UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number 001-35996

Organovo Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**27-1488943**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
440 Stevens Ave, Suite 200, Solana Beach, CA 92075	**(858) 224-1000**
(Address of principal executive offices and zip code)	**(Registrant's telephone number, including area code)**

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

Title of each class	Trading symbol	Name of Each Exchange on which registered
Common Stock, $0.001 par value	**ONVO**	**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 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 any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of August 1, 2020, a total of 130,618,203 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

ORGANOVO HOLDINGS, INC.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Organovo Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands except for share and per share data)

	June 30, 2020 (Unaudited)	March 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 24,787	$ 27,356
Accounts receivable	84	111
Prepaid expenses and other current assets	630	851
Total current assets	25,501	28,318
Other assets, net	120	123
Total assets	$ 25,621	$ 28,441
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 110	$ 720
Accrued expenses	725	1,090
Total current liabilities	835	1,810
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 130,618,203 and 130,558,098 shares issued and outstanding at June 30, 2020 and March 31, 2020, respectively	131	131
Additional paid-in capital	306,889	305,965
Accumulated deficit	(282,234)	(279,465)
Total stockholders' equity	24,786	26,631
Total Liabilities and Stockholders' Equity	$ 25,621	$ 28,441

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

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss
(in thousands except share and per share data)

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019
Revenues		
Products and services	$ —	$ 606
Collaborations and licenses	—	10
Grants	—	52
Total Revenues	—	668
Cost of revenues	—	51
Research and development expenses	—	3,823
Selling, general and administrative expenses	2,786	3,315
Total costs and expenses	2,786	7,189
Loss from Operations	(2,786)	(6,521)
Other Income (Expense)		
Gain on fixed asset disposals	6	1
Interest income	8	197
Other Income	5	—
Total Other Income	19	198
Income Tax Expense	(2)	—
Net Loss	$ (2,769)	$ (6,323)
Net loss per common share—basic and diluted	$ (0.02)	$ (0.05)
Weighted average shares used in computing net loss per common share—basic and diluted	130,588,481	126,854,907
Comprehensive Loss:		
Net loss	$ (2,769)	$ (6,323)
Comprehensive loss	$ (2,769)	$ (6,323)

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

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity
(in thousands)

	Three Months Ended June 30, 2019				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at March 31, 2019	**124,015**	**$ 124**	**$ 296,929**	**$ (260,755)**	**$ 36,298**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	177	—	(52)	—	(52)
Issuance of common stock from public offering, net	6,087	6	4,990	—	4,996
Stock-based compensation expense	—	—	1,220	—	1,220
Net loss	—	—	—	(6,323)	(6,323)
Balance at June 30, 2019 (Unaudited)	**130,279**	**$ 130**	**$ 303,087**	**$ (267,078)**	**$ 36,139**

	Three Months Ended June 30, 2020				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at March 31, 2020	**130,558**	**$ 131**	**$ 305,965**	**$ (279,465)**	**$ 26,631**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	60	—	(1)	—	(1)
Stock-based compensation	—	—	925	—	925
Net loss	—	—	—	(2,769)	(2,769)
Balance at June 30, 2020 (Unaudited)	**130,618**	**$ 131**	**$ 306,889**	**$ (282,234)**	**$ 24,786**

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

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019
Cash Flows From Operating Activities		
Net loss	$ (2,769)	$ (6,323)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of fixed assets	(6)	(1)
Depreciation and amortization	4	205
Stock-based compensation	925	1,220
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	27	(35)
Grants receivable	—	(44)
Inventory	—	(16)
Prepaid expenses and other assets	224	360
Accounts payable	(610)	(75)
Accrued expenses	(365)	(1,142)
Deferred revenue	—	7
Operating lease right-of-use assets and liabilities, net	—	(91)
Net cash used in operating activities	(2,570)	(5,935)
Cash Flows From Investing Activities		
Proceeds from disposals of fixed assets	2	1
Net cash provided by investing activities	2	1
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	—	4,996
Employee taxes paid related to net share settlement of equity awards	(1)	(52)
Net cash provided by (used in) financing activities	(1)	4,944
Net decrease in cash, cash equivalents, and restricted cash	(2,569)	(990)
Cash, cash equivalents, and restricted cash at beginning of period	27,356	36,556
Cash, cash equivalents, and restricted cash at end of period	$ 24,787	$ 35,566
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 24,787	$ 35,487
Restricted cash	—	79
Total cash, cash equivalent and restricted cash	$ 24,787	$ 35,566
Supplemental Disclosure of Cash Flow Information:		
Receivable related to fixed asset sales	$ 5	$ —
Assets held for sale	$ 1	$ —
Income taxes paid	$ (2)	$ —

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

Note 1. Description of Business

Nature of operations

Organovo Holdings, Inc. ("Organovo Holdings," "Organovo," and "the Company") is an early-stage biotechnology company that has focused on pioneering the development of bioprinted 3D human tissues that emulate key aspects of human biology and disease. Except where specifically noted or the context otherwise requires, references to "Organovo Holdings," "the Company," and "Organovo" in these notes to the unaudited condensed consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc. and Opal Merger Sub, Inc.

Historical Operations and Strategic Alternatives Process

Prior to August 2019, the Company has focused its efforts on developing its *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. The Company also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. In the past, the Company also explored the development of *in vitro* tissues, including proof of concept models of diseased tissues, for use in drug discovery and development.

In August 2019, after a rigorous assessment of its *in vitro* liver therapeutic tissue program, the Company concluded that the variability of biological performance and related duration of potential benefits no longer supported an attractive opportunity due to redevelopment challenges and lengthening timelines to compile sufficient data to support an IND filing. As a result, the Company suspended development of its lead program and all other related in-house pipeline development activities.

The Company's Board also engaged a financial advisory firm to explore the Company's available strategic alternatives, including evaluating a range of ways to generate value from its technology platform and intellectual property, its commercial and development capabilities, its listing on the Nasdaq Capital Market, and the Company's remaining financial assets. These strategic alternatives included possible mergers and business combinations, sales of part or all of our assets, and licensing and partnering arrangements. The Company implemented various restructuring steps to manage its resources and extend its cash runway, including reducing commercial activities related to its liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from its long-term facility lease, selling various assets, and reducing its workforce. Additionally, in November 2019, the Company sold certain inventory and equipment and related proprietary information held by its wholly-owned subsidiary, Samsara Sciences, Inc. ("Samsara"), and as a result of such sale, Samsara ceased its operations.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of more than 27 non-binding indications of interest from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with Tarveda, on December 13, 2019, the Company entered into a merger agreement with Tarveda (the "Merger Agreement"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, the Company's wholly-owned merger subsidiary would merge (the "Merger") into Tarveda, with Tarveda surviving the Merger. The Merger Agreement included various conditions to the consummation of the Merger, including approval by the Company's stockholders at a Special Meeting of Stockholders to be held on April 7, 2020 (the "Special Meeting").

At the Special Meeting, the Merger was not approved by the Company's stockholders. As a result, the Company terminated the Merger Agreement with Tarveda. Pursuant to the terms of the Merger Agreement, the Company was obligated to reimburse certain of Tarveda's merger-related expenses not to exceed $300,000, which was offset by Tarveda's portion of shared expenses incurred by Organovo in fiscal 2020.

The Cooperation Agreement and Advisory Nominees Proposal

Following the Special Meeting and the termination of the Merger Agreement, the Company's Board continued to solicit stockholder feedback regarding the Company's strategic alternatives and how to maximize stockholder value. In response to feedback from its largest stockholder regarding its desire for the Board to consider opportunities in the 3D bioprinting field and suggestion that the Board should speak with Keith Murphy, the Company's founder, stockholder and former Chief Executive Officer and Chairman, for potential business ideas, the Company's Board initiated discussions with Mr. Murphy. Based on these discussions, the Company entered into a Cooperation Agreement with Mr. Murphy on July 14, 2020 (the "Cooperation Agreement"). Under the terms of the Cooperation Agreement, the Board appointed Mr. Murphy and Adam K. Stern to the Board as Class III directors, and two of the

Company's existing directors, Richard Maroun and David Shapiro, resigned from the Board and all Board committees. The Board also agreed to nominate, recommend, support and solicit proxies for the re-election of Messrs. Murphy and Stern at the Company's 2020 Annual Meeting of Stockholders (the "2020 Annual Meeting"). The Board also agreed to nominate, recommend, support and solicit proxies for an advisory stockholder vote (the "Advisory Nominees Proposal") at the 2020 Annual Meeting to appoint three individuals, Douglas Jay Cohen, David Gobel and Alison Tjosvold Milhous (collectively, the "Advisory Nominees"), to the Board. Mr. Murphy identified each of the Advisory Nominees. If the final vote tabulation for the Advisory Nominees Proposal receives more votes cast "FOR" than "AGAINST" its approval, the Board has approved the appointment of the Advisory Nominees, to be automatically effective immediately following the final adjournment of the 2020 Annual Meeting. In addition, immediately following the appointment of the Advisory Nominees, each of our existing directors (other than Messrs. Murphy and Stern) will resign from the Board, which will result in Messrs. Murphy and Stern and the Advisory Nominees constituting the full membership of the Board (collectively, the "New Director Slate").

Proposed Drug Discovery Business

The New Director Slate has advised the Company that if the Advisory Nominees Proposal is approved at the 2020 Annual Meeting, the New Director Slate intends to recommence operations and focus the Company's efforts on developing highly customized human tissues as living, dynamic models of human biology and disease for use in drug discovery and development. The New Director Slate has advised the Company that it believes the Company's proprietary technology can be used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, and function. The New Director Slate also believes the Company can utilize its proprietary technology to develop highly customized and dynamic models of human disease, including cell type-specific compartments, prevalent intercellular tight junctions, and microvascular structures. They believe these features can facilitate the Company's development of complex, multicellular disease models for use in the development of targeted therapeutics for various diseases including, among others, intestine, kidney, skin and breast diseases. Market opportunities may include externally-partnered or internally-directed drug discovery and the clinical development of new molecular entities or repurposed drugs in-licensed from other pharmaceutical companies. The goal of the New Director Slate is for the Company to establish a pipeline of drug candidates in high-value disease areas, aiming to commence human clinical testing for at least one drug candidate within a three to four year timeframe.

If the Advisory Nominees Proposal is approved, the New Director Slate intends to restart the Company's research operations by hiring a team of R&D professionals with the experience required to develop bioprinted and other 3D tissues for use in drug discovery, to leverage 3D models of disease to discover new drug candidates, and to develop new drug candidates for the initiation of clinical studies.

The New Director Slate has advised the Company that they expect our research and development staff to grow to seven to ten employees. They also expect to maintain or grow a general and administrative staff of three to five employees to support the Company's operations and reporting requirements as a public company.

If the Advisory Nominees Proposal is approved, the New Director Slate has advised us that the Company expects to lease sufficient office and laboratory space to support its requirements. They expect that the Company will need space in the short term in the 3,000-7,000 sq. ft. range, with mixed office and laboratory space. They expect to lease a new facility in San Diego at prevailing market terms.

COVID-19

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. In particular, the continued coronavirus pandemic could adversely impact the Company's operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on the Company's business and financial results.

Note 2. Summary of Significant Accounting Policies

Basis of presentation and principles of consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not necessarily include all information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at March 31, 2020 is derived from the Company's audited consolidated balance sheet at that date.

The unaudited condensed consolidated financial statements include the accounts of Organovo Holdings and its wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of the Company's financial position, results of operations, stockholders' equity and cash flows. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended March 31, 2020, as filed with the Securities and Exchange Commission ("SEC"). Operating results for interim periods are not necessarily indicative of operating results for the Company's fiscal year ending March 31, 2021 (see "Note 1. Description of Business").

Liquidity

As of June 30, 2020, the Company had cash and cash equivalents of approximately $24.8 million and an accumulated deficit of approximately $282.2 million. The Company also had negative cash flows from operations of approximately $2.6 million during the three months ended June 30, 2020.

Through June 30, 2020, the Company has financed its operations primarily through the sale of convertible notes, warrants, the private placement of equity securities, the sale of common stock through public and at-the-market ("ATM") offerings, and through revenue derived from product and research service-based agreements, collaborative agreements, licenses, and grants. During the three months ended June 30, 2020, the Company issued no shares of its common stock through its ATM facility.

Throughout the strategic alternatives assessment process, the Company has taken steps to manage its resources and extend its cash runway including selling various assets and reducing its workforce to the minimum level necessary to explore and support these strategic alternatives as well as to support the remainder of the Company's on-going business activities and assets, including its intellectual property platform and collaborations with research institutions and universities.

The Company believes its cash and cash equivalents on hand will be sufficient to meet its financial obligations for at least the next 12 months of operations. If the Advisory Proposal is approved, this will trigger a "Change of Control" under Organovo's severance plan, as well as its Directors and Officers ("D&O") liability insurance policies, requiring the following cash outlays: i) approximately $3.0 million for severance obligations and ii) approximately $2.0 million (or $1.7 million net of returned premium) for a six year D&O tail insurance policy. In addition, to the extent the New Director Slate recommences the Company's operations and focus its efforts on drug discovery and development, the Company will need to raise additional capital to implement this new business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises. If required, the Company may seek to raise additional capital through debt or equity financings, or through some other financing arrangement. However, the Company cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company's business, operating results, financial condition and ability to continue as a going concern.

