

**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 June 30, 2020**

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

(State or other jurisdiction  
of incorporation or organization)

98-0583166

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

20271 Goldenrod Lane  
Germantown, MD 20876

(Address of principal executive offices) (Zip Code)

(480) 659-6404

(Registrant's telephone number, including area code)

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 August 6, 2020, there were 22,094,470 shares of registrant's common stock outstanding

**ORGENESIS INC.**  
**FORM 10-Q**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2020 AND 2019**

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## PART I – FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

Assets	As of	
	June 30, 2020	December 31, 2019
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 97,487	\$ 107
Restricted cash	608	467
Accounts receivable, net	3,950	1,831
Prepaid expenses and other receivables	1,885	382
Grants receivable	206	204
Inventory	176	136
Current assets of discontinued operations, see Note 3	-	75,221
<b>Total current assets</b>	<b>104,312</b>	<b>78,348</b>
<b>NON-CURRENT ASSETS:</b>		
Deposits	\$ 269	\$ 299
Loans to related party, see Note 6	3,211	2,623
Property, plant and equipment, net	2,295	2,305
Intangible assets, net	3,044	3,348
Operating lease right-of-use assets	605	725
Goodwill	4,658	4,812
Other assets	802	35
<b>Total non-current assets</b>	<b>14,884</b>	<b>14,147</b>
<b>TOTAL ASSETS</b>	<b>\$ 119,196</b>	<b>\$ 92,495</b>

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

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

	As of	
	June 30, 2020	December 31, 2019
<b>Liabilities and Equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,625	\$ 5,549
Accrued expenses and other payables	2,701	1,615
Income tax payable	12,580	-
Employees and related payables	1,664	1,672
Advance payments on account of grant	376	523
Short-term loans and current maturities of long- term loans	-	391
Contract liabilities, mainly related party	162	325
Current maturities of long-term finance leases	9	-
Current maturities of operating leases	248	357
Current maturities of convertible loans	393	416
Current liabilities of discontinued operations, see Note 3	-	31,586
<b>Total current liabilities</b>	<b>19,758</b>	<b>42,434</b>
<b>LONG-TERM LIABILITIES:</b>		
Non-current operating leases	\$ 363	\$ 455
Convertible loans	10,262	12,143
Retirement benefits obligation	44	41
Deferred taxes	20	58
Long-term finance leases	76	-
Other long-term liabilities	284	331
<b>Total long-term liabilities</b>	<b>11,049</b>	<b>13,028</b>
<b>TOTAL LIABILITIES</b>	<b>30,807</b>	<b>55,462</b>
<b>COMMITMENTS</b>		
<b>REDEEMABLE NON-CONTROLLING INTEREST OF DISCONTINUED OPERATIONS</b>	<b>-</b>	<b>30,955</b>
<b>EQUITY:</b>		
Common stock, par value \$0.0001 per share, 145,833,334 shares authorized, 22,094,470 and 16,140,962 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	2	2
Additional paid-in capital	122,502	94,691
Accumulated other comprehensive income	10	213
Accumulated deficit	(34,280)	(89,429)
Equity attributable to Orgenesis Inc.	88,234	5,477
Non-controlling interest	155	601
<b>Total equity</b>	<b>88,389</b>	<b>6,078</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 119,196</b>	<b>\$ 92,495</b>

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

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

	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Revenues	\$ 1,470	\$ 575	\$ 2,855	\$ 994
Revenues from related party	279	556	772	556
Total revenues	1,749	1,131	3,627	1,550
Cost of revenues	243	1,007	413	1,312
Cost of research and development and research and development services, net	24,720	2,073	29,423	7,373
Amortization of intangible assets	(52)	108	171	217
Selling, general and administrative expenses	3,611	2,789	7,129	5,775
Other income, net	(1)	(1)	(4)	(4)
Operating loss	26,772	4,845	33,505	13,123
Financial expenses, net	337	47	666	148
Loss from continuing operation before income taxes	27,109	4,892	34,171	13,271
Tax expenses (income)	12	(19)	(35)	(68)
Net loss from continuing operation	27,121	4,873	34,136	13,203
Net loss (income) from discontinued operations, net of tax, see Note 3	(6,721)	952	(88,760)	1,072
Net loss (income)	20,400	5,825	(54,624)	14,275
Net loss (income) attributable to non-controlling interests (including redeemable) from continuing operation	6	(13)	(33)	(34)
Net income attributable to non-controlling interests (including redeemable) from discontinued operations	-	(611)	(492)	(729)
Net loss (income) attributable to Orgenesis Inc.	20,406	5,201	(55,149)	13,512
Loss (earnings) per share:				
Basic from continuing operations	\$ 1.26	\$ 0.30	\$ 1.73	\$ 0.83
Basic from discontinued operations	\$ (0.31)	\$ 0.06	\$ (4.52)	\$ 0.08
Net loss (earnings) loss per share	\$ 0.95	\$ 0.36	\$ (2.79)	\$ 0.91
Diluted from continuing operations	\$ 1.26	\$ 0.30	\$ 1.73	\$ 0.83
Diluted from discontinued operations	\$ (0.31)	\$ 0.06	\$ (4.52)	\$ 0.08
Net loss (earnings) per share	\$ 0.95	\$ 0.36	\$ (2.79)	\$ 0.91
Weighted average number of shares used in computation of Basic and Diluted loss (earnings) per share:				
Basic	21,515,254	16,001,439	19,648,042	15,772,333
Diluted	21,515,254	16,001,439	19,648,042	15,772,333
Comprehensive loss (income):				
Net loss from continuing operations	\$ 27,121	\$ 4,873	\$ 34,136	\$ 13,203
Net loss (income) from discontinued operations, net of tax	(6,721)	952	(88,760)	1,072
Other comprehensive loss (income)- translation adjustments	(247)	(188)	397	296
Release of translation adjustment due to sale of subsidiary	-	-	(194)	-
Comprehensive loss (income)	20,153	5,637	(54,421)	14,571
Comprehensive income attributed to non-controlling interests (including redeemable) from continuing operations	6	(13)	(33)	(34)
Comprehensive income attributed to non-controlling interests (including redeemable) from discontinued operations	-	(611)	(492)	(729)
Comprehensive loss (income) attributed to Orgenesis Inc.	\$ 20,159	\$ 5,013	\$ (54,946)	\$ 13,808

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			Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non- Controlling Interest	Total
	Number	Par Value	Additional Paid-in Capital					
<b>Balance at January 1, 2020</b>	16,140,962	\$ 2	\$ 94,691	\$ 213	\$ (89,429)	\$ 5,477	\$ 601	\$ 6,078
<b>Changes during the six months ended June 30, 2020:</b>								
Stock-based compensation to employees and directors	-	-	910	-	-	910	-	910
Stock-based compensation to service providers	**270,174	*-	787	-	-	787	-	787
Stock-based compensation for Tamir purchase agreement, (see Note 6)	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	-	-	(414)	-	-	(414)	-	(414)
Comprehensive income (loss) for the period	-	-	-	(203)	55,149	54,946	(33)	54,913
<b>Balance at June 30, 2020</b>	<u>22,094,470</u>	<u>\$ 2</u>	<u>\$ 122,502</u>	<u>\$ 10</u>	<u>\$ (34,280)</u>	<u>\$ 88,234</u>	<u>155</u>	<u>88,389</u>

(\*) represent an amount lower than \$ 1 thousand

(\*\*) out of which 135,000 shares have additional restrictions on transfer until services have been provided.

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

	<u>Common Stock</u>			Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non- Controlling Interest	Total
	Number	Par Value	Additional Paid-in Capital					
<b>Balance at January 1, 2019</b>	15,540,333	\$ 2	\$ 90,597	\$ 669	\$ (65,163)	\$ 26,105	\$ 645	\$ 26,750
<b>Changes during the six months ended June 30, 2019:</b>								
Stock-based compensation to employees and directors	-	-	1,466	-	-	1,466	31	1,497
Stock-based compensation to service providers	50,000	*-	467	-	-	467	-	467
Stock based Compensation for JV collaborations	525,000	*-	2,641	-	-	2,641	-	2,641
Adjustment to redemption value of redeemable non-controlling interest	-	-	(853)	-	-	(853)	-	(853)
Issuance of warrants with respect to convertible loans	-	-	97	-	-	97	-	97
Comprehensive loss for the period	-	-	-	(296)	(13,512)	(13,808)	(37)	(13,845)
<b>Balance at June 30, 2019</b>	<u>16,115,333</u>	<u>\$ 2</u>	<u>\$ 94,415</u>	<u>\$ 373</u>	<u>\$ (78,675)</u>	<u>\$ 16,115</u>	<u>\$ 639</u>	<u>\$ 16,754</u>

(\*)represent an amount lower than \$ 1 thousand

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

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

	Common Stock			Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non- Controlling Interest	Total
	Number	Par Value	Additional Paid-in Capital					
Balance at April 1, 2020	18,361,050	\$ 2	\$ 103,623	\$ (237)	\$ (13,874)	\$ (89,514)	\$ 149	\$ 89,663
Changes during the three months ended June 30, 2020:								
Stock-based compensation to employees and directors	-	-	284	-	-	284	-	284
Stock-based compensation to service providers	**250,086	*-	547	-	-	547	-	547
Stock-based compensation for Tamir Purchase Agreement, (see Note 6)	3,400,000	*-	17,748	-	-	17,748	-	17,748
Exercise of options	83,334	*-	300	-	-	300	-	300
Comprehensive income (loss) for the period	-	-	-	247	(20,406)	(20,159)	6	(20,153)
Balance at June 30, 2020	<u>22,094,470</u>	<u>\$ 2</u>	<u>\$ 122,502</u>	<u>\$ 10</u>	<u>\$ (34,280)</u>	<u>\$ 88,234</u>	<u>\$ 155</u>	<u>\$ 88,389</u>

