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, 2019

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.)**
6275 Nancy Ridge Drive, Suite 110, San Diego, CA 92121	**(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 Stock Market LLC** (Nasdaq Global 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, 2019, a total of 130,279,463 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, 2019 (Unaudited)	March 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	$ 35,487	$ 36,477
Accounts receivable	538	503
Grant receivable	99	55
Inventory, net	506	490
Prepaid expenses and other current assets	726	1,049
Total current assets	37,356	38,574
Fixed assets, net	1,594	1,832
Restricted cash	79	79
Operating lease right-of-use assets	4,288	—
Other assets, net	134	138
Total assets	$ 43,451	$ 40,623
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 553	$ 628
Accrued expenses	1,407	2,549
Deferred revenue	532	525
Deferred rent	—	35
Operating lease liability, current portion	1,046	—
Total current liabilities	3,538	3,737
Deferred rent, net of current portion	—	588
Operating lease liability, net of current portion	3,774	—
Total liabilities	7,312	4,325
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 130,279,463 and 124,015,429 shares issued and outstanding at June 30, 2019 and March 31, 2019, respectively	130	124
Additional paid-in capital	303,087	296,929
Accumulated deficit	(267,078)	(260,755)
Total stockholders' equity	36,139	36,298
Total Liabilities and Stockholders' Equity	$ 43,451	$ 40,623

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, 2019	Three Months Ended June 30, 2018
Revenues		
Products and services	$ 606	$ 546
Collaborations and licenses	10	43
Grants	52	100
Total Revenues	668	689
Cost of revenues	51	120
Research and development expenses	3,823	3,379
Selling, general and administrative expenses	3,315	4,767
Total costs and expenses	7,189	8,266
Loss from Operations	(6,521)	(7,577)
Other Income (Expense)		
Gain on fixed asset disposals	1	2
Interest income	197	162
Total Other Income	198	164
Income Tax Expense	—	(3)
Net Loss	$ (6,323)	$ (7,416)
Comprehensive Loss	$ (6,323)	$ (7,416)
Net loss per common share—basic and diluted	$ (0.05)	$ (0.07)
Weighted average shares used in computing net loss per common share—basic and diluted	126,854,907	111,458,445

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, 2018					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Income (Loss)	Total
Balance at March 31, 2018	**111,033**	**$ 111**	**$ 278,595**	**$ (234,120)**	**$ —**	**$ 44,586**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	200	—	(103)	—	—	(103)
Issuance of common stock from public offering, net	2,085	2	3,008	—	—	3,010
Stock-based compensation expense	—	—	1,279	—	—	1,279
Net loss	—	—	—	(7,416)		(7,416)
Balance at June 30, 2018 (Unaudited)	**113,318**	**$ 113**	**$ 282,779**	**$ (241,536)**	**$ —**	**$ 41,356**

	Three Months Ended June 30, 2019					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Income (Loss)	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	—	—	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**

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, 2019	Three Months Ended June 30, 2018
Cash Flows From Operating Activities		
Net loss	$ (6,323)	$ (7,416)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of fixed assets	(1)	(2)
Depreciation and amortization	205	288
Stock-based compensation	1,220	1,279
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(35)	255
Grants receivable	(44)	45
Inventory	(16)	(202)
Prepaid expenses and other assets	360	236
Accounts payable	(75)	(68)
Accrued expenses	(1,142)	(1,346)
Deferred revenue	7	(42)
Deferred rent	—	(49)
Operating lease right-of-use assets and liabilities, net	(91)	—
Net cash used in operating activities	(5,935)	(7,022)
Cash Flows From Investing Activities		
Proceeds from disposals of fixed assets	1	2
Net cash provided by investing activities	1	2
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	4,996	3,010
Employee taxes paid related to net share settlement of equity awards	(52)	(103)
Net cash provided by financing activities	4,944	2,907
Net decrease in cash, cash equivalents, and restricted cash	(990)	(4,113)
Cash, cash equivalents, and restricted cash at beginning of period	36,556	43,853
Cash, cash equivalents, and restricted cash at end of period	$ 35,566	$ 39,740
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 35,487	$ 39,613
Restricted cash	79	127
Total cash, cash equivalent and restricted cash	$ 35,566	$ 39,740
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	$ —	$ (3)

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," "we," "us," "our," "the Company" and "our Company") is a biotechnology company pioneering the development of bioprinted human tissues that emulate human biology and disease. We have been 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.

Except where specifically noted or the context otherwise requires, references to "Organovo Holdings," "the Company," "we," "our," and "us" in these notes to the unaudited condensed consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc. and Samsara Sciences, Inc.

The Company's activities are subject to significant risks and uncertainties including failing to successfully develop products and services based on its technology, failing to achieve regulatory approvals for its therapeutic candidates, and failing to achieve the market acceptance necessary to generate sufficient revenues to achieve and sustain profitability.

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 balance sheet at March 31, 2019 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, 2019, 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, 2020.

Liquidity

As of June 30, 2019, the Company had cash and cash equivalents of approximately $35.5 million and restricted cash of approximately $0.1 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease of its facilities. The Company had an accumulated deficit of approximately $267.1 million at June 30, 2019. The Company also had negative cash flows from operations of approximately $5.9 million during the three months ended June 30, 2019.

Through June 30, 2019, 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, 2019, the Company issued 6,087,382 shares of its common stock through its ATM facility and received net proceeds of approximately $5.0 million.

After a rigorous assessment of the Company's liver therapeutic tissue program following completion of various preclinical studies, it has concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity. As a result, the Company has suspended development of its lead program and its Board of Directors has engaged a financial advisory firm to explore its available strategic alternatives, including evaluating a range of ways to generate value from our technology platform and intellectual property, our commercial and development capabilities, and our financial assets. These strategic alternatives may include possible mergers and business combinations, a sale of part or all of its assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. The Company believes it is in its

stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives it may identify in the near term. The Company is also taking restructuring steps to manage its resources and extend its cash runway as the Company evaluates these strategic alternatives. While the Company believes that it can maintain its current operations for at least the next 12 months, based on its current plans and available resources, the assessment by the Company discussed above with respect to its liver therapeutic tissue program raises substantial doubt over the Company's ability to successfully finance its other programs on a long-term basis. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Although the Company is actively pursuing strategic alternatives, there is no assurance that it will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, the Company's expenses may exceed its current plans and expectations, which could require the Company to complete a transaction or wind-down its operations sooner than anticipated. Additionally, any transaction the Company consummates may offer limited value for the Company's existing business and proprietary technology and may not enhance stockholder value or provide the expected benefits. If the Company is unable to successfully complete a strategic transaction or secure additional capital on a timely basis and on terms that are acceptable to its stockholders, the Company may be required to cease its operations altogether.

