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

# FORM 10-Q

(Mark One)

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

**For the Quarterly Period Ended September 30, 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** | **98-0583166** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**20271 Goldenrod Lane**
**Germantown, MD 20876**
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☒ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

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

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

As of November 5, 2020, there were24,156,183 shares of registrant's common stock outstanding.

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

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ITEM 1. FINANCIAL STATEMENTS

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

| | As of | |
|---|---|---|
| | **September 30, 2020** | **December 31, 2019** |
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 88,758 | $ 107 |
| Restricted cash | 466 | 467 |
| Accounts receivable, net | 4,077 | 1,831 |
| Prepaid expenses and other receivables | 1,324 | 382 |
| Grants receivable | 205 | 204 |
| Inventory | 153 | 136 |
| Current assets of discontinued operations, see Note 3 | - | 75,221 |
| Total current assets | 94,983 | 78,348 |
| **NON-CURRENT ASSETS:** | | |
| Deposits | $ 276 | $ 299 |
| Loans to related party, see Note 6 | 3,256 | 2,623 |
| Property, plant and equipment, net | 2,560 | 2,305 |
| Intangible assets, net | 3,041 | 3,348 |
| Operating lease right-of-use assets | 954 | 725 |
| Goodwill | 4,763 | 4,812 |
| Other assets | 919 | 35 |
| Total non-current assets | 15,769 | 14,147 |
| **TOTAL ASSETS** | $ 110,752 | $ 92,495 |

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

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

| | As of | |
|---|---|---|
| | **September 30, 2020** | **December 31, 2019** |
| **Liabilities and Equity** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable | $ 3,587 | $ 5,549 |
| Accrued expenses and other payables | 1,032 | 1,615 |
| Income tax payable | 5,388 | - |
| Employees and related payables | 1,116 | 1,672 |
| Advance payments on account of grant | 361 | 523 |
| Short-term loans and current maturities of long- term loans | - | 391 |
| Contract liabilities, mainly related party | 163 | 325 |
| Current maturities of long-term finance leases | 20 | - |
| Current maturities of operating leases | 295 | 357 |
| Current maturities of convertible loans | 393 | 416 |
| Current liabilities of discontinued operations, see Note 3 | - | 31,586 |
| Total current liabilities | 12,355 | 42,434 |
| **LONG-TERM LIABILITIES:** | | |
| Non-current operating leases | $ 678 | $ 455 |
| Convertible loans | 10,503 | 12,143 |
| Retirement benefits obligation | 49 | 41 |
| Deferred taxes | 3 | 58 |
| Long-term finance leases | 63 | - |
| Other long-term liabilities | 293 | 331 |
| Total long-term liabilities | 11,589 | 13,028 |
| **TOTAL LIABILITIES** | 23,944 | 55,462 |
| **COMMITMENTS** | - | - |
| **REDEEMABLE NON-CONTROLLING INTEREST OF DISCONTINUED OPERATIONS** | - | 30,955 |
| **EQUITY:** | | |
| 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 September 30, 2020 and December 31, 2019, respectively | 2 | 2 |
| Additional paid-in capital | 123,073 | 94,691 |
| Accumulated other comprehensive income | 292 | 213 |
| Accumulated deficit | (36,707) | (89,429) |
| Equity attributable to Orgenesis Inc. | 86,660 | 5,477 |
| Non-controlling interest | 148 | 601 |
| Total equity | 86,808 | 6,078 |
| **TOTAL LIABILITIES AND EQUITY** | $ 110,752 | $ 92,495 |

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

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

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, 2020 | September 30, 2019 | September 30, 2020 | September 30, 2019 |
| Revenues | $ 1,450 | $ 543 | $ 4,305 | $ 1,537 |
| Revenues from related party | 279 | 689 | 1,051 | 1,245 |
| Total revenues | 1,729 | 1,232 | 5,356 | 2,782 |
| Cost of research and development and research and development services, net | 6,951 | 2,508 | 36,787 | 11,193 |
| Amortization of intangible assets | 87 | 106 | 258 | 323 |
| Selling, general and administrative expenses | 4,042 | 2,412 | 11,171 | 8,437 |
| Other income, net | (5) | (11) | (9) | (15) |
| Operating loss | 9,346 | 3,783 | 42,851 | 17,156 |
| Financial expenses, net | 238 | 446 | 904 | 594 |
| Loss from continuing operation before income taxes | 9,584 | 4,229 | 43,755 | 17,750 |
| Tax income | (18) | (44) | (53) | (112) |
| Net loss from continuing operation | 9,566 | 4,185 | 43,702 | 17,638 |
| Net loss (income) from discontinued operations, net of tax, see Note 3 | (7,132) | 729 | (95,892) | 1,551 |
| Net loss (income) | 2,434 | 4,914 | (52,190) | 19,189 |
| Net loss attributable to non-controlling interests from continuing operation | (7) | (19) | (40) | (53) |
| Net loss attributable to non-controlling interests (including redeemable) from discontinued operations | - | (346) | (492) | (1,075) |
| Net loss (income) attributable to Orgenesis Inc. | 2,427 | 4,549 | (52,722) | 18,061 |
| | | | | |
| Loss (earnings) per share: | | | | |
| Basic from continuing operations | $ 0.43 | $ 0.26 | $ 2.13 | $ 1.11 |
| Basic from discontinued operations | $ (0.32) | $ 0.18 | $ (4.69) | $ 0.24 |
| Net loss (earnings) loss per share | $ 0.11 | $ 0.44 | $ (2.56) | $ 1.35 |
| | | | | |
| Diluted from continuing operations | $ 0.43 | $ 0.26 | $ 2.13 | $ 1.11 |
| Diluted from discontinued operations | $ (0.32) | $ 0.18 | $ (4.69) | $ 0.24 |
| Net loss (earnings) per share | $ 0.11 | $ 0.44 | $ (2.56) | $ 1.35 |
| | | | | |
| Weighted average number of shares used in computation of Basic and Diluted loss (earnings) per share: | | | | |
| Basic | 22,094,470 | 16,028,518 | 20,469,470 | 15,858,666 |
| Diluted | 22,094,470 | 16,028,518 | 20,469,470 | 15,858,666 |
| | | | | |
| Comprehensive loss (income): | | | | |
| Net loss from continuing operations | $ 9,566 | $ 4,185 | $ 43,702 | $ 17,638 |
| Net loss (income) from discontinued operations, net of tax | (7,132) | 729 | (95,892) | 1,551 |
| Other comprehensive loss (income)- translation adjustments | (282) | 1,124 | 115 | 1,420 |
| Release of translation adjustment due to sale of subsidiary | - | - | (194) | - |
| Comprehensive loss (income) | 2,152 | 6,038 | (52,269) | 20,609 |
| Comprehensive income attributed to non-controlling interests (including redeemable) from continuing operations | (7) | (19) | (40) | (53) |
| Comprehensive income attributed to non-controlling interests (including redeemable) from discontinued operations | - | (346) | (492) | (1,075) |
| Comprehensive loss (income) attributed to Orgenesis Inc. | $ 2,145 | $ 5,673 | $ (52,801) | $ 19,481 |

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

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

| | Common Stock | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Number | Par Value | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Equity Attributed to Orgenesis Inc. | Non-Controlling Interest | Total |
| Balance at January 1, 2020 | 16,140,962 | $ 2 | $ 94,691 | $ 213 | $ (89,429) | $ 5,477 | $ 601 | $ 6,078 |
| Changes during the nine months ended September 30, 2020: | | | | | | | | |
| Stock-based compensation to employees and directors | - | - | 1,178 | - | - | 1,178 | - | 1,178 |
| Stock-based compensation to service providers | **270,174 | * | 1,090 | - | - | 1,090 | - | 1,090 |
| Stock-based compensation for Tamir purchase agreement, 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 | - | - | - | 79 | 52,722 | 52,801 | (40) | 52,761 |
| Balance at September 30, 2020 | 22,094,470 | $ 2 | $ 123,073 | $ 292 | $ (36,707) | $ 86,660 | $ 148 | $ 86,808 |

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

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

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

| | Common Stock | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Number | Par Value | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Equity Attributed to Orgenesis Inc. | Non-Controlling Interest | Total |
| **Balance at January 1, 2019** | 15,540,333 | $ 2 | $ 90,597 | $ 669 | $ (65,163) | $ 26,105 | $ 645 | $ 26,750 |
| **Changes during the nine months ended September 30, 2019:** | | | | | | | | |
| Stock-based compensation to employees and directors | - | - | 1,846 | - | - | 1,846 | 42 | 1,888 |
| Stock-based compensation to service providers | 75,629 | * | 538 | - | - | 538 | - | 538 |
| Stock based Compensation for JV collaborations | 525,000 | * | 2,641 | - | - | 2,641 | - | 2,641 |
| Transaction With noncontrolling interest GPP | - | - | 2,034 | - | - | 2,034 | - | 2,034 |
| Adjustment to redemption value of redeemable non-controlling interest | - | - | (3,314) | - | - | (3,314) | - | (3,314) |
| Issuance of warrants with respect to convertible loans | - | - | 97 | - | - | 97 | - | 97 |
| Comprehensive loss for the period | - | - | - | (1,420) | (18,061) | (19,481) | (56) | (19,537) |
| **Balance at September 30, 2019** | 16,140,962 | $ 2 | $ 94,439 | $ (751) | $ (83,224) | $ 10,466 | $ 631 | $ 11,097 |

