are presented as income from discontinued operations, net of tax on the Company's Condensed Consolidated Statement of Comprehensive Loss (Income). The following table presents the financial results associated with the Masthercell Business operations as reflected in the Company's Condensed Consolidated Comprehensive loss (Income) (in thousands):

	The period from January 1, 2020 until the disposal date
OPERATIONS	
Revenues	$ 2,556
Cost of revenues	1,482
Cost of research and development and research and development services, net	7
Amortization of intangible assets	137
Selling, general and administrative expenses	1,896
Other expenses, net	305
Operating loss	1,271
Financial income, net	(29)
Loss before income taxes	1,242
Income tax benefit	(30)
Net loss from discontinuing operations, net of tax	$ 1,212
DISPOSAL	
Gain on disposal before income taxes	$ 96,960
Provision for income taxes	(5,430)
Gain on disposal	$ 91,530
Net profit from discontinuing operations, net of tax	$ 90,318

The following table represents the components of the cash flows from discontinued operations (in thousands):

	The period from January 1, 2020 until the disposal date
Net cash flows used in operating activities	$ (2,409)
Net cash flows used in investing activities	$ (579)
Net cash flows used in financing activities	$ (51)

Disaggregation of Revenue

The following table disaggregates the Company's revenues by major revenue streams related to discontinued operations (in thousands):

	The period from January 1, 2020 until the disposal date
Revenue stream:	
Cell process development services	$ 2,556
Total	$ 2,556

NOTE 4 – EQUITY

During the nine months period ended September 30, 2021, the Company received approximately $1.9 million from the exercise of warrants for the purchase of the Company's Common Stock at a price of $6.24. A total of 305,523 shares were issued during the nine months ended September 30, 2021.

During the nine months ended September 30, 2021, the Company received $50 thousand from the exercise of employee options for the purchase of 8,750 shares of the Company's Common Stock at a weighted average price of $5.56.

During the nine months ended September 30, 2021, the Company repurchased its shares under the stock repurchase plan (the "Stock Repurchase Plan"). The following table summarizes the share repurchase activity pursuant to the Stock Repurchase Plan

during the nine months ended September 30, 2021:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Value that May Yet Be Purchased Under the Plans or Programs
				(in thousands)
January 2021	2,306	$ 4.45	2,306	$ 9,740
April 2021	8,850	4.49	8,850	9,699
May 2021	195,625	4.34	195,625	8,841
	206,781	$ 4.34	206,781	$ 8,841

NOTE 5 – CONVERTIBLE LOANS

During the three months period ended September 30, 2021, the Company and certain convertible loan holders agreed to extend the maturity date on loans due during the fourth quarter of 2021 to June 30, 2023. The principal amount extended was $2.25 million and the interest rate on the extended loans varies between 2% and 8%. The loan holders may request that the Company repay them on November 21, 2022 (the "Early Redemption Option"). In consideration for the extension, warrants to purchase 926,413 shares of common stock of the Company were issued to the loan holders at an exercise price of $6.24 per share. If the Early Redemption Option is exercised, the warrants will be cancelled. The latest date to exercise the warrants is June 30, 2023.

The Company concluded that the change in the terms constitute a debt restructuring. The Company therefore applied the guidance in ASC 470-50, Modifications and Extinguishments. The accounting treatment is determined by whether terms of the new debt and original debt are substantially different. The new debt and the old debt are considered "substantially different" pursuant to ASC 470-50 when the change in the fair value of the embedded conversion option is at least 10% of the carrying amount of the original debt instrument immediately before the modification or exchange or the value of the cash flows under the terms of the new debt instrument is at least 10% different from the present value of the remaining cash flows under the terms of the original instrument (including the incremental fair value resulting from issuing new warrants held by the lender). If the original and new debt instruments are substantially different, the original debt is derecognized and the new debt should be initially recorded at fair value, with the difference recognized as an extinguishment gain or loss. Based on the analysis, the Company concluded that the change in terms should be accounted for as an extinguishment. The extinguishment resulted in a loss of $1,865 thousand. The Company concluded that, since the warrants cannot be exercised prior to the expiry date of the Early Redemption Option, the warrants are considered embedded in the convertible loan and not freestanding instruments. It also concluded that the prepayment option and the embedded warrants should not be bifurcated from the debt host. In accordance with ASC 470-20-25-13, if a convertible debt instrument is issued at a substantial premium, there is a presumption that such premium represents paid-in capital. Since the fair value of the new convertible loan instrument issued as part of the change in terms are higher than the par value of the loan and the premium is substantial, the Company allocated the premium to paid in capital and the reminder to the convertible loan.

The fair value of the conversion feature was estimated using the binomial model. The total fair value of the new instruments is $4.4M.