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 consolidated financial statements include those assumed in revenue recognition, the measurement of operating lease right-of-use assets and lease liabilities, the valuation of stock-based compensation expense, and the valuation allowance on deferred tax assets. On an ongoing basis, management reviews these estimates and assumptions.

Revenue recognition

The Company generates 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 recognizes revenue under Topic 606, *Revenue from Contracts with Customers* ("Topic 606") when (or as) the promised services are transferred to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those services. To determine revenue recognition for arrangements the Company concludes are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the performance obligation(s) are satisfied. At contract inception, the Company assesses the goods or services promised within each contract, assesses whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of June 30, 2019 and March 31, 2019, the Company had approximately $532,000 and $525,000, respectively, in deferred revenue related to its research service agreements, collaborative agreements, and licenses within the scope of Topic 606. In the three months ended June 30, 2019, the Company recognized revenue on approximately $25,000 that had been recorded as deferred revenue at March 31, 2019.

Service revenues

The Company's service-based business, Organovo, Inc., utilizes 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 contain 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 are 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 does 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 can be customized for each customer, it is 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 utilizes point-in-time recognition under Topic 606.

For service contracts, the Company allocates 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 is not observable through past transactions, the Company estimates 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 is a fixed consideration.

Product sales, net

The Company's product-based business, Samsara Sciences, Inc., produces high-quality cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognizes product revenue when the performance obligation is satisfied, which is at the point in time the customer obtains control of the Company's product, typically upon delivery. Product revenues are recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration does not differ materially from its historical practices. Variable consideration is 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 reflects the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

The Company provides no right of return to its customers except in cases where a customer obtains authorization from the Company for the return. To date, there have been no product returns. The Company will continue to assess its estimates of variable consideration as it accumulates additional historical data and will adjust its estimates accordingly.

Collaborative research, development, and licenses

The Company enters 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 analyzes 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 considers a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company evaluates each performance obligation to determine if it can 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 are considered fixed, while milestone payments are identified as variable consideration which must be evaluated to determine if it is 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 provide 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 has determined the intellectual property license is not distinct from the continued support promised under the agreement and is therefore a single combined performance obligation. The Company recognizes revenue for these combined performance obligations over time for the duration of the license period, as the combined performance obligation will not be fully satisfied until the end of the contract.

For the three months ended June 30, 2019, all collaborations and licenses revenue was within the scope of Topic 606 and recognized accordingly. 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 has concluded this government grant is 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 has concluded this government grant does meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity and the grant is with a governmental agency.

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

Revenue recognized under this grant was approximately $52,000 and $100,000 for the three months ended June 30, 2019 and 2018, respectively.

Cost of revenues

The Company reported approximately $0.1 million in cost of revenues for the three months ended June 30, 2019 and 2018. Cost of revenues consists 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, 2019 or 2018, 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 were approximately 14.6 million at June 30, 2019 and 2018.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the 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 February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, Leases ("ASC 842"), which supersedes the lease guidance under ASC 840 – Leases. The new accounting standard requires an entity to recognize right-of-use assets and corresponding lease liabilities on the balance sheet for all leases with terms of more than 12 months and to disclose key information about leasing arrangements. This new guidance became effective for the Company on April 1, 2019. The Company adopted ASC 842 on April 1, 2019 and elected the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and did not require restatement of prior periods. The Company elected the package of practical expedients permitted under the transition guidance, but not the hindsight practical expedient. Please refer to "Note 6. Leases" for more information regarding the Company's adoption of the new lease standard.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement – Reporting Comprehensive Income* ("Topic 220"), which allows stranded tax effects resulting from the Tax Cuts and Jobs Act to be reclassified from accumulated other comprehensive income to retained earnings. The amendment only relates to the reclassification of the income tax effects of the Tax Cuts and Jobs Act; thus, the underlying guidance relating to the effect of a change in tax laws be included in income from continuing operations is not affected. The amendments in Topic 220 are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. This new guidance became effective for the Company on April 1, 2019. The requirements of ASU 2018-02 did not have a significant impact on the Company's financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation - Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting*, which aligns the measurement and classification guidance for share-based payment to non-employees with the guidance for share-based payments to employees. Under the new guidance, the measurement period for equity-classified non-employee awards will be fixed at the grant date. This new guidance became effective for the Company on April 1, 2019. The requirements of ASU 2018-07 did not have a significant impact on the Company's financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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 is effective for us on April 1, 2020. The Company is currently evaluating the impact that this guidance will have on its 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, 2019	Three Months Ended June 30, 2018
Research and development	$ 164	$ 202
General and administrative	$ 1,056	$ 1,077
Total	$ 1,220	$ 1,279

The total unrecognized compensation cost related to unvested stock option grants as of June 30, 2019 was approximately $6,528,000 and the weighted average period over which these grants are expected to vest is 2.55 years.

The total unrecognized compensation cost related to unvested restricted stock units (not including performance-based restricted stock units) as of June 30, 2019 was approximately $3,295,000, which will be recognized over a weighted average period of 2.56 years.

The total unrecognized compensation cost related to unvested performance-based restricted stock units as of June 30, 2019 was approximately $127,000, which will be recognized over a weighted average period of 3.82 years.

The total unrecognized stock-based compensation cost related to unvested employee stock purchase plan shares as of June 30, 2019 was approximately $4,000, which will be recognized over a period of 2 months.

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 fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Three Months Ended June 30, 2019*	Three Months Ended June 30, 2018
Dividend yield	—	—
Volatility	0.00%	72.25%
Risk-free interest rate	0.00%	2.82%
Expected life of options	0 years	6 years
Weighted average grant date fair value	$ —	$ 1.21

*No options were granted during the three months ended June 30, 2019, as such the weighted average assumptions are not applicable.

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Prior to fiscal year 2020, the Company used a blend of historical volatility and implied volatility of comparable companies. As of April 1, 2019, the Company is using the Company-specific historical volatility rate as it is more reflective of market conditions and a better 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. Prior to fiscal year 2020, certain options granted to consultants were subject to variable accounting treatment and were required to be revalued until vested. As of April 1, 2019, the measurement and classification of share-based payment to non-employees is consistent with the measurement and classification of share-based payment to employees.

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, 2019	Three Months Ended June 30, 2018
Dividend yield	—	—
Volatility	43.69%	61.35%
Risk-free interest rate	2.52%	1.85%
Expected term	6 months	6 months
Grant date fair value	$ 0.29	$ 0.30

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).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), Nasdaq will provide the Company with a period of 180 calendar days, or until December 23, 2019, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of the Company's common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. In the event that the Company does not regain compliance within this 180-day period, the Company may be eligible to seek an additional compliance period of 180 calendar days if it elects to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. 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, with the exception of the bid price requirement, and would need to provide written notice of its intention to cure the bid price deficiency during the second compliance period. The Company's failure to regain compliance during this second compliance period could result in delisting.