* 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 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Number | Par Value | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Equity Attributed to Orgenesis Inc. | Non-Controlling Interest | Total |
| **Balance at July 1, 2020** | 22,094,470 | $ 2 | $ 122,502 | $ 10 | $ (34,280) | $ 88,234 | $ 155 | $ 88,389 |
| **Changes during the three months ended September 30, 2020:** | - | - | | - | | | | |
| Stock-based compensation to employees and directors | - | - | 268 | - | - | 268 | - | 268 |
| Stock-based compensation to service providers | - | - | 303 | - | - | 303 | - | 303 |
| Comprehensive income (loss) for the period | - | - | - | 282 | (2,427) | (2,145) | (7) | (2,152) |
| **Balance at September 30, 2020** | 22,094,470 | $ 2 | $ 123,073 | $ 292 | $ (36,707) | $ 86,660 | $ 148 | $ 86,808 |

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

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

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

| | Common Stock | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Number | Par Value | Additional Paid-in Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Equity Attributed to Orgenesis Inc. | Non-Controlling Interest | Total |
| **Balance at July 1, 2019** | 16,115,333 | $ 2 | $ 94,415 | $ 373 | $ (78,675) | $ 16,115 | $ 639 | $ 16,754 |
| **Changes during the three months ended September 30, 2019:** | | | | | | | | |
| Stock-based compensation to employees and directors | - | - | 380 | - | - | 380 | 11 | 391 |
| Stock-based compensation to service providers | 25,629 | * | 71 | - | - | 71 | - | 71 |
| Transaction With noncontrolling interest GPP | - | - | 2,034 | - | - | 2,034 | - | 2,034 |
| Adjustment to redemption value of redeemable non-controlling interest | - | - | (2,461) | - | - | (2,461) | - | (2,461) |
| Comprehensive income (loss) for the period | - | - | - | (1,124) | (4,549) | (5,673) | (19) | (5,692) |
| **Balance at September 30, 2019** | 16,140,962 | $ 2 | $ 94,439 | $ (751) | $ (83,224) | $ 10,466 | $ 631 | $ 11,097 |

* represent an amount lower than $ 1 thousand

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

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

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net income (loss) | $ 52,190 | $ (19,189) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 2,268 | 2,426 |
| Stock-based compensation to strategic collaborations | - | 2,641 |
| Stock-based compensation for Tamir Purchase Agreement, see Note 4 and Note 6 | 17,048 | - |
| Capital loss (gain), net | 14 | (49) |
| Gain on disposal of subsidiaries | (102,534) | - |
| Depreciation and amortization expenses | 1,004 | 2,843 |
| Effect of exchange differences on inter-company balances | 171 | 205 |
| Net changes in operating leases | 4 | (531) |
| Interest expenses accrued on loans and convertible loans (including amortization of beneficial conversion feature) | 397 | 181 |
| Changes in operating assets and liabilities: | | |
| Increase in accounts receivable | (2,569) | (2,048) |
| Increase in inventory | (96) | (291) |
| Increase in other assets | (136) | (1) |
| Decrease (increase) in prepaid expenses and other accounts receivable | (1,358) | 179 |
| Increase (decrease) in accounts payable | (2,882) | 1,652 |
| Increase in accrued expenses and other payables | 4,528 | 152 |
| Increase (decrease) in employee and related payables | (536) | 424 |
| Increase (decrease) in contract liabilities | (63) | 801 |
| Change in advance payments and receivables on account of grant, net | (186) | (314) |
| Increase (decrease) in deferred taxes liability | (83) | 405 |
| Net cash used in operating activities | $ (32,819) | $ (10,514) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Increase in loan to JV with a related party | (500) | (1,000) |
| Sale of property and equipment | 4 | 80 |
| Purchase of property and equipment | (1,292) | (6,122) |
| Proceed from sale of subsidiaries, net | 105,634 | - |
| Repayment (investment) in short term deposits | 19 | (227) |
| Net cash provided by (used in) investing activities | $ 103,865 | $ (7,269) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| 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 | (438) | (452) |
| Proceeds from issuance of loans payable | - | 34 |
| Net cash provided by financing activities | $ 6,150 | $ 13,682 |
| **NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH** | $ 77,196 | $ (4,101) |
| **EFFECT OF EXCHANGE RATE CHANGES ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH** | (13) | (191) |
| **CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD** | 12,041 | 14,999 |
| **CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD (*)** | $ 89,224 | $ 10,707 |
| **SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES** | | |
| Finance leases of property, plant and equipment | $ 365 | $ 65 |
| Acquisition of other asset | $ 700 | $ - |
| Right-of-use assets obtained in exchange for new operating lease liabilities, net | $ 653 | $ - |
| Purchase of property, plant and equipment included in accounts payable | $ 286 | $ 1,183 |
| Transaction costs of issuance of convertible loans | $ - | $ 400 |

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

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

## 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").

The Company is committed to the validation, adoption and development of systems, technologies and processes for mobile processing unit and labs ("OMPUL"). OMPULs are intended to be used and/or distributed through Company's point of care network of partners, collaborators and joint ventures for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved cell or gene therapy products in a safe, reliable and cost-effective manner. This provides an industrial solution for any clinical institution in the world to provide more therapies at the point of care.

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, thus enabling wide-scale access to these life-changing treatments.

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 the vast majority 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).

Since the Masthercell Sale, the Company has entered into restated and updated joint venture agreements with some of its joint venture partners and new joint venture agreements with new partners in various jurisdictions. This has allowed the Company to grow its infrastructure and expand its processing sites into new markets and jurisdictions. In addition, the Company has engaged some of these joint venture partners to perform research and development services to improve the Orgenesis Background IP. It also has allowed the Company the manpower and financial resources to focus on manufacturing and rolling out OMPULs to be used and/or distributed through Company's point of care network of partners, collaborators and joint ventures.

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.
- 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, Atvio and the Korean subsidiary, 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 $ 2.5 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. (See Note 6).

See Note 10 regarding the material definitive agreement with Koligo Therapeutics Inc.

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 September 30, 2020, the Company has accumulated losses of approximately $37 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 these 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 divesture 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 divesture 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 divesture 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).

*Reclassifications*

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

*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 $18.7 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.

In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting For Convertible Instruments and Contracts in an Entity's Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after December 15, 2021, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the impact that this new guidance will have on its consolidated financial statements.

*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 OPERATIONS**

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 $315 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):

SCHEDULE OF DISCONTINUED OPERATION

| | Nine Months Ended September 30, 2020 | Three Months Ended September 30, 2019 | Nine Months Ended September 30, 2019 |
|---|---|---|---|
| **OPERATIONS** | | | |
| Revenues | $ 2,556 | $ 8,247 | $ 22,730 |
| Cost of revenues | 1,482 | 4,956 | 13,341 |
| Cost of research and development and research and development services, net | 7 | (4) | 39 |
| Amortization of intangible assets | 137 | 408 | 1,224 |
| Selling, general and administrative expenses | 1,896 | 3,553 | 9,011 |
| Other (income) expenses, net | 305 | (24) | (89) |
| Operating loss | 1,271 | 642 | 796 |
| Financial income, net | (29) | (51) | (6) |
| Loss before income taxes | 1,242 | 591 | 790 |
| Tax expenses (income) | (30) | 138 | 761 |
| Net loss from discontinuing operation, net of tax | $ 1,212 | $ 729 | $ 1,551 |
| | | | |
| **DISPOSAL** | | | |
| Gain on disposal before income taxes | $ 102,534 | $ - | $ - |
| Provision for income taxes (*) | (5,430) | - | - |
| Gain on disposal | $ 97,104 | $ - | $ - |
| | | | |
| Net profit (loss) from discontinuing operation, net of tax | $ 95,892 | $ (729) | $ (1,551) |

* Provision for income taxes was updated in the three months period ended September 30, 2020 in the amount of $7.2 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):

| Assets | As of December 31, 2019 |
|---|---|
| **ASSETS:** | |
| 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 |
| **TOTAL ASSETS OF DISCONTINUED OPERATIONS** | $ 75,221 |

| | As of December 31, 2019 |
|---|---|
| **LIABILITIES:** | |
| 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 |
| **TOTAL LIABILITIES OF DISCONTINUED OPERATIONS** | $ 31,586 |

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

| | Nine Months Ended September 30, 2020 | Three Months Ended September 30, 2019 | Nine Months Ended September 30, 2019 |
|---|---|---|---|
| Net cash flows provided by (used in) operating activities | $ (2,409) | $ 297 | $ (2,119) |
| Net cash flows used in investing activities | $ (579) | $ (3,224) | $ (5,524) |
| Net cash flows (used in) provided by financing activities | $ (51) | $ (148) | $ 6,148 |

*Disaggregation of Revenue*

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

| | Nine Months Ended September 30, 2020 | Three Months Ended September 30, 2019 | Nine Months Ended September 30, 2019 |
|---|---|---|---|
| Revenue stream: | | | |
| Cell process development services | $ 2,556 | $ 2,889 | $ 12,511 |
| Tech transfer services | - | 1,864 | 5,396 |
| Cell manufacturing services | - | 3,494 | 4,823 |
| Total | $ 2,556 | $ 8,247 | $ 22,730 |

**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 in the amount of $0.8 million.

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 nine months ended September 30, 2020, the Company issued270,174 shares of common stock to service providers. As of September 30, 2020,82,500 shares have additional restrictions on transfer until such services have been provided.

During the nine months ended September 30, 2020, one option holder exercised options to purchase83,334 shares of common stock at an exercise price of $3.60, 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 $250 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 nine months ended September 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 September 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.

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 in India. 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. $1,051 Thousand for these services was recognized during the nine months ended September 30, 2020 as revenue.

Apart from the above, there was no activity in the India joint venture during the nine months ended September 30, 2020 (See Note 10).

*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 U.S. subsidiary of Hemo ("Hemo-LLC"), entered into a loan agreement. During the nine months ended September 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 and research and development services net.