(\*) represent an amount lower than \$ 1 thousand

(\*\*) out of which 135,000 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)

	<u>Common Stock</u>			Accumulated Other Comprehensive Income	Accumulated Deficit	Equity Attributed to Orgenesis Inc.	Non- Controlling Interest	Total
	Number	Par Value	Additional Paid-in Capital					
<b>Balance at April 1, 2019</b>	16,102,000	\$ 2	\$ 94,049	\$ 185	\$ (73,474)	\$ 20,762	\$ 639	\$ 21,401
<b>Changes during the three months ended June 30, 2019:</b>								
Stock-based compensation to employees and directors	-	-	728	-	-	728	11	739
Stock-based compensation to service providers	13,333	*	152	-	-	152	-	152
Adjustment to redemption value of redeemable non-controlling interest	-	-	(611)	-	-	(611)	-	(611)
Issuance of warrants with respect to convertible loans	-	-	97	-	-	97	-	97
Comprehensive income (loss) for the period	-	-	-	188	(5,201)	(5,013)	(11)	(5,024)
<b>Balance at June 30, 2019</b>	<u>16,115,333</u>	<u>\$ 2</u>	<u>\$ 94,415</u>	<u>\$ 373</u>	<u>\$ (78,675)</u>	<u>\$ 16,115</u>	<u>\$ 639</u>	<u>\$ 16,754</u>

\* represent an amount lower than \$ 1 thousand

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

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

	<b>Six Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 54,624	\$ (14,275)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,697	1,964
Stock-based compensation to for strategic collaborations	-	2,641
Stock-based compensation for Tamir Purchase Agreement, see Note 4 and Note 6	17,048	-
Capital loss (gain), net	14	(5)
Gain on disposal of subsidiaries	(102,594)	-
Depreciation and amortization expenses	739	1,907
Effect of exchange differences on inter-company balances	124	103
Net changes in operating leases	(9)	(700)
Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature)	201	58
Changes in operating assets and liabilities:		
Increase in accounts receivable	(2,453)	(3,678)
Increase in inventory	(123)	(571)
Increase in other assets	(20)	-
Decrease (increase) in prepaid expenses and other accounts receivable	(512)	47
Increase (decrease) in accounts payable	(4,748)	1,803
Increase (decrease) in accrued expenses and other payables	13,451	(111)
Increase in employee and related payables	12	62
Increase (decrease) in contract liabilities	(64)	2,198
Change in advance payments and receivables on account of grant, net	(156)	(49)
Increase (decrease) in deferred taxes liability	(65)	438
Net cash used in operating activities	\$ (22,834)	\$ (8,168)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Increase in loan to JV with a related party	(500)	(1,000)
Sale of property and equipment	4	80
Purchase of property and equipment	(974)	(2,802)
Proceed from sale of subsidiaries	104,222	-
Repayment (investment) in short term deposits	20	(225)
Net cash provided by (used in) investing activities	\$ 102,772	\$ (3,947)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Increase in redeemable non-controlling interests received from GPP	-	6,600
Proceeds from issuance of shares and warrants (net of transaction costs)	8,738	-
Proceeds from issuance of convertible loans (net of transaction costs)	250	7,500
Repayment of convertible loans and convertible bonds	(2,400)	-
Repayment of short and long-term debt	(430)	(304)
Other financing activities	1	-
Net cash provided by financing activities	\$ 6,159	\$ 13,796
<b>NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>\$ 86,097</b>	<b>\$ 1,681</b>
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>(43)</b>	<b>(25)</b>
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD</b>	<b>12,041</b>	<b>14,999</b>
<b>CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD (*)</b>	<b>\$ 98,095</b>	<b>\$ 16,655</b>
<b>SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES</b>		
Finance leases of property, plant and equipment	\$ 363	\$ -
Acquisition of other asset	\$ 700	\$ -
Right-of-use assets obtained in exchange for new operating lease liabilities, net	\$ 231	\$ -
Purchase of property, plant and equipment included in accounts payable	\$ 200	\$ -

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

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

**ORGENESIS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Period Ended June 30, 2020 and 2019**  
**(Unaudited)**

**NOTE 1 – DESCRIPTION OF BUSINESS**

*a. General*

Orgenesis Inc., a Nevada corporation (the “Company”), is a pioneering global biotech company in the Cell & Gene Therapy (“CGT”) industry focused on unlocking the full potential of its therapeutics products and personalized therapies and closed processing systems with the ultimate aim of providing life-changing treatments to large numbers of patients at reduced costs in a point-of-care setting. It pursues this strategy through a point-of-care platform (“CGT Biotech Platform”) that combines therapeutics, technologies, processes, and systems via a network of collaborative partners, and research institutes and hospitals around the world.

The Company’s CGT Biotech Platform consists of: (a) POCare Therapeutics, a pipeline of licensed CGTs, anti-viral and proprietary scientific know-how; (b) POCare Technologies, a suite of proprietary and in-licensed technologies which are engineered to create customized processing systems for affordable point-of-care therapies; and (c) a POCare Network, a collaborative, international ecosystem of leading research institutions and hospitals committed to clinical development and supply of CGTs at the point-of-care (“POCare Network”). By combining science, technology, including its mobile processing units that it is developing, and a collaborative network, the Company believes that it is able to identify the most promising new autologous therapies and provide a pathway for them to reach patients more quickly, more efficiently and in a scalable way, thereby unlocking the power of cell and gene therapy for all patients.

The Company had historically also operated a Contract Development and Manufacturing Organization (“CDMO”) platform, which provided contract manufacturing and development services for biopharmaceutical companies (the “CDMO Business”). On February 2, 2020, the Company entered into a Stock Purchase Agreement (the “Purchase Agreement”) with GPP-II Masthercell LLC (“GPP” and together with the Company, the “Sellers”), Masthercell Global Inc. (“Masthercell”) and Catalent Pharma Solutions, Inc. (the “Buyer”). Pursuant to the terms and conditions of the Purchase Agreement, on February 10, 2020, the Sellers sold 100% of the outstanding equity interests of Masthercell (the “Masthercell Business”), which comprised the majority of the CDMO Business, to the Buyer (the “Masthercell Sale”) for an aggregate nominal purchase price of \$315 million, subject to customary adjustments. After accounting for GPP’s liquidation preference and equity stake in Masthercell as well as other investor interests in its Belgian subsidiary MaSTherCell, S.A. (“MaSTherCell”), distributions to Masthercell option holders and transaction costs, the Company received approximately \$126.7 million. The Company incurred an additional approximately \$5.6 million in transaction costs.

The Company has determined that the Masthercell Business (“Discontinued Operation”) meets the criteria to be classified as a discontinued operation as of the first quarter of 2020. The Discontinued Operation includes most of the previous CDMO Business, including majority-owned Masthercell, including its subsidiaries Cell Therapy Holdings, MaSTherCell and Masthercell U.S. (collectively, the “Masthercell Global Subsidiaries”) (See Note 3).

The Chief Executive Officer (“CEO”) is the Company’s chief operating decision-maker. Management has determined that effective from the first quarter of 2020, all of the Company’s continuing operations are in the point-of-care business via the Company’s CGT Biotech Platform. Therefore, no segment report 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 (as defined below).
- European Union: Orgenesis Belgium SRL (the “Belgian Subsidiary”) is the center of activity in Europe currently focused on process development and preparation of European clinical trials.

- Israel: Orgenesis Ltd. (the “Israeli Subsidiary”) is the center for research and technology, as well as a provider of regulatory, clinical and pre-clinical services, and Atvio Biotech Ltd. (“Atvio”) is a provider of cell-processing services in Israel.
- Korea: Orgenesis Korea Co. Ltd. (the “Korean Subsidiary”), previously known as CureCell Co. Ltd., 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, including the U.S. Subsidiary, the Belgian Subsidiary, the Israeli Subsidiary, the Korean subsidiary, Atvio and the Discontinued Operation.

On April 7, 2020, the Company entered into an Asset Purchase Agreement (the “Tamir Purchase Agreement”) with Tamir Biotechnology, Inc. (“Tamir” or “Seller”), pursuant to which the Company agreed to acquire certain assets and liabilities of Tamir related to the discovery, development and testing of therapeutic products for the treatment of diseases and conditions in humans, including all rights to Ranpirnase and use for antiviral therapy (collectively, the “Purchased Assets and Assumed Liabilities” and such acquisition, the “Tamir Transaction”). The Tamir Transaction closed on April 23, 2020. As aggregate consideration for the acquisition, the Company paid \$ 2.462 million in cash and issued an aggregate of 3,400,000 shares (the “Shares”) of Common Stock to Tamir resulting in a total consideration of \$20.2 million. \$4.5 million of the consideration was attributable to research and development related inventory and most of the remaining amount reflected the cost of intangible assets (See Note 6).

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*

As of June 30, 2020, the Company has accumulated losses of approximately \$34 million.