The June 25, 2019 Notice does not result in the immediate delisting of the Company's common stock from the Nasdaq Global Market. The Company will continue to monitor the closing bid price of its common stock over the 180-day period to see if its closing bid price may increase based on its future filings with the Securities and Exchange Commission or any future announcements the Company may be able to issue regarding its business. The Company will also consider its available options to regain compliance, including effecting a reverse stock split, which would be subject to the prior approval of the Company's stockholders. On July 26, 2019, the Company filed a proxy statement in connection with the Company's annual meeting of stockholders to be held on

September 5, 2019. At the annual meeting, the Company is requesting stockholders to authorize the Board, in its discretion but in no event later than the date of the 2020 annual meeting of stockholders, to amend the Company's Certificate of Incorporation, as previously amended, to effect a reverse stock split of the Company's common stock, at a ratio in the range of 1-for-5 to 1-for-20, such ratio to be determined by the Board of Directors and included in a public announcement. 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 for the Company to maintain the listing of its common stock on the Nasdaq Global Market. In addition, there is no assurance that our stockholders will authorize our Board of Directors to effect a reverse stock split at the 2019 annual meeting of stockholders.

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, 2019, the Company issued 6,087,382 shares of common stock for net proceeds of $5.0 million in at-the-market offerings under the 2018 Sales Agreement. During the three months ended June 30, 2018, the Company issued 2,085,540 shares of common stock for net proceeds of approximately $3.0 million under the 2018 Sales Agreement.

As of June 30, 2019, 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. The Company intends to use the net proceeds raised through any at-the-market sales for general corporate purposes, general administrative expenses, and working capital and capital expenditures.

On July 26, 2018, the Company filed an amendment to its certificate of incorporation to increase the number of authorized shares of common stock to 200,000,000 shares.

Restricted stock units

During the three months ended June 30, 2019, the Company issued restricted stock units for an aggregate of 585,926 shares of common stock to its employees and directors. These shares of common stock will be issued upon vesting of the restricted stock units.

A summary of the Company's restricted stock unit (not including performance-based restricted stock units) activity from March 31, 2019 through June 30, 2019 is as follows:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2019	2,080,723	$ 1.80
Granted	585,926	$ 0.97
Vested	(253,219)	$ 2.49
Cancelled / forfeited	(88,992)	$ 1.53
Unvested at June 30, 2019	2,324,438	$ 1.53

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. Based on changes to the Company's strategy, 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% 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, 2019, no tranches are currently expected to vest in fiscal year 2020.

Based on the amended PBRSU vesting terms, which the Company believes are probable of being achieved, 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.

A summary of the Company's performance-based restricted stock unit activity from March 31, 2019 through June 30, 2019 is as follows:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2019	158,706	$ 1.04
Granted	—	$ —
Vested	—	$ —
Cancelled / forfeited	—	$ —
Unvested at June 30, 2019	158,706	$ 1.04

Stock options

A summary of the Company's stock option activity from March 31, 2019 to June 30, 2019 is as follows:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2019	12,039,264	$ 2.24	$ —
Options granted	—	$ —	$ —
Options cancelled / forfeited	(101,077)	$ 1.88	$ —
Options exercised	—	$ —	$ —
Outstanding at June 30, 2019	11,938,187	$ 2.24	$ —
Vested and Exercisable at June 30, 2019	4,108,458	$ 3.60	$ —

The weighted average remaining contractual term of options exercisable and outstanding at June 30, 2019 was approximately 6.74 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, 2019, there were 1,188,718 shares available for purchase under the ESPP.

Warrants

The following table summarizes warrant activity for the three months ended June 30, 2019:

	Warrants	Weighted Average Exercise Price
Balance at March 31, 2019	145,000	$ 7.11
Granted	—	$ —
Exercised	—	$ —
Cancelled	—	$ —
Balance at June 30, 2019	145,000	$ 7.11

The warrants outstanding at June 30, 2019 are exercisable at prices of $6.84 and $7.62 per share and have a weighted average remaining term of approximately 0.28 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at June 30, 2019:

Common stock warrants outstanding	145,000
Common stock options outstanding and reserved under the 2012 Plan	8,875,281
Common stock reserved under the 2012 Plan	13,068,863
Common stock reserved under the 2016 Employee Stock Purchase Plan	1,188,718
Restricted stock units outstanding under the 2012 Plan	2,163,724
Common stock options outstanding and reserved under the Incentive Award Agreement	3,062,906
Restricted stock units outstanding under the Incentive Award Agreement	160,714
Performance-based restricted stock units outstanding under the Incentive Award Agreement	158,706
Total at June 30, 2019	28,823,912

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 $10,000 has been recorded under this agreement for the three months ended June 30, 2019 and 2018.

In April 2017, the Company signed a collaborative non-exclusive research affiliation with a university, under which the Company received a one-time non-refundable payment toward the placement of a NovoGen® Bioprinter at the university for the purpose of specific research projects mutually agreed upon by the university and the Company in the field of volumetric muscle loss. The Company received an up-front payment in May 2017, which was recorded as deferred revenue. Revenue of approximately $0 and $14,000 has been recorded under this agreement for the three months ended June 30, 2019 and 2018, respectively. In addition, during April 2017, the Company signed a non-exclusive patent license agreement with the university including an annual fee of $75,000 for each of the two years for the license to the Company patents for research use limited to the field of volumetric muscle loss. The Company received the first annual payment of $75,000 in April 2017 and the second annual payment of $75,000 in May 2018, which were initially recorded as deferred revenue. Revenue of $0 and $19,000 has been recorded under this agreement for the three months ended June 30, 2019 and 2018, respectively.

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. 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 such 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.

As of June 30, 2019, the Company had no claims outstanding.

Note 6. Leases

Adoption of ASC 842

As of April 1, 2019, the Company adopted ASC 842, which requires lessees to recognize a right-of-use asset (ROU asset) and lease liability for leases with terms of greater than twelve months. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company implemented this new accounting standard using the modified retrospective method for its existing leases, which did not cause any adjustments to prior year financial statements. The Company elected the package of practical expedients available for existing contracts, which allowed it to carry forward its historical assessments of whether contracts are or contain leases and the classification of its existing operating leases. Additionally, the Company elected the practical expedient to treat lease and non-lease components as a single lease component.