Use of estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Significant estimates used in preparing the unaudited condensed consolidated financial statements include those assumed in the valuation of stock-based compensation expense, the valuation of impairment of long-lived assets, our assessment of contingent liabilities that would require the establishment of a reserve, and the valuation allowance on deferred tax assets. On an ongoing basis, management reviews these estimates and assumptions. Though the impact of the COVID-19 pandemic to its business and operating results presents additional uncertainty, the Company continues to use the best information available to inform its critical accounting estimates.

Impairment of long-lived assets

In accordance with ASC 360-10, the Company records an impairment loss on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets (i.e. not able to be recovered). The Company's pursuit of strategic alternatives requires the reevaluation of the recoverability of the gross carrying value of its long-lived assets. The Company performed an asset impairment analysis on its long-lived asset group, consisting primarily of licensed intangible assets, computer equipment, and software following the completion of various asset sales prior to June 30, 2020, which concluded that the carrying amount is not recoverable. However, the Company's analysis indicated that carrying amount of the asset group does not exceed its fair value. As such, no impairment loss is required to be recognized. Nonetheless, it is reasonably possible that the impairment analysis may change in the near term resulting in the need to write down those assets to fair value. The Company will continue to monitor assets for impairment.

Revenue recognition

The Company has generated revenues from payments received from research service agreements, product sales, collaborative agreements with partners including pharmaceutical and biotechnology companies and academic institutions, licenses, and grants from the National Institutes of Health ("NIH") and private not-for-profit organizations.

The Company recognized revenue under Topic 606, *Revenue from Contracts with Customers* ("Topic 606") when (or as) the promised services were transferred to customers in an amount that reflects the consideration to which it expected to be entitled in exchange for those services. To determine revenue recognition for arrangements the Company concluded were within the scope of ASC 606, the Company performed the following five steps: (i) identified the contract(s) with a customer; (ii) identified the performance obligation(s) in the contract; (iii) determined the transaction price; (iv) allocated the transaction price to the performance obligation(s) in the contract; and (v) recognized revenue when (or as) the performance obligation(s) were satisfied. At contract inception, the Company assessed the goods or services promised within each contract, assessed whether each promised good or service was distinct and identified those that were performance obligations. The Company recognized as revenue the amount of the transaction price that was allocated to the respective performance obligation when (or as) the performance obligation was satisfied.

Billings to customers or payments received from customers were included in deferred revenue on the consolidated balance sheet until all revenue recognition criteria were met. As of June 30, 2020 and March 31, 2020, the Company had no deferred revenue.

Service revenues

The Company's service-based business, Organovo, Inc., utilized its NovoGen® bioprinting platform to provide customers access to its highly specialized tissues that model human biology and disease, and to *in vitro* testing services based on that technology. These contracts with customers contained multiple performance obligations including: (i) bioprinting tissues for the customer, (ii) reporting the results of tests performed on the printed tissues pursuant to the agreed upon work plan through exposure of the tissue to various factors (including the customer's proprietary compound), and (iii) delivering specific byproduct study materials, which were satisfied, respectively, at each of the following points in time: (i) upon completion of manufacturing of the bioprinted tissue for the customer, (ii) upon delivery of the report on tests performed on the tissue, and (iii) upon making certain study materials generated from the aforementioned testing process available to the customer. The customer did not have access or control of any performance obligation prior to the point in time of full completion of the corresponding performance satisfying event as defined above. Furthermore, although the service could be customized for each customer, it was not so highly customized as to not have an alternative use either to other customers or to the Company without significant economic consequences or rework. Accordingly, the Company's service-based business utilized point-in-time recognition under Topic 606.

For service contracts, the Company allocated the transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. If the standalone selling price was not observable through past transactions, the Company estimated the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations. The transaction price for service business contracts was a fixed consideration.

In connection to the Company's decision to pursue its strategic alternatives, the Company halted commercial activities related to its liver tissues. The Company is expected to continue to maintain its external research collaborations and its intellectual property portfolio.

Product sales, net

The Company's former product-based business, Samsara Sciences, Inc., produced high-quality cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognized product revenue when the performance obligation was satisfied, which was at the point in time the customer obtained control of the Company's product,

typically upon delivery. Product revenues were recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration did not differ materially from its historical practices. Variable consideration was estimated using the expected value method which considers the sum of probability-weighted amounts in a range of possible amounts under the contract. Product revenue reflected the Company's best estimates of the amount of consideration to which it was entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may have differed from the Company's estimates. If actual results varied materially from the Company's estimates, the Company would have adjusted these estimates, which would have affected revenue from product sales and earnings in the period such estimates were adjusted.

The Company provided no right of return to its customers except in cases where a customer obtained authorization from the Company for the return. To date, there have been no product returns.

In March 2020, the Company dissolved Samsara.

Collaborative research, development, and licenses

The Company has entered into collaborative agreements with partners that typically include one or more of the following: (i) non-exclusive license fees; (ii) non-refundable up-front fees; (iii) payments for reimbursement of research costs; (iv) payments associated with achieving specific development milestones; and (v) royalties based on specified percentages of net product sales, if any. At the initiation of an agreement, the Company analyzed whether it results in a contract with a customer under Topic 606 or in an arrangement with a collaborator subject to guidance under ASC 808, *Collaborative Arrangements* ("Topic 808").

The Company considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements were distinct performance obligations, whether there were determinable stand-alone prices, and whether any licenses were functional or symbolic. The Company evaluated each performance obligation to determine if it could be satisfied and recognized as revenue at a point in time or over time. Typically, non-exclusive license fees, non-refundable upfront fees, and funding of research activities were considered fixed, while milestone payments were identified as variable consideration which must be evaluated to determine if it was constrained and, therefore, excluded from the transaction price.

The Company's collaborative agreements that were not completed at the implementation of Topic 606 on April 1, 2018, consisted of research collaboration and limited technology access licenses. These agreements provided the licensee with a non-exclusive, non-transferable, limited, royalty-free technology license, including access to Organovo's proprietary bioprinter platform, training, and continued support by means of consumables and consultation throughout the duration of the contract. The Company determined that the intellectual property license was not distinct from the continued support promised under the agreement and was therefore a single combined performance obligation. The Company recognized revenue for these combined performance obligations over time for the duration of the license period, as the combined performance obligation would not be fully satisfied until the end of the contract.

As of September 30, 2019, the Company completed its obligations under the existing agreements with respect to receipts of revenue and does not anticipate recording any further revenue. See "Note 4. Collaborative Research, Development, and License Agreements" for more information on the Company's collaborative agreements.

Grant revenue

In July 2017, the NIH awarded the Company a "Research and Development" grant totaling approximately $1,657,000 of funding over three years. The Company concluded this government grant was not within the scope of Topic 606, as government entities do not meet the definition of a "customer" as defined by Topic 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company concluded this government grant did meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* did not apply, as the Company is a business entity and the grant was with a governmental agency.

Revenues from this grant were based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue was recognized as the Company incurred expenses that were related to the grant. The Company believes this policy was consistent with the overarching premise in Topic 606, to ensure that it recognized revenues to reflect the transfer of promised goods or services to customers in an amount that reflected the consideration to which it expected to be entitled in exchange for those goods or services, even though there was no "exchange" as defined in the ASC. The Company believed the recognition of revenue as costs were incurred and amounts became earned/realizable was analogous to the concept of transfer of control of a service over time under Topic 606.

In connection to the Company's decision to pursue its strategic alternatives, specific to the NIH NASH grant, all internal research activities have been halted and transferred to the University of California, San Diego, leaving a remaining available balance of approximately $0.5 million that will not be utilized by the Company.

Cost of revenues

The Company reported no cost of revenues for the three months ended June 30, 2020 and approximately $0.1 million in cost of revenues for the three months ended June 30, 2019. Cost of revenues consisted of costs related to manufacturing and delivering product and service revenue.

Net loss per share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and warrants, shares reserved for purchase under the Company's 2016 Employee Stock Purchase Plan ("ESPP"), the assumed release of restriction of restricted stock units, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the three months ended June 30, 2020 or 2019, as the Company reported a net loss for each respective period and the effect would have been anti-dilutive.

Common stock equivalents excluded from computing diluted net loss per share due to their anti-dilutive effect were approximately 12.0 million at June 30, 2020 and 14.6 million at June 30, 2019.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies. Unless otherwise stated, the Company believes that the impact of the recently issued accounting pronouncements that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

Adoption of New Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606, which provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. The amendments in this update provide more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. The key improvements to GAAP for collaborative arrangements resulting from this amendment are to (i) clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit-of-account, (ii) add unit-of-account guidance in Topic 808 to align with the guidance in Topic 606, and (iii) require that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments in this ASU are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. This new guidance became effective for the Company on April 1, 2020 and did not have a significant impact on the Company's unaudited condensed consolidated financial statements.

Note 3. Stockholders' Equity

Stock-based compensation expense and valuation information

Stock-based awards include stock options and restricted stock units under the 2012 Equity Incentive Plan, as amended ("2012 Plan") and Inducement Awards, performance-based restricted stock units under an Incentive Award Performance-Based Restricted Stock Unit Agreement, and rights to purchase stock under the 2016 Employee Stock Purchase Plan ("ESPP"). The Company calculates the grant date fair value of all stock-based awards in determining the stock-based compensation expense.

Stock-based compensation expense for all stock-based awards consists of the following (in thousands):

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019
Research and development	$ —	$ 164
General and administrative	$ 925	$ 1,056
Total	$ 925	$ 1,220

The total unrecognized compensation cost related to unvested stock option grants as of June 30, 2020 was approximately $2,651,000 and the weighted average period over which these grants are expected to vest is 1.58 years, assuming no change of control.

The total unrecognized compensation cost related to unvested restricted stock units (not including performance-based restricted stock units) as of June 30, 2020 was approximately $702,000, which will be recognized over a weighted average period of 1.48 years, assuming no change of control.

The total unrecognized compensation cost related to unvested performance-based restricted stock units as of June 30, 2020 was approximately $1,038,000, which will be recognized over a weighted average period of 1.19 years, assuming no change of control.

As of June 30, 2020, there are no participants enrolled into the employee stock purchase plan for the current purchase period, beginning March 1, 2020.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. Stock-based compensation expense is recognized over the vesting period using the straight-line method. The assumed dividend yield is based on the Company's expectation of not paying dividends in the foreseeable future. The Company uses the Company-specific historical volatility rate as the indicator of expected volatility. The risk-free interest rate assumption was based on U.S. Treasury rates. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options. The measurement and classification of share-based payments to non-employees is consistent with the measurement and classification of share-based payments to employees. There were no options granted in the three months ended June 30, 2020 and 2019.

The fair value of each restricted stock unit and performance-based restricted stock unit is recognized as stock-based compensation expense over the vesting term of the award. The fair value is based on the closing stock price on the date of the grant.

The Company uses the Black-Scholes valuation model to calculate the fair value of shares issued pursuant to the Company's ESPP. Stock-based compensation expense is recognized over the purchase period using the straight-line method. The fair value of ESPP shares was estimated at the purchase period commencement date using the following assumptions:

	Three Months Ended June 30, 2020*	Three Months Ended June 30, 2019
Dividend yield	—	—
Volatility	0.00%	43.69%
Risk-free interest rate	0.00%	2.52
Expected term	0 months	6 months
Grant date fair value	$ -	$ 0.29

*There are no participants in the ESPP for the current purchase period (beginning March 1, 2020).

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The Company uses the Company-specific historical volatility rate as the indicator of expected volatility. The risk-free interest rate assumption was based on U.S. Treasury rates. The expected life is the 6-month purchase period.

Preferred stock

The Company is authorized to issue 25,000,000 shares of preferred stock. There are no shares of preferred stock currently outstanding, and the Company has no current plans to issue shares of preferred stock.

Common stock

On June 25, 2019, the Company received a notice letter from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company no longer meets the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, the Company obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market. On March 26, 2020, the Company obtained shareholder approval to effect a reverse stock split in a range from 20:1 to 40:1, which remains subject to the approval of the Company's board of directors, in order to meet the minimum closing bid price per share requirement under the Nasdaq Listing Rules. On April 17, 2020 the Company received an additional notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since the Company had 66 calendar days remaining in its compliance period as of April 16, 2020, the Company will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. The Company can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. The Company intends to comply with the Price-based Requirements by effecting the Reverse Stock Split. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market. There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other listing requirements necessary to maintain the listing of its common stock on The Nasdaq Capital Market. The Company's failure to regain compliance during this second compliance period could result in delisting.

The Company has an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus previously declared effective by the Securities and Exchange Commission (the "SEC") on February 22, 2018 (the "2018 Shelf"), that expires on February 22, 2021, which registered $100,000,000 of common stock, preferred stock, warrants and units, or any combination of the foregoing.

On March 16, 2018, the Company entered into a Sales Agreement ("2018 Sales Agreement") with H.C. Wainwright & Co., LLC and Jones Trading Institutional Services LLC (each an "Agent" and together, the "Agents") and filed a prospectus supplement to the 2018 Shelf, pursuant to which the Company may offer and sell, from time to time through the Agents, shares of its common stock in at-the-market sales transactions having an aggregate offering price of up to $50,000,000 (the "Shares"). Any shares offered and sold will be issued pursuant to the Company's 2018 Shelf.

During the three months ended June 30, 2020 and 2019, the Company issued 0 and 6,087,382 shares of common stock, respectively, for net proceeds of $0 and $5.0 million in at-the-market offerings under the 2018 Sales Agreement.