*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 nine months ended September 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 and research and development services net.

*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"). During the third quarter of 2020, the Company and Theracell entered into an amended and restated joint venture agreement that supersedes the Greek JVA (the "new Greek JVA"). Pursuant to the new Greek JVA, the parties will collaborate in the clinical development and commercialization of the Company's products (hereinafter, the "Company Products") in Greece, Turkey, Cyprus, the Balkan countries and Israel (the "Territory") and the clinical development and commercialization of Theracell's products (hereinafter, the "Theracell Products") worldwide (the "Theracell Project"). Under the new Greek JVA, Theracell will be responsible to obtain required marketing approvals for the Theracell Products and the Company Products in the Territory based on Clinical Trials (as defined in the Greek JVA) and regulatory requirements, and be responsible for procuring and funding the clinic elements of the Clinical Trials and regulatory approvals for the Theracell Products and the Company Products in the Territory. The Company will be responsible to fund the production costs of the Theracell Products and the Company Products required for the Clinical Trials within the Territory and either supply the Theracell Products and/or the Company Products for the Clinical Trials or cover the relevant production/processing costs.

In addition, each of the parties will be responsible to provide the Greek JV Entity (as defined below) with funding in an amount of at least five million US Dollars ($5,000,000), to cover the operation costs of the Greek JV Entity. Such additional investments may be made in the form of an equity investment for additional shares in the Greek JV Entity, a convertible loan, and/or procured services (the "Additional Investment"), if required (as determined by the board of directors) in order to maintain the activity of the Greek JV Entity or to maintain such party's pro-rata holding percentage in the share capital of the Greek JV Entity, in any future financing round.

The Company may choose to provide the funding required as part of its obligations under the new Greek JVA as well as the Additional Investment by engaging Theracell or the Greek JV Entity to perform activities, and research and development services to create, optimize, improve the Orgenesis Background IP, technology, processes, system, and validation, ("ORGS Procured Services") in an amount of up to fifteen million US Dollars ($15,000,000). The ORGS Procured Services will be subject to and will be carried out by Theracell or the Greek JV Entity (as applicable) in accordance with a separate Master Services Agreement ("MSA"). The Company and Theracell executed such MSA in the third quarter of 2020, pursuant to which Theracell will provide the Company with services in the amount of $11.5 million according to an approved work program. All results of the ORGS Procured Services shall be owned by the Company. During the third quarter of 2020, Theracell provided such services in the amount of $1,500 thousand, which are reflected in R&D and R&D services.

Theracell also agreed to grant to the Greek JV Entity, during the term, an exclusive, sublicensable right and license to the Theracell Background IP as required solely to manufacture, distribute and market and sell Theracell Products within the Territory, subject and in accordance with the terms of a separate license agreement to be signed between Theracell and the Greek JV Entity ("Theracell License Agreement"). In consideration of the rights and the Theracell licenses to be granted to the Greek JV Entity during the Term under the Theracell License Agreement, Theracell shall receive royalty in an amount of up to ten percent (10%) of the net sales generated by the Greek JV Entity and/or its sublicensees (as applicable) with respect to the Theracell Products, as to be more fully stipulated and set forth under the Theracell License Agreement; and grant the Company an exclusive, sublicensable right and license to the Theracell Background IP as required solely to manufacture, distribute and market and sell the Theracell Products outside of the Territory under the terms of separate license agreement to be entered into between Theracell and the Company , in consideration for payment of a royalty in an amount of up to ten percent (10%) of the net sales generated by the Company and/or its sublicensees (as applicable) with respect to the Theracell Products outside of the Territory.

The Company agreed to grant to the Greek JV Entity, during the term, an exclusive, sublicensable, royalty bearing, right and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell the Company Products within the Territory, subject and in accordance with the terms of a separate license agreement to be signed between the Company and the Greek JV Entity ("Orgenesis License Agreement"). In consideration of the rights and the Orgenesis license to be granted to the Greek JV Entity during the Term under the Orgenesis License Agreement, the Company shall receive royalty in an amount of ten percent (10%) of the net sales generated by the Greek JV Entity and/or its sublicensees (as applicable) with respect to the Company Products.

Once the Greek JV Entity is profitable, the Company shall be entitled to an additional share of fifteen percent (15%) of the Greek JV Entity's contribution margin over and above all rights granted pursuant to the Company's participating interest in the Greek JV.

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 new Greek JVA. The Greek JV Entity will have a steering committee that will act as the board of directors of the Greek JV Entity and shall be composed of a total of three members, with one member appointed by each party and independent member to be mutually appointed. 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 Greek JV Entity for a consideration to be calculated in accordance with a valuation of the JV Entity to be determined by an independent third party expert to be mutually selected by the parties.

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 nine months ended September 30, 2020, the Company recognized point of care service revenue in the amount of $1,068 thousand.

During the nine months ended September 30, 2020, the Company recorded expenses related to activities in the Territory in the amount of $896 thousand (See Note 10).

*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 nine months ended September 30, 2020, the Company recognized point of care services revenue in the amount of $1,143 thousand.

During January 2020, the U.S. Subsidiary and Broaden entered into a convertible loan agreement pursuant to which the Company agreed to lend Broaden 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 nine months ended September 30, 2020, the Company recorded research and development expenses related to activities in the Broaden JVA in the amount of $830 thousand.

Apart from the above, as of September 30, 2020, the Broaden JV Entity had not been incorporated (See Note 10).

*Cure Therapeutics*

During 2019, the Company entered into a master service agreement with Cure Therapeutics ("CT") whereby the Company, subject to mutually agreed timing and definition of the scope of services, will provide point-of-care services to CT during 2020 and 2021. During the nine months ended September 30, 2020, the Company recognized point of care services revenue in the amount of $1,029 thousand.

As described in Note 12 to the financial statements as of December 31, 2019, on May 7, 2018, the Company and CT entered into a collaboration agreement for the development of therapies based on liver and NK cells. An amount of $1,827 thousand was charged during the nine months ended September 30, 2020. As of September 30, 2020, the development project had not been completed. As part of the agreement, Cure Therapeutics subcontracted development and contract manufacturing activities to the Korean subsidiary. An amount of $1,035 thousand was recognized as revenues by the Korean subsidiary during the nine months ended September 30, 2020.

In addition, during the third quarter of 2020, the Company and CT entered into a joint venture agreement ("CT JVA"), pursuant to which the parties will collaborate in point of care ("POC"), processing, regulatory and governmental affairs and therapy development and commercialization of Company's and CT's products (excluding HEPA and NK cells products) within the territories of South Korea and Japan (the "CT Territory").

The parties intend to pursue the CT JVA through a joint venture by forming a JV entity (the "CT JV Entity"). Until the CT JV Entity is formed, all JV activities are being carried out by CT. The Company by itself, or together with a designee, will hold a 50% participating interest in the CT JV Entity, with the remaining 50% participating interest being held by CT or its affiliate following the parties' contributions to the CT JV Entity. The CT JV Entity will have a steering committee that will act as the board of directors of the CT JV Entity and shall be composed of a total of three members, with one member appointed by each party and an independent industry expert member to be mutually appointed. 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 CT to transfer to the Company the entirety of CT's equity interest in the CT JV Entity for a consideration to be calculated in accordance with a valuation of the CT JV Entity to be determined by an independent third party expert to be mutually selected by the parties.

As of September 30, 2020, the CT JV entity had not yet been incorporated.

Under the CT JVA, CT will be responsible to obtain required marketing approvals for the CT and Company Products in the CT Territory based on clinical trials and regulatory requirements.

In addition, each of the Parties will be responsible to provide the CT JV with funding in an amount of at least ten million US Dollars ($10,000,000), to cover the operation costs of the CT JV, half of which may be in the form of in kind contributions. Company's such additional investments may be made in the form of an equity investment for additional shares in the CT JV, a convertible loan, and/or procured services (the "Additional Investment"), if required (as determined by the board of directors) in order to maintain the activity of the CT JV or to maintain such Party's pro-rata holding percentage in the share capital of the CT JV, in any future financing round.

The Company may choose to provide the funding required as part of its obligations under the CT JVA by engaging CT or the CT JV to perform services, and research and development services to create, optimize, improve the Orgenesis Background IP, technology, processes, system, and validation, ("CT-ORGS Procured Services"). The CT-ORGS Procured Services will be subject to, and will be carried out by CT or the CT JV (as applicable) in accordance with a separate Master Services Agreement (the "CT MSA"). All results of the ORGS Procured Services shall be owned by Company. The Company and CT executed such CT MSA in the third quarter of 2020, pursuant to which CT agreed to provide the Company with services in the amount of $4.5 million according to an approved work program. The Company did not recognize any such procured services in the third quarter of 2020 (See Note 10).

CT also agreed to grant to the CT JV, during the term, an exclusive, sublicensable right and license to the CT Background IP (as defined in the CT MSA) as required solely to manufacture, distribute and market and sell CT Products (as defined in the CT MSA) within the CT Territory, subject and in accordance with the terms of a separate license agreement to be signed between CT and the CT JV ("CT License Agreement"). In consideration of the rights and the CT licenses to be granted to the CT JV during the Term under the CT License Agreement, CT shall receive royalty in an amount of up to ten percent ( 10%) of the net sales generated by the CT JV and/or its sublicensees (as applicable) with respect to the CT Products, as to be more fully stipulated and set forth under the CT License Agreement; and grant Company an exclusive, sublicensable right and license to the CT Background IP as required solely to manufacture, distribute and market and sell CT Products outside of the CT Territory under the terms of a separate license agreement to be entered into between CT and the Company, in consideration for payment of a royalty in an amount of up to ten percent ( 10%) of the net sales generated by the Company and/or its sublicensees (as applicable) with respect to the CT Products outside of the CT Territory.