Following are the main estimates and assumptions that were used for the valuation of the new instruments as of the valuation date:

Parameter	8% Note	2% Note	warrants
Notional (USD)	1,500,000	750,000	926,413
Accrued Coupon (USD)	224,603	41,945	-
Coupon Rate	8.00%	2.00%	-
Conversion Ratio (USD)	7.00	7.00	-
Exercise Price (USD)	-	-	6.24
Stock Price (USD)	5.02	5.02	5.02
Expected Term (years)	1.79	1.79	1.79
Risk Free Rate	0.20%	0.20%	0.20%
Volatility	72.84%	72.84%	72.84%
Yield	7.87%	7.84%	-

NOTE 6 – STOCK-BASED COMPENSATION

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, 2021 to September 30, 2021:

	No. of Options Granted	Exercise Price	Vesting Period	Fair Value at Grant (in thousands)	Expiration Period
Employees	213,500	$ 5.02-$5.12	Quarterly over a period of two years	$ 696	10 years

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

	During the Period from January 1, 2021 to September 30, 2021
Value of one common share	$ 5.02-5.12
Dividend yield	0%

Expected stock price volatility	76%-77%
Risk free interest rate	0.96%
Expected term (years)	5.56

NOTE 7 – LOSS (EARNINGS) 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, 2021	September 30, 2020	September 30, 2021	September 30, 2020
	(in thousands, except per share data)			
Basic and diluted:				
Net loss from continuing operations attributable to Orgenesis Inc.	$ 10,159	$ 9,559	$ 13,037	$ 43,662
Net income from discontinued operations attributable to Orgenesis Inc. for earning per share	-	(7,132)	-	(90,810)
Adjustment of redeemable non-controlling interest to redemption amount	-	-	-	(5,160)
	-	(7,132)	-	(95,970)
Net (income) loss attributable to Orgenesis Inc. for loss (earning) per share	10,159	2,427	13,037	(52,308)
Weighted average number of common shares outstanding	24,275,276	22,094,470	24,278,292	20,469,470
Loss per common share from continuing operations	$ 0.42	$ 0.43	$ 0.54	$ 2.13
Earnings per common share from discontinued operations	$ -	$ (0.32)	$ -	$ (4.69)
Net loss (earnings) per share	$ 0.42	$ 0.11	$ 0.54	$ (2.56)

For the nine months ended September 30, 2021 and September 30, 2020, 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 7,441,212 shares underlying outstanding options and warrants and 1,658,324 shares upon conversion of convertible loans for the nine months ended September 30, 2021, because the effect of their inclusion in the computation would be antidilutive. Diluted loss per share does not include 10,214,034 shares underlying outstanding options and warrants and 1,607,007 shares upon conversion of convertible loans for the nine months ended September 30, 2020, because the effect of their inclusion in the computation would be antidilutive.

NOTE 8 – REVENUES

Disaggregation of Revenue

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

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
	(in thousands)			
Revenue stream:				
POC and hospital services (Mainly POC)	$ 7,916	$ 1,266	$ 26,244	$ 4,291
Cell process development services	760	463	2,366	1,065
Total	$ 8,676	$ 1,729	$ 28,610	$ 5,356

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

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
	(in thousands)			
Revenue earned:				
Customer A	$ 1,845	$ 783	$ 6,008	$ 2,064
Customer B	$ 1,792	$ -	$ 5,922	$ -
Customer C	$ 1,934	$ 337	$ 5,210	$ 1,143
Customer D	$ 751	$ -	$ 3,333	$ -
Customer E	$ 976	$ 335	$ 2,985	$ 1,068

Customer F – related party	$ 1,070	$ 279	$ 2,954	$ 1,051

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, 2021	September 30, 2020
	(in thousands)	
Balance as of beginning of period	$ 3,085	$ 1,831
Additions	28,716	4,101
Collections	(15,769)	(1,869)
Exchange rate differences	(82)	14
Balance as of end of period	$ 15,950	$ 4,077

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

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Balance as of beginning of period	$ 744	$ -
Additions	2,954	820
Collections	(2,628)	(500)
Balance as of end of period	$ 1,070	$ 320

The activity for contract liabilities is comprised of:

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Balance as of beginning of period	$ 59	$ 325
Additions	-	597
Realizations	-	(759)
Balance as of end of period	$ 59	$ 163

* The activity of the related party included in the contract liabilities activity above is comprised of

	Nine Months Ended
	September 30, 2020
	(in thousands)
Balance as of beginning of period	$ 231
Additions	(231)
Balance as of end of period	$ -

NOTE 9 – SIGNIFICANT TRANSACTIONS DURING THE PERIOD

Johns Hopkins University

During the nine months ended September 30, 2021, the Company and Johns Hopkins University entered into a sublease and construction agreement for the establishment of a clinical therapeutic development and point of care center in Maryland of approximately 6,830 rentable square feet. Pursuant to the agreement, the Company will pay for certain leasehold improvements in the premises according to plans and specifications to be agreed upon. The Company advanced an initial $510 thousand for this purpose. The annual base rent is initially $260 thousand per year, increasing to $324 thousand per year over the 10-year initial lease term. The Company has an option to renew the sublease for two additional periods of five years each under the same terms and conditions. The Company is expected to gain occupancy of the premises during the fourth quarter of 2021.

Neuro-Immunotherapy Exclusive License Agreement

During the nine months ended September 30, 2021, the Company entered into an exclusive license agreement in the field of neuro-immunotherapy. Pursuant to the agreement, the Company received an exclusive, worldwide, sublicensable, royalty-bearing license of certain technology and patents for the purpose of developing, manufacturing, using, and commercializing the licenced technology. Royalties of between 0.5% and 5% on royalty-bearing sales are payable for up to 15 years from the date of first sale in any country in which licensed products are sold, and sublicense fees are payable at the rate of 12% on sublicense income (but no less than two percent (2.0%) of sublicenses' net sales). Pursuant to the agreement, the Company is required to invest within thirty-six (36) months of the effective date an aggregate amount of at least $2 million in its efforts to develop the licensed technology.