As of June 30, 2020, the Company has sold an aggregate of 17,719,185 shares of common stock in at-the-market offerings under the 2018 Sales Agreement, with gross proceeds of approximately $18.7 million. Based on these sales, the Company cannot raise more than an aggregate of $81.3 million in future offerings under the 2018 Shelf, including the $31.3 million remaining available for future issuance through its at-the-market program under the 2018 Sales Agreement.

Restricted stock units

The following table summarizes the Company's restricted stock units (not including performance-based restricted stock units) activity from March 31, 2020 through June 30, 2020:

	Number of Shares		Weighted Average Price
Unvested at March 31, 2020	480,256	$	1.95
Granted	—	$	—
Vested	(61,626)	$	2.57
Cancelled / forfeited	—	$	—
Unvested at June 30, 2020	418,630	$	1.85

Performance-based restricted stock units

On April 24, 2017, the Company issued a Performance-Based Restricted Stock Unit Award for 208,822 shares of common stock (the "PBRSU") to its newly hired Chief Executive Officer. The PBRSU was issued outside of the 2012 Plan, in the Inducement Award Agreement, as an "inducement award" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of these awards are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. On August 23, 2017, the Board of Directors formally approved the vesting criteria for the PBRSU. The vesting of the PBRSU is divided into five separate tranches each with independent vesting criteria. The first four tranches had performance criteria related to annual revenue goals with measurement at the end of fiscal year 2018 (20 percent), fiscal year 2019 (20 percent), fiscal year 2020 (20 percent), and fiscal year 2021 (20 percent). The fifth tranche had a performance metric related to a path to profitability goal measured as Negative Adjusted Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") achievable at any point between the grant date and the end of fiscal year 2020 (20 percent). The number of units that ultimately vest for each tranche will range from 0 percent to 120 percent of the target amount, not to exceed 208,822 in aggregate. On December 12, 2018, the Board of Directors formally approved an amendment to the vesting criteria for the PBRSUs. As of December 12, 2018, 100 percent of the Negative Adjusted EBITDA tranche, or 41,764 shares had vested and 8,352 units had been forfeited. Based on the amendment to the vesting criteria, the remaining 158,706 units eligible to vest upon future performance were divided into three separate but equal tranches with independent vesting criteria based on the achievement of certain regulatory milestones. As of June 30, 2020, no tranches are expected to vest unless there is a change in control.

Based on the amended PBRSU vesting terms, a Type III modification, the modified grant date fair value of the PBRSUs is $165,000 of which one-third is being recognized over the expected service period of each tranche ending on April 23, 2023. The Company began recording stock-based compensation expense for the initial performance tranches after the August 23, 2017 grant date when the initial financial performance goals were established and approved and has modified its recording of compensation expense in accordance with the amended performance tranches beginning on December 12, 2018.

On July 2, 2019, the Company issued Performance-Based Restricted Stock Unit Awards (the "PBRSU Retention Awards") for an aggregate of 6,027,899 shares of common stock to its management team. The PBRSUs were issued pursuant to the 2012 Plan. The PBRSU Retention Awards will vest in full upon the earlier of the Company's engagement in a pre-IND meeting with the FDA, twenty-four months from the grant date, or a change in control. As of June 30, 2020, all PBRSUs are expected to vest twenty-four months from the grant date.

The following table summarizes the Company's performance-based restricted stock unit activity from March 31, 2020 through June 30, 2020:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2020	3,952,927	$ 0.51
Granted	—	$ —
Vested	—	$ —
Cancelled / forfeited	—	$ —
Unvested at June 30, 2020	3,952,927	$ 0.51

Stock options

The following table summarizes the Company's stock option activity from March 31, 2020 to June 30, 2020:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2020	7,638,076	$ 2.08	$ 37,440
Options granted	—	$ —	$ —
Options cancelled / forfeited	—	$ —	$ —
Options exercised	—	$ —	$ —
Outstanding at June 30, 2020	7,638,076	$ 2.08	$ 79,237
Vested and Exercisable at June 30, 2020	4,593,119	$ 2.48	$ 3,396

The weighted average remaining contractual term of options exercisable and outstanding at June 30, 2020 was approximately 7.13 years.

Employee Stock Purchase Plan

In June 2016, our Board of Directors adopted, and in August 2016 stockholders subsequently approved, the 2016 Employee Stock Purchase Plan ("ESPP"). The Company reserved 1,500,000 shares of common stock for issuance thereunder. The ESPP permits employees after five months of service to purchase common stock through payroll deductions, limited to 15 percent of each employee's compensation up to $25,000 per employee per year or 10,000 shares per employee per six-month purchase period. Shares under the ESPP are purchased at 85 percent of the fair market value at the lower of (i) the closing price on the first trading day of the six-month purchase period or (ii) the closing price on the last trading day of the six-month purchase period. The initial offering period commenced in September 2016. At June 30, 2020, there were 1,188,718 shares available for purchase under the ESPP.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at June 30, 2020:

Common stock options outstanding and reserved under the 2012 Plan	5,549,864
Common stock reserved under the 2012 Plan	14,158,654
Common stock reserved under the 2016 Employee Stock Purchase Plan	1,188,718
Restricted stock units outstanding under the 2012 Plan	418,630
Performance-based restricted stock units outstanding under the 2012 Plan	3,794,221
Common stock options outstanding and reserved under the Incentive Award Agreement	2,088,212
Performance-based restricted stock units outstanding under the Incentive Award Agreement	158,706
Total at June 30, 2020	27,357,005

Note 4. Collaborative Research, Development, and License Agreements

In December 2016, the Company signed a collaborative non-exclusive research affiliation with a university medical school and a non-profit medical charity, under which the Company received a one-time grant from the charity towards the placement of a NovoGen® Bioprinter at the university for the purpose of developing a kidney organoid for potential therapeutic applications. The Company received up-front payments in January and March 2017, which has been recorded as deferred revenue. Revenue of $0 and $10,000 was recorded under this agreement for the three months ended June 30, 2020 and 2019, respectively. The Company completed its obligations under this agreement and does not anticipate recording any further revenue.

Note 5. Commitments and Contingencies

Legal matters

In addition to commitments and obligations in the ordinary course of business, the Company may be subject, from time to time, to various claims and pending and potential legal actions arising out of the normal conduct of its business.

On January 30, 2020, the Company received a demand letter (the "Letter") from a purported stockholder alleging that the disclosures in the Form S-4 filed with the SEC on December 23, 2019 violated federal securities laws by failing to disclose certain allegedly material information. The Letter demands, among other things, that the Company make corrective disclosures and reserves the right to pursue legal action. The Company believes the assertions in the Letter are without merit and now moot.

On March 4, 2020, the Company received a letter from the SEC regarding an inquiry into certain of the Company's prior disclosures and related operations. The Company is cooperating with the SEC in response to a subpoena.

The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing litigation contingencies is subjective and requires judgments about future events. When evaluating contingencies, the Company may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against it may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of its potential liability.

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures. During the period presented, the Company has not recorded any accrual for loss contingencies associated with any claims or legal proceedings; determined that an unfavorable outcome is probable or reasonably possible; or determined that the amount or range of any possible loss is reasonably estimable. However, the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, if one or more of these legal matters were resolved against the Company in a reporting period, the Company's consolidated financial statements for that reporting period could be materially adversely affected.

Note 6. Leases

Operating Leases

In October 2019, the Company entered into an agreement to rent office space at 440 Stevens Avenue, Suite 200, Solana Beach, California 92075. This agreement is a month-to-month contract and can be terminated at-will by either party at any time. As such, the Company has concluded that this agreement does not contain a lease and will be expensed as incurred. Monthly rental payments are approximately $4,000 per month.

The Company recorded operating lease expense for its former facilities on 6275 Nancy Ridge Drive, San Diego, California 92121 and its copy machines on a straight-line basis over the life of the leases, which were terminated in the third quarter of fiscal 2019. For the three months ended June 30, 2020 and 2019, the Company recorded operating lease expense of approximately $0 and $262,000, respectively. In addition, the Company recorded rent expense for the office space of approximately $12,000 and $0 for the three months ended June 30, 2020 and 2019, respectively. Variable lease costs associated with the Company's leases, such as payments for additional monthly fees to cover the Company's share of certain facility expenses (common area maintenance, or CAM) are expensed as incurred. Variable lease expense was approximately $0 and $107,000 for the three months ended June 30, 2020 and 2019, respectively. Short-term lease cost for the three months ended June 30, 2020 and 2019 was approximately $0 and $15,000, respectively. The short-term lease was terminated in the second quarter of fiscal 2020.

Note 7. Concentrations

Credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company maintains cash balances at various financial institutions located within the United States. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. Balances may exceed federally insured limits. The Company has not experienced losses in such accounts and management believes that the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

The Company is also potentially subject to concentrations of credit risk in its revenues and accounts receivable. Because it was in the early commercial stage, the Company's revenues to date have been derived from a relatively small number of customers and collaborators. However, the Company has not historically experienced any accounts receivable write-downs and management does not believe significant credit risk exists as of June 30, 2020.

Note 8. Related Parties

From time to time, the Company will enter into an agreement with a related party in the ordinary course of its business and on terms and conditions it believes are as fair as those it offers and receives from independent third parties. These agreements are ratified by the Company's Board of Directors or a committee thereof pursuant to its related party transaction policy.

During fiscal 2020, the Company provided services to Viscient Biosciences ("Viscient"), an entity for which Keith Murphy, the Company's director, as of July 15, 2020, and former Chief Executive Officer and President, serves as the Chief Executive Officer and President. In addition to the services provided by Organovo, Viscient has purchased primary human cell-based products from its former subsidiary, Samsara. There was approximately $84,000 of accounts receivable outstanding as of June 30, 2020 and $60,000 of accounts receivable outstanding as of June 30, 2019. The Company and Viscient have agreed on a payment plan under which Viscient has made a payment of approximately $28,000 on or before June 17, 2020 and will make a payment of approximately $28,000 on or before July 24, 2020; $19,000 on or before August 23, 2020; $19,000 on or before September 22, 2020, and $19,000 on or before October 22, 2020. Through the date of filing, Viscient has made payments in aggregate of $84,000. Further, in July 2020, we entered into a Cooperation Agreement with Mr. Murphy. See "Note 1. Description of Business" and "Note 10. Subsequent Events" for more information.

Note 9. Restructuring

In August 2019, after a rigorous assessment of the Company's lead liver therapeutic tissue program following completion of various preclinical studies, the Company's Board of Directors (the "Board") concluded that the variability of biological performance and related duration of potential benefits presented development challenges and lengthy redevelopment timelines that no longer supported an attractive opportunity for the Company and its stockholders. Furthermore, the Board deemed the stage of development of the Company's other therapeutic pipeline assets, including stem cell based tissue programs, to be too premature to potentially reach IND filing status within an acceptable investment horizon and with the Company's available resources. As a result, the Company suspended all development of its lead program and all other related pipeline development activity and engaged a financial advisory firm to explore its strategic alternatives, including evaluating a range of ways to generate value from the Company's technology platform and intellectual property, its commercial and development capabilities, its listing on the Nasdaq Stock Market, and its remaining financial assets. Under the restructuring plan, the Company terminated the employment of 52 employees, or 90 percent of its workforce and recorded a restructuring charge during the year ended March 31, 2020 of approximately $2.7 million, related to employee severance and benefits costs, of which approximately $1.7 million was paid out during the fiscal second quarter, approximately $0.9 million was paid out during the fiscal third quarter, approximately $0.1 million was paid out during the fiscal fourth quarter, and less than $0.1 million was paid out during the first quarter of fiscal 2021.

No restructuring charges were recorded during the three months ended June 30, 2020 and 2019.

The following table summarizes the activity and balances of the restructuring reserve (in thousands):

	Severance for Involuntary Employee Terminations
Balance at March 31, 2020	$ 21
Reserve established	—
Increase to reserve	—
Utilization of reserve:	
Payments	(21)
Balance at June 30, 2020	$ —

Note 10. Subsequent Events

On July 14, 2020, we entered into a Cooperation Agreement with Mr. Murphy. Pursuant to the Cooperation Agreement, the Board appointed Messrs. Murphy and Stern to the six member Board as Class III directors, with terms expiring at the Company's 2020 Annual Meeting and two of the Company's existing directors, Richard Maroun and David Shapiro, resigned from the Board and from each Board committee on which they serve, effective immediately. The Board also agreed to nominate, recommend, support and solicit proxies for the re-election of Messrs. Murphy and Stern at the 2020 Annual Meeting. The Board also agreed to nominate, recommend, support and solicit proxies for an advisory stockholder vote (the "Advisory Nominees Proposal") at the 2020 Annual Meeting to appoint three individuals, Douglas Jay Cohen, David Gobel and Alison Tjosvold Milhous (collectively, the "Advisory Nominees"), to the Board. If the final vote tabulation for the Advisory Nominees Proposal receives more votes cast "FOR" than "AGAINST" its approval, our Board has approved the appointment of the Advisory Nominees, to be automatically effective immediately following the final adjournment of the 2020 Annual Meeting. In addition, immediately following the appointment of the Advisory Nominees, each of our existing directors (other than Messrs. Murphy and Stern) will resign from the Board, which will result in Messrs. Murphy and Stern and the Advisory Nominees constituting the full membership of the Board (collectively, the "New Director Slate") and will trigger a "Change of Control" under Organovo's severance plan, as well as its Directors and Officers ("D&O") liability insurance policies, requiring the following cash outlays: i) approximately $3.0 million for severance obligations and ii) approximately $2.0 million (or $1.7 million net of returned premium) for a six year D&O tail insurance policy. Please see "Note 1. Business Description" for a discussion of the new business plan the New Director Slate intends for the Company to pursue if they are appointed to the Board following the final adjournment of the 2020 Annual Meeting.