The Company agreed to grant to the CT JV, during the term, an exclusive, sublicensable, royalty bearing, right and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell Orgenesis Products within the CT Territory, subject and in accordance with the terms of a separate license agreement to be signed between Orgenesis and the CT JV ("CT-Orgenesis License Agreement"). In consideration of the rights and the Orgenesis license to be granted to the CT JV during the Term under the CT-Orgenesis License Agreement, Orgenesis shall receive royalty in an amount of ten percent ( 10%) of the net sales generated by the CT JV and/or its sublicensees (as applicable) with respect to the Orgenesis Products.

Once the CT JV is profitable, the Company shall be entitled to an additional share of fifteen percent(15%) of the CT JV's Audited GAAP profit after tax, over and above all rights granted pursuant to the Company's participating interest in the CT JV.

*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 of 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 nine months ended September 30, 2020, the Company recorded research and development expenses related to the development plan in the amount of $800 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 ("Mircod 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 Mircod 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 Mircod 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 September 30, 2020, the loan agreement was not executed.

*HekaBio K.K*

As described in Note 12 to the financial statements as of December 31, 2019, on July 10, 2018, the Company and HekaBio K.K. ("HB"), a corporation organized under the laws of Japan entered into a joint venture agreement (the "HB JVA") pursuant to which the parties will collaborate in the clinical development and commercialization of regeneration and cell and gene therapeutic products in Japan, and on October 3, 2018, the Company entered into a license agreement with the joint venture company pursuant to the HB JVA.

During the third quarter of 2020, the Company and HV agreed to terminate such license agreement.

Apart from the above, as of September 30, 2020, no material activity had begun in the HB JVA.

*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 September 30, 2020, the Company had advanced $450 thousand to Kidney Cure on account of its obligations under the Kidney Cure JVA.

Apart from the above, as of September 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 (See Note 10).

*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 $1 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 September 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.

As aggregate consideration for the acquisition, the Company paid $2.5 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 based on the Company's share price at the closing date. $59 thousand and 340,000 Shares are being 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 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. Because substantially all (more than 90%) of the fair value of the gross assets acquired are concentrated in a single asset being the right to Tamir's intellectual property and related assets ("IPR&D"), the Company determined that the acquisition is not considered a business in accordance with ASC 805-10-55-5A. Therefore, the Company accounted the transaction as an asset acquisition. The fair value associated with Tamir's IPR&D in the amount of $ 19.5 million was charged to research and development expenses under ASC 730. The remaining amount was attributed to the above-mentioned share in a private company, which is presented in the balance sheet as long term "other assets.

*Extracellular Vesicle ("EV") Technology License*

During the third quarter of 2020, the Company purchased the IP and related EV technology from a service provider (the "Service Provider") pursuant to an EV agreement (the "EV agreement"). According to the EV agreement, the Service Provider sold to the Company all of its rights in the EV technology that it had produced, in the amount of $500 thousand, to be paid in equal installments over the next 12 months from September 2020. During September 2020, the Company paid $50 thousand to the Service Provider. The $500 thousand were recorded in R&D expenses. In addition, the Service Provider granted the Company an exclusive worldwide license to use the EV IP technology for any purpose.

**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 September 30, 2020:

| | No. of Options Granted | Exercise Price | Vesting Period | Fair Value at Grant (in thousands) | Expiration Period |
|---|---|---|---|---|---|
| Employees | 422,450 | $2.99-$6.84 | Quarterly over a period of two years | 980 | 10 years |
| Directors | 68,750 | $2.99-$4.70 | 91% on the one-year anniversary and the remaining 9% in three equal instalments on the first, second and third year anniversaries | $ 147 | 10 years |

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

| | During the Period from January 1, 2020 to September 30, 2020 |
|---|---|
| Value of one common share | $2.99-$6.84 |
| Dividend yield | 0% |
| Expected stock price volatility | 80%-86% |
| Risk free interest rate | 0.36%-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 September 30, 2020:

| | No. of Options Granted | Exercise Price | Vesting Period | Fair Value at Grant (in thousands) | Expiration Period |
|---|---|---|---|---|---|
| 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:

| | During the Period from January 1, 2020 to September 30, 2020 |
|---|---|
| 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 nine months ended September 30, 2020, the Company granted193,178 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 | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, 2020 | September 30, 2019 | September 30, 2020 | September 30, 2019 |
| | (in thousands, except per share data) | | | |
| **Basic:** | | | | |
| Net loss from continuing operations attributable to Orgenesis Inc. | $ 9,559 | $ 4,166 | $ 43,662 | $ 17,585 |
| Net (income) loss from discontinued operations attributable to Orgenesis Inc. for loss per share | (7,132) | 383 | (96,384) | 476 |
| Adjustment of redeemable non-controlling interest to redemption amount | - | 2,461 | 414 | 3,314 |
| | (7,132) | 2,844 | (95,970) | 3,790 |
| Net (income) loss attributable to Orgenesis Inc. for loss per share | 2,427 | 7,010 | (52,308) | 21,375 |
| Weighted average number of common shares outstanding | 22,094,470 | 16,028,518 | 20,469,470 | 15,858,666 |
| Loss per common share from continuing operations | $ 0.43 | $ 0.26 | $ 2.13 | $ 1.11 |
| Net (earnings) loss common share from discontinued operations | $ (0.32) | $ 0.18 | $ (4.69) | $ 0.24 |
| Net (earnings) loss per share | $ 0.11 | $ 0.44 | $ (2.56) | $ 1.35 |
| **Diluted:** | | | | |
| Net loss from continuing operations attributable to Orgenesis Inc. for loss per share | 9,559 | 4,166 | 43,662 | 17,585 |
| Net (income) loss from discontinued operations attributable to Orgenesis Inc. for loss per share | (7,132) | 2,844 | (95,970) | 3,790 |
| Net (income) loss attributable to Orgenesis Inc. for loss per share | 2,427 | 7,010 | (52,308) | 21,375 |
| Weighted average number of shares used in the computation of basic and diluted loss per share | 22,094,470 | 16,028,518 | 20,469,470 | 15,858,666 |
| Net loss per common share from continuing operations | $ 0.43 | $ 0.26 | $ 2.13 | $ 1.11 |
| Net (earnings) loss per common share from discontinued operations | $ (0.32) | $ 0.18 | $ (4.69) | $ 0.24 |
| Net (earnings) loss per share | $ 0.11 | $ 0.44 | $ (2.56) | $ 1.35 |

For the nine months ended September 30, 2020, September 30, 2019 and for the three months ended September 30, 2020, September 30, 2019, all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

**NOTE 9 – REVENUES**

*Disaggregation of Revenue*

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

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, 2020 | September 30, 2019 | September 30, 2020 | September 30, 2019 |
| | (in thousands) | | | |
| Revenue stream: | | | | |
| Cell process development services | $ 463 | $ 220 | $ 1,065 | $ 808 |
| Point-of-care services | 1,266 | 1,012 | 4,291 | 1,974 |
| Total | $ 1,729 | $ 1,232 | $ 5,356 | $ 2,782 |

*Contract Assets and Liabilities*

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

The activity for trade receivables is comprised of:

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (in thousands) | |
| Balance as of beginning of period | $ 1,831 | $ 129 |
| Additions | 4,101 | 996 |
| Collections | (1,869) | (364) |
| Exchange rate differences | 14 | (13) |
| Balance as of end of period | $ 4,077 | $ 748 |

The activity for contract liabilities is comprised of:

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (in thousands) | |
| Balance as of beginning of period | $ 325 | $ 56 |
| Additions | 597 | 1,097 |
| Realizations | (759) | (981) |
| Balance as of end of period | $ 163 | $ 172 |

**NOTE 10 – SUBSEQUENT EVENTS**

1. Material Definitive Agreement with Koligo Therapeutics Inc.

On September 26, 2020, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among the Company, Orgenesis Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), Koligo Therapeutics Inc., a Kentucky corporation ("Koligo"), the shareholders of Koligo (collectively, the "Shareholders"), and Long Hill Capital V, LLC ("Long Hill"), solely in its capacity as the representative, agent and attorney-in-fact of the Shareholders. The Merger Agreement provides for the acquisition of Koligo by the Company through the merger of Merger Sub with and into Koligo, with Koligo surviving as a wholly-owned subsidiary of the Company (the "Merger"). The Merger was announced in a Current Report on Form 8-K filed with the Securities and Exchange Commission on October 1, 2020, to which a copy of the Merger Agreement, along with copies of certain other ancillary agreements, were annexed as exhibits. On October 15, 2020 (the "Effective Time"), the Company closed the Merger.

Koligo was a privately-held US regenerative medicine company. Koligo's first commercial product is KYSLECEL® (autologous pancreatic islets) for chronic and acute recurrent pancreatitis. Koligo's 3D-V technology platform incorporates the use of advanced 3D bioprinting techniques and vascular endothelial cells to support development of transformational cell and tissue products for serious diseases.

Pursuant to the terms of the Merger Agreement, at the Effective Time, the shares of capital stock of Koligo that were issued and outstanding immediately prior to the Effective Time were automatically cancelled and converted into the right to receive, subject to customary adjustments, an aggregate of 2,061,713 shares of Company common stock were issued to Koligo's accredited investors (with certain non-accredited investors being paid solely in cash in the amount of approximately $20 thousand) in accordance with the terms of the Merger Agreement. In connection with the Merger, the Company assumed an aggregate of approximately $ 1.9 million of Koligo's liabilities, which were substantially all of Koligo's liabilities at the closing of the Merger.