On February 10, 2020, the Company received approximately \$126.7 million, of which \$7.2 million was used for the repayment of intercompany loans and payables, from the Masthercell Sale. In addition, on January 20, 2020, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company received gross proceeds of approximately \$9.24 million before deducting related offering expenses (See Note 4).

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and expected level of expenditures for at least 12 months from the date of the issuance of the financial statements. If there are further increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, the Company may decide to seek additional financing.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES**

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

*Cash and cash equivalents*

The Company considers cash equivalents to be all short-term, highly liquid investments, which include money market instruments, that are not restricted as to withdrawal or use, and short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

### *Discontinued operations*

Upon divestiture of a business, the Company classifies such business as a discontinued operation, if the divested business represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. For disposals other than by sale such as abandonment, the results of operations of a business would not be recorded as a discontinued operation until the period in which the business is actually abandoned.

The Masthercell Business divestiture qualifies as a discontinued operation and therefore have been presented as such.

The results of businesses that have qualified as discontinued operations have been presented as such for all reporting periods. Results of discontinued operations include all revenues and expenses directly derived from such businesses; general corporate overhead is not allocated to discontinued operations. Any loss or gain that arose from the divestiture of a business that qualifies as discontinued operations has been included within the results of the discontinued operations. The Company included information regarding cash flows from discontinued operations (See Note 3).

### *Newly issued and recently adopted accounting pronouncements*

The Company early adopted ASU 2019-12 on January 1, 2020 which did not have a material impact on the Consolidated Financial Statements except for the removal of the exception related to intra-period tax allocations. Commencing from January 1, 2020, the Company followed the general intra-period allocation of tax expenses. The Company had incurred a loss from continuing operations and subsequent to the adoption of ASU 2019-12, the Company determined the amount attributable to continuing operations without regard to the tax effect of other items. The ASU 2019-12 amendment related to the intra-period tax allocation was applied prospectively.

Had the Company not adopted ASU 2019-12, an approximately \$11.5 million tax benefit would have been recognized along with corresponding decreases to net loss from continuing operations with a corresponding increase in tax expenses and decrease in net income resulting from discontinued operations. The Company had no intra-period tax allocation items in prior years.

### *Use of Estimates*

The preparation of our consolidated financial statements 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 and the amount of revenues and expenses. 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.

### **NOTE 3 – DISCONTINUED OPERATION**

On February 2, 2020, the Company entered into a Purchase Agreement with GPP, Masthercell and the Buyer. Pursuant to the terms and conditions of the Purchase Agreement, Sellers agreed to sell 100% of the outstanding equity interests of Masthercell to Buyer for an aggregate nominal purchase price of \$15 million, subject to customary adjustments. The Company has determined that the Masthercell Business meets the criteria to be classified as a discontinued operation.

On February 10, 2020, the Masthercell Sale was consummated in accordance with the terms of the Purchase Agreement. After accounting for GPP's liquidation preference and equity stake in Masthercell, as well as SFPI – FPIM's interest in MaSTherCell, distributions to Masthercell option holders and transaction costs, the Company received approximately \$126.7 million at the closing of the Masthercell Sale, of which \$7.2 million was used for the repayment of intercompany loans and payables, including \$4.6 million of payables to MaSTherCell. Included in this amount is \$1.5 million which was deposited into an escrow account in connection with potential adjustments based on working capital and indebtedness at closing. The escrow amount was transferred to the Company at the end of July 2020.

Due to the sale of the controlling interest in Masthercell, the Company retrospectively reclassified the assets and liabilities of these entities as assets and liabilities of discontinued operations and included the financial results of these entities (as of the February 10, 2020) in discontinued operations in the Company's consolidated financial statements.

Discontinued operations relate to the Masthercell Business. The comprehensive loss and balance sheet for this operation are separately reported as discontinued operations for all periods presented.

The financial results of the Masthercell Business are presented as income (loss) from discontinued operations, net of income taxes on the Company's consolidated statement of comprehensive loss. The following table presents the financial results associated with the Masthercell Business operation as reflected in the Company's Consolidated Comprehensive loss (in thousands):

	<u>Six Months Ended</u> <u>June 30,</u> <u>2020</u>	<u>Three Months Ended</u> <u>June 30,</u> <u>2019</u>	<u>Six Months Ended</u> <u>June 30,</u> <u>2019</u>
<b>OPERATIONS</b>			
Revenues	\$ 2,556	\$ 6,626	\$ 13,508
Cost of revenues	1,482	3,928	7,967
Cost of research and development and research and development services, net	7	(364)	(514)
Amortization of intangible assets	137	408	816
Selling, general and administrative expenses	1,896	3,094	5,708
Other (income) expenses, net	305	(31)	(65)
Operating loss	1,271	409	404
Financial (income) expenses, net	(29)	6	45
Loss before income taxes	1,242	415	449
Tax expenses (income)	(30)	537	623
Net loss from discontinuing operation, net of tax	\$ 1,212	\$ 952	\$ 1,072
<b>DISPOSAL</b>			
Gain on disposal before income taxes	\$ 102,594	\$ -	\$ -
Provision for income taxes (*)	(12,622)	-	-
Gain on disposal	\$ 89,972	\$ -	\$ -
Net profit (loss) from discontinuing operation, net of tax	<u>\$ 88,760</u>	<u>\$ (952)</u>	<u>\$ (1,072)</u>

\* Provision for income taxes was updated in the three months period ended June 30, 2020 in the amount of \$6.7 million due to tax benefit recognized from net loss from continuing operation according to ASU 2019-12, see also Note 2.

The following table is a summary of the assets and liabilities of discontinued operations (in thousands):

	<b>As of December 31, 2019</b>	
<b>Assets</b>		
<b>ASSETS:</b>		
Cash and cash equivalents	\$	11,281
Restricted cash		186
Accounts receivable, net		6,654
Prepaid expenses and other receivables		845
Grants receivable		1,979
Inventory		1,907
Deposits		326
Property and equipment, net		22,149
Intangible assets, net		10,858
Operating lease right-of-use assets		8,860
Goodwill		10,129
Other assets		47
<b>TOTAL ASSETS OF DISCONTINUED OPERATIONS</b>	<b>\$</b>	<b>75,221</b>
	<b>As of December 31, 2019</b>	
<b>LIABILITIES:</b>		
Accounts payable	\$	5,756
Accrued expenses and other payables		372
Employees and related payables		2,047
Advance payments on account of grant		2,227
Short-term loans and current maturities of long- term loans		372
Contract liabilities		8,301
Current maturities of long-term finance leases		291
Current maturities of operating leases		1,365
Non-current operating leases		7,069
Loans payable		1,230
Deferred taxes		1,868
Long-term finance leases		688
<b>TOTAL LIABILITIES OF DISCONTINUED OPERATIONS</b>	<b>\$</b>	<b>31,586</b>

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

	<u>Six Months Ended</u> June 30, 2020	<u>Three Months Ended</u> June 30, 2019	<u>Six Months Ended</u> June 30, 2019
Net cash flows provided by (used in) operating activities	\$ (2,409)	\$ 2,271	\$ (2,416)
Net cash flows used in investing activities	\$ (579)	\$ (1,356)	\$ (2,300)
Net cash flows (used in) provided by financing activities	\$ (51)	\$ (216)	\$ 6,296

## Disaggregation of Revenue

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

	<u>Six Months Ended</u> <u>June 30,</u> <u>2020</u>	<u>Three Months Ended</u> <u>June 30,</u> <u>2019</u>	<u>Six Months Ended</u> <u>June 30,</u> <u>2019</u>
Revenue stream:			
Cell process development services	\$ 2,556	\$ 3,891	\$ 8,647
Tech transfer services	-	1,702	3,532
Cell manufacturing services	-	1,033	1,329
Total	<u>\$ 2,556</u>	<u>\$ 6,626</u>	<u>\$ 13,508</u>

### NOTE 4 – EQUITY

On January 20, 2020, the Company entered into a Securities Purchase Agreement (the "January Purchase Agreement") with certain investors pursuant to which the Company issued and sold, in a private placement (the "Offering"), 2,200,000 shares of Common Stock at a purchase price of \$4.20 per share (the "Shares") and warrants to purchase up to 1,000,000 shares of Common Stock at an exercise price of \$5.50 per share (the "Warrants") which are exercisable between June 2021 and January 2023. The Company received gross proceeds of approximately \$9.24 million before deducting related offering expenses.

During April 2020, the Company and Tamir Biotechnology, Inc. ("Tamir") entered into an Asset Purchase Agreement pursuant to which 3,400,000 shares of Common Stock were issued to Tamir (See Note 6).

During the six months ended June 30, 2020, the Company issued 270,174 ordinary shares to service providers. As of June 30, 2020, 135,000 shares have additional restrictions on transfer until such services have been provided.

During the three months ended June 30, 2020, one option holder exercised 83,334 options at an exercise price of \$3.60 for 83,334 ordinary shares, and the Company received \$300 thousand.

### NOTE 5 – CONVERTIBLE LOANS

On January 2, 2020, the Company entered into private placement subscription agreements with investors for an aggregate amount of \$50 thousand of convertible loans. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into shares of Common Stock of the Company at a conversion price per share equal to \$7.00. In addition, the Company granted the investors 151,428 warrants to purchase an equal number of additional shares of Common Stock at a price of \$7.00 per share.

During the six months ended June 30, 2020, the Company repaid \$2,746 thousand on account of the principal amount and accrued interest of convertible loans.