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

The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with our historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020. This discussion and analysis contains forward-looking statements, such as statements related to our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions such as "will," "may," "could," "should," or similar expressions, identify certain of these forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties, including those described in this Quarterly Report on Form 10-Q, as well as the risk factors disclosed in our Annual Report on the Form 10-K for the fiscal year ended March 31, 2020, filed with the Securities and Exchange Commission on May 28, 2020, that could cause our actual results or events to differ materially from those expressed or implied by such forward-looking statements. Except to the limited extent required by applicable law, the Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report.

Basis of Presentation

The unaudited condensed consolidated financial statements included in this Form 10-Q have been prepared in accordance with the Securities and Exchange Commission (the "SEC") instructions to Quarterly Reports on Form 10-Q. Accordingly, the unaudited condensed consolidated financial statements presented elsewhere in this Form 10-Q and discussed below are unaudited and do not contain all the information required by U.S. generally accepted accounting principles ("GAAP") to be included in a full set of financial statements. The audited financial statements for the year ended March 31, 2020, filed with the SEC on Form 10-K on May 28, 2020 include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Overview

We are an early-stage biotechnology company that has focused on pioneering the development of bioprinted 3D human tissues that emulate key aspects of human biology and disease.

Historical Operations and Strategic Alternatives Process

Prior to August 2019, we have focused our efforts on developing our *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. We also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. In the past, we also explored the development of *in vitro* tissues, including proof of concept models of diseased tissues, for use in drug discovery and development.

In August 2019, after a rigorous assessment of our *in vitro* liver therapeutic tissue program, we concluded that the variability of biological performance and related duration of potential benefits no longer supported an attractive opportunity due to redevelopment challenges and lengthening timelines to compile sufficient data to support an IND filing. As a result, we suspended development of our lead program and all other related in-house pipeline development activities.

Our Board also engaged a financial advisory firm to explore our available strategic alternatives, including evaluating a range of ways to generate value from our technology platform and intellectual property, our commercial and development capabilities, our listing on the Nasdaq Capital Market, and our remaining financial assets. These strategic alternatives included possible mergers and business combinations, sales of part or all of our assets, and licensing and partnering arrangements. We implemented various restructuring steps to manage our resources and extend our cash runway, including reducing commercial activities related to our liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from our long-term facility lease, selling various assets, and reducing our workforce. Additionally, in November 2019, we sold certain inventory and equipment and related proprietary information held by our wholly-owned subsidiary, Samsara Sciences, Inc. ("Samsara"), and as a result of such sale, Samsara ceased its operations.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of more than 27 non-binding indications of interest from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with

Tarveda, on December 13, 2019, we entered into a merger agreement with Tarveda (the "Merger Agreement"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, our wholly-owned merger subsidiary would merge (the "Merger") into Tarveda, with Tarveda surviving the Merger. The Merger Agreement included various conditions to the consummation of the Merger, including approval by our stockholders at a Special Meeting of Stockholders scheduled for April 7, 2020 (the "Special Meeting").

At the Special Meeting, the Merger was not approved by our stockholders. As a result, we terminated the Merger Agreement with Tarveda. Pursuant to the terms of the Merger Agreement, we were obligated to reimburse certain of Tarveda's merger-related expenses not to exceed $300,000, which was offset by Tarveda's portion of shared expenses incurred by Organovo in fiscal 2020.

The Cooperation Agreement and Advisory Nominees Proposal

Following the Special Meeting and the termination of the Merger Agreement, our Board continued to solicit stockholder feedback regarding the Company's strategic alternatives and how to maximize stockholder value. In response to feedback from our largest stockholder regarding its desire for the Board to consider opportunities in the 3D bioprinting field and suggestion that the Board should speak with Keith Murphy, the Company's founder, stockholder and former Chief Executive Officer and Chairman, for potential business ideas, our Board initiated discussions with Mr. Murphy. Based on these discussions, we entered into a Cooperation Agreement with Mr. Murphy on July 14, 2020 (the "Cooperation Agreement"). Under the terms of the Cooperation Agreement, the Board appointed Mr. Murphy and Adam K. Stern to the Board as Class III directors, and two of the Company's existing directors, Richard Maroun and David Shapiro, resigned from the Board and the committees thereof. The Board also agreed to nominate, recommend, support and solicit proxies for the re-election of Messrs. Murphy and Stern at the Company's 2020 Annual Meeting of Stockholders (the "2020 Annual Meeting"). The Board also agreed to nominate, recommend, support and solicit proxies for an advisory stockholder vote (the "Advisory Nominees Proposal") at the 2020 Annual Meeting to appoint three individuals, Douglas Jay Cohen, David Gobel and Alison Tjosvold Milhous (collectively, the "Advisory Nominees"), to the Board. Mr. Murphy identified each of the Advisory Nominees. If the final vote tabulation for the Advisory Nominees Proposal receives more votes cast "FOR" than "AGAINST" its approval, the Board has approved the appointment of the Advisory Nominees, to be automatically effective immediately following the final adjournment of the 2020 Annual Meeting. In addition, immediately following the appointment of the Advisory Nominees, each of our existing directors (other than Messrs. Murphy and Stern) will resign from the Board, which will result in Messrs. Murphy and Stern and the Advisory Nominees constituting the full membership of the Board (collectively, the "New Director Slate").

Proposed Drug Discovery Business

The New Director Slate has advised us that if the Advisory Nominees Proposal is approved at the 2020 Annual Meeting, the New Director Slate intends to recommence operations and focus our future efforts on developing highly customized human tissues as living, dynamic models of human biology and disease for use in drug discovery and development. The New Director Slate has advised us that it believes our proprietary technology can be used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, and function. The New Director Slate also believes we can utilize our proprietary technology to develop highly customized and dynamic models of human disease, including cell type-specific compartments, prevalent intercellular tight junctions, and microvascular structures. They believe these features can facilitate the development of complex, multicellular disease models for use in the development of targeted therapeutics for various diseases including, among others, intestine, kidney, skin and breast diseases. Market opportunities may include externally-partnered or internally-directed drug discovery and the clinical development of new molecular entities or repurposed drugs in-licensed from other pharmaceutical companies. The goal of the New Director Slate is to establish a pipeline of drug candidates in high-value disease areas, aiming to commence human clinical testing for at least one drug candidate within a three to four year timeframe.

The New Director Slate advised us that it believes we have a significant opportunity to change the classic model of drug discovery using 3D bioprinted human tissues and other 3D models (sometimes known as "organoids" or "organs on a chip"). They have advised that the Company's new paradigm will involve augmenting available animal disease models, or replacing animal disease models altogether, in the discovery process with more relevant disease models utilizing 3D bioprinted human tissues developed by the Company. They believe our 3D bioprinted human tissues may enable us to study the treatment of human disease by replicating key aspects of human biology in areas where this is currently a challenge with existing models. Rather than offering contract research services (as we have done in the past), they believe we should focus on identifying and developing our own drug candidates, including from unique compounds or repurposed drugs in-licensed from other pharmaceutical companies. After identifying a drug candidate, they may have us out-license the drug candidate or they may elect to have us develop the drug candidate internally. In addition to drug discovery, they believe we should continue to evaluate opportunities to monetize our intellectual property and technologies along the way as a means to generate funds to support our primary business. They also believe that we should continue to identify and work with partners and collaborators, including leading academic research sites, to develop new enabling applications which can support its discovery and development mission.

If the Advisory Nominees Proposal is approved, the New Director Slate intends to restart our research and development operations by hiring a team of R&D professionals with the experience required to develop bioprinted and other 3D tissues for use in drug discovery, to leverage 3D models of disease to discover new drug candidates, and to develop new drug candidates for the initiation of clinical studies.

The New Director Slate has advised us that they expect our research and development staff to grow to seven to ten employees. They also expect to maintain or grow a general and administrative staff of three to five employees to support our operations and reporting requirements as a public company.

If the Advisory Nominees Proposal is approved, the New Director Slate has advised us that they expect to lease sufficient office and laboratory space to support our requirements. They expect that we will need space in the short term in the 3,000-7,000 sq. ft. range, with mixed office and laboratory space. They expect to lease a new facility in San Diego at prevailing market terms.

In the event the Advisory Nominees Proposal is not approved by our stockholders, we may pursue one of the following courses of action, which include but are not limited to the following actions:

- Pursue another strategic transaction similar to the Merger. We may resume our process of evaluating other candidate companies interested in pursuing a strategic transaction and, if a candidate is identified, focus our attention on negotiating and completing such strategic transaction with such candidate.

- Continue to operate and expand our business. We could elect to continue to operate and expand our business and pursue licensing or partnering transactions or utilize our intellectual property and platform technology to pursue the redevelopment of our liver tissues or the development of therapeutic tissues currently being studied by our collaborators. Due to the early development stage of our, and our collaborators', potential therapeutic tissues, any such redevelopment or development efforts would require a significant amount of time and financial resources, and would be subject to all the risk and uncertainties involved in the development of novel, early stage therapeutic products, research tools, and drug screening technologies. There is no assurance that we could raise sufficient capital to support these efforts, that our development efforts would be successful commercially in the case of research applications or that we could successfully obtain any required regulatory approvals required to market any therapeutic product we pursued. We would also need to increase qualified scientific, sales and marketing, and administrative staffing, lease a suitable facility and make other expenditures necessary to support these efforts.

- Dissolve and liquidate our assets. Our Board may determine that it is in the best interests of the Company and our stockholders to dissolve and liquidate our assets, subject to approval by our stockholders. In that event, we would be required to pay all of our debts and contractual obligations and to set aside certain reserves for potential future claims. If we dissolve and liquidate our assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to our stockholders after paying our debts and other obligations and setting aside funds for our contingent liabilities.

COVID-19

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. In particular, the continued COVID-19 pandemic could adversely impact our operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products each of which could have an adverse impact on our business and our financial results. However, our employees and consultants have been working remotely prior to the COVID-19 pandemic and we currently believe our operations have not otherwise been negatively impacted by the pandemic.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to stock-based compensation expense, the valuation of impairment of long-lived assets, and the valuation allowance on deferred tax assets. Though the impact of the COVID-19 pandemic to our business and operating results presents additional uncertainty, we continue to use the best information available to inform our critical accounting estimates. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known. Besides the estimates identified above that are considered critical, we make many other accounting estimates in preparing our financial statements and related disclosures. All estimates, whether or not deemed critical, affect reported amounts of assets, liabilities, revenues and expenses, as well as disclosures of contingent assets and liabilities. These estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known, even for estimates and judgments that are not deemed critical.

There have been no significant changes to our critical accounting policies since March 31, 2020. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements, refer to Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Note 1. Description of Business and Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended March 31, 2020, filed with the SEC on May 28, 2020.

Results of Operations

Comparison of the three months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019 (in thousands, except %):

	Three months ended June 30,		Increase (decrease)	
	2020	2019	$	%
Revenues	$ -	$ 668	$ (668)	(100%)
Cost of revenues	$ -	$ 51	$ (51)	(100%)
Research and development	$ -	$ 3,823	$ (3,823)	(100%)
Selling, general and administrative	$ 2,786	$ 3,315	$ (529)	(16%)
Other income	$ 19	$ 198	$ (179)	(90%)

Revenues

We had no revenue for the three months ended June 30, 2020 compared to $0.7 million of revenue for the three months ended June 30, 2019, due to a cessation of revenue generating activities following our decision to restructure operations to preserve capital as we pursue various strategic alternatives.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services was zero for the three months ended June 30, 2020, compared to approximately $0.1 million for the three months ended June 30, 2019. The decrease was due to the cessation of revenue generating activities following our decision to restructure operations to preserve capital as we pursue various strategic alternatives.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2020 and 2019 (in thousands, except %):

	Three months ended June 30, 2020	% of total	Three months ended June 30, 2019	% of total	Increase (decrease) $	Increase (decrease) %
Research and development	$ -	0%	$ 3,528	92%	$ (3,528)	(100%)
Non-cash stock-based compensation	-	0%	164	4%	(164)	(100%)
Depreciation and amortization	-	0%	131	4%	(131)	(100%)
Total research and development expenses	**$ -**	**0%**	**$ 3,823**	**100%**	**$ (3,823)**	**(100%)**

Research and development expenses were zero, a decrease of $3.8 million, or 100%, from the prior year period as we eliminated all research and development activities following our decision to pursue our strategic alternatives during the second quarter of fiscal 2020. This action caused a $1.7 million reduction of personnel related costs, a $0.8 million reduction in lab supply costs, a $0.8 million reduction in facilities costs, and a $0.5 million reduction in all other costs. The Company's average full-time research and development staff decreased from an average of forty-one full-time employees for the three months ended June 30, 2019 to an average of zero full-time employees for the three months ended June 30, 2020. Going forward, based on the outcome of the Advisory Proposal vote and strategic decisions that the Board may make, the Company may elect to pursue renewed research and development activities with an associated increase in expenses.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended June 30, 2020 and 2019 (in thousands, except %):

	Three months ended June 30, 2020	% of total	Three months ended June 30, 2019	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 1,857	67%	$ 2,185	66%	$ (328)	(15%)
Non-cash stock-based compensation	925	33%	1,056	32%	(131)	(12%)
Depreciation and amortization	4	0%	74	2%	(70)	(95%)
Total selling, general and administrative expenses	**$ 2,786**	**100%**	**$ 3,315**	**100%**	**$ (529)**	**(16%)**

For the three months ended June 30, 2020, selling, general and administrative expenses were approximately $2.8 million, a decrease of $0.5 million, or 16%, over the prior year period as we restructured our operations to preserve capital as we explore strategic alternatives. These actions caused a $0.9 million decrease in personnel costs and a $0.1 million decrease in all other costs, which were offset by a $0.3 million increase in corporate costs and a $0.2 million increase in allocated facilities costs. Our average selling, general and administrative headcount was six full-time employees for the three months ended June 30, 2020 compared to twenty-one full-time employees in the prior year period.