The Merger Agreement contains customary indemnification provisions whereby the Shareholders of Koligo will indemnify the Company and certain affiliated parties for any losses arising out of breaches of the representations, warranties and covenants of Koligo and the Shareholders under the Merger Agreement. As partial security for the indemnification and purchase price adjustment obligations of Koligo shareholders under the Merger Agreement, $7 thousand in cash and 328,587 shares of Company common stock of the merger consideration otherwise payable in the Merger to the Shareholders were placed in a third party escrow account. The aggregate indemnification obligations of the Koligo shareholders under the Merger Agreement is capped at the amounts in escrow, subject to certain limited exceptions.

In addition, according to the agreement between the parties, the Company has also funded an additional cash consideration of $500 thousand (with $100 thousand of such reducing the ultimate consideration payable to Koligo) for the acquisition of the assets of Tissue Genesis, LLC ("Tissue Genesis") by Koligo that was consummated on October 14, 2020. The Tissue Genesis assets include the entire inventory of Tissue Genesis Icellator® devices, related kits and reagents, a broad patent portfolio to protect the technology, registered trademarks, clinical data, and existing business relationships for commercial and development stage use of the Icellator technology.

In connection with the Merger Agreement, the Company, Long Hill and Maxim Group LLC ("Maxim") entered into a Registration Rights and Lock-Up Agreement pursuant to which Long Hill will have one demand registration right to require the registration of the shares of Company common stock received by Long Hill in the Merger and Long Hill and Maxim will have certain piggyback registration rights. In addition, Long Hill agreed with the Company that, during the applicable Restriction Period (as defined below), it shall not sell or transfer, subject to certain limited exceptions, the portion of the shares received in the Merger during the applicable Restriction Period, subject to a limitation on the number of shares sold per any trading day not to exceed 10% of the average daily trading volume of the Common Stock, as reported by Bloomberg Financial L.P. "Restriction Period" means (a) in relation to 70% of all of the shares received in the Merger that Long Hill is entitled to receive under or in connection with the Merger Agreement, the period beginning on the date of the closing and ending on the date that is the four month anniversary thereof, and (b) in relation to the remaining 30% of all of the shares received in the Merger that Long Hill is entitled to receive under or in connection with the Merger Agreement, the period beginning on the date of the closing and ending on the date that is the twelve month anniversary thereof.

In addition, pursuant to separate Lock-Up Agreements entered into by the Shareholders other than Long Hill with the Company (the "Shareholders Lock-Up Agreement"), such Shareholders agreed that they will not transfer any of their shares received in the Merger except in accordance with the following lock-up release schedule whereby one fifth of such holder's respective shares will be released from such restriction every six months, starting six months from the closing of the Merger. Each holder's sales of such shares are subject to a resale limit of its pro rata portion of 10% of the average daily trading volume, allocated to the Shareholders other than Long Hill pro-rata.

The acquisition will be accounted in accordance with Accounting Standards Codification Topic 805, "Business Combinations". As the acquisition was completed subsequent to September 30, 2020, the consolidated financial statements do not include the results or the financial position of Koligo. Under the disclosure requirements of ASC 805 the Company is required to provide information regarding the effect of the business combination. Because the Company hasn't completed the work of the purchase price allocation needed under ASC 805, the initial accounting for the business combination was incomplete at the time of the issuance of the financial statements, therefore, the Company did not include the above mentioned information as permitted by ASC 805-10-50-4 and ASC 805-30-50-3.

**2.** Material Definitive Agreements with Educell D.O.O.

On October 1, 2020, the Company and Educell D.O.O. ("Educell") entered into a Joint Venture Agreement ("Educell JVA") pursuant to which the parties will collaborate in (i) Point of Care (POC), processing, regulatory and governmental affairs and therapy development, (ii) setting up POC facilities within the territories of Croatia, Serbia and Slovenia ("Educell Territory"), (iii) clinical development and commercialization of Company and Educell products in the Educell Territory and (iv) clinical development and commercialization of Educell products worldwide.

Under the Educell JVA, Educell will be responsible for obtaining required marketing approvals for the Educell and Company Products in the Educell Territory based on clinical trials and regulatory requirements. In addition, Educell will be responsible for procuring and funding the clinic elements of the clinical trials and regulatory approvals for the Company's products in the territory and use the services of the Company as a subcontractor under a Master Services Agreement, detailed below.

The parties intend to pursue the joint venture by forming a JV entity (the "Educell JV"). Until the Educell JV is formed, all JV activities are being carried out by Educell. The Company by itself, or together with a designee, will hold a 50% participating interest in the Educell JV, and Educell or its affiliate will hold the remaining 50% participating interest. The Educell JV will have a board of directors that will initially also act as a steering committee of the Educell JV and shall be composed of a total of three members, with one member appointed by each party and the third member to be appointed upon mutual agreement of the 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 Educell to transfer to the Company the entirety of Educell equity interest in the JV Entity for a consideration to be calculated in accordance with a valuation of the JV Entity to be determined by an independent third party expert to be mutually selected by the parties which will not be less than $1 million as adjusted by additional equity investment by the parties.

In addition, each of the Parties will be responsible for providing the Educell JV with funding in an amount of at least ten million US Dollars ($0,000,000) each, for covering the operational costs of the JV entity in accordance with the Work Plan, half of which may be in the form of in-kind contributions.

In addition, each party will have the right to invest additional sums in the Company if required (as determined by the board of directors) (the "Additional Investment"), in order to maintain the activity of the Educell JV or to maintain such party's pro-rata holding percentage in the share capital of the Educell JV, in any future financing round. The additional payment may be made in the form of a cash investment for additional shares of the UAE JV, a convertible loan, and/or procured services.

The ORGS Procured Services will be subject to, and will be carried out by Educell or the Educell JV (as applicable) in accordance with a separate Master Services Agreement ("MSA") between the Company and Educell and as shall be agreed upon from time to time between the parties in statements of work ("SOW"). All results of the ORGS Procured Services shall be owned by the Company. The Company and Educell executed such an MSA in the fourth quarter of 2020 whereby Educell will provide the Company with services in the amount of $2 million according to an approved work program and upon completion of milestones in the SOW for additional services of up to $6 million. The Company advanced $613 thousand to Educell on account of such services.

In addition, the Company entered into a MSA and SOW with Educell 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 i.e. POCare (including Facility adaptation and commissioning, Training and Technical runs, QMS, Operation and Co-Development Services) during 2021 and 2022 for a fee of $1.3 million.

Educell shall grant to the Educell JV, during the term, an exclusive, sublicensable right and license to the Educell Background IP as required solely to manufacture, distribute and market and sell Educell Products within the Educell Territory, subject and in accordance with the terms of a separate license agreement to be signed between Educell and the Educell JV ("Educell License Agreement"). In consideration of the rights and the Educell licenses to be granted to the Educell JV during the Term under the Educell License Agreement, Educell shall receive royalties in an amount of up to ten percent (10%) of the net sales generated by the Educell JV and/or its sublicensees (as applicable) with respect to the Educell Products, as to be more fully stipulated and set forth under the Educell License Agreement; and grant the Company an exclusive, sublicensable right and license to the Educell Background IP as required solely to manufacture, distribute and market and sell Educell Products outside of the Educell Territory under the terms of a separate license agreement to be entered into between Educell and the Company, in consideration for payment of royalties in an amount of up to ten percent (10%) of the net sales generated by us and/or our sublicensees (as applicable) with respect to the Educell Products outside the Educell Territory.

The Company shall grant to the Educell JV, during the term, an exclusive, sublicensable, royalty-bearing, right and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell Orgenesis Products within the Educell Territory, subject and in accordance with the terms of a separate license agreement to be signed between the Company and the Educell JV ("Educell-Orgenesis License Agreement"). In consideration of the rights and the Orgenesis license to be granted to the Educell JV during the Term under the Educell-Orgenesis License Agreement, the Company shall receive royalties in an amount of ten percent ( 10%) of the net sales generated by the Educell JV and/or its sublicensees (as applicable) with respect to the Company's Products.

Once the Educell JV is profitable, the Company shall be entitled (in addition to any of its rights as the holder of 50% of the JV Entity) to additional royalties at a rate of fifteen percent (15%) of the Educell JV's Audited GAAP profit after tax, over and above all rights granted pursuant to Company's participating interest in the Educell JV.

Under the Educell JVA, the parties have agreed to negotiate the terms of a manufacturing and supply agreement whereby the Company and its affiliates will exclusively manufacture the products resulting from the product IP and the Educell JV shall purchase all of its requirement for such products exclusively from the Company and its affiliates.

As of September 30, 2020, the Educell JV had not yet been incorporated.

3. Material Definitive Agreements with Image Securities (Related Party)

As described in Note 12 to the financial statements as of December 31, 2019, on July 11, 2018, the Company and Image Securities Ltd. entered into a Joint Venture Agreement (the "Indian JVA"). Image Securities Ltd. assigned the Indian JVA to Image Securities FZC, a corporation organized under the laws of United Arab Emirates ("Image Securities") and the Company and Image Securities entered into an Amended and Restated Joint Venture Agreement which supersedes the Indian JVA ("new Indian JVA"). Pursuant to the new Indian JVA, the parties will collaborate in the development and commercialization of the Company's products, including but not limited to regeneration and cell and gene therapeutic products (hereinafter, the "Company Products") and building of POCare processing centers/units within the territory of India (the "Indian Territory") and the clinical development and commercialization of Image Securities' products ("Image Securities Products"). Under the new Indian JVA, Image Securities will be responsible to obtain required marketing approvals for the Company Products in the Indian Territory based on Clinical Trials and regulatory requirements, and be responsible for procuring and funding the clinic elements of the Clinical Trials and regulatory requirements for the Company Products in the Indian Territory. Image Securities will be responsible for procuring and funding the clinic elements of the Clinical Trials and regulatory approvals for the Image Securities Products and the Orgenesis Products in the Indian Territory and will use the services of the Company as a subcontractor under a separate services agreement for such purpose, all in accordance with the Work Plan.