Celleska Pty Ltd

During the nine months ended September 30, 2021, the Company and Celleska Pty Ltd., an Australian company ("Celleska"), entered into a Joint Venture Agreement ("AJVA") to facilitate the collaboration in the field of Cell and Gene therapies development and development of the Company's worldwide POCare network in Australia. Under the AJVA, the Company will hold a 50% share of the equity of the Australian joint venture entity ("AJVE"). Until the AJVE is incorporated, Celleska will manage the joint venture activities. The AJVE will be managed by a steering committee consisting of three members which will act as the AJVE's board of directors. The Company is entitled to appoint one member, Celleska is entitled to appoint one member, and the Company and Celleska will jointly appoint the third member. The Company has the right to exercise a call option to acquire the Celleska's entire share in the AJVE based on the occurrence of certain events and according to an agreed-upon mechanism subject to a minimum valuation of $5 million. Each party will provide funding to the AJVE in an amount of up to $10 million, of which $5 million may be funded via in-kind investments. Each of the Company and Celleska will grant to the AJVE an exclusive, sublicensable, royalty-bearing right and license to the relevant party's background intellectual property as required solely to manufacture, distribute and market and sell such party's products within the territory of Australia. Each party shall receive royalties in an amount of ten percent (10%) of the net sales generated by the AJVE and/or its sublicensees. In addition, Company shall receive an exclusive, sublicensable, royalty-bearing right and license to Celleska's background intellectual property as required solely to manufacture, distribute and market and sell Celleska products outside the territory of Australia in consideration for royalties in an amount of ten percent (10%) of the net sales generated by the Company or its sublicensees with respect to sale of Celleska products. Once the AJVE is profitable, the Company will be entitled (in addition to any of its rights as the holder of the AJVE) to an additional share of fifteen percent (15%) of the AJVE's GAAP profit after tax, over and above all rights granted pursuant to Company's participating interest in the AJVE. As of September 30, 2021 the AJVE had not yet been incorporated.

Savicell

On June 14, 2021 the Company and Savicell Ltd ("Savicell") entered into a collaboration agreement (the "Savicell Agreement") to collaborate in the evaluation, continued development, validation, and use of Savicell's platform designed for the early detection and diagnosis of diseases and conditions and for quality control and monitoring purposes, in conjunction with the Company's systems. Pursuant to the Savicell Agreement, the Company shall provide to Savicell funding for performance of certain tasks agreed upon by the parties in a work plan. In consideration for such funding, Savicell shall supply the Company with products developed under the Savicell Agreement at preferential rates and grant to the Company a worldwide exclusive licence to sell such products in the Company's point-of-care network of hospitals, clinics and institutions for quality control and monitoring of manufacturing and processing of autologous immune cells manipulated by cell and gene therapies, subject to a royalty of 10%.

Stromatis Pharma

On June 15, 2021, the Company and Stromatis Pharma Inc. ("Stromatis") entered into a Collaboration and Sublicense Agreement (the "Stromatis Agreement") to collaborate in refining methods for GMP manufacturing of CAR-T/CAR-NK CT109; and the development and validation of the Stromatis technology as it relates to the CAR-T/CAR-NK CT109 antibody up to and inclusive of filing of Investigational New Drug Application relating to Stromatis' CAR-T/CAR-NK CT109 antibody ("Licensed Product"), in accordance with the agreed project plan ("Project"). The Company will fund the Project by providing Stromatis an amount of up to $1.2 million. Stromatis will grant the Company certain exclusive rights to manufacture, process and supply the Licensed Product ("Manufacturing Rights") and exclusive rights to market and sell and offer for sale the Licensed Product within the Company's point of care network ("Marketing Rights"). Stromatis has the option to convert the exclusive Manufacturing Rights to non-exclusive rights subject to payment by Stromatis of an amount equal to funding provided by the Company and an additional payment by Stromatis of an ongoing revenue share of five percent (5%) of revenues of any kind received by Stromatis or its affiliates from the sale or transfer of Licensed Products or license of rights under the licensed technology. The Company shall pay Stromatis in consideration for the Marketing Rights and royalties of up to 12% of net revenues of Licensed Products received by the Company. The Company advanced to Stromatis an initial sum of $500 thousand under the Stromatis Agreement, which was recorded as cost of services and other research and development expenses.

Revacel Srl

In July 2021, the Company via the Belgian subsidiary invested approximately $260 thousand in Revacel Srl (“Revacel”), a newly incorporated entity in Belgium. The Company holds 51% of the share capital of Revacel and has the right to appoint two members to the Revacel board of directors. The Company’s partner, Revatis SA, (a Belgian entity) holds the remaining 49% and has the right to appoint two members to the Revacel board of directors. The fifth Revacel board member will be an independent industry expert appointed with the mutual agreement of the Company and Revatis SA. Revacel will develop products in the field of muscle-derived mesenchymal stem/progenitor cells. There were no other material transactions in Revacel during the period.

Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)) (“HMGU”)

During the three months ended September 30, 2021, HMGU granted an exclusive licence to the Company in the field of certain human stem cells. The Company incurred a one-time up-front payment of approximately $60 thousand and annual license maintenance fees of between $18 thousand and $36 thousand. In addition, payments will be due by the Company upon certain milestones. The agreement also includes payment of royalties of between 3% and 4% on net sales of licensed product and 5% in service revenues and payment of between 10% and 18% on sublicense revenues.