The Company leases property and equipment under operating leases, specifically its office building and various copier machines. The Company also has a short-term lease (lease term is less than 12 months), which is not required to be recorded on the balance sheet under ASC 842. Instead, under ASC 842, the Company has elected the accounting policy for short term leases to recognize lease payments as an expense on a straight-line basis over the lease term. Upon adoption of ASC 842, the Company recognized ROU assets and corresponding lease liabilities based on the present value of remaining lease payments over the lease terms. ROU assets were measured as lease liabilities plus prepaid rent less any deferred rent. As interest rates were not implicitly stated in the respective lease agreements, nor were they readily determinable, the Company used its incremental borrowing rate as the discount rate when measuring lease liabilities. Upon adoption of ASC 842, the Company recorded ROU assets and lease liabilities of $4.5 million and $5.0 million, respectively. The Company also classified deferred rent of $0.6 million as an offset to the Company's ROU asset upon adoption.

The impact of the adoption of ASC 842 on the consolidated balance sheet as of April 1, 2019 is as follows (in thousands):

	ASC 840		ASC 842
	March 31, 2019	Impact of Adoption	April 1, 2019
Deferred Rent	$ 35	$ (35)	$ —
Deferred Rent, net of current portion	$ 588	$ (588)	$ —
Prepaid Rent	$ 88	$ (88)	$ —
Operating right-of-use assets	$ —	$ 4,451	$ 4,451
Operating lease liability	$ —	$ 1,038	$ 1,038
Operating lease liability, net of current portion	$ —	$ 3,948	$ 3,948

After the initial adoption of ASC 842, on an on-going basis, the Company evaluates all contracts upon inception and determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of identified asset in exchange for consideration over a period of time. If a lease is identified, the Company will apply the guidance from ASC 842 to properly account for the lease.

Operating Leases

Since July 2012, the Company has leased its main facilities at 6275 Nancy Ridge Drive, San Diego, California 92121. The lease, as amended in 2013, 2015, 2016, 2018, and 2019, consisted of approximately 45,580 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are approximately $87,000 with 3% annual escalators. The lease for 14,685 of the total rentable square footage was amended to accelerate the expiration date from December 15, 2018 to October 31, 2018. On November 30, 2018, the Company agreed to extend the term for the remainder of the total rentable square footage under the lease from August 31, 2021 to August 31, 2024 in exchange for $500,000 of landlord funded tenant improvements and a rescission of its option to terminate the lease on or after September 1, 2019 with 9 months prior written notice.

In addition to the Company's main facilities' lease, on March 21, 2019, the Company entered into an agreement to lease several copy machines for a term of 36 months. The lease contains fixed monthly payments through the entire term of the lease, and it does not contain an option to extend the term or a bargain purchase option. This lease was also carried forward as an operating lease through the adoption of Topic 842.

The table below summarizes the Company's lease liabilities and corresponding right-of-use assets as of June 30, 2019 (in thousands):

	June 30, 2019
ASSETS	
Operating lease right-of-use assets	$ 4,288
Total lease right-of-use assets	$ 4,288
LIABILITIES	
Current	
Operating lease liability	$ 1,046
Noncurrent	
Operating lease liability, net of current portion	$ 3,774
Total lease liabilities	$ 4,820
Weighted average remaining lease term:	5.15 years
Weighted average discount rate:	8%

The Company records operating lease expense on a straight-line basis over the life of the leases. This is consistent with the Company's historical treatment of the lease costs included in operating expenses (referred to as "Rent Expense" prior to adoption of Topic 842). For the three months ended June 30, 2019, the Company recorded operating lease expense of approximately $262,000. For the three months ended June 30, 2018, the Company recorded rent expense of approximately $325,000. 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 not included in operating lease right-of use assets and lease liabilities, but rather expensed as incurred. Variable lease expense was approximately $107,000 for the three months ended June 30, 2019. Short term lease cost for the three months ended June 30, 2019 was approximately $15,000.

The table below is a summary of the cash flows associated with the Company's leases for the three months ended June 30, 2019 (in thousands):

	For the Three Months Ended June 30, 2019
Cash paid for amount included in measurement of liabilities:	
Operating cash flows from operating leases	$ 265

Future lease payments relating to the Company's operating lease liabilities as of June 30, 2019, are as follows (in thousands):

Fiscal year ended March 31, 2020	$	729
Fiscal year ended March 31, 2021		1,113
Fiscal year ended March 31, 2022		1,153
Fiscal year ended March 31, 2023		1,183
Fiscal year ended March 31, 2024		1,219
Thereafter		514
Total future lease payments		5,911
Less: Imputed interest		(1,091)
Total lease obligations		4,820
Less: Current obligations		(1,046)
Noncurrent lease obligations	$	3,774

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 primarily 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 is 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, 2019.

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.

In August 2017, the Company entered into a research services agreement with Cirius Therapeutics, Inc. ("Cirius"), an entity for which Robert Baltera, Jr., a director of the Company, serves as Chief Executive Officer and President. Under this agreement, the Company is providing standard research services to Cirius utilizing its ExVive™ Liver Tissue platform. The Company has provided and recognized revenue for ExVive™ Liver Tissue Services for Cirius in the amount of $281,000 to date. Organovo completed its obligations as of December 2018. No further revenues are expected.

In November 2018, the Company entered into a research services Quote with Viscient Biosciences ("Viscient"), an entity for which Keith Murphy, the Company's former director, Chief Executive Officer, and President, serves as the Chief Executive Officer and President. Under this Quote, the Company is providing research services in the amount of $142,000, amended in April 2019 to include an additional $7,000 of services. As of March 31, 2019, the Company recognized revenue of $42,000 for services provided and the remaining amount of $107,000 was recognized as revenue in the three months ended June 30, 2019. In addition to the services provided by Organovo, Viscient has purchased primary human cell-based products from our subsidiary, Samsara. Pursuant to the terms of multiple Quotes, $12,000 and $2,000 was recognized as revenue in the three months ended June 30, 2019 and 2018, respectively.

Note 9. Subsequent Events

On August 7, 2019, the Company undertook a business restructuring to better focus and align resources, reducing approximately 40 positions, or 69% of its overall workforce. This restructuring allows the Company to manage resources and extend its cash runway as the Company explores its available strategic alternatives, including as it evaluates a range of ways to generate value from its technology platform and intellectual property, its commercial and development capabilities, and its financial assets. As a result, the Company expects to record a restructuring charge in the fiscal second quarter of approximately $1.3 million, primarily related to employee severance and benefits costs. The actions associated with the restructuring announcement are anticipated to be complete by the end of fiscal second quarter 2020, with liabilities anticipated to be paid by the end of fiscal second quarter 2020 and yield approximately $5.3 million of annual savings to employee costs.