### NOTE 6 – COLLABORATIONS, LICENSE AGREEMENTS AND COMMITMENTS

#### *Image Securities Ltd. (a related party)*

As described in Note 12 to the financial statements of December 31, 2019, on July 11, 2018, the Company and Image Securities Ltd., a corporation with its registered office in Grand Cayman, Grand Cayman Islands ("India Partner"), entered into a Joint Venture Agreement (the "India JVA") pursuant to which the parties will collaborate in the development, marketing, clinical development and/or commercialization of cell therapy products in India (the "Cell Therapy Products"). The India Partner will collaborate with a network of healthcare facilities and a healthcare infrastructure as well as financial partners to advance the development and commercialization of the cell therapy products in India. As of June 30, 2020, the Company had advanced \$3 million, of which \$500 thousand was transferred in the first quarter of 2020, as part of its financing obligations under the India JVA to the India Partner, who is holding the loan in escrow on behalf of the Company. The loan is reflected on the balance sheet as a loan to a related party.



As part of the agreement, the India joint venture will procure consulting services from the Company. During January 2020, the Company entered into a new statement of work pursuant to the master services agreement signed in 2019 for the provision of certain services during 2020 and 2021. The Company, subject to mutually agreed timing and definition of the scope of services, will provide regulatory services, pre-clinical studies, intellectual property services, point-of-care services and co-development services to the India Partner. The Company received \$500 thousand as payments for such services during the six months ended June 30, 2020. \$72 thousand for these services was recognized during the six months ended June 30, 2020 as income under ASC 606.

Apart from the above, there was no activity in the India joint venture during the six months ended June 30, 2020.

#### *Hemogenyx Pharmaceuticals PLC.*

As described in Note 12 to the financial statements of December 31, 2019, on October 18, 2018, the Company and Hemogenyx Pharmaceuticals PLC., a corporation with its registered office in the United Kingdom, and Hemogenyx-Cell, a corporation with its registered office in Belgium, and which is engaged in the development of cell replacement bone marrow therapy technology (“H-Cell” and, collectively with the Company, “Hemo”), entered into a Collaboration Agreement (the “Hemo Agreement”) pursuant to which the parties will collaborate in the funding of the continued development of and commercialization of, the Hemo technology via the Hemo group companies. Pursuant to the Hemo Agreement, the Company and Hemogenyx LLC, a wholly owned USA subsidiary of Hemo (“Hemo-LLC”), entered into a loan agreement. During the six months ended June 30, 2020, the Company advanced \$250 thousand under the loan agreement, which was charged to expenses under ASC 730-10-50 and 20-50 and presented as research and development costs.

#### *Immugenyx LLC*

As described in Note 12 to the financial statements as of December 31, 2019, on October 16, 2018, the Company and Immugenyx LLC, (“Immu”), which is engaged in the development of technology related to the production and use of humanized mice, entered into a Collaboration Agreement (the “Immu Agreement”) pursuant to which the parties will collaborate in the funding of the continued development of, and commercialization of, the Immu technology. The Company received the worldwide rights to market the products under the Immu Agreement in consideration for the payment of a 12% royalty, subject to the terms of the agreement. Pursuant to the Immu Agreement, the Company and Immu also entered into a loan agreement. During the six months ended June 30, 2020, the Company advanced \$250 thousand under the loan agreement, which was charged to expenses under ASC 730-10-50 and ASC 20-50 and presented as research and development costs.

#### *Theracell Advanced Biotechnology*

As described in Note 12 to the financial statements as of December 31, 2019, on February 14, 2019, the Company and Theracell Advanced Biotechnology, a corporation organized under the laws of Greece (“Theracell”), entered into a Joint Venture Agreement (the “Greek JVA”) pursuant to which the parties will collaborate in the clinical development and commercialization of the Company’s products (hereinafter, the “Company Products”) in Greece, Turkey, Cyprus and Balkan countries (the “Territory”) and the clinical development and commercialization of Theracell’s products (hereinafter, the “Theracell Products”) worldwide (the “Theracell Project”). The parties intend to pursue the Theracell Project through a joint venture (“JV”) by forming a JV entity (the “Greek JV Entity”). Until the Greek JV Entity is formed, all JV activities are being carried out by Theracell. The Company by itself, or together with a designee, will hold a 50% participating interest in the Greek JV Entity, with the remaining 50% participating interest being held by Theracell or its affiliate following the parties’ contributions to the Greek JV Entity as set forth under the Greek JVA. Each of the parties committed to contribute \$10 million to the JV Entity, of which \$5 million will be provided as in-kind contributions. The Greek JV Entity will have a steering committee that will act as the board of directors of the Greek JV Entity and shall be composed of a total of five members, with two members appointed by each party and one industry expert to be appointed by both parties. The Company shall have the option, at its sole discretion and subject to all rules and regulations to which it is then subject, to require Theracell to transfer to the Company the entirety of Theracell’s equity interest in the JV Entity for a consideration of shares of Common Stock according to an agreed-upon formula.

During January 2020, the Company entered into a new statement of work pursuant to the master services agreement signed in 2019 with Theracell for the provision of certain services by the Company during 2020 and 2021. During the six months ended June 30, 2020, the Company recognized point of care service revenue in the amount of \$733 thousand.

During the six months ended June 30, 2020, the Company recorded expenses related to activities in the territory in the amount of \$96 thousand.

As of June 30, 2020, the Greek JV had not yet been incorporated.

#### *Broaden Bioscience and Technology Corp*

As described in Note 12 to the financial statements as of December 31, 2019, on November 10, 2019, the U.S. Subsidiary and Broaden Bioscience and Technology Corp, a Delaware corporation ("Broaden"), entered into a Joint Venture Agreement (the "Broaden JVA") pursuant to which the parties will collaborate in the development and/or marketing, clinical development and commercialization of cell therapy products and the setting up of point-of-care processing facilities in China and the Middle East (the "Broaden Project"). The parties intend to pursue the Broaden Project through a joint venture by forming a joint venture entity (the "Broaden JV Entity").

During January 2020, the Company entered into a master service agreement with Broaden whereby the Company, subject to mutually agreed timing and definition of the scope of services, will provide regulatory services, pre-clinical studies, intellectual property services, GMP process translation services and co-development services to Broaden during 2020 and 2021. During the six months ended June 30, 2020, the Company recognized point of care services revenue in the amount of \$806 thousand.

During January 2020, the U.S. Subsidiary and Broaden Bioscience and Technology Corp entered into a convertible loan agreement pursuant to which the Company agreed to lend Broaden Bioscience and Technology Corp an amount of up to \$5 million as a convertible loan as part of Company's investment in the Broaden JV. As of the date of this report, the Company has not lent Broaden Bioscience and Technology Corp any funds as part of this loan.

During the six months ended June 30, 2020, the Company recorded research and development expenses related to activities in the Broaden JVA in the amount of \$30 thousand.

Apart from the above, as of June 30, 2020, the Broaden JV Entity had not been incorporated.

#### *Cure Therapeutics*

During 2019, the Company entered into a master service agreement with Cure Therapeutics whereby the Company, subject to mutually agreed timing and definition of the scope of services, will provide point-of-care services to Cure Therapeutics during 2020 and 2021. During the six months ended June 30, 2020, the Company recognized point of care services revenue in the amount of \$714 thousand.

As described in Note 12 to the financial statements as of December 31, 2019, on May 7, 2018, the Company and Cure Therapeutics entered into a collaboration agreement for the development of therapies based on liver and NK cells. An amount of \$976 thousand was charged during the six months ended June 30, 2020. As of June 30, 2020, the development project had not been completed. As part of the agreement, Cure Therapeutics subcontracted development and contract manufacturing activities to Orgenesis Korea. An amount of \$567 thousand was recognized as revenues by Orgenesis Korea during the six months ended June 30, 2020.

### *Mircod Limited*

As described in Note 12 to the financial statements as of December 31, 2019, on June 19, 2018, the Company and Mircod Limited, a company formed under the laws of Cyprus (“Mircod”), entered into a Collaboration and License Agreement (the “Mircod Collaboration Agreement”) for the adaptation of Mircod’s background technologies related to biological sensing for use for the Company’s clinical development and manufacturing projects (the “Development Project”). The Development Project is to be carried out in accordance with an agreed development plan. During the six months ended June 30, 2020, the Company recorded research and development expenses related to the development plan in the amount of \$500 thousand.

In addition, during the first quarter of 2020, as per the Mircod Collaboration agreement, Mircod formed a wholly-owned US subsidiary named Mircod Biotech (the “Mircod Subsidiary”). The Mircod Subsidiary shall perform the duties of Mircod under the Collaboration Agreement, provided that Mircod shall remain responsible for the performance of the Mircod Subsidiary. At any time, the Company shall have the option, at its sole discretion, to transfer and require Mircod or the Mircod Subsidiary to transfer the Development Project and/or the rights and licenses granted by Mircod to a joint venture company (“JV Entity”) which shall be established by the parties for the purposes of carrying out and commercializing the Development Project, and in which the Company and Mircod will each hold 50%. The Company shall also have the option to, at its sole discretion and subject to all rules and regulations to which it is then subject, require Mircod to transfer to the Company the entirety of Mircod’s equity interest in the JV Entity for a consideration of shares of Common Stock according to an agreed formula. The parties agreed to amend the development plan to reflect the fact that the parties shall collaborate with each other on: (i) point-of-care processing, regulatory and therapy development; (ii) setting up one or more point-of-care processing facilities in institutions or hospitals the territory of Russia; (iii) the supply of the Company’s products and services within Russia, and (iv) clinical, regulatory, development and commercialization in Russia. The Company may, at its sole discretion, agree to provide Mircod with a convertible loan (which may be converted into shares of Mircod then outstanding or into the JV Entity, upon a valuation to be agreed between the parties and validated by a third party subject to terms to be agreed upon by the parties in a separate convertible loan agreement). The convertible loan will be used to finance the modification of the processing facility or facilities including, planning, designing, testing, training or supervising, as required for obtaining cGMP status approval(s) and/or relevant certification for any processing facility and other activities. As at June 30, 2020, the loan agreement was not executed.