Image Securities FZC (a related party) (“Image”)

During the three months ended September 30, 2021, the Company entered into a convertible loan agreement with Image whereby, pursuant to the terms of the Image joint venture agreement, the Company agreed to loan Image up to $5 million. The loan bears interest at the rate of 6% and is subject to repayment by August 21, 2022, unless the Company agrees to an extension or the loan is converted into shares of Image or, if established, Image’s Indian joint venture. As of September 30, 2021, the Company transferred $3 million to Image under the loan agreement, and this has been reflected as a short term asset on the Company’s balance sheet.

Educell D.O.O (“Educell”)

During the three months ended September 30, 2021, the Company entered into a convertible loan agreement with Educell whereby, pursuant to the terms of the Educell joint venture agreement, the Company agreed to advance up to $1.2 million to Educell until a joint venture entity between the Company and Educell has been incorporated. To date, the Educell joint venture entity has not been incorporated. The loan bears interest at the rate of 4.5% and is subject to repayment by August 20, 2026, unless the Company agrees to an extension or the loan is converted into shares of Educell or the Educell joint venture entity, if established. During the nine months ended September 30, 2021, the Company transferred $970 thousand to Educell under the loan agreement, which was recorded as cost of services and other research and development expenses.

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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2021. 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 and the effects that the COVID-19 outbreak, any of its variants, or similar pandemics, could have on our business and CGT Biotech Platform. 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.

The full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the impact of COVID-19 within our financial statements, and although there is currently no major impact, there may be changes to those estimates in future periods. Actual results may differ from these estimates.

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, Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"); Orgenesis Belgium SRL, a Belgian-based entity (the "Belgian Subsidiary"); Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"); Orgenesis Maryland Inc., a Maryland corporation (the "U.S. Subsidiary"); Orgenesis Switzerland Sarl, which was incorporated in October 2020 (the "Swiss Subsidiary"); Orgenesis Biotech Israel Ltd. ("OBI"); Koligo Therapeutics Inc., a Kentucky corporation, purchased in 2020 ("Koligo"), Orgenesis Germany GmbH, a German entity which was incorporated in the second quarter of 2021; and Masthercell Global Inc. (which consisted mainly of the following two subsidiaries: MaSTherCell S.A. in Belgium and Masthercell U.S., LLC in the United States (collectively, "Masthercell")). The Company sold all of its equity interests in Masthercell and its subsidiaries in February 2020.

Corporate Overview

Orgenesis Inc., a Nevada corporation, 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"). We mostly focus on autologous therapies, with processes and systems that are developed for each therapy using a closed and automated processing system approach that is validated for compliant production near the patient at their point of care for the treatment of patients. 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 the 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 Point of Care Platform ("POCare Platform") comprised of three enabling components: (i) a pipeline of licensed advanced therapies that are designed to be processed and produced, (ii) automated closed POCare Technology systems, and (iii) a collaborative worldwide network of POCare research institutes and hospitals ("POCare Network"). The POCare Platform relies in particular on the development of its own production capacity to ensure that therapies are accessible at the point of treatment (the "POCare Center"). These POCare Centers are based on a global approach and local adaptation where replication and expansion are the key words. Global harmonization is ensured by a central quality system, replicability of infrastructure and equipment becoming commodities and centralized monitoring and data management. We are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. Via a combination of science, technology, engineering, and networking, we are working to provide a more efficient and scalable pathway for advanced therapies to reach patients more rapidly at lowered costs. The workflow of a POCare Center is designed to allow rapid capacities expansion meanwhile integrating new technologies as we also draw on extensive medical expertise to identify promising new autologous therapies to leverage within the POCare Platform either via ownership or licensing.

Our POCare Network brings together patients, doctors and industry partners with a goal of achieving harmonized, regulated clinical development and production of POCare advanced therapies.

POCare Platform Operations via Subsidiaries

We currently conduct our core business operations ourselves and through our subsidiaries, which are all wholly-owned except as otherwise stated below (collectively, the "Subsidiaries"). The Subsidiaries are as follows:

United States

- Orgenesis Maryland Inc. (the "U.S. Subsidiary") is the center of activity in North America and is currently focused on setting up the POCare Network.

- Koligo Therapeutics Inc. ("Koligo") is a Kentucky corporation that we acquired in 2020 and is currently focused on developing the POCare network and therapies.

Europe

- Orgenesis Belgium SRL (the "Belgian Subsidiary") is a center of activity in Europe and is currently focused on process development and the preparation of European clinical trials.

- Orgenesis Germany GmbH (the "German Subsidiary") is currently focused on certain aspects of clinical trials.

- Orgenesis Switzerland Sarl (the "Swiss Subsidiary"), was incorporated in October 2020, and is currently focused on providing management services to us.

Asia

- Orgenesis Ltd. (the "Israeli Subsidiary") is a provider of regulatory, clinical and pre-clinical services in Israel.
- Orgenesis Biotech Israel Ltd. ("OBI"), is a provider of cell-processing services in Israel.
- Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"), is a provider of processing and pre-clinical services in Korea. We own 94.12% of the Korean Subsidiary.