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). On August 7, 2019, events and circumstances relating to a forecast of operating cash flow losses and the expectation that, more likely than not, an asset group will be sold or disposed of significantly before the end of its previously estimated useful life indicated that long-lived assets of approximately $5.9 million might be impaired. The Company performed an asset impairment analysis on its long-lived asset group, consisting of its property, plant and equipment, leases, and intangibles, which concluded that the carrying amount is not recoverable. Further, the Company's analysis indicated that carrying amount of the asset group does not exceed its fair value. Thus, 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.

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, 2019. 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, 2019, filed with the Securities and Exchange Commission on June 3, 2019, 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 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 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, 2019, filed with the SEC on Form 10-K on June 3, 2019 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 a biotechnology company pioneering the development of bioprinted human tissues that emulate human biology and disease. We have been 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.

In May 2019, we announced plans to conduct additional preclinical studies necessary to optimize our manufacturing processes and complete additional preclinical studies that 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 have concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity. As a result, we have suspended development of our lead program and our Board of Directors has 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, and our financial assets. These strategic alternatives may include possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. We are also taking restructuring steps to manage our resources and extend our cash runway as we explore these strategic alternatives. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Additionally, any transaction we consummate may offer limited value for our existing business and proprietary technology and may not enhance stockholder value or provide the expected benefits. Based on our current plans and available resources, we believe that we can maintain our current operations for at least the next 12 months, however, if we are unable to successfully complete a strategic transaction or secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

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 revenue recognition, stock-based compensation expense, and the valuation allowance on deferred tax assets. 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, 2019, with the exception of changes made upon adoption of Accounting Standards Update ("ASU") 2016-02, Leases ("ASC 842") and the related supplemental ASUs. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our 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, 2019, filed with the SEC on June 3, 2019. For a description of accounting policy changes resulting from the adoption of ASC 842 and the related supplemental ASUs, refer to Note 1 to our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q.

Results of Operations

Comparison of the three months ended June 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended June 30, 2019 and 2018 (in thousands, except %):

	Three months ended June 30,		Increase (decrease)	
	2019	2018	$	%
Revenues	$ 668	$ 689	$ (21)	(3%)
Cost of revenues	$ 51	$ 120	$ (69)	(58%)
Research and development	$ 3,823	$ 3,379	$ 444	13%
Selling, general and administrative	$ 3,315	$ 4,767	$ (1,452)	(30%)
Other income	$ 198	$ 164	$ 34	21%

Revenues

For the three months ended June 30, 2019, total revenue was $0.7 million, a decrease of less than $0.1 million, or 3%, from the three months ended June 30, 2018, primarily due to lower grant revenue. Product and service revenues of approximately $0.6 million for the three months ended June 30, 2019 increased 11% from the prior year period. The increase in product and services revenues was primarily driven by increased revenue from sales of primary human liver cells and related products. Collaboration revenue and licensing revenue of less than $0.1 million for the three months ended June 30, 2019 decreased 77% from the prior year period due to the absence of revenue from a collaboration agreement that concluded in the prior year. Grant revenue decreased by less than $0.1 million for the three months ended June 30, 2019 due to a lower level of activity under our National Institutes of Health ("NIH") grant during the first quarter of fiscal 2020.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services was less than $0.1 million for the three months ended June 30, 2019, compared to $0.1 million for the three months ended June 30, 2018. The decrease was primarily due to the sale of previously reserved primary human liver cells and related products and a higher margin on liver tissue research services during the three months ended June 30, 2019.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2019 and 2018 (in thousands, except %):

	Three months ended June 30, 2019	% of total	Three months ended June 30, 2018	% of total	Increase (decrease) $	Increase (decrease) %
Research and development	$ 3,528	92%	$ 3,034	90%	$ 494	16%
Non-cash stock-based compensation	164	4%	202	6%	(38)	(19%)
Depreciation and amortization	131	4%	143	4%	(12)	(8%)
Total research and development expenses	**$ 3,823**	**100%**	**$ 3,379**	**100%**	**$ 444**	**13%**

Research and development expenses were approximately $3.8 million, an increase of $0.4 million, or 13%, from the prior year period. The increase was primarily due to a $0.3 million increase in professional services costs, a $0.2 million increase in allocated facilities costs, and a $0.1 million increase in lab supply costs, which were offset by a $0.2 million decrease in personnel related costs, which was driven by a reduction in staffing. The Company's average full-time research and development staff decreased from an average of fifty-one full-time employees for the three months ended June 30, 2018 to an average of forty-one full-time employees for the three months ended June 30, 2019.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended June 30, 2019 and 2018 (in thousands, except %):

	Three months ended June 30, 2019	% of total	Three months ended June 30, 2018	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 2,185	66%	$ 3,545	74%	$ (1,360)	(38%)
Non-cash stock-based compensation	1,056	32%	1,077	23%	(21)	(2%)
Depreciation and amortization	74	2%	145	3%	(71)	(49%)
Total selling, general and administrative expenses	**$ 3,315**	**100%**	**$ 4,767**	**100%**	**$ (1,452)**	**(30%)**

For the three months ended June 30, 2019, selling, general and administrative expenses were approximately $3.3 million, a decrease of $1.4 million, or 30%, over the prior year period. This decrease was largely due to a $0.9 million decline in personnel related costs, a $0.2 million decrease in allocated facilities costs, a $0.2 million reduction in professional services, and a $0.1 million reduction in corporate costs. The decrease in personnel related costs was driven by a reduction in staffing. Our average selling, general and administrative headcount was twenty-one full-time employees for the three months ended June 30, 2019 compared to twenty-four full-time employees in the prior year period.

Other Income (Expense)

Other income was approximately $0.2 million for each of the three months ended June 30, 2019 and 2018 and primarily consisted of interest income. Interest income slightly increased from the same period of fiscal 2019 as higher average yields more than offset lower average investment balances.

Financial Condition, Liquidity and Capital Resources

We have 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.

As of June 30, 2019, we had cash and cash equivalents of approximately $35.5 million and an accumulated deficit of $267.1 million. We also had negative cash flow from operations of $5.9 million during the three months ended June 30, 2019. At March 31, 2019, we had cash and cash equivalents of approximately $36.5 million and an accumulated deficit of $260.8 million.

At June 30, 2019, we had total current assets of approximately $37.4 million and current liabilities of approximately $3.5 million, resulting in working capital of $33.9 million. At March 31, 2019, we had total current assets of approximately $38.6 million and current liabilities of approximately $3.8 million, resulting in working capital of $34.8 million.