Other Income (Expense)

Other income was less than $0.1 million for the three months ended June 30, 2020 as compared to $0.2 million for the three months ended June 30, 2019, due to a decrease in interest income caused by lower average yields and investment balances.

Financial Condition, Liquidity and Capital Resources

Until our recent decision to explore strategic alternatives, we had primarily devoted our efforts to developing and commercializing a platform technology to produce and study living tissues that emulate key aspects of human biology and disease, raising capital and building infrastructure. Following the decision to explore strategic alternatives, we have taken steps to manage our resources and extend our cash runway, including reducing all commercial and research and development laboratory activities, except for sales of primary human cells out of inventory, negotiating an exit from our long-term facility lease, selling lab equipment and inventory, and reducing our workforce to the minimum level necessary to explore and support these strategic alternatives and maintain our core intellectual property, licenses and collaborations with research institutions and universities.

As of June 30, 2020, we had cash and cash equivalents of approximately $24.8 million and an accumulated deficit of $282.2 million. We also had negative cash flow from operations of $2.6 million during the three months ended June 30, 2020. At March 31, 2020, we had cash and cash equivalents of approximately $27.4 million and an accumulated deficit of $279.5 million.

At June 30, 2020, we had total current assets of approximately $25.5 million and current liabilities of approximately $0.8 million, resulting in working capital of $24.7 million. At March 31, 2020, we had total current assets of approximately $28.3 million and current liabilities of approximately $1.8 million, resulting in working capital of $26.5 million.

The following table summarizes the primary sources and uses of cash for the three months ended June 30, 2020 and 2019 (in thousands):

	Three months ended June 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (2,570)	$ (5,935)
Investing activities	2	1
Financing activities	(1)	4,944
Net decrease in cash, cash equivalents, and restricted cash	$ (2,569)	$ (990)

Operating activities

Net cash used in operating activities for the three months ended June 30, 2020 was approximately $2.6 million as compared to $5.9 million used in operating activities for the three months ended June 30, 2019. This $3.4 million decrease in operating cash usage can be attributed primarily to a $3.1 million improvement in the net loss less depreciation and amortization and stock-based compensation, resulting from the Company's restructuring and reduction of headcount and a $0.3 million reduction in the change in working capital between the two periods.

Investing activities

Net cash provided by investing activities was less than $0.1 million for the three months ended June 30, 2020 and 2019.

Financing activities

Net cash used by financing activities was less than $0.1 million during the three months ended June 30, 2020 compared to net cash provided by financing activities of approximately $4.9 million during the three months ended June 30, 2019. Financing in the prior year period was driven by the sale of common stock through at-the-market ("ATM") offerings.

Operations funding requirements

Through June 30, 2020, we have financed our operations primarily through the sale of common stock in public offerings, the private placement of equity securities, from revenue derived from products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes.

Throughout the strategic alternatives assessment process, the Company has taken steps to manage its resources and extend its cash runway including selling various assets and reducing its workforce to the minimum level necessary to explore and support these strategic alternatives as well as to support the remainder of the Company's on-going business activities and assets, including its intellectual property platform and collaborations with research institutions and universities.

The Company believes its cash and cash equivalents on hand will be sufficient to meet its financial obligations for at least the next 12 months of operations If the Advisory Proposal is approved, and the New Director Slate recommences the Company's operations and focuses its efforts on drug discovery and development, the Company will need to raise additional capital to implement this new business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises.

Based on our use of the 2018 Shelf through June 30, 2020, we cannot raise more than $81.3 million in future offerings under the 2018 Shelf, including through our at-the-market program.

Having insufficient funds may require us to relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. We cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company's business, operating results, financial condition and ability to continue as a going concern.

On June 25, 2019, we received a notice letter from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, we obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. On April 17, 2020 we received an additional notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since we had 66 calendar days remaining in the compliance period as of April 16, 2020, we will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. We can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market. We intend to comply with the Price-based Requirements by effecting a Reverse Stock Split.

As of June 30, 2020, we had 130,618,203 total issued and outstanding shares of common stock.

In addition, our 2008 Equity Incentive Plan provided for the issuance of up to 1,521,584 shares of common stock upon the exercise of outstanding stock options, of which 896,256 shares were issued. The 2008 Equity Incentive Plan terminated on July 1, 2018. The 2012 Equity Incentive Plan, as amended, provides for the issuance of up to 28,553,986 shares of our common stock, of which 14,158,654 shares remain available for issuance as of June 30, 2020, to executive officers, directors, advisory board members, employees and consultants. Additionally, 1,500,000 shares of common stock have been reserved for issuance under the 2016 ESPP, of which 1,188,718 shares remain available for future issuance as of June 30, 2020. Lastly, 2,246,918 shares of common stock have been reserved for issuances under Inducement Award Agreements. In aggregate, issued and outstanding common stock, shares underlying outstanding warrants, and shares issuable under outstanding equity awards or reserved for future issuance under the 2008 and 2012 Equity Incentive Plans, the Inducement Award Agreements, and the 2016 ESPP total 157,975,208 shares of common stock as of June 30, 2020.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We have certain warrants and options outstanding but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the underlying securities are registered, and/or all restrictions on trading, if any, are removed, and in either case the trading price of our common stock is significantly greater than the applicable exercise prices of the options and warrants.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies under Item 305(e).

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed pursuant to the Securities Exchange Act of 1934, as amended (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 and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the quarterly period covered by this report were designed and operating effectively.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on 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. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 5 of the Notes to the Unaudited Condensed Consolidated Financial Statements within this Form 10-Q for a discussion of our legal proceedings and contingencies.

ITEM 1A. RISK FACTORS

Investment in our common stock involves a substantial degree of risk and should be regarded as speculative. As a result, the purchase of our common stock should be considered only by persons who can reasonably afford to lose their entire investment. Before you elect to purchase our common stock, you should carefully consider the risk and uncertainties described below in addition to the other information incorporated herein by reference. Additional risks and uncertainties of which we are unaware or which we currently believe are immaterial could also materially adversely affect our business, financial condition or results of operations. If any of the risks or uncertainties discussed in this Annual Report occur, our business, prospects, liquidity, financial condition and results of operations could be materially and adversely affected, in which case the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to COVID-19

We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The continued COVID-19 pandemic could adversely impact our operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on our business and our financial results.

In addition, the stock market has been unusually volatile during the COVID-19 pandemic and such volatility may continue. Our stock price has also experienced volatility during this time, including occasional significant increases and decreases, and such increases and decreases may repeat or continue for the foreseeable future.

There are no comparable recent events which may provide guidance as to the effect of the COVID-19 pandemic, and, as a result, the ultimate impact of the pandemic, or any similar health epidemic that may occur in the future, is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects may have a material adverse impact on our future results of operations.

Risks Related to the Proposed Go Forward Business

If the Advisory Nominees Proposal is approved at the 2020 Annual Meeting, the New Director Slate has advised us that it intends for the Company to recommence operations and focus our efforts on utilizing our 3D bioprinting technology to develop human tissues and disease models for drug discovery and development. In this case, the Company will be recommencing its operations as an early-stage company with an unproven business strategy, and may never achieve profitability.

If the Advisory Nominees Proposal is approved at the Annual Meeting, the New Director Slate has advised us that it intends for the Company to recommence operations and focus its efforts on utilizing its 3D bioprinting technology to develop human tissues and disease models for drug discovery and development. In this case, the Company will be recommencing its operations as an early-stage company with an unproven business strategy, and may never achieve profitability. Our success will depend upon the viability of our platform technology and any disease models we develop, as well as on our ability to determine which drug candidates we should pursue. Our success will also depend on our ability to select an appropriate development strategy for any drug candidates we identify, including internal development or partnering or licensing arrangements with pharmaceutical companies. We may never achieve profitability, or even if we achieve profitability, we may not be able to maintain or increase our profitability.

The New Director Slate has advised us that they expect that the Company will incur substantial additional operating losses over the next several years as our research and development activities increase.

The New Director Slate has advised us that they expect that the Company will incur substantial additional operating losses over the next several years as our research and development activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things:

- successfully developing human tissues and disease models for drug discovery and development that enable us to identify drug candidates;
- successfully outsource certain portions of our development efforts;
- entering into partnering or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;
- obtaining any necessary regulatory approval for any drug candidates we identify; and
- raising sufficient funds to finance our activities and long-term business plan.

We might not succeed at any of these undertakings. If we are unsuccessful at one or more of these undertakings, our business, prospects, and results of operations will be materially adversely affected.

Using our platform technology to develop human tissues and disease models for drug discovery and development is new and unproven.

Utilizing our 3D bioprinting platform technology to develop human tissues and disease models for drug discovery and development will involve new and unproven technologies, disease models and approaches, each of which is subject to the risk associated with new and evolving technologies. To date, we have not identified or developed any drug candidates utilizing the business model recommended by the New Director Slate. Our future success will depend on our ability to utilize our 3D bioprinting platform to develop human tissues and disease models that will enable us to identify and develop viable drug candidates. We may experience unforeseen technical complications, unrecognized defects and limitations in our technology or our ability to develop disease models or identify viable drug candidates. These complications could materially delay or substantially increase the anticipated costs and time to identify and develop viable drug candidates, which would have a material adverse effect on our business and financial condition and our ability to continue operations.

We will face intense competition in our drug discovery efforts.

The biotechnology industry is subject to intense competition and rapid and significant technological change. There are many potential competitors for the disease indications we may pursue, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources, experience and expertise in the following areas than we have, including:

- research and technology development;
- development of or access to disease models;
- identification and development of drug candidates;
- regulatory processes and approvals; and
- identifying and entering into agreements with potential collaborators.

Principal competitive factors in our industry include: the quality, scientific and technical support, management and the execution of drug development and regulatory approval strategies; skill and experience of employees, including the ability to recruit and retain skilled, experienced employees; intellectual property portfolio; range of capabilities, including drug identification, development and regulatory approval; and the availability of substantial capital resources to fund these activities.

In order to effectively compete, we may need to make substantial investments in our research and technology development, drug candidate identification and development, testing and regulatory approval and licensing and business development activities. There is no assurance that we will be successful in discovering effective drug candidates using our 3D bioprinted tissues or disease models. Our technologies and drug development plans also may be rendered obsolete or noncompetitive as a result of technologies, products and services introduced by competitors. Any of these risks may prevent us from building a successful drug discovery business or entering into a strategic partnership or collaboration related to, any drug candidates we identify on favorable terms, or at all.

If we purse drug development through 3D bioprinted tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our development activities.

If we pursue drug development through 3D bioprinted tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our development activities. We typically purchased certain qualified human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We formed our wholly-owned subsidiary, Samsara, to eventually serve as a key source of the primary human cells we utilized in our business and we recently dissolved Samsara in connection with pursuing the proposed Merger with Tarveda, which was not successful. If we recommence our development operation, we will need to identify one or more sources of qualified human cells and there can be no guarantee that we would be able to access the quantity and quality of raw materials needed at a cost-effective price. In this event, any failure to obtain a reliable supply of sufficient human cells or a supply at cost effective prices would harm our business and our results of operations and could cause us to be unable to obtain a sufficient supply of human cells to support our drug development efforts.

The business plan proposed by the New Director Slate will be adversely impacted if we are unable to successfully attract, hire and integrate key additional employees or contractors.

Our future success depends in part on our ability to successfully attract and then retain key additional executive officers and other key employees and contractors to support our proposed drug discovery plans. Recruiting and retaining qualified scientific and clinical personnel is critical to our success. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we are unable to attract and retain high quality personnel, our ability to pursue our drug discovery business will be limited, and our business, prospects, financial condition and results of operations may be adversely affected.

The business plan proposed by the New Director Slate will be adversely impacted if we are unable to secure adequate laboratory facilities and equipment.

In connection with our strategic alternatives process and restructuring beginning in August 2019, we exited our lease agreement for our prior company headquarters (which included laboratory space) and sold most of our lab equipment (with the exception of our bioprinters). In order to proceed with our proposed business plan, we will need to secure adequate lab space and equipment. If we are unable to secure such space and equipment at all, or on commercially reasonable terms, our business opportunity would be adversely impacted.

We may require substantial additional funding to pursue the business plan proposed by the New Director Slate. Raising additional capital would cause dilution to our existing stockholders and may restrict our operations or require us to relinquish rights to our technologies or to a drug candidate.