Business Strategy

Our aim is to provide a pathway to bring ATMPs in the cell and gene therapy industry from research to patients worldwide through our POCare Platform. We define point of care as a process of collecting, processing, and administering cells within the patient care environment, namely through academic partnerships in a hospital setting. We believe that this approach is an attractive proposition for personalized medicine because of our strategic partnerships with suppliers that help us to customize closed systems into effective mobile clean room facilities. This will potentially help to minimize or eliminate the need for cell transportation, which is a high-risk and costly aspect of the supply chain.

We aim to build value in various aspects of our company ranging from supply related processes including development and distribution systems, clinical and regulatory services, engineering and devices such as OMPULs discussed below, delivery systems, therapies including immuno-oncology, anti-aging, anti-viral, metabolic, nephrology, dermatology, orthopedic, as well as regenerative technologies.

We have worked to develop and validate POCare technologies that can be combined within mobile production units for advanced therapies. We have made significant investments in the development of several types of Orgenesis Mobile Processing Units and Labs ("OMPULs") with the expectation of use and/or distribution through our POCare Network and/or partners, collaborators, and joint ventures. As of the date of this report, the OMPULs are still in the development stage.

OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved cell and gene therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The design delivers a potential industrial solution for us to deliver CGTs to most clinical institutions at the point of care.

Revenue Model and Business Development

Our Point of Care ("POCare") Platform is comprised of three enabling components: a multitude of licensed cell based POCare therapies that are produced in closed, automated POCare technology systems and a collaborative POCare Network. The POCare Platform relies in particular on the development of its own production capacity to ensure that therapies are accessible at the point of treatment (the "POCare Center"). These POCare Centers are based on a global approach and local adaptation. Our therapies include, but are not limited to, autologous, cell-based immunotherapies, therapeutics for metabolic diseases, anti-viral diseases, and tissue regeneration. We are establishing and positioning the business to bring point-of-care therapies to patients in a scalable way working directly with hospitals and through regional joint venture partners ("JVs") and JVs active in autologous cell therapy product development, including facilities in various countries in North America, Europe, Latin America, Asia, the Middle East, and Australia. The POCare Platform's goal is to enable a rapid, globally harmonized pathway for these therapies to reach large numbers of patients at lowered costs through efficient and decentralized production. Global harmonization is ensured by a central quality system, replicability of infrastructure and equipment becoming commodities and centralized monitoring and data management. The POCare Network brings together industry partners, research institutes and hospitals worldwide to achieve harmonized, regulated clinical development and production of the therapies.

We are focused on technology in-licensing and therapeutic collaborations, and we out-license therapies marketing rights and manufacturing rights to partners and / or to the JVs. In many cases, the JVs are responsible for the preparation of clinical trials, local regulatory approvals and regional marketing activities. Such licensing includes exclusive or nonexclusive, sublicensable, royalty bearing rights and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell Orgenesis Products within the relevant territories. In consideration for the rights and the licenses so granted, we receive a royalty in the range of ten percent of the net sales generated by the JVs and/or its sublicensees (as applicable) with respect to the Orgenesis Products.

In addition, in many cases, once the JVs become profitable, we will be entitled (in addition to any of its rights as holder of the JVs and prior to any other distributions of dividends by the JVs to shareholders of the JVs) to certain royalties pursuant to an Orgenesis License Agreement, to receive from the JVs royalties at a range of 10 to 15 percent of the JV's audited U.S. GAAP profit, after tax.

The Company has signed POCare Master Services Agreements ("MSAs") with our JV partners. In terms of the MSAs, we provide certain broadly defined development services that relate to our licensed therapies designed to develop or enhance the therapy with the objective of preparing it for clinical use. Such services, per therapy, include regulatory services, pre-clinical studies, intellectual property services, development services, and GMP process translation.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 to the Three Months Ended September 30, 2020.

The following table presents our results of operations for the three months ended September 30, 2021 and 2020:

	Three-Months Ended	
	September 30, 2021	**September 30, 2020**
	(in thousands)	
Revenues	$ 7,606	$ 1,450
Revenues to related party	1,070	279
Total revenues	8,676	1,729
Cost of services and other research and development expenses	10,007	6,951
Amortization of intangible assets	236	87
Selling, general and administrative expenses	6,092	4,042
Other income, net	(3)	(5)
Financial expenses, net	2,410	238
Share in net loss of associated company	18	-
Loss before income taxes	$ 10,084	$ 9,584

Revenues

During the three months ended September 30, 2021, we recognized point-of-care development service revenue in the amount of $ 8,676 thousand, as compared to $1,729 thousand during the three months ended September 30, 2020, representing an increase of 402%. The increase is attributable to increased activity under master service agreements with our customers.

Of such $8,676 thousand of revenue during the three months ended September 30, 2021, we recognized $1,070 thousand of point-of-care development service revenue from a related party as compared to $279 thousand during the three months ended September 30, 2020, representing an increase of 283%. The increase is attributable to increased services provided and expanded activities in that territory.

Expenses

Cost of services and other research and development expenses

	Three-Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Salaries and related expenses	$ 2,984	$ 1,036
Stock-based compensation	141	129
Subcontracting, professional and consulting services	3,321	814
Lab expenses	599	488
Depreciation expenses, net	220	152
Other research and development expenses	2,742	4,363
Less – grant	-	(31)
Total	$ 10,007	$ 6,951

Cost of services and other research and development expenses for the three months ended September 30, 2021 were $10,007 thousand, as compared to $6,951 thousand for the three months ended September 30, 2020, representing an increase of 44%. The changes contributing to the net increase during the quarter were attributable to:

● Salaries and related expenses increased as a result of additional staff hired to continue the development of our CGT product pipeline as we expand our POC operations globally. We continue to invest in the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work with partners that address POCare needs.