The following table sets forth a summary of the primary sources and uses of cash for the three months ended June 30, 2019 and 2018 (in thousands):

	Three months ended June 30,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	$ (5,935)	$ (7,022)
Investing activities	1	2
Financing activities	4,944	2,907
Net decrease in cash, cash equivalents, and restricted cash	$ (990)	$ (4,113)

Operating activities

Net cash used by operating activities for the three months ended June 30, 2019 was approximately $6.0 million as compared to $7.0 million used in operating activities for the three months ended June 30, 2018. This $1.0 million decrease in operating cash usage can be attributed primarily to a $0.9 million improvement in the net loss less depreciation and amortization and stock-based compensation, resulting from the Company's restructuring and reduction of headcount, combined with a $0.1 million reduction in the change in working capital.

Investing activities

Net cash provided by investing activities was less than $0.1 million for the three months ended June 30, 2019 and 2018.

Financing activities

Net cash provided by financing activities was approximately $4.9 million during the three months ended June 30, 2019 compared to $2.9 million during the three months ended June 30, 2018. Financing in both periods was driven by the sale of common stock through at-the-market ("ATM") offerings.

Operations funding requirements

Through June 30, 2019, we have financed our operations primarily through the sale of convertible notes, the private placement of equity securities, the sale of common stock through public and ATM offerings, and from revenue derived from grants and royalty payments, collaborative agreements, product sales and research-based services. Based on our current operating plan and available cash resources, we have sufficient resources to fund our ongoing operations as currently planned for at least the next twelve months.

After a rigorous assessment of our liver therapeutic tissue program following completion of certain additional studies, we have concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity. As a result, we have suspended development of our lead program. Our Board of Directors has 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, and our financial assets. These strategic alternatives may include possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, our expenses may exceed our current plans and expectations, which could require us to complete a transaction or wind-down our operations sooner than anticipated. Additionally, any transaction we consummate may offer limited value for our existing business and proprietary technology and may not enhance stockholder value or provide the expected benefits. If we are unable to successfully complete a strategic transaction or secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

We are also taking restructuring steps to manage our resources and extend our cash runway as we explore various strategic alternatives. Based on our current plans and available resources, we believe that we can maintain our current operations for at least the next 12 months. 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 have an effective shelf registration statement on Form S-3 (File No. 333-222929), or the 2018 Shelf, that registered $100,000,000 of common stock, preferred stock, warrants and units, or any combination of the foregoing, which expires on February 22, 2021. On March 16, 2018, we filed a prospectus supplement to the 2018 Shelf to register the sale of up to $50.0 million of shares of our common stock that may be issued in at-the-market offerings pursuant to an equity offering sales agreement we entered into with two investment banking firms as of the same date. During the three months ended June 30, 2019, we sold 6,087,382 shares of common stock in at-the-market offerings, with net proceeds of approximately $5.0 million under the 2018 Shelf.

Based on our use of the 2018 Shelf through June 30, 2019, we can offer 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, prior to its expiration date on February 22, 2021.

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or 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 continue to raise additional funds from the issuance of equity securities, there will be substantial dilution to our existing stockholders. 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.

On June 25, 2019, we 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 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).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), Nasdaq will provide us with a period of 180 calendar days, or until December 23, 2019, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. In the event that we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we elect 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, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the bid price deficiency during the second compliance period. Our failure to regain compliance during this second compliance period could result in delisting.

The June 25, 2019 Notice does not result in the immediate delisting of our common stock from the Nasdaq Global Market. We will continue to monitor the closing bid price of our common stock over the 180-day period to see if the closing bid price may increase based on our future filings with the Securities and Exchange Commission or any future announcements we may be able to issue regarding our business. We will also consider our available options to regain compliance, including effecting a reverse stock split, which would be subject to the prior approval of our stockholders. On July 26, 2019, we filed a proxy statement in connection with our annual meeting of stockholders to be held on September 5, 2019. At the annual meeting, we are requesting stockholders to authorize our Board of Directors, in its discretion but in no event later than the date of the 2020 annual meeting of stockholders, to amend the our Certificate of Incorporation, as previously amended, to effect a reverse stock split of our common stock, at a ratio in the range of 1-for-5 to 1-for-20, such ratio to be determined by the Board of Directors and included in a public announcement. 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 Global Market or the Nasdaq Capital Market. In addition, there is no assurance that our stockholders will authorize our Board of Directors to effect a reverse stock split at the 2019 annual meeting of stockholders.

As of June 30, 2019, we had 130,279,463 total issued and outstanding shares of common stock, and five-year warrants to purchase an additional 145,000 shares of common stock at exercise prices between $6.84 and $7.62 per share.

In addition, our 2008 Equity Incentive Plan provides for the issuance of up to 896,256 shares of our outstanding common stock and the 2012 Equity Incentive Plan, as amended, provides for the issuance of up to 28,553,986 shares of our common stock, of which 8,875,281 options and 2,163,724 restricted stock units remain outstanding and 13,068,863 shares remain available for issuance as of June 30, 2019, to executive officers, directors, advisory board members, employees and consultants. We have also issued time-based and performance-based inducement awards under the Incentive Award Agreements for up to 3,382,326 shares of our common stock. Additionally, 1,188,718 shares of common stock remain available for issuance under our 2016 Employee Stock Purchase Plan. 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 and the 2016 Employee Stock Purchase Plan total 159,103,375 shares of common stock out of the 200,000,000 shares of common stock authorized for issuance as of June 30, 2019.

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

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our condensed consolidated financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any unfavorable events or circumstances actually occurs, our business may suffer, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to our Strategic Alternatives Process and Restructuring Plans

We may not be successful in negotiating and consummating a strategic transaction on favorable terms, or at all.

In May 2019, we announced plans to conduct additional preclinical studies necessary to optimize our manufacturing processes and complete additional preclinical studies that 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 have concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity. As a result, we have suspended development of our lead program and our Board of Directors has 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, and our financial assets. These strategic alternatives may include possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. We are also taking restructuring steps to manage our resources and extend our cash runway as we explore these strategic alternatives. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on terms that are favorable to our stockholders, on a timely basis, or at all. Additionally, any transaction we consummate may offer limited value for our existing business and proprietary technology and may not enhance stockholder value.

We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to complete a strategic transaction.

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).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), Nasdaq has provided us with a period of 180 calendar days, or until December 23, 2019, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. In the event that we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we elect 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, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the bid price deficiency during the second compliance period. Our failure to regain compliance during this second compliance period could result in delisting.