In addition, each of the parties will be responsible to provide the JV Entity with funding in an amount of at least five million US Dollars (**$**,000,000), to cover the operation costs of the JV Entity. Such additional investments may be made in the form of a cash contribution, a convertible loan, and/or procured services (the "Additional Investment"), if required (as determined by the board of directors) in order to maintain the activity of the Indian joint venture or to maintain such party's pro-rata holding percentage in the share capital of the Indian joint venture, in any future financing round. The valuation of the JV Entity for the purposes of such Additional Investment will be determined by an independent third-party expert to be mutually selected by the parties which will not be less than $1 million as adjusted by additional equity investment by the parties.

The ORGS Procured Services will be subject to and will be carried out by Image Securities or the Indian joint venture (as applicable) in accordance with a separate Master Services Agreement ("MSA"). The Company and Image Securities executed such a MSA in the fourth quarter of 2020 whereby Image Securities will provide Company with services in the amount of $4.8 million according to an approved work program. All results of the ORGS Procured Services shall be owned by Company.

The parties intend to pursue the Image Securities Project through a joint venture ("JV") by forming a JV entity (the "Indian JV Entity"). The Company by itself, or together with a designee, will hold a 50% participating interest in the Indian JV Entity, with the remaining 50% participating interest being held by Image Securities or its affiliate following the parties' contributions to the Indian JV Entity as set forth under the new Indian JVA.

The Company shall grant to the JV Entity, during the term, an exclusive, sublicensable, royalty bearing, right and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell Orgenesis Products within the Indian Territory, subject and in accordance with the terms of a separate license agreement to be signed between Company and the JV Entity ("Indian-Orgenesis License Agreement"). In consideration of the rights and the Orgenesis license to be granted to the JV Entity during the Term under the Indian-Orgenesis License Agreement, Company shall receive royalty in an amount of ten percent ( 10%) of the net sales generated by the JV Entity and/or its sublicensees (as applicable) with respect to the Orgenesis Products.

Once the JV Entity is profitable, the Company shall be entitled (in addition to any of its rights as holder of 50% of the JV Entity and prior to any other distributions of dividends by the JV Entity to shareholders of the JV Entity) to an additional share of fifteen percent 15% of the audited US GAAP profits after tax over and above all rights granted pursuant to Company's participating interest in the Indian JV.

The Company and Image Securities intend to form a steering committee composed of one representative from the Company, and one representative from Image Securities, as well as an industry expert appointed jointly by the Company and Image Securities, to facilitate and oversee development under the Work Plan. 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 Image Securities to transfer to the Company the entirety of Image Securities' equity interest in the Indian JV Entity for a consideration to be calculated in accordance with a valuation of the JV Entity to be determined by an independent third party expert to be mutually selected by the parties provided, that such valuation may not be lower than $1 million plus additional equity investments in the Indian JV Entity.

4. Material Definitive Agreements with Med Centre for Gene and Cell Therapy FZ-LLC

On October 15, 2020, the Company and Med Centre for Gene and Cell Therapy FZ-LLC ("MCGCT") from the United Arab Emirates ("UAE") entered into a joint venture agreement ("UAE JVA") to collaborate in the development, marketing, clinical development, and commercialization of the Company's products within the territory the UAE and other countries as will be agreed between the parties ("UAE Territory").

Under the UAE JVA, MCGCT will be responsible for obtaining required marketing approvals for the MCGCT and Company Products in the UAE Territory and for the Company's products based on clinical trials and regulatory requirements. In addition, MCGCT will be responsible for procuring and funding the clinic elements of the clinical trials and regulatory approvals for our products in the UAE Territory and use the services of Orgenesis as a subcontractor under a Master Services Agreement, as detailed below. The Company will contribute to the UAE JV by providing funding for modification of the facilities as defined in the JVA.

The parties intend to pursue the joint venture ("JV") by forming a JV entity (the "UAE JV"). The Company by itself, or together with a designee, will hold a 50% participating interest in the UAE JV, and MCGCT or its affiliate will hold the remaining 50% participating interest. The UAE JV will have a board of directors that will initially also act as a steering committee of the UAE JV and shall be composed of a total of three members, with one member appointed by each party and the third member to be appointed upon mutual agreement of the parties.

The Company has the option, at its sole discretion and subject to all rules and regulations to which it is then subject, to require MCGCT to transfer to the Company the entirety of MCGCT equity interest in the JV Entity for a consideration to be calculated in accordance with a valuation of the JV Entity to be determined by an independent third party expert to be mutually selected by the parties.

Each of the parties will be responsible for providing the UAE JV with funding in an amount of at least five million US Dollars (**$**,000,000) each and in aggregate ten million US Dollars ($10,000,000), to cover the operation costs of the UAE JV, of which may be in the form of in-kind contributions. The Company's investments may be made in the form of a cash investment for additional shares in the UAE JV, a convertible loan, and/or procured services.

In addition, each party will have the right to invest additional sums in the Company if required (as determined by the Board) (the "Additional Investment"), in order to maintain the activity of the UAE JV or to maintain such party's pro-rata holding percentage in the share capital of the UAE JV, in any future financing round. The additional payment may be made in the form of a cash investment for additional shares of the UAE JV, a convertible loan, and/or procured services.

The procured services of the Company is subject to, and will be carried out by MCGCT in accordance with a separate Master Services Agreement ("MSA") that was entered into concurrently with the UAE JVA. The Company has engaged MCGT to provide the Company with certain procurement and services in support of its activity as shall be agreed upon from time to time between the parties in statements of work ("SOW"). All results of these procured services shall be owned by Company. The initial SOW signed in October 2020 provides for MCGCT to develop, setup and procure point of care processing unit in the UAE for a fee of $5 million to be paid by Orgenesis according to an approved work program which will also be considered the fulfilment of its contribution obligation to the UAE JV.

The Company will grant to the UAE JV, during the term, an exclusive, sublicensable, royalty-bearing, right and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell Orgenesis Products within the UAE Territory, subject and in accordance with the terms of a separate license agreement to be signed between Orgenesis and the UAE JV ("UAE-Orgenesis License Agreement"). In consideration of the rights and the Orgenesis license to be granted to the UAE JV during the term under the UAE-Orgenesis License Agreement, Orgenesis shall receive royalties in an amount of ten percent (10%) of the net sales generated by the UAE JV and/or its sublicensees (as applicable) with respect to the Orgenesis Products.

The UAE JV entity will grant Orgenesis an exclusive, perpetual, irrevocable, worldwide, sublicensable under a separate license agreement to be signed between the UAE JV and the Company ("UAE JV License Agreement") to use the project IP (as defined in the UAE License Agreement) for any and all lawful purposes outside the UAE Territory. In consideration of the rights and the UAE JV Licenses to be granted by the UAE JV during the term under the UAE JV License Agreement, the Company will pay royalties in an amount equal to ten percent (10%) of the net sales generated by the Company and/or its sublicensees (as applicable) with respect to providing treatment to patients within treatment facilities where such treatment utilizes project IP, as to be more fully stipulated and set forth under the UAE JV License Agreement.

Once the UAE JV is profitable, the Company will be entitled (in addition to any of its rights as the holder of 50% of the JV entity) to an additional share of fifteen percent (15%) of the UAE JV's Audited GAAP profit after tax, over and above all rights granted pursuant to Company's participating interest in the UAE JV.

In addition, on October 16th, 2020, the U.S. Subsidiary entered into a Master Service Agreement ("Co-Development MSA") with MCGCT whereby the Company, subject to mutually agreed timing and definition of the scope of services, will provide certain services in support of the MCGCT's activity as shall be agreed upon from time to time between the parties in a statements of work for a fee of $11.6 million. The agreement will be in effect until December 31, 2022 unless terminated earlier by the parties.

Under the UAE JVA, the parties have agreed to negotiate the terms of a manufacturing and supply agreement whereby the Company and its affiliates will exclusively manufacture the products resulting from the product IP and the UAE JV shall purchase all of its requirement for such products exclusively from the Company and its affiliates.

As of September 30, 2020, the UAE JV had not yet been incorporated.

5. KC JV entity

During the fourth quarter of 2020 the Company transferred a further $500 thousand to Kidney Cure as part of the Company's participation in the KC JV. The KC JV entity was incorporated in October 2020.

6. Greek JV

During the fourth quarter of 2020, the Company transferred $3 million to Theracell as part of its obligations under the procured services agreement signed with Theracell. The Greek JV was incorporated in October 2020.

7. Cure Therapeutics JV

During the fourth quarter of 2020, the Company transferred $1.5 million to Cure Therapeutics as part of its obligations under the procured services agreement signed with Cure Therapeutics.

8. Material Definitive Agreements with Broaden Bioscience and Technology Corp

As described in Note 12 to the financial statements as of December 31, 2019, during 2019, the Company and Broaden Bioscience and Technology Corp, a Delaware corporation ("Broaden"), entered into a Joint Venture Agreement (the "Broaden JVA"). During the fourth quarter of 2020 the Company and Broaden entered into an Amended and Restated Joint Venture Agreement which supersedes the Broaden JVA ("new Broaden JVA"). Pursuant to the new Broaden JVA, the parties will collaborate in the development and commercialization of the Company's and Broaden's products, including but not limited to regeneration and cell and gene therapeutic products (hereinafter, the "Products") and building of POCare processing centers/units in China and the Middle East (the "Broaden Project"). Under the new Broaden JVA, Broaden will be responsible to obtain required marketing approvals for the Company's and Broaden's Products in the Broaden Project based on clinical trials and regulatory requirements, and be responsible for procuring and funding the clinic elements of the clinical trials and regulatory requirements for the Company's and Broaden's Products in the Broaden Project. Broaden will also be responsible to obtain required marketing approvals for Broaden's Products worldwide based on clinical trials and regulatory requirements.