We currently do not have any committed external source of funds and do not expect to generate any meaningful revenue in the foreseeable future. The New Director Slate has advised us that they believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under the proposed business plan for at least 12 months. They have based these estimates on assumptions that may prove to be wrong, and the Company may use its available capital resources sooner than it currently expects if the operating plans change. If the New Director Slate elects to change the proposed business plan and decide that the Company should pursue further research and development activities, the Company will require substantial additional funding to operate its proposed business, including expanding its facilities and hiring additional qualified personnel, and would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders.

Further, additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our technology and any drug candidates we identify. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.

Before obtaining marketing approval from regulatory authorities for the sale of any drug candidates we identify, any such drug candidates must undergo extensive clinical trials to demonstrate the safety and efficacy of the drug candidates in humans. Human clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. The New Director Slate has advised us that they may elect to have the Company complete this testing, or some portion thereof, internally or enter into a partnering or development agreement with a pharmaceutical company to complete these trials. Our inability, or the inability of any third party with whom we enter into a partnering or development agreement, to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenues or receive development or milestone payments. Our future success is dependent on our ability, or the ability of any pharmaceutical company with who we enter into a partnering or development agreement, to successfully develop, obtain regulatory approval for, and then successfully commercialize any drug candidates we identify.

Any drug candidates we identify will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in applicable jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our drug candidates.

We, or any third party with whom we enter into a partnering or development agreement, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to earn development or milestone payments or for any drug candidates to obtain regulatory approval, including:

- we, or any third party with whom we enter into a partnering or development agreement, may experience delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we, or any third party with whom we enter into a partnering or development agreement, may fail to obtain sufficient enrollment in clinical trials or participants may fail to complete clinical trials;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we, or any pharmaceutical company with who we enter into a partnering or development agreement, may decide, or regulators may require, additional clinical trials;
- we, or any third party with whom we enter into a partnering or development agreement, may decide, or regulators or institutional review boards may require the suspension or termination of clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require additional or unanticipated clinical trials to obtain approval or any drug candidates may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving any drug candidates, or such requirements may not be as anticipated;
- the cost of clinical trials for any drug candidates may be greater than anticipated;
- the supply or quality of any drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate or may be delayed;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution; and
- we may experience delays due to the recent COVID-19 pandemic, including with respect to the receipt of drug candidates or other materials, submission of NDAs, filing of INDs and starting any clinical trials for other indications or programs.

If we, or any third party with whom we enter into a partnering or development agreement, experience delays in the completion of, or termination of, any clinical trial of any drug candidates that we develop, or are unable to achieve clinical endpoints due to unforeseen events, such as the COVID-19 pandemic, the commercial prospects of our drug candidates will be harmed, and our ability to develop milestones, development fees or product revenues from any of these drug candidates will be delayed.

The New Director Slate has advised us that they expect that the Company will rely upon third-party contractors and service providers for the execution of critical aspects of any future development programs. Failure of these collaborators to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of any future development programs.

The New Director Slate has advised us that they expect that the Company will outsource certain functions, tests and services to contract research organizations ("CROs"), medical institutions and collaborators as well as outsourcing manufacturing to collaborators and/or contract manufacturers, and we rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. They may elect in the future to engage a CRO to run all aspects of a clinical trial on our behalf. There is no assurance that such individuals or organizations will be able to provide the functions, tests, biologic supply or services as agreed upon or in a quality fashion and we could suffer significant delays in the development of our drug candidates or development programs.

In some cases, there may be only one or few providers of such services, including clinical data management or manufacturing services. In addition, the cost of such services could be significantly increased over time. We may rely on third parties and collaborators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties and collaborators for clinical development activities reduces our control over these activities. Our reliance on these parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with GCP regulations and the investigational plan and protocols contained in the regulatory agency applications. In addition, these third parties may not complete activities on schedule or may not manufacture under cGMP conditions. Preclinical or clinical studies may not be performed or completed in accordance with GLP regulatory requirements or our trial design. If these third parties or collaborators do not successfully carry out their contractual duties or meet expected deadlines, obtaining regulatory approval for manufacturing and commercialization of our drug candidates may be delayed or prevented. We may rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval.

In addition, we will exercise limited control over our third-party partners and vendors, which makes us vulnerable to any errors, interruptions or delays in their operations. If these third parties experience any service disruptions, financial distress or other business disruption, or difficulties meeting our requirements or standards, it could make it difficult for us to operate some aspects of our business.

The near and long-term viability of the drug discovery and development efforts proposed by the New Director Slate will depend on the Company's ability to successfully establish strategic relationships.

The near and long-term viability of the drug discovery and development efforts proposed by the New Director Slate will depend in part on the Company's ability to successfully establish new strategic partnering, collaboration and licensing arrangements with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and or government agencies. Establishing strategic relationships is difficult and time-consuming. Potential partners and collaborators may not enter into relationships with us based upon their assessment of our technology or drug candidates or our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of strategic relationships on acceptable terms, we may not be able to develop and obtain regulatory approval for our drug candidates or generate sufficient revenue to fund further research and development efforts. Even if we establish new strategic relationships, these relationships may never result in the successful development or regulatory approval for any drug candidates we identify for a number of reasons both within and outside of our control.

Risks Related to our Historical Business

The development of new biopharmaceutical products involves a lengthy and complex process.

We previously focused the majority of our resources on the development of our liver tissue candidate. In addition to our liver tissue candidate, we conducted initial research and development activities on several other tissue candidates. Each of our therapeutic tissue candidates were in the early stages of research and development and would have required substantial financial resources, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. If we decide to renew our focus on developing our liver tissue candidate and expend funds for such development, this process could take many years of effort without any assurance of ultimate success. Product development efforts with respect to a tissue candidate could fail for many reasons, including:

- the failure of the tissue candidate in preclinical or clinical studies, including failing to demonstrate sufficient durability and functionality to support further development activities;
- the inability to satisfy the regulatory requirements to successfully submit an IND with the FDA;
- adverse patient reactions to the tissue candidate or indications of other safety concerns;

- insufficient clinical trial data to support the effectiveness or superiority of the tissue candidate;
- inability to manufacture sufficient quantities of the tissue candidate for development, clinical, or commercialization activities in a timely and cost-efficient manner;
- failure to obtain, or delays in obtaining, the required regulatory approvals for the tissue candidate, the facilities or the process used to manufacture the tissue candidate;
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;
- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and
- the development of a competitive product or therapy.

The 3D bioprinted tissue candidates that we were developing represent new therapeutic approaches that could be subject to heightened regulatory scrutiny, delays in clinical development and/or delays in achieving the regulatory approvals required for commercialization.

Our liver tissue candidate represented a new approach to treating liver disease, inborn errors of metabolism, and other diseases. Similarly, our other early stage therapeutic tissue candidates represented new therapeutic approaches in their respective disease areas. However, we were unable to achieve satisfactory results with the liver tissue candidate which we were developing. As a result, the development of these therapeutic tissue candidates would be subject to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of 3D bioprinted human tissues developing and deploying consistent and reliable processes for manufacturing 3D bioprinted tissues for implantation into patients;
- utilizing these tissue candidates in combination with other therapies, which may increase the risk of adverse side effects;
- developing processes for the safe administration of these tissues, including long-term follow-up for all patients who receive these tissue candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process these tissue candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- qualifying, engaging, and training clinical trial investigators and institutions who will be able to implement the institutionally-approved protocols, recruit and treat patients, and generate data in accordance with targeted goals and timelines; and
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities.

The regulatory approval process for novel tissue candidates, such as our therapeutic tissue candidates, can be more expensive and take longer than for other, better known or extensively studied product candidates.

Further, the manufacturing processes we would be required to use in connection with our therapeutic tissue candidates may not yield a sufficient supply of satisfactory products that are safe, effective, scalable, or profitable.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment options.

Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt novel therapies, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of a new therapy do not or will not outweigh its costs.

We have not yet tested any bioprinted therapeutic tissue candidates in clinical trials. Results in early preclinical studies may not be indicative of results obtained in later preclinical studies. Similarly, results from early clinical trials may not be indicative of results obtained in later clinical trials.

Our tissue candidates involve novel technologies and have never been evaluated in clinical trials. It is unknown how translatable the preclinical animal models used in our preclinical studies are to humans. If we elect to resume the development of our therapeutic tissues, we would be required to demonstrate through adequate and well-controlled clinical trials that our tissue candidates are safe and effective, with a favorable risk-benefit profile, for use in their target indications before we could have sought regulatory approvals for their commercial sale. Initial positive results we have observed for our tissue candidates in preclinical animal models may not be predictive of results from our later preclinical trial results, nor of results from future clinical trials in humans. For example, in May 2019, we announced that data generated from a larger group of animal studies differed from our earlier pilot studies and put into question the durability and functionality of our liver tissue candidate. In August 2019, we announced our decision to stop pursuing the development of our liver tissue candidate following our completion of additional studies that did not resolve the durability and functionality issues we had identified. We also announced that as a result of these adverse study results, our board of directors determined that it is in the best interests of our stockholders to explore our available strategic alternatives, rather than to continue to pursue our therapeutic liver tissue and other early stage development projects.

Our experience manufacturing therapeutic tissues is limited. We believe that manufacturing issues, including technical or quality issues or issues, contributed to the viability and functionality issues with our liver tissue candidate, and our ultimate decision to stop the development of this tissue. There is no assurance that we can solve these and any future manufacturing issues.

Before initiating a clinical trial or commercializing any of our tissue candidates, we would have been required to demonstrate to the FDA that the chemistry, manufacturing and controls for our tissue products meet applicable requirements. Because no bioprinted tissue product has been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements, and therefore the timeframe and requirements for demonstrating compliance to the FDA's satisfaction is uncertain.

Bioprinted tissue manufacturing is an emerging industry. To our knowledge, there are no contract manufacturing organizations with experience in manufacturing bioprinted tissue products under GMP conditions. We have conducted all of our manufacturing internally.

We conducted all of our research in research facilities and we were in the process of implementing applicable FDA manufacturing requirements. However, we have limited experience as a company in developing a manufacturing facility that meets all applicable GMP requirements, and we may never have been successful in developing our own manufacturing facility.

Manufacturing our therapeutic tissue candidates is complicated and presents novel technical challenges. We believe that manufacturing issues, including technical or quality issues, contributed to the viability and functionality issues with our liver tissue candidate, and our ultimate decision to stop the development of this tissue. If we elect to resume the development of our therapeutic tissues, we may encounter problems achieving adequate quantities and quality of clinical-grade materials to conduct our clinical trials, or to meet FDA, European Medicines Agency or other applicable standards or specifications with consistent and acceptable production yields and costs.

We have not scaled up the manufacturing process for our therapeutic liver tissue beyond the scale used for research and nonclinical studies. The time and efforts required for us to develop and validate our manufacturing process to support clinical use would potentially delay our ability to develop this program in accordance with our expected timelines.

In order to manufacture and supply any of our tissue candidates on a commercial scale in the future, we would be required to bolster our quality control and quality assurance capabilities, including by augmenting our manufacturing processes and adding personnel. We may encounter problems hiring and retaining the experienced specialist scientific and manufacturing personnel needed to operate our manufacturing process, which could result in additional delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Further, if we engage in scale-up manufacturing of any approved product, we may encounter unexpected issues relating to the manufacturing processes, donor variability, or the quality, purity or stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Resolving these issues could result in significant additional delays and result in significantly increased costs.

Further, any unresolved problems in our manufacturing process could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our ability to successfully enter into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vivo* therapeutic tissues and manufacturing technologies on favorable terms, or at all.

We obtained our clinical grade livers from a single source, and if we elect to resume the development of our therapeutic liver tissue, we will need to reestablish a commercial source for our clinical grade livers or isolated cells to support our clinical trials and/or commercialization.

Our liver tissue candidate was manufactured using human primary liver cells from non-transplantable livers we receive from the International Institute for the Advancement of Medicine. We relied upon this single source to obtain the clinical grade non-transplantable livers that served as the starting materials for manufacturing the liver cells we used in our therapeutic liver tissue. The availability and quality of clinical grade livers may be sporadic and unpredictable. As a result, if we elect to renew our focus on development of our therapeutics tissues, we will need to reestablish a commercial source for our clinical grade livers or isolated cells to supply our clinical program or meet commercial demand, and our development plans may be delayed or stalled, which would significantly harm our business. In addition, in order to preserve resources, we discontinued our ability to isolate liver cells from donated organs by restructuring our operations and dissolving our Samsara subsidiary. In order to recommence isolating liver cells from donated organs, we would need to reestablish the access to cell isolation capabilities either through an external collaboration or internally, which could require significant time and financial resources.

Our liver tissue candidate included primary cells from two donors. If the FDA did not authorize us to include cells from more than one donor, our development timeline would be delayed.

Our NovoTissues Liver product was manufactured using cells from a liver donor and cells from an umbilical cord donor. Under 21 CFR §1271, cells from more than one donor cannot be combined in the manufacturing process absent a waiver from the FDA. We applied to the FDA for a waiver authorizing us to include cells from two donors in manufacturing our therapeutic liver tissue for clinical trials. As a result, even if we elected to resume the development of our therapeutic liver tissues, we would be required to redesign our therapeutic liver tissue unless we received a waiver from the FDA. This decision by the FDA could result in additional development costs and a delay in our development timeline, in which case our business would be materially harmed.

If we elect to resume the development of our therapeutic tissues, we may not enjoy the market exclusivity benefits of any orphan drug designation.