● We experienced an increase in subcontracting, professional and consulting service fees of $ 2,507 thousand. As indicated above, we continue to invest in the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work with partners that address POCare needs.

Other research and development expenses for the three months ended September 30, 2021 were $2,742 thousand, as compared to $4,363 thousand for the three months ended September 30, 2020, representing a decrease of 37%. The decrease was attributable to reduced development costs for Orgenesis Mobile Processing Units and Labs (OMPULs). In 2020, we made significant investments in the development of several types of OMPULs with the expectation of use and/or distribution through our POCare Network of partners, collaborators, and joint ventures. OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved cell and gene therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations.

Selling, General and Administrative Expenses

	Three-Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Salaries and related expenses	$ 4,056	$ 721
Stock-based compensation	151	446
Accounting and legal fees	660	1,657
Professional fees	319	403
Rent and related expenses	85	151
Business development	226	282
Depreciation expenses, net	10	26
Other general and administrative expenses	585	356
Total	$ 6,092	$ 4,042

Selling, general and administrative expenses for the three months ended September 30, 2021 were $6,092 thousand, as compared to $4,042 thousand for the three months ended September 30, 2020, representing an increase of 51%. The increase in selling, general and administrative expenses in the three months ended September 30, 2021 compared to the three months ended September 30, 2020 is primarily attributable to:

- an increase in salaries and related expenses, mainly as a result of a discretionary bonus to the Company's Chief Executive Officer, Vered Caplan, in the amount of $3.6 million pursuant to the discretionary bonus provisions of the Personal Employment Agreement between Ms. Caplan and Orgenesis Services Sàrl. The bonus was paid during September 2021.

- a decrease in accounting and legal fees as a result of decreased corporate investment activities in 2021 compared to 2020.

Financial Expenses, net

	Three-Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Interest expense on convertible loans and loans	$ 254	$ 249
Foreign exchange loss (gain), net	291	59
Loss from extinguishment in connection with convertible loan	1,865	-
Other income	-	(70)
Total	$ 2,410	$ 238

The increase was mainly as a result of an increase in foreign exchange losses and the loss from the extinguishment in connection with the convertible loans. See Note 5.

Comparison of the Nine Months Ended September 30, 2021 to the Nine Months Ended September 30, 2020.

The following table presents our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Revenues	$ 25,656	$ 4,305
Revenues to related party	2,954	1,051
Total revenue	28,610	5,356
Cost of services and other research and development expenses	25,861	36,787
Amortization of intangible assets	713	258
Selling, general and administrative expenses	11,961	11,171
Other income, net	(31)	(9)
Financial expenses, net	3,049	904
Share in net income of associated company	33	-
Loss before income taxes	$ 12,976	$ 43,755

Revenues

Our revenues for the nine months ended September 30, 2021 were $ 28,610 thousand, as compared to $5,356 thousand for the nine months ended September 30, 2020, representing an increase of 434%. The increase in revenues for the nine months ended September 30, 2021 was attributable to the increase in point-of-care services revenue as a result of increased activity under master service agreements with our customers.

Of such $28,610 thousand of revenue during the nine months ended September 30, 2021, we recognized $2,954 thousand of point-of-care development service revenue from a related party as compared to $1,051 thousand during the nine months ended September 30, 2020, representing an increase of 181%. The increase is attributable to expanded activities and additional services provided in the territory.

Expenses

Cost of services and other research and development expenses

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Salaries and related expenses	$ 7,751	$ 3,231
Stock-based compensation	449	348
Subcontracting, professional and consulting services	9,354	1,789
Lab expenses	2,056	1,638
Tamir purchase agreement.	-	19,510
Depreciation expenses, net	639	415
Other research and development expenses	5,612	10,025
Less – grant	-	(169)
Total	$ 25,861	$ 36,787

Cost of services and other research and development expenses for the nine months ended September 30, 2021 were $25,861 thousand, as compared to $36,787 thousand for the nine months ended September 30, 2020, representing a decrease of 30%. The changes contributing to the net decrease during the period were attributable to:

● In 2020, we purchased the assets of Tamir Biotechnology Inc., and we accounted for these as Research and Development expenses under ASC 730.

● Salaries and related expenses increased by $ 4,520 thousand, as a result of additional staff hired to continue the development of our CGT product pipeline as we expand our POC operations globally. We continue to invest in the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work with partners that address POCare needs.

● We experienced an increase in subcontracting, professional and consulting services of $ 7,565 thousand. As indicated above, we continue to invest in the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work with partners that address POCare needs.

● We experienced a decrease in other research and development expenses. In 2020, we invested heavily in the development of our OMPULS.