### *Kidney Cure Ltd*

During April 2020, the Company entered into a joint venture agreement with Kidney Cure Ltd. (“Kidney Cure” and the “Kidney Cure JVA,” respectively), pursuant to which the parties will collaborate in the (i) implementation of a point-of-care strategy; (ii) assessment of the options for development and manufacture of various cell-based types (including kidney derived cells, MSC cells, exosomes, gene therapies) development; and (iii) development of protocols and tests for kidney therapies (the “Project”). The parties intend to pursue the joint venture through a newly established company (hereinafter, the “KC JV Entity”), which the Company, directly or indirectly by itself, will hold a 49% participating interest therein, with the remaining 51% participating interest being held by Kidney Cure. The board of directors of the KC JV Entity will act as a steering committee KC JV Entity and shall be composed of a total of three members, with one member appointed by each party and the third member appointed by both parties.

The Company will procure services from the Kidney Cure JVA in the amount of \$5 million, subject to and in accordance with a development and manufacturing plan to be mutually agreed upon by the parties. Under the Kidney Cure JVA, the Company can require Kidney Cure to sell to the Company its participating (including equity) interest in the KC JV Entity in consideration for the issuance of Common Stock based on an agreed-upon formula for determining the KC JV Entity’s valuation, provided that Company has contributed at least \$5 million. As of June 30, 2020, the Company had advanced \$200 thousand to Kidney Cure on account of its obligations under the Kidney Cure JVA and a further \$250 thousand was advanced during July 2020.

Apart from the above, as of June 30, 2020, no activity has begun in the said KC JV Entity, no contributions were made therein and the KC JV Entity had not been incorporated.

### *Sescom Ltd*

During April 2020, the Company entered into a joint venture agreement with Sescom Ltd (“Sescom”), pursuant to which the parties will collaborate in (i) the assessment of relevant tools and technologies to be used in the Company’s information security system (the “ISS”); (ii) the implementation of the ISS within the Company and in the Company’s point-of-care network; and (iii) the operation and maintenance of the ISS. The parties intend to pursue the joint venture through a company to be established (the “Sescom JV Entity”), which shall be 50% owned by the Company and 50% owned by Sescom. The Sescom JV Entity will have a steering committee that will act as the board of directors of the Sescom JV Entity and shall be composed of a total of three members, with one member appointed by each party and one industry expert.

Sescom has agreed to provide Sescom JV Entity with: (a) a non-exclusive, transferable and sublicensable worldwide royalty-free license to use its background IP, to the extent required for carrying out the development activities by the Sescom JV Entity; and (b) to make available to the Sescom JV Entity all relevant know-how and royalty-free licenses to any proprietary technologies to be implemented as part of the ISS.

The Company has agreed to procure services from Sescom or the Sescom JV Entity in an amount of up to \$ million, of which \$500 thousand was paid to Sescom during April 2020. In addition, the Company has agreed to provide the Sescom JV Entity with: (a) a non-exclusive, not transferable and non-sublicensable worldwide royalty-free license to use its background IP, to the extent required for carrying out certain activities by the Sescom JV Entity; and (b) access to its point-of-care network and relevant data to be used for the certain activities.

The parties agreed that at any time after the Company has contributed \$1 million in Sescom or the Sescom JV Entity, the Company shall have the right, in its sole discretion, to purchase from Sescom all of Sescom's then-issued and outstanding shares in the Sescom JV Entity based on a valuation of the Sescom JV Entity to be determined by an agreed-upon formula.

Apart from the above, as of June 30, 2020, no other activity had taken place in the Sescom JV Entity and the Sescom JV Entity had not been incorporated.

*Tamir Biotechnology, Inc.*

On April 7, 2020, the Company entered into the Tamir Purchase Agreement with Tamir, pursuant to which the Company agreed to acquire certain assets and liabilities of Tamir related to the discovery, development and testing of therapeutic products for the treatment of diseases and conditions in humans, including all rights to Ranpirnase and use for antiviral therapy. The Tamir Transaction closed on April 23, 2020.

The Tamir Transaction closed upon the occurrence of the closing conditions contained in the Tamir Purchase Agreement. As aggregate consideration for the acquisition, the Company paid \$2.462 million in cash and issued an aggregate of 3,400,000 shares (the "Shares") of Common Stock to Tamir resulting in a total consideration of \$20.2 million. \$59 thousand and 340,000 Shares will be held in an escrow account for a period of 18 months from closing to secure indemnification obligations of Tamir pursuant to the terms of the Tamir Purchase Agreement. \$ 4.5 million of the consideration was attributable to research and development related inventory and most of the remaining amount reflected the cost of intangible assets.

Included in the purchased assets and assumed liabilities was the assumption by the Company of a worldwide license to a private company of certain Tamir technologies in the field of treatment, amelioration, mitigation or prevention of diseases or conditions of the eye and its adnexa in return for certain development and sales milestone payments to be paid to Tamir. This license fee and the right to receive future milestone payments (of up to \$11 million assuming that certain milestones are reached) and royalties (of up to \$35 million based on net sales milestones), were assumed by the Company in connection with the Tamir Purchase Agreement together with a less than 10% share interest. To date, no milestones have been reached.

The Company's acquired right to Tamir's intellectual property represents a single identifiable asset sourced from the agreement. Therefore, all the fair value associated with the agreement is concentrated in one identifiable asset and is not considered a business in accordance with ASC 805-10-55-5A. The Company therefore accounted for the right to Tamir's intellectual property and other assets acquired under the agreement as an acquisition of an asset and recognized \$ 19.5 million as research and development expenses under ASC 730.

**NOTE 7 – STOCK-BASED COMPENSATION**

*a. Options Granted to employees*

The table below summarizes the terms of options for the purchase of shares in the Company granted to employees and directors during the period from January 1, 2020 to June 30, 2020:

	<b>No. of Options Granted</b>	<b>Exercise Price</b>	<b>Vesting Period</b>	<b>Fair Value at Grant (in thousands)</b>	<b>Expiration Period</b>
Employees	359,450	\$ 2.99-\$6.84	Quarterly over a period of two years 91% on the one-year anniversary and the remaining 9% in three equal installments on the first, second and third year anniversaries	768	10 years
Directors	68,750	\$ 2.99-\$4.70		\$ 147	10 years

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

	<b>During the Period from January 1, 2020 to June 30, 2020</b>
Value of one common share	\$ 2.99-\$6.84
Dividend yield	0%
Expected stock price volatility	82%-86%
Risk free interest rate	0.48%-1.71%
Expected term (years)	5.5.6

*b. Options Granted to Non-Employees*

The table below summarizes all the options for the purchase of shares in the Company granted to consultants and service providers during the period from January 1, 2020 to June 30, 2020:

	<b>No. of Options Granted</b>	<b>Exercise Price</b>	<b>Vesting Period</b>	<b>Fair Value at Grant (in thousands)</b>	<b>Expiration Period</b>
Non-employees	42,500	\$ 2.99-\$6.84	Quarterly over a period of two years	\$ 132	10 years

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

	<b>During the Period from January 1, 2020 to June 30, 2020</b>
Value of one common share	\$ 2.99-\$6.84
Dividend yield	0%
Expected stock price volatility	89%
Risk free interest rate	0.73%-1.12%
Expected term (years)	10

*c. Warrants and Shares Issued to Non-Employees*

The fair value of Common Stock issued was the share price of the shares issued at the day of grant.

During the six months ended June 30, 2020, the Company granted 193,178 warrants to several consultants at an exercise price of between \$3.14 and \$5.34 per share and exercisable for up to for three years. The fair value of those warrants as of the date of grant using the Black-Scholes valuation model was \$77 thousand.

See also Notes 4 and 5.