The June 25, 2019 Notice does not result in the immediate delisting of our common stock from the Nasdaq Global Market. During the 180-day period, we will monitor the closing bid price of our common stock. We will also consider our available options to regain compliance, including effecting a reverse stock split, which would be subject to the prior approval of our stockholders. For example, on July 26, 2019, we filed a proxy statement in connection with our 2019 annual meeting of stockholders to be held on September 5, 2019. At the annual meeting, we are requesting stockholders to authorize our Board, in its discretion but in no event later than the date of the 2020 annual meeting of stockholders, to amend the our Certificate of Incorporation, as previously amended, to effect a reverse stock split of our common stock, at a ratio in the range of 1-for-5 to 1-for-20, with the actual ratio to be determined by the Board of Directors and included in a public announcement. 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 for the Company to maintain the listing of its common stock on the Nasdaq Global Market. In addition, there is no assurance that our stockholders will authorize our Board of Directors to effect a reverse stock split at the 2019 annual meeting of stockholders. If our common stock is eventually delisted from Nasdaq, the liquidity of our stock and our ability to complete a strategic transaction on favorable terms, or at all, may be adversely affected.

We may fail to not achieve the expected cost savings and related benefits from our August 2019 restructuring.

On August 7, 2019, our Board of Directors approved a business restructuring to conserve our available cash resources, reducing approximately 40 positions, or 69% of our overall workforce. This restructuring allows us to manage resources and extend our cash runway as we 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, and our financial assets. As a result, we expect to record a restructuring charge in the fiscal second quarter of approximately $1.3 million, primarily related to employee severance and benefits costs. The actions associated with the restructuring announcement are anticipated to be complete by the end of the fiscal second quarter 2020, with liabilities anticipated to be paid by the end of the fiscal second quarter 2020.

We may fail to effectively execute on our restructuring and cost reduction plans. These actions may cost more and take more time than we currently estimate and we may not realize the expected benefits or be able to extend our runway sufficiently to achieve a successful strategic transaction. Any failure to properly execute our restructuring plans could cause us not to achieve the expected benefits of these actions, and adversely affect our financial condition and our ability to complete a strategic transaction.

Risks Related to our Development of *In Vivo* Therapeutic Tissue Candidates

We may not be successful in 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.

Our *in vivo* liver tissue was our lead therapeutic candidate. In May 2019, we announced our need to conduct additional preclinical studies and to optimize our manufacturing processes to generate decisive scientific data regarding the prolonged functionality and therapeutic benefits of our liver tissue candidate. The requirement to complete additional studies and to optimize our manufacturing processes resulted from data generated from a larger group of animal studies that differed from our earlier pilot studies. These studies continued to show statistically meaningful reductions in toxic globules in the A1AT animal models over a three-month period. However, in these and other animal models, we observed shorter tissue duration than we observed in our pilot studies, as measured by human protein output and the quantity of hepatocytes.

On August 7, 2019, we announced that after a rigorous assessment of our liver therapeutic tissue program following our completion of additional studies, we have concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity. We also announced that we suspended development of our lead program and our Board of Directors had 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, and our financial assets.

Given the results of these studies, and the costs, time and risks associated with the required redesign and development of our therapeutic liver tissue, there is no assurance that we will be successful in 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 existing business and proprietary technology and may not enhance stockholder value.

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 have conducted initial research and development activities on several other tissue candidates. Each of our therapeutic tissue candidates are in the early stages of research and development and would require substantial financial resources, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process can take many years of effort without any assurance of ultimate success. Our 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;
- our inability to manufacture sufficient quantities of the tissue candidate for development, clinical, or commercialization activities in a timely and cost-efficient manner;
- our 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.

As a result of these risks and our available cash resources, 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 these early stage development projects. Given the costs, time and risks associated with these early stage development projects, however, there is no assurance that we will be successful in 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 tissues 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.

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 represent new therapeutic approaches in their respective disease areas. As a result, the development of these therapeutic tissue candidates is 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 have yielded 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 have adversely influenced 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. Success 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 elected to continue to pursue 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.

If we had elected to continue to pursue the development of our therapeutic tissues, we would be required to rely on third parties to conduct certain aspects of our preclinical studies and to conduct our clinical trials. If these third parties did not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we would not be able to obtain regulatory approval of or commercialize any potential tissue candidates.

If we had elected to continue to pursue the development of our therapeutic tissues, we would be required to depend upon third parties to conduct certain aspects of our preclinical studies and to conduct our clinical trials. This would require us to negotiate budgets and contracts with such third parties, and if we were unsuccessful or if the negotiations took longer than anticipated, this would result in delays to any planned development timelines and result in increased costs.

We would rely especially heavily on third parties over the course of our clinical trials, and, as a result, would have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties would not relieve us of our regulatory responsibilities. We and these third parties would be required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for tissue candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties failed to comply with applicable GCP requirements, the clinical data generated in any clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving any marketing applications. We cannot be certain that, upon inspection, such regulatory authorities would determine that any of these clinical trials complied with the GCP requirements. In addition, our clinical trials would need to be conducted with biologic product produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business would be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials would not be our employees and, except for remedies that may be available to us under any such agreements with such third parties, we cannot control whether or not they would devote sufficient time and resources to any such preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials.

If we had elected to continue to pursue the development of our therapeutic tissues, we may have experienced delays or difficulties in the enrollment of patients in clinical trials, which could delay or prevent necessary regulatory approvals.

If we had elected to continue to pursue the development of our therapeutic tissues, we may have been unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Our ability to enroll patients may also be adversely impacted if competitors have ongoing clinical trials for tissue candidates that treat the same indications as any tissue candidate we elected to pursue. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the eligibility criteria for, and design of, the clinical trial in question, including factors such as frequency of required assessments, length of the study, and ongoing monitoring requirements;
- the perceived risks and benefits of the tissue candidate under study, including the potential advantages or disadvantages of the tissue candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- the patient referral practices of physicians;
- inability to obtain or maintain patient informed consents;
- risk that enrolled patients will drop out before completion;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Any enrollment delays in the clinical trials we elected to pursue would result in increased development costs for our tissue candidates, or the inability to complete development of our tissue candidates, which would limit our ability to obtain additional financing, and materially impair our ability to obtain regulatory approvals.

Our experience manufacturing NovoTissues 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 a nascent industry. To our knowledge, there are no contract manufacturing organizations (CMO) with experience in manufacturing bioprinted tissue products under GMP conditions. We have conducted all of our manufacturing internally.

We conducted all of our research to date 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 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. If we elected to continue to pursue the development of our therapeutic tissues, we may have encountered problems achieving adequate quantities and quality of clinical-grade materials to conduct our clinical trials, or to meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

As of the date of this report, we had not yet 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 may have further delayed or impaired 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 have been required to bolster our quality control and quality assurance capabilities, including by augmenting our manufacturing processes and adding personnel. We may have encountered problems hiring and retaining the experienced specialist scientific and manufacturing personnel needed to operate our manufacturing process, which could have resulted in additional delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Further, if we engaged in scale-up manufacturing of any approved product, we may have encountered unexpected issues relating to the manufacturing processes, donor variability, or the quality, purity or stability of the product, and we may have been required to refine or alter our manufacturing processes to address these issues. Resolving these issues could have resulted in significant additional delays and resulted 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.