Selling, General and Administrative Expenses

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Salaries and related expenses	$ 5,479	$ 1,590
Stock-based compensation	733	1,474
Accounting and legal fees	2,361	5,074
Professional fees	1,156	1,229
Rent and related expenses	168	280
Business development	532	707
Depreciation expenses, net	32	76
Other general and administrative expenses	1,500	741
Total	$ 11,961	$ 11,171

Selling, general and administrative expenses for the nine months ended September 30, 2021 were $11,961 thousand, as compared to $11,171 thousand for the nine months ended September 30, 2020, representing an increase of 7%. There was an increase in salaries and related expenses, mainly as a result of a discretionary bonus to Vered Caplan, the Chief Executive Officer of the Company, in the amount of $3.6 million pursuant to the discretionary bonus provisions of the Personal Employment Agreement between Vered Caplan and Orgenesis Services Sàrl. Accounting and legal fees decreased as a result of reduced corporate investment activities in 2021 compared to 2020.

Financial Expenses, net

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Interest expense on convertible loans and loans	$ 778	$ 988
Foreign exchange loss, net	485	224
Loss from extinguishment in connection with convertible loan	1,865	-
Other expenses (income)	(79)	(308)
Total	$ 3,049	$ 904

The increase was mainly as a result of a decline in other income and the loss from the extinguishment in connection with the convertible loans. See Note 5.

Working Capital

	As of	
	September 30, 2021	December 31, 2020
	(in thousands)	
Current assets	$ 36,341	$ 50,077
Current liabilities	13,566	16,285
Working capital	$ 22,775	$ 33,792

Current assets decreased by $13,736 thousand between December 31, 2020 and September 30, 2021 due mainly to a decrease in cash and cash equivalents of $30,006 thousand as a result of payments of operating expenses and an increase in accounts receivable of $12,865 as a result of increased POC revenue.

Current liabilities decreased by $2,719 thousand between December 31, 2020 and September 30, 2021 primarily as a result of a reduction in accounts payable and accrued expenses.

Liquidity and Financial Condition

	Nine Months Ended	
	September 30, 2021	September 30, 2020
	(in thousands)	
Net income (loss)	$ (13,041)	$ 46,616
Net cash used in operating activities	(24,402)	(32,819)
Net cash provided by (used in) investing activities	(6,644)	103,865
Net cash provided by financing activities	989	6,150
Increase in cash and cash equivalents	$ (30,057)	$ 77,196

During nine months period ended September 30, 2021, we funded our operations from existing funds.

Net cash used in operating activities for the nine months ended September 30, 2021 was approximately $24 million, as compared to net cash used in operating activities of approximately $33 million for the nine months ended September 30, 2020.

Net cash used in investing activities for the nine months ended September 30, 2021 was approximately $7 million, as compared to net cash provided by investing activities of approximately $104 million for the nine months ended September 30, 2020. The change was mainly due to the proceeds from Masthercell in the first quarter of 2020.

Liquidity & Capital Resources Outlook

We believe that our current cash balance as well as revenues from our current operations results will provide sufficient liquidity to fund our operating needs for at least the next 12 months, although no assurance can be given that it will not need additional funds prior to such time. Additionally, there are factors that can impact our ability to continue to fund our operating needs, including:

- restrictions on our ability to expand sales volume from our CGT Biotech Platform; and
- the need for us to continue to invest in operating activities to remain competitive or acquire other businesses and technologies and to complement our products, expand the breadth of our business, enhance our technical capabilities or otherwise offer growth opportunities.

If there are material further increases in operating costs for facilities expansion or investments required to fund the Company's collaborations, research and development, commercial and clinical activity, or decreases in revenues from customers, the Company will need to seek additional financing. In addition, in order to fund the Company's operations until such time that the Company can generate sustainable positive cashflows, the Company may need to raise additional funds.

Loan to Related Party under Joint Venture Agreement

On August 24, 2021, we entered into a convertible loan agreement with Image Securities FZC ("Image"), a related party affiliated with Ashish Nanda, a member of our board of directors, whereby pursuant to the terms of the joint venture agreement between us and Image, dated as of October 16, 2020, we agreed to loan Image up to $5 million to finance the project under the joint venture agreement. In addition, we have the option to loan up to an additional $5 million on the same terms as the original loan amount. The proceeds of the loan shall be used solely to fund the work plan for the project under the joint venture, which is a collaboration in the development, marketing, clinical development and/or commercialization of cell therapy products in India. The loan bears interest at the rate of 6% and is subject to repayment by August 24, 2022, unless we agree to an extension or the loan is converted into shares of Image or, if established, Image's Indian joint venture entity. Such loan is senior to any and all other indebtedness of Image or, after its establishment, Image's joint venture entity. We shall have a first priority security interest on all of Image's or, if established, Image's joint venture entity's, present and future assets. As of September 30, 2021, we transferred $3 million to Image under the loan agreement, and this has been reflected as an asset on our balance sheet.

Extension of Maturity Date on Convertible Loans

On September 13, 2021, we and certain convertible loan holders agreed to extend the maturity date on loans due during the fourth quarter of 2021 to June 30, 2023. The principal amount extended was $2.25 million and the interest rate on the extended loans varies between 2% and 8%. The loan holders may request that we repay them on November 21, 2022 (the "Early Redemption Option"). In consideration for the extension, warrants to purchase an aggregate of 926,413 shares of common stock of the Company were issued to the loan holders. The warrants are exercisable until June 30, 2023 at an exercise price of $6.24 per share. The warrants will be cancelled if the Early Redemption Option is exercised.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2021 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

ITEM 1A. RISK FACTORS

An investment in the Company's Common Stock involves a number of very significant risks. You should carefully consider the risk factors included in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 9, 2021, 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. 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, 2020. The Company's business, operating results and financial condition could be adversely affected due to any of those risks.