## NOTE 8 – LOSS PER SHARE

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

	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
	(in thousands, except per share data)			
<b>Basic:</b>				
Net loss from continuing operations attributable to Orgenesis Inc.	\$ 27,127	\$ 4,860	\$ 34,103	\$ 13,169
Net (income) loss from discontinued operations attributable to Orgenesis Inc. for loss per share	(6,721)	341	(89,252)	343
Adjustment of redeemable non-controlling interest to redemption amount	-	611	414	853
	(6,721)	952	(88,838)	1,196
Net (income) loss attributable to Orgenesis Inc. for loss per share	20,406	5,812	(54,735)	14,365
Weighted average number of common shares outstanding	21,515,254	16,001,439	19,648,042	15,772,333
Loss per common share from continuing operations	\$ 1.26	\$ 0.30	\$ 1.73	\$ 0.83
Net (earnings) loss common share from discontinued operations	\$ (0.31)	\$ 0.06	\$ (4.52)	\$ 0.08
Net (earnings) loss per share	\$ 0.95	\$ 0.36	\$ (2.79)	\$ 0.91
<b>Diluted:</b>				
Net loss from continuing operations attributable to Orgenesis Inc. for loss per share	27,127	4,860	34,103	13,169
Net (income) loss from discontinued operations attributable to Orgenesis Inc. for loss per share	(6,721)	952	(88,838)	1,196
Net (income) loss attributable to Orgenesis Inc. for loss per share	20,406	5,812	(54,735)	14,365
Weighted average number of shares used in the computation of basic and diluted loss per share	21,515,254	16,001,439	19,648,042	15,772,333
Net loss per common share from continuing operations	\$ 1.26	\$ 0.30	\$ 1.73	\$ 0.83
Net (earnings) loss per common share from discontinued operations	\$ (0.31)	\$ 0.06	\$ (4.52)	\$ 0.08
Net (earnings) loss per share	\$ 0.95	\$ 0.36	\$ (2.79)	\$ 0.91

**NOTE 9 – REVENUES***Disaggregation of Revenue*

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(in thousands)</b>			
Revenue stream:				
Cell process development services	\$ 575	\$ 169	\$ 602	\$ 588
Point-of-care services	1,174	962	3,025	962
<b>Total</b>	<b>\$ 1,749</b>	<b>\$ 1,131</b>	<b>\$ 3,627</b>	<b>\$ 1,550</b>

*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:

	<b>Six Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(in thousands)</b>	
Balance as of beginning of period	\$ 1,831	\$ 129
Additions	2,944	654
Collections	(828)	(157)
Exchange rate differences	3	(8)
<b>Balance as of end of period</b>	<b>\$ 3,950</b>	<b>\$ 618</b>

The activity for contract liabilities is comprised of:

	<b>Six Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(in thousands)</b>	
Balance as of beginning of period	\$ 325	\$ 56
Additions	597	518
Realizations	(760)	(116)
<b>Balance as of end of period</b>	<b>\$ 162</b>	<b>\$ 458</b>

## 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, 2019 as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2020. 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, 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.

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-owned subsidiaries, Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"), formerly known as CureCell, and its wholly owned subsidiaries Orgenesis Belgium SRL, a Belgian-based entity which is engaged in development and manufacturing activities, together with clinical development studies in Europe (the "Belgian Subsidiary"), Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"), Orgenesis Maryland Inc., a Maryland corporation (the "U.S. Subsidiary") and Atvio Biotech Ltd. ("Atvio"). The subsidiaries of our former subsidiary Masthercell Global Inc. ("Masthercell"), include Cell Therapy Holdings S.A., MaSTherCell, S.A. ("MaSTherCell"), a Belgian-based subsidiary and a Contract Development and Manufacturing Organization ("CDMO") specialized in cell therapy development and manufacturing for advanced medicinal products, and Masthercell U.S., LLC ("Masthercell U.S."), a U.S.-based CDMO.

### *Corporate Overview*

We are a pioneering global biotech company in the Cell & Gene Therapy ("CGT") industry focused on unlocking the full potential of personalized therapies and closed processing systems with the ultimate aim of providing life-changing treatments to large numbers of patients at reduced costs in a point-of-care setting. We pursue this strategy through a point-of-care platform ("CGT Biotech Platform") that combines therapeutics and technologies via a network of collaborative research institutes and hospitals, and including via its mobile processing units, around the world.



We had historically also operated a Contract Development and Manufacturing Organization (“CDMO”) platform, which provided contract manufacturing and development services for biopharmaceutical companies (the “CDMO Business”). On February 2, 2020, we sold our CDMO Business when we entered into a Stock Purchase Agreement (the “Purchase Agreement”) with GPP-II Masthercell LLC (“GPP” and together with the Company, the “Sellers”), Masthercell Global and Catalent Pharma Solutions, Inc. (the “Buyer”). Pursuant to the terms and conditions of the Purchase Agreement, on February 10, 2020, the Sellers sold 100% of the outstanding equity interests of Masthercell Global to Buyer (the “Masthercell Sale”) for an aggregate nominal purchase price of \$315 million, subject to customary adjustments. After accounting for GPP’s liquidation preference and equity stake in Masthercell as well as other investor interests in MaSTherCell, distributions to Masthercell Global option holders and transaction costs, we received approximately \$126.7 million. We determined that the Masthercell Global business (“Discontinued Operation”) met the criteria to be classified as a discontinued operation as of the first quarter of 2020. The Discontinued Operation includes most of the previous CDMO Business, including majority-owned Masthercell Global, including its subsidiaries Cell Therapy Holdings S.A., MaSTherCell and Masthercell U.S. (collectively, the “Masthercell Global Subsidiaries”).

We conduct our operations through our wholly-owned subsidiaries. The subsidiaries are as follows:

- United States: Orgenesis Maryland Inc. (the “U.S. Subsidiary”) is the center of activity in North America currently focused on technology licensing and the setting up of the POCare Network (as defined below).
- European Union: Orgenesis Belgium SRL (the “Belgian Subsidiary”) is the center of activity in Europe currently focused on process development and preparation of European clinical trials.
- Israel: Orgenesis Ltd. (the “Israeli Subsidiary”) is the center for research and technology, as well as a provider of regulatory, clinical and pre-clinical services, and Atvio Biotech Ltd. (“Atvio”) is a provider of cell-processing services in Israel.
- Korea: Orgenesis Korea Co. Ltd. (the “Korean Subsidiary”), previously known as CureCell Co. Ltd., is a provider of processing and pre-clinical services in Korea. We own 94.12% of the Korean Subsidiary.

#### *CGT Biotech Platform*

#### **Business Strategy**

Our CGT Biotech Platform consists of: (a) POCare Therapeutics, a pipeline of licensed CGTs, anti-viral and proprietary scientific know-how; (b) POCare Technologies, a suite of proprietary and in-licensed technologies which are engineered to create customized processing systems for affordable point-of-care therapies; and (c) a POCare Network, a collaborative, international ecosystem of leading research institutions and hospitals committed to clinical development and supply of CGTs at the point-of-care (“POCare Network”). By combining science, technologies and a collaborative network, we believe that we are able to identify the most promising new autologous therapies and provide a pathway for them to reach patients more quickly, more efficiently and in a scalable way, thereby unlocking the power of cell and gene therapy for all patients. Autologous therapies are produced from a patient’s own cells, instead of mass-cultivated donor-cells, or allogeneic cells. Allogeneic therapies are derived from donor cells and, through the construction of master and working cell banks, are produced on a large scale. Autologous therapies are derived from the treated patient and manufactured through a defined protocol before re-administration and generally demand a more complex supply chain. Currently with the CGT market relying heavily on production and supply chain of manufacturing sites, we believe our CGT Biotech Platform may help overcome some of the development and supply challenges with bringing these therapies to patients.

In pursuit of this focus, we have been forming key strategic relationships with leading research institutions and hospitals around the world. We are also licensing breakthrough technologies, including via our mobile processing units, that complement our offerings and support our model. As a result, we believe that we now have significant expertise and capabilities across a wide range of therapies and supporting technologies including, but not limited to, Tumor Infiltrating Lymphocytes (“TILs”), CAR-T and CAR-NK, dendritic cell technologies, exosomes and bioxomes and viral vectors. We believe that these capabilities enable us to launch an aggressive push into a wide array of promising new potential therapies.

We are developing an efficient and streamlined organization, whereby we are able to share both costs and revenues with our partners in order to avoid the historically high development costs associated with CGT drug development. We believe we have developed a truly unique model with the ability to cost-effectively develop and produce CGTs at scale, which we believe has the potential to transform the CGT industry.

We consider the following to be the four pillars in order to advance our business strategy under our CGT Biotech Platform:

- Innovation– This leverages our unique know-how and expertise for industrial processes, operational excellence, process development and optimization, quality control assays development, quality management systems and regulatory expertise.
- Systems– We are developing cell production cGMP systems utilizing sensor technology and unique systems for biological production, closed system technology for processing cells, proprietary virus/ media technologies and partnerships with key system providers.
- Cell & Gene Products– We intend to grow our internal asset pipeline consisting of our unique portfolio of immuno-oncology related technologies, anti-viral therapies, MSC and liver-based therapies and secretome-based therapies.
- Distribution– This is our POCare Network which is designed to enable development, commercialization and distribution of CGTs via the installation of point-of-care systems in major hospitals in key geographies (i.e., Europe, North America, Asia, South America etc.), thereby creating a regional and international system network to serve as our distribution channel.

While our CGT Biotech Platform is currently limited to early stage development to overcome certain industry challenges, we intend to continue developing our global POCare Network, with the goal of developing CGTs via joint ventures with partners who bring strong regional networks. Such networks include partnerships with leading research institutions and local hospitals which allows us to engage in continuous in-licensing of, namely, autologous therapies from academia and research institutes, co-development of hospital and academic-based therapies, and utilization of hospital networks for clinical development of therapies.

Our IP portfolio includes trans-differentiation technology licensed by our Israeli Subsidiary. Our development plan calls for conducting additional pre-clinical safety and efficacy studies with respect to diabetes and other potential indications prior to initiating human clinical trials.