Under the Orphan Drug Act, the first product with an orphan drug designation receives market exclusivity, which prohibits the FDA from approving the "same" drug for the same indication. The FDA has stated that drugs can be the "same" even when they are not identical, but has not provided guidance with respect to how it will determine "sameness" in the context of 3D bioprinted tissues. If we elected to continue to pursue the development of our therapeutic tissues, it could be possible that another bioprinted therapeutic tissue product could be approved for the treatment of a disease one of our orphan products is intended to treat before our product is approved, which means that we would not obtain orphan drug exclusivity and could also potentially be blocked from approval until the first product's orphan drug exclusivity for a product expires or until we demonstrated, if we could, that our product is superior. Further, if we obtained orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted orphan drug exclusivity, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care.

If we elect to resume the development of our therapeutic tissues, a competitor may achieve regulatory approval before we do or develop therapies that are more advanced or effective than ours, which would harm our business and financial condition, and our ability to successfully market or commercialize any tissue candidates.

The biotechnology and pharmaceutical industries, including the fields of gene therapies, cellular therapies, and engineered tissue products, are characterized by rapid technological progress, competition, and a strong emphasis on intellectual property. We are aware of several companies focused on developing gene therapies and cellular therapies for use in treating end stage liver disease and/or inborn errors of metabolism. If we elect to resume the development of our therapeutic tissues, we may face competition from large or specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies, and public and private research institutions.

Some of our potential competitors, alone or with their strategic partners, have greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in these industries may result in even greater concentration of resources among a smaller number of competitors. If we elect to resume the development of our therapeutic tissues, these competitors may obtain FDA or other regulatory approval for their products more rapidly than us, which could result in our competitors establishing a strong market position before we would be able to enter the market, if ever. Further, new or advanced technologies may render our tissue candidates uneconomical or obsolete. Our competitors could also develop products that are safer, more effective, have fewer or less side effects, or are more convenient or less expensive than any tissue candidates that we elected to develop.

If we elect to resume the development of our in vitro tissues business, such business would depend on new and unproven technology and approaches, and we may be unable to establish it as a profitable, standalone business.

Our *in vitro* products and services involve new and unproven models and approaches. We began offering our first commercial product (and related research services), our ExVive™ Human Liver Tissue, on a limited basis in April 2014 and more broadly in November 2014. We began offering our second product (and related research services), our ExVive™ Human Kidney Tissue, for predictive preclinical testing of drug compounds in September 2016. In May 2019, we announced plans to conduct additional preclinical studies necessary to optimize our manufacturing processes and complete additional preclinical studies that would generate consistent scientific data regarding the prolonged functionality and therapeutic benefits of our *in vivo* liver tissues. After a rigorous assessment of our liver therapeutic tissue program following completion of these additional studies, we concluded that the variability of biological performance and related duration of potential benefits presented development challenges and lengthy timelines that no longer supported an attractive opportunity. As a result, we suspended development of our lead program. We also suspended development of all other related pipeline development activity.

Our commercial products reflected a novel approach to preclinical testing of drug compounds and disease modeling, and even if we elect to resume the development of our products there is no assurance that they would perform as expected or as would be required by our customers. The commercial acceptance of, and the results of our efforts to increase customer awareness and demand for, our drug discovery and biological research tools, products and services, did not result in our development of a profitable, standalone business. In addition, we experienced that some of our customers continued to require unique features, cell sourcing, validation data, or greater degrees of reproducibility than we were able to achieve to date, in order to utilize our commercial products in their drug discovery, biological research or development programs. Even if we or our customers are successful in our respective efforts, we or our customers may not be able to discover or develop commercially viable therapeutics or other products therefrom. Based on these and other risks, there is no assurance that, if we elect to resume the development of our *in vitro* tissues business, that we would be successful in our efforts to advance the programs and commercialize our products.

The successful commercialization of our in vitro products and services is subject to a variety of risks.

If we elect to pursue the commercialization of our *in vitro* products and services, any such efforts would be subject to risks and uncertainties, including:

- failing to develop products or services that are effective, reproducible, and competitive;
- failing to demonstrate the commercial and technical viability of any products or services that we successfully develop, failing to meet customer expectations or requirements or otherwise failing to achieve market acceptance of such products or services;
- failing to be cost effective and timely;
- being unable to implement features or functionality required by customers;
- being difficult or impossible to manufacture on a large scale;
- being unable to establish and maintain supply and manufacturing relationships with reliable third parties;
- being unable to obtain a sufficient supply of human cells for our products, services and research and development activities on a timely basis and at acceptable quality levels and costs;
- failing to develop our products and services before the successful marketing of similar products and services by competitors;
- being unable to hire and retain qualified personnel; and
- infringing the proprietary rights of third parties or competing with superior products marketed by third parties.

If we elect to resume the development and commercialization of our *in vitro* products, any of these or any other risks and uncertainties could occur, our efforts to commercialize our *in vitro* products and services may be unsuccessful, which would harm our business and results of operations. Further, these risks may prevent us from successfully entering into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vivo* therapeutic liver tissue on favorable terms, or at all. If we fail to do so, any strategic transaction we consummate may offer limited value for our business and proprietary technology and may not enhance stockholder value.

If we elect to resume the development and commercialization of our in vitro products, we would face intense competition which could result in reduced acceptance and demand for our in vitro products and services.

The biotechnology industry is subject to intense competition and rapid and significant technological change. There are many potential competitors for our *in vitro* products and services, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources, experience and expertise in the following areas than we have, including:

- research and technology development;
- product identification and development;
- regulatory processes and approvals;
- production and manufacturing;
- securing government contracts and grants to support their research and development efforts;
- sales and marketing of products, services and technologies; and
- identifying and entering into agreements with potential collaborators.

Principal competitive factors in our industry include: the quality, scientific and technical support, price and breadth of technology and services; management and the execution of product development and commercialization strategies; skill and experience of employees, including the ability to recruit and retain skilled, experienced employees; intellectual property portfolio; range of capabilities, including product identification, development, regulatory approval, manufacturing and marketing; and the availability of substantial capital resources to fund these activities.

In order to effectively compete, we would need to make substantial investments in our research and technology development, product identification and development, testing and regulatory approval, manufacturing, customer awareness activities, publications of our technology and results in scientific publications and sales and marketing activities. If we elected to do so, there is no assurance that we would be successful in commercializing and gaining significant market share for any products or services we offer in part through use of our technology. Our technologies, products and services also may be rendered obsolete or noncompetitive as a result of products and services introduced by competitors. Any of these risks may prevent us from successfully building a successful *in vitro* business or entering into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vitro* business on favorable terms, or at all. If we fail to do so, any strategic transaction we consummate may offer limited value for our business and proprietary technology and may not enhance stockholder value.

If we elect to resume the development and commercialization of our in vitro products, we would require access to a constant, steady, reliable supply of human cells to successfully develop and commercialize our in vitro products and services.

If we elect to resume the development and commercialization of our *in vitro* products, we would require a reliable supply of qualified human cells for our commercial products and services and for our research and product development activities. We typically purchased certain qualified human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We formed our wholly-owned subsidiary, Samsara, to eventually serve as a key source of the primary human cells we utilized in our business and we recently dissolved Samsara in connection with pursuing the proposed Merger with Tarveda, which was not successful. We have relied on a combination of third-party suppliers and Samsara to meet our demand for human cells for our *in vitro* business. We worked closely with Samsara and our third-party suppliers to assure adequate supply while maintaining high quality and reliability. Following any resumption of the development and commercialization of our *in vitro* products and services, if demand for our products and services were to grow significantly, we would most likely need to identify additional sources of qualified human cells and there can be no guarantee that we would be able to access the quantity and quality of raw materials needed at a cost-effective price. In this event, any failure to obtain a reliable supply of sufficient human cells or a supply at cost effective prices would harm our business and our results of operations and could cause us to be unable to comply with the associated contractual obligations we would owe to our customers and collaboration partners.

Risks Related to Government Regulation

Violation of government regulations or quality programs could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.

To the extent that our products are used in the manufacturing or testing processes for customers drug and medical device products, such end-products or services may be regulated by the FDA under Quality System Regulations (“QSR”) or the Centers for Medicare & Medicaid Services under Clinical Laboratory Improvement Amendments of 1988 (“CLIA’88”) regulations. The customer is ultimately responsible for QSR, CLIA’88 and other compliance requirements for their products. Failure to comply with these requirements could result in lost sales of our products and regulatory delays or objections and potential product liability claims. In

addition, customers may require that services be conducted pursuant to the requirements of Good Laboratory Practice ("GLP") in order to provide suitable data for their INDs and other regulatory filings. No regulatory review of data from our platform technology has yet been conducted and there is no guarantee that our technology will be acceptable under GLP, or that compliance with GLP requirements could be achieved on the timetable required by customers. As a result, the violation of government regulations or failure to comply with quality requirements could harm demand for these products or services, and the evolving nature of government regulations could have an adverse impact on our ability to commercialize our products or services or sell the assets or intellectual property associated with these products and services on favorable terms, or at all. If we fail to do so, any strategic transaction we consummate may offer limited value for our existing business and proprietary technology and may not enhance stockholder value.

In the past, we have used hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our product manufacturing, research and development, and testing activities have involved the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. We cannot eliminate the risks of accidental contamination or the accidental spread or discharge of these materials, or any resulting injury from such an event. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. We were also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, and the experimental use of animals. Our operations may have required that environmental permits and approvals be issued by applicable government agencies. If we failed to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance.

Risks Related to Our Capital Requirements, Finances and Operations

Our board of directors may decide to pursue a dissolution and liquidation of the Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

If the Advisory Proposal is not approved at the 2020 Annual Meeting, our board of directors may decide to pursue a dissolution and liquidation of the Company, which would also require stockholder approval. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations, and the costs that would be incurred to effect such liquidation or dissolution. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our remaining cash assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of the Company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

We may be unable to continue as a going concern in the future.

We have had recurring losses from operations since inception and will likely not generate meaningful revenue for the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan. However, if our operating plans change and our projected operating requirements increase, we may be unable to continue as a going concern. In this event, the perception that we may not be able to continue as a going concern may have an adverse impact on our business due to concerns about our ability to meet our future contractual obligations or pursue additional strategic transactions. Further, if we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation and dissolution could be significantly lower than the values reflected in our financial statements and an investor could lose all or part of its investment in our equity.

If we were to resume our research and development activities and pursue development of any of our pipeline products, we would require substantial additional funding. Raising additional capital would cause dilution to our existing stockholders and may restrict our operations or require us to relinquish rights to our technologies or to a product candidate.

We currently do not have any committed external source of funds and do not expect to generate any meaningful revenue in the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect if our operating plans change. If

our current operating plans change and we decide to pursue further research and development activities, we will require substantial additional funding to operate our business, including to expand our facilities and hire additional qualified personnel, and would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations.

Given our failure to obtain stockholder approval for the proposed Merger with Tarveda, raising additional funding through debt or equity financing will be difficult or not successful at all, would be dilutive and may cause the market price of our common stock to decline further. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our therapeutic candidates. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings.

We have a history of operating losses and expect to incur significant additional operating losses.

We have generated operating losses each year since we began operations, including $2.8 million and $6.5 million for the three months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had incurred cumulative operating losses of $232.7 million and cumulative net losses totaling $282.3 million. We expect to incur substantial additional operating losses over the next several years. To achieve profitability, we must either generate sufficient revenue through our *in vitro* tissues business to offset the costs of operating our business, or we must successfully develop and obtain regulatory approval for one or more of our therapeutic candidates and effectively market and sell any products we develop. Even if we are successful in commercializing a therapeutic product that receives regulatory approval, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. We may never generate significant revenue, and even if we do generate significant revenue, we may never achieve profitability.

Our quarterly operating results may vary, which could negatively affect the market price of our common stock.

Our results of operations in any quarter may vary from quarter to quarter and are influenced by such factors as expenses related to:

- evaluating and implementing strategic alternatives, technology licensing opportunities, potential collaborations, and other strategic transactions;
- responding to the SEC inquiry;
- responding to shareholder demand letters; and
- changes in costs related to the COVID-19 pandemic or the general global economy.

We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results. Nonetheless, fluctuations in our quarterly operating results could negatively affect the market price of our common stock.

Our business could be adversely impacted if we are unable to retain our executive officers and other key personnel.

Our future success will depend to a significant degree upon the continued contributions of our key personnel, especially our executive officers. We do not currently have long-term employment agreements with our executive officers or our other key personnel, and there is no guarantee that our executive officers or key personnel will remain employed with us. Moreover, we have not obtained key man life insurance that would provide us with proceeds in the event of the death, disability or incapacity of any of our executive officers or other key personnel. Further, the process of attracting and retaining suitable replacements for any executive officers and other key personnel we lose in the future would result in transition costs and would divert the attention of other members of our senior management from our existing operations. Additionally, such a loss could be negatively perceived in the capital markets. The election of the New Director Slate would represent a change of control, whereby the officers will likely leave the company and need to be replaced.

We may be subject to security breaches or other cybersecurity incidents that could compromise our information and expose us to liability.