In addition, each of the Parties will be responsible to provide the JV Entity with funding in an amount of at least ten million US Dollars of which 5 million US Dollars may be in the form of in-kind funding, to cover the operation costs of the JV Entity. Such additional investments may be made in the form of a cash contribution, a convertible loan, and/or procured services (the "Additional Investment"), if required (as determined by the Board) in order to maintain the activity of the Broaden joint venture or to maintain such Party's pro-rata holding percentage in the share capital of the Broaden venture, in any future financing round. The valuation of the JV Entity for the purposes of such Additional Investment will be determined by an independent third-party expert to be mutually selected by the parties which will not be less than $1 million as adjusted by additional equity investment by the parties.

The ORGS Procured Services will be subject to and will be carried out by Broaden or the Broaden joint venture (as applicable) in accordance with a separate Master Services Agreement ("MSA"). The Company and Broaden executed such a MSA in the fourth quarter of 2020 whereby Broaden will provide Company with services in the amount of $5.2 million according to an approved work program. All results of the ORGS Procured Services shall be owned by Company.

The parties intend to pursue the Broaden Project through a joint venture ("JV") by forming a JV entity (the "Broaden JV Entity"). The Company by itself, or together with a designee, will hold a 50% participating interest in the Broaden JV Entity, with the remaining 50% participating interest being held by Broaden or its affiliate following the parties' contributions to the Broaden JV Entity as set forth under the new Broaden JVA.

Broaden shall grant to the Broaden JV Entity, during the term, an exclusive, sublicensable right and license to the Broaden's Background IP as required solely to manufacture, distribute and market and sell Broaden Products within the territory, subject and in accordance with the terms of a separate license agreement to be signed between Broadem and the Broaden JV Entity ("Broaden License Agreement"). In consideration of the rights and the Broaden licenses to be granted to the Broaden JV Entity during the term under the Broaden License Agreement, Broaden shall receive royalties in an amount of up to ten percent ( 10%) of the net sales generated by the Broaden JV Entity and/or its sublicensees (as applicable) with respect to the Broaden Products, as to be more fully stipulated and set forth under the Broaden License Agreement; and grant the Company an exclusive, sublicensable right and license to the Broaden Background IP as required solely to manufacture, distribute and market and sell Broaden Products outside of the territory under the terms of a separate license agreement to be entered into between Broaden and the Company, in consideration for payment of royalties in an amount of up to ten percent (10%) of the net sales generated by the Company and/or its sublicensees (as applicable) with respect to the Broaden Products outside the Broaden Project.

The Company shall grant to the Broaden JV Entity, during the term, an exclusive, sublicensable, royalty bearing, right and license to the Orgenesis Background IP as required solely to manufacture, distribute and market and sell Orgenesis Products within the Broaden project, subject and in accordance with the terms of a separate license agreement to be signed between Company and the Broaden JV Entity ("Broaden-Orgenesis License Agreement"). In consideration of the rights and the Orgenesis license to be granted to the Broaden JV Entity during the Term under the Broaden-Orgenesis License Agreement, Company shall receive royalties in an amount of ten percent ( 10%) of the net sales generated by the Broaden JV Entity and/or its sublicensees (as applicable) with respect to the Orgenesis Products.

Once the Broaden JV Entity is profitable, the Company shall be entitled (in addition to any of its rights as holder of 50% of the Broaden JV Entity and prior to any other distributions of dividends by the Broaden JV Entity to shareholders of the Broaden JV Entity) to an additional share of fifteen percent 15% of the audited US GAAP profits after tax over and above all rights granted pursuant to Company's participating interest in the Broaden JV.

The Company and Broaden will form a steering committee composed of one representative from the Company, and one representative from Broaden, as well as an mutually appointed representative, to facilitate and oversee development under the Work Plan 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 Broaden to transfer to the Company the entirety of Broaden's equity interest in the Broaden JV Entity for a consideration to be calculated in accordance with a valuation of the JV Entity to be determined by an independent third party expert to be mutually selected by the parties provided, that such valuation may not be lower than $1 million plus additional equity investments in the Broaden JV Entity.

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 the vast majority 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 (unless otherwise stipulated below). The subsidiaries are as follows:

- United States: Orgenesis Maryland Inc. 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 is the center of activity in Europe currently focused on process development and preparation of European clinical trials.
- Israel: Orgenesis Ltd. is the center for research and technology, as well as a provider of regulatory, clinical and pre-clinical services, and Atvio Biotech Ltd. is a provider of cell-processing services in Israel.
- Korea: Orgenesis Korea Co. Ltd., 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, which 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.

The Company is committed to the validation, adoption and development of systems, technologies and processes for mobile processing unit and labs ("OMPUL"). OMPULs will be used and/or distributed through Company's point of care network of partners, collaborators and JV's for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved cell or gene therapy products in a safe, reliable and cost-effective manner. This provides an industrial solution for any clinical institution in the world to provide more therapies at the point of care.

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, thus enabling wide-scale access to these life-changing treatments.

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 two (32) foreign-issued patents, thirty three (33) pending applications in the United States, fifty eight (58) 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 five (5) international Patent Cooperation Treaty ("PCT") patent applications. These patents and applications relate, among others, to (1) the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis; (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, and their use for treating cancer and viral diseases; (6) compositions comprising ranpirnase and other ribonucleases for treating viral diseases; (7) tumor infiltrating lymphocytes (TILs) and their use for treating cancer; (8) compositions comprising plasma from recovered patients and their use for treating COVID-19; (9) methods for producing antibodies; (10) cysteinazed ribonucleases; (11) transdifferentiated cells for treating central nervous system (CNS) disorders and methods for administering them intranasally; (12) chimeric antigen receptors (CARs); (13) whole-cell antiviral vaccines; (14) therapeutic compositions comprising exosomes, bioxomes, and redoxomes; and (15) extracorporeal therapeutic devices for processing cells or derivatives thereof. 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").

Since the Masthercell Sale, the Company has entered into a restated and updated joint venture agreements with some of our joint venture partners and new joint venture agreements with new partners in various jurisdictions. This has allowed the Company to grow its infrastructure and expand its processing sites into new markets and jurisdictions. In addition, the Company has engaged some of these joint venture partners to perform research and development services to improve the Orgenesis Background IP. It also has allowed the Company the manpower and financial resources to focus on manufacturing and rolling out OMPULs to be used and/or distributed through Company's point of care network of partners, collaborators and JV's

**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 September 30, 2020

**Restated, new and updated joint venture agreements**

During the third quarter of 2020, we entered into restated and updated joint venture agreements with some of our joint venture partners and new joint venture agreements with new partners in various jurisdictions. This has allowed us to grow our infrastructure and expand our processing sites into new markets. In addition, we have engaged some of these joint venture partners to perform research and development services to improve the Orgenesis Background IP ("ORGS Procured Services") in an amount of approximately $46 million under separate master services agreements, according to work programs that have been approved by the board of directors, during 2020 and 2021. The results of such ORGS Procured Services shall be owned by the Company. During the third quarter of 2020, these joint venture partners provided such services in the amount of $1.5 million which are reflected in R&D and R&D services.

**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 September 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.

**Sponsored Research and Exclusive License Agreement with Health Corporation of the Wolfson Medical Center**

During the third quarter of 2020, we entered into a Framework Agreement ("Framework Agreement") with Health Corporation of the Wolfson Hospital ("MRC") whereby we will provide financial support for sponsored research by MRC with the scope of the research and the budget to be agreed by parties in advance. Any clinical trial will be governed by the terms of a clinical trial agreement to be negotiated between us and MRC. We shall provide a Mobile Processing Unit to be stationed on the MRC site. Ownership of the results of the sponsored research shall belong to us. The term of the Framework Agreement is 5 years unless terminated sooner according to its terms.

*Results of Operations*

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

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

| | Three-Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Revenues | $ 1,450 | $ 543 |
| Revenues to Related Party | 279 | 689 |
| Cost of research and development and research and development services | 6,951 | 2,508 |
| Amortization of intangible assets | 87 | 106 |
| Selling, general and administrative expenses | 4,042 | 2,412 |
| Financial expenses, net | 238 | 446 |
| Other income, net | (5) | (11) |
| Loss before income taxes | $ 9,584 | $ 4,229 |

Our revenues for the three months ended September 30, 2020 were $1,729 thousand, as compared to $1,232 thousand for the three months ended September 30, 2019, representing an increase of 40%. The increase in revenues for the three months ended September 30, 2020 is attributable to the increase in point-of-care services revenue.

**Expenses**

Research and Development and Research and Development Services Expenses

| | Three-Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Salaries and related expenses | $ 1,036 | $ 696 |
| Stock-based compensation | 129 | 143 |
| Professional fees and consulting services | 814 | 841 |
| Lab expenses | 488 | 779 |
| Depreciation expenses, net | 152 | 171 |
| Other research and development expenses | 4,363 | 129 |
| Less – grant | (31) | (251) |
| Total | $ 6,951 | $ 2,508 |

Research and development expenses for the three months ended September 30, 2020 were $6,951 thousand, as compared to $2,508 thousand for the three months ended September 30, 2019, representing an increase of 177%. The increase is mainly attributable to the following:

- expansion of the Company's pipeline of licensed CGTs with a harmonized pathway for regulatory approval;
- investment in automated processing units & processes;
- developing owned and licensed advanced therapies to enable commercial production;
- works with partners to enable efficient closed processing system technologies addressing POCare needs; and
- 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 (See Note 6).