We own or have exclusive rights to twenty eight (28) United States, thirty (30) foreign-issued patents, twenty nine (29) pending applications in the United States, fifty seven (57) pending applications in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Panama, Russia, Singapore, South Africa, and South Korea, and four (4) international Patent Cooperation Treaty (“PCT”) patent applications. These patents and applications relate, among others, to (1) the trans-differentiation of cells (including hepatic cells) to cells having pancreatic  $\beta$ -cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis; (2) scaffolds, including alginate and sulfated alginate scaffolds, polysaccharides thereof, and scaffolds for use for cell propagation, trans-differentiation, and transplantation in the treatment of autoimmune diseases, including diabetes; (3) bioconjugates comprising sulfated polysaccharides and diverse bioactive peptides, and their use in the treatment of inflammatory conditions; (4) bioreactors for cell culture; (5) dendritic and macrophages based vaccines; (6) compositions comprising ranpimase and their use in the treatment of viral diseases; (7) tumor infiltrating lymphocytes (TILs) and their use for treating cancer; (8) compositions and methods for treating COVID-19; (9) methods for producing antibodies; and (10) cysteinized ribonucleases. In June 2019, the United States Food & Drug Administration (the “FDA”) granted us the Orphan Drug designation for our Autologous Insulin Producing (“AIP”) cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy (“TP”) due to chronic pancreatitis (“CP”).

## Revenue Model

We believe that our CGT Biotech Platform is a novel business model in that it brings autologous therapies in a cost-effective, high-quality and scalable manner to patients. We believe that this approach is an attractive proposition for personalized medicine because point-of-care therapy facilitates the development of technologies through our strategic partnerships and utilizes closed systems that have the potential of reducing the required grade of clean room facilities, thus substantially reducing manufacturing costs. Furthermore, cell transportation, which is a high-risk and costly aspect of the supply chain, could be minimized or eliminated. We are establishing and positioning our CGT Biotech Platform in order to bring therapies to patients in a scalable way via a network of leading research institutions and hospitals committed to clinical development and supply of CGTs, including facilities in Germany, Austria, Greece, the U.S., Korea and India, or otherwise referred to as our POCare Network. We established our POCare Network through licensing, collaboration and joint venture agreements. Once established, along with our POCare Therapeutics and POCare Technologies, this network can then reach patients at the point-of-care. Our POCare Therapeutics and POCare Technologies allow us to offer a range of technologies and processes to provide CGTs worldwide that potentially generate revenues within our POCare Network. This includes:

- **Development Services** – These are services for industrial manufacturing know-how to our network of licensing partners, thus reducing cost of goods and facilitating regulatory scrutiny, higher automation level required to increase process robustness and reduce attrition rates, biological assay development, assay validation and assay optimization.
- **Licensing Fees** – Such fees are for (a) innovative technologies such as scaffolds and IoT sensors and closed system-related technologies that allow autologous cell manufacturing in lower grade clean rooms and (b) out-licensing of our portfolio of CGTs to our POCare Network.
- **Point-of-Care Services** – This includes regulatory, development and training assistance to local partners who bring strong regional networks through (a) joint venture partnerships with local hospitals, (b) local regulatory know-how, and (c) local therapeutic development.

Recent Developments During the Three Months Ended June 30, 2020

### Tamir Biotechnology, Inc.

On April 7, 2020, the Company entered into an Asset Purchase Agreement (the “Tamir Purchase Agreement”) with Tamir Biotechnology, Inc. (“Tamir” or “Seller”), pursuant to which the Company agreed to acquire certain assets and liabilities of Tamir related to the discovery, development and testing of therapeutic products for the treatment of diseases and conditions in humans, including all rights to Ranpirnase and use for antiviral therapy (collectively, the “Purchased Assets and Assumed Liabilities” and such acquisition, the “Tamir Transaction”). The Tamir Transaction closed on April 23, 2020.

The Tamir Transaction closed upon the occurrence of the closing conditions contained in the Tamir Purchase Agreement. As aggregate consideration for the Acquisition, the Company paid \$2.462 million in cash and issued an aggregate of 3,400,000 shares (the “Shares”) of Common Stock to Tamir resulting in a total consideration of \$20.2 million. \$59 thousand and 340,000 Shares will be held in an escrow account for a period of 18 months from closing to secure indemnification obligations of Tamir pursuant to the terms of the Tamir Purchase Agreement.

### Coronavirus disease 19 (COVID-19)

Due to the global outbreak of SARS-CoV-2, the novel strain of coronavirus that causes Coronavirus disease 19 (COVID-19), we experienced minor impacts on certain aspects of our business during the three months ended June 30, 2020. The scope and duration of any disruptions, for example, as a result of governmental “stay at home” orders in the interests of public health and safety and the ultimate impacts of COVID-19 on our operations, are currently unknown. We are continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety and that of our patient community, employees, partners, and stockholders. We cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may have on our business, strategy, collaborations, or financial and operating results.

**Comparison of the Three Months Ended June 30, 2020 to the Three Months Ended June 30, 2019.**

The following table presents our results of operations for the three months ended June 30, 2020 and 2019:

	<b>Three-Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(In Thousands)</b>	
Revenues	\$ 1,470	\$ 575
Revenues to Related Party	279	556
Cost of Revenues	243	1,007
Cost of research and development and research and development services	24,720	2,073
Amortization of intangible assets	(52)	108
Selling, general and administrative expenses	3,611	2,789
Financial expenses, net	337	47
Other income, net	(1)	(1)
Loss before income taxes	<u>\$ 27,109</u>	<u>\$ 4,892</u>

Our revenues for the three months ended June 30, 2020 were \$1,749 thousand, as compared to \$1,131 thousand for the three months ended June 30, 2019, representing an increase of 55%. The increase in revenues for the three months ended June 30, 2020 is attributable to the increase in point-of-care services revenue.

**Expenses**

Research and Development and Research and Development Services Expenses

	<b>Three-Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(In Thousands)</b>	
Salaries and related expenses	\$ 1,244	\$ 586
Stock-based compensation	134	132
Professional fees and consulting services	573	516
Lab expenses	443	649
Tamir purchase agreement, see Note 6	19,510	-
Depreciation expenses, net	114	108
Other research and development expenses	2,755	391
Less – grant	(53)	(309)
Total	<u>\$ 24,720</u>	<u>\$ 2,073</u>

Research and development expenses for the three months ended June 30, 2020 were \$24,720 thousand, as compared to \$2,073 thousand for the three months ended June 30, 2019, representing an increase of 1092%. The increase is mainly attributable to the following:

- An increase in salaries and related expenses and other research and development expenses.

Additional R&D staff were hired as the Company expanded its research and development to the evaluation and development of new cell therapies and related technologies in the field of immune-oncology (our novel CD19 CAR-T and CD19.22 CAR-T programs, cellular vaccination for solid cancers, advanced Tumor infiltrating lymphocyte, NK-based therapies, etc.), liver pathologies, stem cell based therapies and other cell based technologies such as the novel delivery system, Bioxomes. The Company invested in converting biological processes to GMP-compliant processes as these therapies progress to clinical stage.

- The Tamir purchase agreement (See Note 6).

On April 7, 2020, the Company entered into the Tamir Purchase Agreement with Tamir pursuant to which it agreed to acquire certain assets and liabilities of Tamir related to the discovery, development and testing of therapeutic products for the treatment of diseases and conditions in humans, including all rights to Ranpirnase and use for antiviral therapy. The Company's acquired right to Tamir's intellectual property represents a single identifiable asset sourced from the agreement. Therefore, all the fair value associated with the agreement is concentrated in one identifiable asset and is not considered a business in accordance with ASC 805-10-55-5A. The Company therefore accounted for the right to Tamir's intellectual property and other assets acquired under the agreement as an acquisition of an asset and recognized \$19.5 million as Research and Development expenses under ASC 730.

#### Selling, General and Administrative Expenses

	<b>Three-Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(In Thousands)</b>	
Salaries and related expenses	\$ 367	\$ 772
Stock-based compensation	697	615
Accounting and legal fees	1,793	496
Professional fees	389	149
Rent and related expenses	68	194
Business development	175	339
Depreciation expenses, net	25	53
Other general and administrative expenses	97	171
<b>Total</b>	<b>\$ 3,611</b>	<b>\$ 2,789</b>

Selling, general and administrative expenses for the three months ended June 30, 2020 were \$3,611 thousand, as compared to \$2,789 thousand for the three months ended June 30, 2019, representing an increase of 29%. The increase in selling, general and administrative expenses in the three months ended in June 2020 compared to the three months ended June 30, 2019 is primarily attributable to (i) An increase in accounting and legal fees of \$1,297 thousand, which is mainly attributable to additional legal fees incurred for recent business and collaboration agreements and (ii) An increase in professional fees of \$240 thousand.

#### Financial Expenses, net

	<b>Three-Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(In Thousands)</b>	
Interest expense on convertible loans and loans	\$ 317	\$ 9
Foreign exchange loss (gain), net	108	(5)
Other expenses (income)	(88)	43
<b>Total</b>	<b>\$ 337</b>	<b>\$ 47</b>

Financial expenses, net for the three months ended June 30, 2020 were \$337 thousand, as compared to \$47 thousand for the three months ended June 30, 2019, representing an increase of 617%. The increase is primarily attributable to interest expenses on convertible loans.