We routinely collect and store sensitive data (such as intellectual property, proprietary business information and personally identifiable information) for the Company, its employees and its suppliers and customers. We make significant efforts to maintain the security and integrity of our computer systems and networks and to protect this information. However, like other companies in our industry, our networks and infrastructure may be vulnerable to cyber-attacks or intrusions, including by computer hackers, foreign governments, foreign companies or competitors, or may be breached by employee error, malfeasance or other disruption. Any such breach could result in unauthorized access to (or disclosure of) sensitive, proprietary or confidential information of ours, our employees or our suppliers or customers, and/or loss or damage to our data. Any such unauthorized access, disclosure, or loss of information could cause competitive harm, result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and/or cause reputational harm.

Risks Related to Our Common Stock and Liquidity Risks

We could fail to maintain the listing of our common stock on The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction.

The Nasdaq Stock Market LLC ("Nasdaq") has established continued listing requirements, including a requirement to maintain a minimum closing bid price of at least $1 per share. If a company trades for 30 consecutive business days below such minimum closing bid price, it will receive a deficiency notice from Nasdaq. Assuming it is in compliance with the other continued listing requirements, Nasdaq would provide such company a period of 180 calendar days in which to regain compliance by maintaining a closing bid price at least $1 per share for a minimum of ten consecutive business days.

On June 25, 2019, we received a notice letter from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, we obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market. On March 26, 2020, we obtained shareholder approval to effect a reverse stock split in a range from 20:1 to 40:1, which is subject to the approval of our board of directors (such final ratio, as determined by our board of directors, the "Reverse Stock Split Ratio" such reverse stock split, the "Reverse Stock Split"). On April 17, 2020 we received an additional notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since we had 66 calendar days remaining in, the compliance period as of April 16, 2020, we will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. We can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. We intend to comply with the Price-based Requirements by effecting the Reverse Stock Split. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other listing requirements necessary for us to maintain the listing of our common stock on The Nasdaq Capital Market. If we are unable to cure the deficiency or regain compliance, our common stock will be delisted from The Nasdaq Capital Market and begin trading on the OTC bulletin board.

A delisting from The Nasdaq Capital Market and commencement of trading on the OTC bulletin board would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on stockholders:

- the liquidity of our common stock;
- the market price of our common stock (and the accompanying valuation of our Company);
- our ability to obtain financing or complete a strategic transaction;
- the number of institutional and other investors that will consider investing in shares of our common stock;
- the number of market markers or broker-dealers for our common stock; and
- the availability of information concerning the trading prices and volume of shares of our common stock.

The Reverse Stock Split that we intend to effect may not increase our stock price over the long-term.

The principal purpose of the Reverse Stock Split is to increase the per share market price of our common stock. It cannot be assured, however, that the Reverse Stock Split will accomplish the objective of increasing the per share market price of our common stock for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of our common stock will proportionally increase the market price of our common stock, it cannot be assured that the Reverse Stock Split will increase the

market price of our common stock by a multiple of the Reverse Stock Split Ratio, as determined by our board of directors, or result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including our business and financial performance, general market conditions and prospects for future success. Therefore, while price of our common stock might meet the continued listing requirements for The Nasdaq Capital Market initially, it cannot be assured that it will continue to do so.

The Reverse Stock Split may decrease the liquidity of our common stock.

Although our board of directors believes that the anticipated increase in the market price of our common stock could encourage interest in our common stock and possibly promote greater liquidity for our stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the Reverse Stock Split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock.

The Reverse Stock Split may lead to a decrease in our overall market capitalization.

Should the market price of our common stock decline after the Reverse Stock Split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the Reverse Stock Split. A reverse stock split may be viewed negatively by the market and, consequently, can lead to a decrease in our market capitalization. If the per share market price does not increase in proportion to the Reverse Stock Split ratio, then the value of our Company, as measured by its stock capitalization, will be reduced. In some cases, the per share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of our common stock will remain the same after the Reverse Stock Split is effected, or that the Reverse Stock Split will not have an adverse effect on the stock price of our common stock due to the reduced number of shares outstanding after the Reverse Stock Split.

Our two largest shareholders have significant influence over key decision making as a result of their concentrated ownership of the voting power of our outstanding capital stock.

Our two largest shareholders, ARK Investment Management LLC (“ARK”) and Nikko Asset Management Americas, Inc. (“Nikko”), collectively own approximately 30% of our outstanding stock and, as demonstrated by the unsuccessful proposed Merger with Tarveda, are able to exercise sufficient voting rights to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation, sale of all or substantially all of our assets, or liquidation or dissolution. This concentrated position could delay, defer, or prevent a change of control, merger, consolidation, or sale of all or substantially all of our assets, or liquidation or dissolution that a substantial portion of our other stockholders support, or conversely this significant influence could potentially result in the consummation of such a transaction or liquidation that a substantial portion of our other stockholders do not support. This significant influence could also discourage a potential investor from acquiring our common stock or a potential counterparty from entering into negotiations about a potential strategic transaction and might harm the trading price of our common stock. As stockholders, even with significant influence, ARK and Nikko are entitled to vote their shares in their own interests, which may not always be in the interests of our stockholders generally.

We have a limited trading history and there is no assurance that an active market in our common stock will continue at present levels or increase in the future.

There is limited trading history in our common stock, and although our common stock is now traded on The Nasdaq Capital Market, there is no assurance that an active market in our common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common stock on the timeline and at the volumes they desire. This factor limits the liquidity of our common stock and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the compliance obligations of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”). The costs of complying with the reporting requirements of the federal securities laws, including preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders, can be substantial.

If we fail to comply with the rules of Section 404 of the Sarbanes-Oxley Act related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, we may be subject to sanctions by regulatory authorities and our stock price could decline.

Section 404 of the Sarbanes-Oxley Act (the "Section 404") requires that we evaluate and determine the effectiveness of our internal control over financial reporting. We believe our system and process evaluation and testing comply with the management certification requirements of Section 404. We cannot be certain, however, that we will be able to satisfy the requirements in Section 404 in all future periods. If we are not able to continue to meet the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or Nasdaq. Any such action could adversely affect our financial results or investors' confidence in us and could cause our stock price to fall. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, we may be required to incur significant additional financial and management resources to achieve compliance.

The price of our common stock may continue to be volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- continued macroeconomic conditions related to the COVID-19 pandemic;
- any announcement regarding the strategic transaction process;
- reduced government funding for research and development activities;
- actual or anticipated variations in our operating results;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- sales of our common stock or other securities in the open market;
- degree of coverage of securities analysts and reports and recommendations issued by securities analysts regarding our business;
- volume fluctuations in the trading of our common stock; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our capital stock.

We are authorized to issue 200,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of June 30, 2020, there were an aggregate of 157,975,208 shares of our common stock issued and outstanding and available for issuance on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 27,357,005 shares of our common stock that may be issued upon the exercise of outstanding stock options or is available for issuance under our equity incentive plans, and 1,188,718 shares of common stock that may be issued through our Employee Stock Purchase Plan ("ESPP").

In the future, we may issue additional authorized but previously unissued equity securities to raise funds to support our continued operations and to implement our business plan. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with hiring or retaining employees, future acquisitions, or for other business purposes. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders may result. In addition, the future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on The Nasdaq Capital Market. Moreover, depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

We do not intend to pay dividends for the foreseeable future.

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock and could significantly affect the value of any investment.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by our board of directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Risks Related to Our Intellectual Property

If we are not able to adequately protect our proprietary rights, our business could be harmed.

Our success will depend to a significant extent on our ability to obtain patents and maintain adequate protection for our technologies, intellectual property and products and service offerings in the United States and other countries. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and gain a competitive advantage.

To protect our products and technologies, we and our collaborators and licensors must prosecute and maintain existing patents, obtain new patents and pursue other intellectual property protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Moreover, the patent positions of many biotechnology and pharmaceutical companies are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, we cannot guarantee that:

- any patent applications filed by us will issue as patents;
- third parties will not challenge our proprietary rights, and if challenged that a court or an administrative board of a patent office will hold that our patents are valid and enforceable;
- third parties will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;
- any patents issued to us will cover our technology and products as ultimately developed;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business; or
- as issued patents expire, we will not lose some competitive advantage.

We may not be able to protect our intellectual property rights throughout the world.

Certain foreign jurisdictions have an absolute requirement of novelty that renders any public disclosure of an invention immediately fatal to patentability in such jurisdictions. Therefore, there is a risk that we may not be able to protect some of our intellectual property in the United States or abroad due to disclosures, which we may not be aware of, by our collaborators or licensors. Some foreign jurisdictions prohibit certain types of patent claims, such as "method-of-treatment/use-type" claims; thus, the scope of protection available to us in such jurisdictions is limited.

Moreover, filing, prosecuting and defending patents on all of our potential products and technologies throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not sought or obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our future products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our collaborators or licensors. Or, our licensors may breach or otherwise prematurely terminate the provisions of our license agreements with them. To counter infringement or unauthorized use, we may be required to file infringement claims or lawsuits, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our collaborators or licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Additionally, our licensors may retain certain rights to use technologies licensed by us for research purposes. Patent disputes can take years to resolve, can be very costly and can result in loss of rights, injunctions and substantial penalties. Moreover, patent disputes and related proceedings can distract management's attention and interfere with running the business.

Furthermore, because of the potential for substantial discovery in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments which could harm our business.

As more companies file patents relating to bioprinters and bioprinted tissues, it is possible that patent claims relating to bioprinters or bioprinted human tissue may be asserted against us, and any such assertions could harm our business. Moreover, we may face claims from non-practicing entities, which have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. Any such claims, with or without merit, could be time-consuming to defend, result in costly litigation and diversion of resources, cause product shipment or delays or require us to enter into royalty or license agreements. These licenses may not be available on acceptable terms, or at all. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

Our current and future research, development and commercialization activities also must satisfy the obligations under our license agreements. Any disputes arising under our license agreements could be costly and distract our management from the conduct of our business. Moreover, premature termination of a license agreement could have an adverse impact on our business.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office ("PTO") to determine the priority of invention. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party.

Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents or those of our collaborators or licensors in the PTO. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

We depend on license agreements with University of Missouri, Clemson, and UniQuest for rights to use certain patents, pending applications, and know how. Failure to comply with obligations under these agreements and any related or other termination of these agreements could materially harm our business and prevent us from developing or commercializing new product candidates.

We are party to license agreements with University of Missouri, Clemson, and UniQuest PC under which we were granted exclusive rights to patents and patent applications that are important to our business and to our ability to develop and commercialize our NovoGen Bioprinters and 3D tissue products fabricated using our NovoGen Bioprinters. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents are subject to the continuation of and our compliance with the terms of our license agreements. If we were to breach the terms of these license agreements and the agreements were terminated as a result, our ability to continue to develop and commercialize our NovoGen Bioprinters and 3D tissue products and to operate our business could be adversely impacted.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibit index shows those exhibits filed with this report and those incorporated herein by reference:

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of December 13, 2019, by and among Organovo Holdings, Inc., Opal Merger Sub, Inc. and Tarveda Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2019).
2.2	First Amendment to Merger Agreement, dated as of January 26, 2020, by and among Organovo Holdings, Inc., Opal Merger Sub, Inc. and Tarveda Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 29, 2020).
2.3	Form of Support Agreement, by and between Organovo, Tarveda and certain directors, officers and stockholders of Tarveda (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2019).
2.4	Form of Support Agreement, by and between Tarveda, Organovo and certain directors and officers of Organovo (incorporated by reference from Exhibit 2.3 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2019).
2.5	Form of Lock-Up Agreement, by and among Tarveda, Organovo and certain directors and officers of Tarveda and Organovo (incorporated by reference from Exhibit 2.4 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2019).
2.6	Cooperation Agreement, dated July 14, 2020, between the Company and Keith Murphy. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 15, 2020).
2.7	Form of Release Agreement by Keith Murphy in favor of the Company's directors and officers (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on July 15, 2020).
2.8	Form of Separation and Mutual Release Agreement with the Company's directors (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on July 15, 2020).
2.9	Form of Separation Agreement and Release with the Company's officers (incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on July 15, 2020).
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.2	Certificate of Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
3.3	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.4	Amendment to Organovo Holdings Bylaws, dated October 10, 2019 (incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 11, 2019).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification pursuant to 18 U.S.C. Section 1350.*
101	Interactive Data File*

* 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.

ORGANOVO HOLDINGS, INC.

Date: August 10, 2020

By: */s/ Taylor Crouch*
Name: Taylor Crouch
Title: Chief Executive Officer and President
(Principal Executive Officer)

Date: August 10, 2020

By: */s/ Craig Kussman*
Name: Craig Kussman
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Taylor Crouch, Chief Executive Officer and President of Organovo Holdings, Inc. (the "Registrant"), certify that:

1. I have reviewed this quarterly report on Form 10-Q of the Registrant;

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 consolidated 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 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

Dated: August 10, 2020

/s/ Taylor Crouch

Taylor Crouch
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Craig Kussman, Chief Financial Officer of Organovo Holdings, Inc. (the "Registrant"), certify that:

1. I have reviewed this quarterly report on Form 10-Q of the Registrant;

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 consolidated 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 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

Dated: August 10, 2020

/s/ Craig Kussman

Craig Kussman
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Organovo Holdings, Inc. (the "Company") for the period ended June 30, 2020, as filed with the Securities and Exchange Commission (the "Report"), I, Taylor Crouch, Chief Executive Officer and President and I, Craig Kussman, Chief Financial Officer of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2020

/s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President
(Principal Executive Officer)

/s/ Craig Kussman
Craig Kussman
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Organovo Holdings, Inc. and will be retained by Organovo Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of Organovo Holdings, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.