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

Sales of Unregistered Equity Securities

On September 13, 2021, the Company issued warrants to purchase an aggregate of 926,413 shares of common stock to certain convertible note holders in the aggregate principal amount of $2.25 million in consideration for the extension of the maturity date of the loans due during the fourth quarter of 2021 to June 30, 2023. The warrants are exercisable until June 30, 2023 at an exercise price of $6.24 per share. The warrants may be cancelled earlier if an early redemption option is exercised and the loans are repaid on or prior to November 21, 2022.

The Company relied upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Act") by virtue of Section 4(a)(2) thereof and/or Regulation S promulgated by the SEC under the Act with respect to the issuance of the warrants.

Issuer Purchases of Equity Securities

On May 14, 2020, our Board of Directors approved the stock repurchase plan (the "Stock Repurchase Plan") pursuant to which we may, from time to time, purchase up to $10 million of our outstanding shares of common stock. The shares may be repurchased from time to time in privately negotiated transactions or the open market, including pursuant to Rule 10b5-1 trading plans, and in accordance with applicable regulations of the SEC. The timing and exact amount of any repurchases will depend on various factors including, general and business market conditions, corporate and regulatory requirements, share price, alternative investment opportunities and other factors. The Repurchase Plan commenced on May 29, 2020 and does not obligate us to acquire any specific number of shares in any period, and may be expanded, extended, modified, suspended or discontinued by the Board of Directors at any time.

There were no repurchases of shares pursuant to the Stock Repurchase Plan during the three-month period ended September 30, 2021.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

On August 24, 2021, the Company entered into a convertible loan agreement (the "Convertible Loan Agreement") with Image Securities FZC ("Image"), a related party affiliated with Ashish Nanda, a member of the Company's board of directors, whereby pursuant to the terms of the joint venture agreement between the Company and Image, dated as of October 16, 2020, the Company agreed to loan Image up to $5 million to finance the project under the joint venture agreement. In addition, the Company has the option to loan up to an additional $5 million on the same terms as the original loan amount. The proceeds of the loan shall be used solely to fund the work plan for the project under the joint venture, which is a collaboration in the development, marketing,

clinical development and/or commercialization of cell therapy products in India. The loan bears interest at the rate of 6% and is subject to repayment by August 21, 2022, unless the Company agrees to an extension or the loan is converted into shares of Image or, if established, Image's Indian joint venture entity. Such loan is senior to any and all other indebtedness of Image or, after its establishment, Image's joint venture entity. The Company shall have a first priority security interest on all of Image's or, if established, Image's joint venture entity's, present and future assets.

On September 13, 2021, the Company entered into (i) a Convertible Credit Line and Unsecured Convertible Note Extension Agreement with Yosef Dotan (the "Dotan Extension Agreement"), (ii) a Convertible Credit Line Extension Agreement with Aharon Lukach (the "Lukach Extension Agreement") and (iii) an Unsecured Convertible Note Extension Agreement with Yehuda Nir (the "Nir Extension Agreement"), each which extended the maturity date of the convertible loans under their respective loan agreements due during the fourth quarter of 2021 to June 30, 2023. The aggregate principal amount extended was $2.25 million and the interest rate on the extended loans varies between 2% and 8%. The loan holders may request that the Company repay them on November 21, 2022 (the "Early Redemption Option"). In consideration for the extension, warrants to purchase an aggregate of 926,413 shares of common stock of the Company (the "Warrants") were issued to the loan holders. The Warrants are exercisable until June 30, 2023 at an exercise price of $6.24 per share. The Warrants will be cancelled if the Early Redemption Option is exercised.

The foregoing summary of each of the Warrants, the Convertible Loan Agreement, the Dotan Extension Agreement, the Lukach Extension Agreement and the Nir Extension Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the form of the Warrant, the Convertible Loan Agreement, the Dotan Extension Agreement, the Lukach Extension Agreement and the Nir Extension Agreement, copies of which are filed as exhibits 4.1, 10.1, 10.2, 10.3 and 10.4, respectively, to this Quarterly Report on Form 10-Q.

ITEM 6. EXHIBITS

Exhibits required by Item 601 of Regulation S-K

No.	Description
(4)	**Instruments Defining the Rights of Securities Holders, Including Indentures**
4.1*	Form of Warrant, dated as of September 13, 2021, issued in connection with Convertible Note Extension Agreements
(10)	**Material Contracts**
10.1*	Convertible Loan Agreement, dated as of August 24, 2021, between the Company and Image Securities FCZ
10.2*	Convertible Credit Line and Unsecured Convertible Note Extension Agreement, dated as of September 13, 2021, between the Company and Yosef Dotan
10.3*	Convertible Credit Line Extension Agreement, dated as of September 13, 2021, between the Company and Aharon Lukach
10.4*	Unsecured Convertible Note Extension Agreement, dated as of September 13, 2021, between the Company and Yehuda Nir
(31)	**Rule 13a-14(a)/15d-14(a) Certification**
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
(32)	**Section 1350 Certification**
32.1*	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2*	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
(101)*	**Interactive Data Files**
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
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 4, 2021

/s/ Neil Reithinger

Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: November 4, 2021