**Comparison of the Six Months Ended June 30, 2020 to the Six Months Ended June 30, 2019.**

The following table presents our results of operations for the six months ended June 30, 2020 and 2019:

	<b>Six Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(In Thousands)</b>	
Revenues	\$ 2,855	\$ 994
Revenues to Related Party	772	556
Cost of Revenues	413	1,312
Cost of research and development and research and development services	29,423	7,373
Amortization of intangible assets	171	217
Selling, general and administrative expenses	7,129	5,775
Financial expenses, net	666	148
Other income, net	(4)	(4)
Loss before income taxes	<u>\$ 34,171</u>	<u>\$ 13,271</u>

Our revenues for the six months ended June 30, 2020 were \$3,627 thousand, as compared to \$1,550 thousand for the six months ended June 30, 2019, representing an increase of 134%. The increase in revenues for the six months ended June 30, 2020 is attributable to the increase in point-of-care services revenue as a result of increased activity under master service agreements with our joint venture partners.

**Expenses**

Research and Development and Research and Development Services Expenses

	<b>Six Months Ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>(In Thousands)</b>	
Salaries and related expenses	\$ 2,090	\$ 1,218
Stock-based compensation	218	299
Professional fees and consulting services	973	1,468
Lab expenses	1,047	1,405
First Choice JVA	-	2,741
Tamir purchase agreement, Note 6	19,510	-
Depreciation expenses, net	218	195
Other research and development expenses	5,505	612
Less – grant	(138)	(565)
Total	<u>\$ 29,423</u>	<u>\$ 7,373</u>

Research and development expenses for the six months ended June 30, 2020 were \$29,423 thousand, as compared to \$7,373 thousand for the six months ended June 30, 2019, representing an increase of 299%.

The increase in research and development and development services is mainly attributable to increases in salaries and related expenses and other research and development expenses as well as the Tamir purchase agreement as detailed above in the “Comparison of the Three Months Ended June 30, 2020 to the Three Months Ended June 30, 2019”.

Selling, General and Administrative Expenses

	Six Months Ended	
	June 30, 2020	June 30, 2019
	(In Thousands)	
Salaries and related expenses	\$ 869	\$ 1,362
Stock-based compensation	1,028	1,397
Accounting and legal fees	3,417	1,221
Professional fees	826	426
Rent and related expenses	129	224
Business development	425	676
Depreciation expenses, net	50	53
Other general and administrative expenses	385	416
Total	<u>\$ 7,129</u>	<u>\$ 5,775</u>

Selling, general and administrative expenses for the six months ended June 30, 2020 were \$7,129 thousand, as compared to \$5,775 thousand for the six months ended June 30, 2019, representing an increase of 23%. The increase in selling, general and administrative expenses in the six months ended in June 2020 compared to the six months ended June 30, 2019 is primarily attributable to the following:

- (i) A decrease in salaries and related expenses of \$493 thousand, due to the accrual of related expenses in the six months ended June 30, 2019, and the reassignment of certain employees from selling, general, and administration to research and development services;
- (ii) An increase in accounting and legal fees of \$2,196 thousand, which is mainly attributable to legal fees incurred for recent business and collaboration agreements; and
- (iii) An increase in professional fees of \$400 thousand, which is related to the increase in the related activities.

Financial Expenses, net

	Six Months Ended	
	June 30, 2020	June 30, 2019
	(In Thousands)	
Interest expense on convertible loans and loans	\$ 739	\$ 11
Foreign exchange loss, net	165	76
Other expenses (income)	(238)	61
Total	<u>\$ 666</u>	<u>\$ 148</u>

Financial expenses, net for the six months ended June 30, 2020 were \$666 thousand, as compared to \$148 thousand for the six months ended June 30, 2019, representing an increase of 350%. The increase is primarily attributable to interest expenses on convertible loans.

## Working Capital

	June 30, 2020	December 31, 2019
	(In Thousands)	
Current assets	\$ 104,312	\$ 78,348
Current liabilities	19,758	42,434
Working capital gain	\$ 84,554	\$ 35,914

Current assets increased, and current liabilities decreased, primarily due to the Masthercell sale.

## Liquidity and Financial Condition

	Six Months Ended	
	June 30, 2020	June 30, 2019
	(In Thousands)	
Net income (loss)	\$ 54,624	\$ (14,275)
Net cash used in operating activities	(22,834)	(8,168)
Net cash provided by (used in) investing activities	102,772	(3,947)
Net cash provided by financing activities	6,159	13,796
Increase in cash and cash equivalents	\$ 86,097	\$ 1,681

As mentioned in above, on February 2, 2020, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with GPP-II Masthercell LLC ("GPP" and together with us, the "Sellers"), Masthercell Global Inc. ("Masthercell") and Catalent Pharma Solutions, Inc. (the "Buyer"). Pursuant to the terms and conditions of the Purchase Agreement, on February 10, 2020, the Sellers sold 100% of the outstanding equity interests of Masthercell to Buyer (the "Masthercell Sale") for an aggregate nominal purchase price of \$315 million, subject to customary adjustments. After accounting for GPP's liquidation preference and equity stake in Masthercell as well as SFPI – FPIM's interest in MaSTherCell, distributions to Masthercell option holders and transaction costs, we received approximately \$126.7 million, of which \$7.2 million was used for the repayment of intercompany loans and payables.

During the six month period ended June 30, 2020, we funded our operations from the Masthercell sale and through various financing activities consisting of proceeds primarily from private placements of our equity securities, debt securities and equity-linked instruments in the net amount of approximately \$9.4 million.

Net cash used in operating activities for the six months ended June 30, 2020 was approximately \$23 million, as compared to net cash used in operating activities of approximately \$8 million for the six months ended June 30, 2019.

Net cash provided by investing activities for the six months ended June 30, 2020 was approximately \$103 million, as compared to net cash used in investing activities of approximately \$4 million for the six months ended June 30, 2019.

### Liquidity & Capital Resources Outlook

We believe that the proceeds from the Masthercell Sale, as well as our business plan, will provide sufficient liquidity to fund our operating needs for at least the next 12 months. However, 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.



The net proceeds of approximately \$126.7 million from the sale of Masthercell were used for the repayment of \$7.2 million of intercompany loans and payables. In addition, on January 20, 2020, we entered into a Securities Purchase Agreement with certain investors pursuant to which we issued an aggregate of 2,200,000 shares of Common Stock and warrants to purchase up to an aggregate of 1,000,000 shares of Common Stock, which resulted in our receipt of gross proceeds of approximately \$9.24 million before deducting related offering expenses.

If there are further increases in operating costs in general and administrative expenses for facilities expansion, funding for some of our collaborations and joint ventures, research and development, commercial and clinical activity or decreases in revenues from customers, we may decide to seek additional financing.

#### Off-Balance Sheet Arrangements

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

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

#### ITEM 4. CONTROLS AND PROCEDURES

##### *Evaluation of Disclosure Controls and Procedures*

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

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

##### *Changes in Internal Control Over Financial Reporting*

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2020 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, 2019, as filed with the SEC on March 9, 2020, in addition to other information contained in our reports and in this quarterly report in evaluating the Company and its business before purchasing shares of our Common Stock. Except as set forth below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2019. The Company's business, operating results and financial condition could be adversely affected due to any of those risks. In addition:

#### *The coronavirus outbreak has the potential to cause disruptions in our business, including our clinical development activities*

The outbreak of the novel strain of coronavirus, or COVID-19, has currently impacted and may continue to impact our business, including our preclinical studies and clinical trials. COVID-19 has spread to multiple countries, including the United States and Israel, where the Company conducts its operations.

Efforts to contain the spread of COVID-19 have intensified and the United States and Israel, among other countries, have implemented and may continue to implement severe travel restrictions, shelter in place orders, social distancing and delays or cancellations of elective surgeries. These and other disruptions have caused, and may continue to cause, a delay in the supply of consumable goods, which could result in further delays and affect our ability to commercialize and develop our product candidates.

The spread of an infectious disease, including COVID-19, may also result in a period of business disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. Although, as of the date of this Quarterly Report on Form 10-Q, we do not expect any material impact on our long-term activity, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

### ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits required by Item 601 of Regulation S-K

<b>No.</b>	<b>Description</b>
<b>(10)</b>	<b>Material Contracts</b>
10.1	<a href="#">Asset Purchase Agreement, dated April 12, 2020, by and between Orgogenesis Inc., and Tamir Biotechnology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 13, 2020).</a>
<b>(31)</b>	<b>Rule 13a-14(a)/15d-14(a) Certification</b>
31.1*	<a href="#">Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002</a>
31.2*	<a href="#">Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002</a>
<b>(32)</b>	<b>Section 1350 Certification</b>
32.1*	<a href="#">Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002</a>
32.2*	<a href="#">Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002</a>
<b>(101)*</b>	<b>Interactive Data Files</b>
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: August 6, 2020

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

Date: August 6, 2020

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

I, Vered Caplan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 of Orgenesis Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Vered Caplan  
Vered Caplan  
President & Chief Executive Officer  
(Principal Executive Officer)

Date: August 6, 2020

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

I, Neil Reithinger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 of Orgenesis Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: August 6, 2020

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

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

- (a) The Quarterly Report on Form 10-Q of Orgenesis Inc. for the quarter ended June 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (b) Information contained in the Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Orgenesis Inc.

By: /s/ Vered Caplan

Vered Caplan  
President & Chief Executive Officer  
(Principal Executive Officer)

Date: August 6, 2020

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

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

- (a) The Quarterly Report on Form 10-Q of Orgenesis Inc. for the quarter ended June 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (b) Information contained in the Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Orgenesis Inc.

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

Date: August 6, 2020

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