Selling, General and Administrative Expenses

| | Three-Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Salaries and related expenses | $ 721 | $ 471 |
| Stock-based compensation | 446 | 217 |
| Accounting and legal fees | 1,657 | 425 |
| Professional fees | 403 | 316 |
| Rent and related expenses | 151 | 6 |
| Business development | 282 | 215 |
| Expenses related to a joint venture | - | 372 |
| Depreciation expenses, net | 26 | 34 |
| Other general and administrative expenses | 356 | 356 |
| Total | $ 4,042 | $ 2,412 |

Selling, general and administrative expenses for the three months ended September 30, 2020 were $4,042 thousand, as compared to $2,412 thousand for the three months ended September 30, 2019, representing an increase of 68%.The increase in selling, general and administrative expenses in the three months ended September 2020 compared to the three months ended September 30, 2019 is primarily attributable to an increase in salaries and related expenses and stock based compensation due to increased compensation, and an increase in accounting and legal fees of $1,232 thousand, which is mainly attributable to additional legal fees incurred for recent business and collaboration agreements.

Financial Expenses, net

| | Three-Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Decrease in fair value financial liabilities and assets measured at fair value | $ - | $ 63 |
| Interest expense on convertible loans and loans | 249 | 14 |
| Foreign exchange loss (gain), net | 59 | 249 |
| Other expenses (income) | (70) | 120 |
| Total | $ 238 | $ 446 |

Financial expenses, net for the three months ended September 30, 2020 were $238 thousand, as compared to $446 thousand for the three months ended September 30, 2019, representing a decrease of 47%.

**Comparison of the Nine Months Ended September 30, 2020 to the Nine Months Ended September 30, 2019.**

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

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Revenues | $ 4,305 | $ 1,537 |
| Revenues to Related Party | 1,051 | 1,245 |
| Cost of research and development and research and development services | 36,787 | 11,193 |
| Amortization of intangible assets | 258 | 323 |
| Selling, general and administrative expenses | 11,171 | 8,437 |
| Financial expenses, net | 904 | 594 |
| Other income, net | (9) | (15) |
| Loss before income taxes | $ 43,755 | $ 17,750 |

Our revenues for the nine months ended September 30, 2020 were $5,356 thousand, as compared to $2,782 thousand for the nine months ended September 30, 2019, representing an increase of 93%. The increase in revenues for the nine months ended September 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

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Salaries and related expenses | $ 3,231 | $ 2,297 |
| Stock-based compensation | 348 | 493 |
| Professional fees and consulting services | 1,789 | 2,591 |
| Lab expenses | 1,638 | 2,679 |
| First Choice JVA | - | 2,741 |
| Tamir Purchase Agreement. Note 6 | 19,510 | - |
| Depreciation expenses, net | 415 | 397 |
| Other research and development expenses | 10,025 | 811 |
| Less – grant | (169) | (816) |
| Total | $ 36,787 | $ 11,193 |

Research and development expenses for the nine months ended September 30, 2020 were $36,787 thousand, as compared to $11,193 thousand for the nine months ended September 30, 2019, representing an increase of 229%.

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 detailed above in the “Comparison of the Three Months Ended September 30, 2020 to the Three Months Ended September 30, 2019,” as well as the Tamir Purchase Agreement.

Selling, General and Administrative Expenses

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Salaries and related expenses | $ 1,590 | $ 1,833 |
| Stock-based compensation | 1,474 | 1,614 |
| Accounting and legal fees | 5,074 | 1,646 |
| Professional fees | 1,229 | 992 |
| Rent and related expenses | 280 | 183 |
| Business development | 707 | 891 |
| Expenses related to a joint venture | - | 372 |
| Depreciation expenses, net | 76 | 87 |
| Other general and administrative expenses | 741 | 819 |
| Total | $ 11,171 | $ 8,437 |

Selling, general and administrative expenses for the nine months ended September 30, 2020 were $11,171 thousand, as compared to $8,437 thousand for the nine months ended September 30, 2019, representing an increase of 32%. The increase in selling, general and administrative expenses in the nine months ended in September 2020 compared to the nine months ended September 30, 2019 is primarily attributable to the following:

(i) A decrease in salaries and related expenses and stock-based compensation of $383 thousand, due the reassignment of certain employees from selling, general, and administration to research and development services; and

(ii) An increase in accounting and legal fees of $3,428 thousand, which is mainly attributable to legal fees incurred for recent business and collaboration agreements.

Financial Expenses, net

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Decrease in fair value financial liabilities and assets measured at fair value | $ - | $ 63 |
| Interest expense on convertible loans and loans | 988 | 25 |
| Foreign exchange loss, net | 224 | 325 |
| Other expenses (income) | (308) | 181 |
| Total | $ 904 | $ 594 |

Financial expenses, net for the nine months ended September 30, 2020 were $904 thousand, as compared to $594 thousand for the nine months ended September 30, 2019, representing an increase of 52%. The increase is primarily attributable to interest expenses on convertible loans.

**Working Capital**

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| | (In Thousands) | |
| Current assets | $ 94,983 | $ 78,348 |
| Current liabilities | 12,355 | 42,434 |
| Working capital gain | $ 82,628 | $ 35,914 |

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

**Liquidity and Financial Condition**

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2020 | September 30, 2019 |
| | (In Thousands) | |
| Net income (loss) | $ 52,190 | $ (19,189) |
| Net cash used in operating activities | (32,819) | (10,514) |
| Net cash provided by (used in) investing activities | 103,865 | (7,269) |
| Net cash provided by financing activities | 6,150 | 13,682 |
| Increase in cash and cash equivalents | $ 77,196 | $ (4,101) |

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 nine month period ended September 30, 2020, we funded our operations with the proceeds of 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 million.

Net cash used in operating activities for the nine months ended September 30, 2020 was approximately $33 million, as compared to net cash used in operating activities of approximately $11 million for the nine months ended September 30, 2019.

Net cash provided by investing activities for the nine months ended September 30, 2020 was approximately $104 million, as compared to net cash used in investing activities of approximately $7 million for the nine months ended September 30, 2019.

Net cash provided by financing activities for the nine months ended September 30, 2020 was approximately $6 million, as compared to net cash provided by financing activities of approximately $14 million for the nine months ended September 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 from the sale of Masthercell were approximately $126.7 million, of which $7.2 million were used for the repayment 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 September 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:

*Risks Related to Our Company and POC Business*

**We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.**

We have entered into collaborations and joint ventures and may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners for which the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not perform their obligations as expected;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them and, in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. The success of our existing and future collaboration arrangements and strategic partnerships, which include research and development services by our collaborators to improve our intellectual property, will depend heavily on the efforts and activities of our collaborators and may not be successful. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

**Our success will depend on strategic collaborations with third parties to develop and commercialize therapeutic product candidates, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.**

A key aspect of our strategy is to seek collaborations with partners, such as a large pharmaceutical organization, that is willing to further develop and commercialize a selected product candidate. To date, we have entered into a number of collaborative arrangements with cell therapy organizations. By entering into any such strategic collaborations, we may rely on our partner for financial resources and for development, regulatory and commercialization expertise. Our partner may fail to develop or effectively commercialize our product candidate because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;

- decide to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture or obtain the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into additional collaborations on acceptable terms, if at all. We face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support. If we are not successful in attracting a partner and entering into a collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

***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

| No. | Description |
|---|---|
| **(2)** | **Plan of Acquisition, Reorganization, Arrangement, Liquidation, or Succession** |
| 2.1 | Agreement and Plan of Merger and Reorganization, dated as of September 26, 2020 by and among Orgenesis Inc., Orgenesis Merger Sub, Inc., Koligo Therapeutics Inc., the Shareholders of Koligo and Long Hill Capital V, LLC, solely in its capacity as representative of the Shareholders (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 2020). |
| **(4)** | **Instruments Defining the Rights of Securities Holders, Including Indentures** |
| 4.1 | Form of Stock Option Agreement (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-8, filed with the SEC on August 7, 2020). |
| **(10)** | **Material Contracts** |
| 10.1 | Form of Registration Rights and Lock-Up Agreement between the Company, Long Hill Capital V, LLC, Maxim Group, LLC and University of Louisville Research Foundation, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 2020). |
| 10.2 | Form of Shareholders Lock-Up Agreement between the Company and Shareholders other than Long Hill Capital V, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 2020). |
| **(31)** | **Rule 13a-14(a)/15d-14(a) Certification** |
| 31.1* | Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 |
| 31.2* | Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 |
| **(32)** | **Section 1350 Certification** |
| 32.1* | Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002 |
| 32.2* | Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002 |
| **(101)*** | **Interactive Data Files** |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) |

* *Filed herewith.*

SIGNATURES

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

**ORGENESIS INC.**

By: */s/ Vered Caplan*

Vered Caplan
President & Chief Executive Officer
(Principal Executive Officer)
Date: November 5, 2020

*/s/ Neil Reithinger*

Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: November 5, 2020

**Exhibit 31.1**

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

I, Vered Caplan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 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: November 5, 2020

**Exhibit 31.2**

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

I, Neil Reithinger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 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: November 5, 2020

**Exhibit 32.1**

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

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

(a) The Quarterly Report on Form 10-Q of Orgenesis Inc. for the quarter ended September 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: November 5, 2020

**Exhibit 32.2**

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

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

(a) The Quarterly Report on Form 10-Q of Orgenesis Inc. for the quarter ended September 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: November 5, 2020