Our tissue candidates are novel, complex, and difficult to manufacture. We have and, if we elected to continue to pursue the development of our therapeutic tissues, could continue to experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.

The manufacturing processes used to produce our tissue candidates are complex, novel, and have not been validated for commercial use. In May 2019, we announced plans to conduct additional preclinical studies necessary to optimize our manufacturing processes and complete additional preclinical studies that generate consistent scientific data regarding the prolonged functionality and therapeutic benefits of our *in vivo* liver tissues. On August 7, 2019, we announced that after a rigorous assessment of our therapeutic liver tissue program following our completion of additional studies (including the analysis and testing of our manufacturing processes), we concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity. As a result, our Board of Directors determined that it was in the best interests of our stockholders to suspended further development of our therapeutic liver tissue and to pursue our strategic alternatives. This decision was based in part on our inability to improve our manufacturing processes in a manner that enhanced the viability and functionality of our therapeutic liver tissue.

Our tissue candidates require processing and manufacturing steps that are more complex than those required for manufacturing most small molecule drugs. Unlike small molecules, the physical and chemical properties of our tissue candidates are challenging to fully characterize. In addition, any future products may have been required to be manufactured “just in time” to be implanted, which would limit the timeframe for conducting release testing on the finished product. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot-to-lot or would perform in the intended manner. As a result, even if we elected to continue to develop our therapeutic tissues, there is no assurance that we would have been able to develop and validate our manufacturing controls, which could have further delayed or stalled any development plans and required regulatory approvals.

Development of combination tissue candidates may present more or different challenges than development of a single-agent product candidate.

The FDA may have designated our liver tissue candidate as a combination product. The development of combination products may present more or different challenges than development of a single-agent product candidate. A combination product is a single therapeutic product that consists of two or more active ingredients, with each component making a contribution to the claimed effect of the drug. The development of combination products may be more complex than the development of single agent products. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not have been able to meet the FDA's approval standards required for combination products. Finally, the FDA's requirements concerning combination products may change in the future. Moreover, the applicable requirements for approval for combination products may differ from country to country.

Even if we had elected to continue to pursue the development of our therapeutic tissues, we may have never obtained approval to commercialize any of our tissue candidates in any foreign jurisdiction.

In order to eventually market any of our tissue candidates in any particular foreign jurisdiction, we would have been required to establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. Approval by the FDA in the United States, if obtained, would not have ensured approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not have been accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval for our therapeutic tissue products could have resulted in additional costs and required additional preclinical studies or clinical trials.

We obtain our clinical grade livers from a single source, and if we had elected to continue to pursue the development of our therapeutic liver tissue, we may have been unable to obtain sufficient quantities of clinical grade livers to support our clinical trials and/or commercialization.

Our liver tissue candidate is manufactured using human primary liver cells from non-transplantable livers we receive from IIAM. 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, we may have been unable to obtain sufficient quantities and qualities of clinical grade livers to supply our clinical program or meet commercial demand, and our development plans may have been delayed or stalled, which would have harmed our business.

Our liver tissue candidate includes primary cells from two donors. If the FDA does not authorize us to include cells from more than one donor, this may have further delayed our development timeline.

Our NovoTissues Liver product is 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 had elected to continue to pursue 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 have resulted in additional development costs and a delay in our development timeline, in which case our business would have been materially harmed.

Any contamination in our manufacturing facility, shortage of raw materials or reagents, or failure of any of our key suppliers to deliver necessary materials could result in delays in our clinical development.

Given the nature of manufacturing engineered tissue products, there is a risk of contamination. If we had elected to continue to pursue the development of our therapeutic tissues, any contamination could have materially adversely affected our ability to produce our tissue candidates on schedule and could therefore harmed our results of operations and caused reputational damage.

We may not enjoy the market exclusivity benefits of any orphan drug designation.

Although we may obtain orphan designations in the treatment of certain diseases our therapeutic products are intended to treat, the designation may not be applicable to any particular product we might get approved and that product may not be the first product to receive approval for that indication. 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. Even if we had elected to continue to pursue the development of our therapeutic tissues, it would have been 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 was 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 we demonstrated, if we could, that our product is superior. Further, even 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.

Even if we had elected to continue to pursue the development of our therapeutic tissues, a competitor may have achieved regulatory approval before we did or developed 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 had elected to continue to pursue the development of our therapeutic tissues, we may have also faced 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. Even if we had elected to continue to pursue the development of our therapeutic tissues, these competitors may have obtained 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 have rendered 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.

Risks Related to Our Financial Position

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 $6.5 million and $7.6 million for the three months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had incurred cumulative operating losses of $214.9 million and cumulative net losses totaling $267.1 million. We expect to incur significant additional operating losses as we implement our restructuring plans and purse our strategic alternatives. Even if we are successful in entering into a strategic partnership or collaboration, or otherwise license or sell our assets or intellectual property, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. We may therefore never generate significant revenue, and even if we do generate significant revenue, we may never achieve profitability.

If we had elected to continue to pursue the development of our therapeutic tissues, we would have been required to secure significant additional capital to support these efforts.

We do not have sufficient capital resources on-hand to engage in a lengthy redesign or redevelopment of our manufacturing processes or our liver tissue candidate or to complete the preclinical studies necessary to submit an IND for another tissue candidate. If we had elected to continue to pursue these efforts, we would have been required to secure significant additional capital resources in order to complete the required preclinical and clinical development activities and to seek the required regulatory approvals. We would be required to cover these future operating expenses through cash on hand, the issuance of additional equity or debt securities, and from revenue derived from research service agreements, product sales, grants, and collaborative research agreements. Depending on market conditions, we cannot be sure that additional financing would have been available when needed or that, if available, financing could be obtained on terms favorable to us or to our stockholders. Having insufficient funds would require us to delay, scale back, or eliminate some or all of our development programs, relinquish rights to our technology, or pursue a strategic transaction 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. Further, if we raised additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raised 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 could restrict our ability to operate our business.

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:

- The cost and time to complete our strategic transaction process, including our associated restructuring and cost reduction actions;
- the results of our development and regulatory approval progress for our therapeutic tissue candidates;
- our reported revenues and financial results;

- the commencement, postponement, delay, progress, completion, or cancellation of client contracts or collaborations in the quarter;
- changes in the mix of our products and services;
- changes in the general global economy;
- competitive pricing pressures;
- the extent of cost overruns or delays in our product development and regulatory approval plans;
- holiday buying patterns of our clients;
- budget cycles of our clients.

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 will be adversely impacted if we are unable to successfully retain our executive officers and other key personnel.

Our ability to successfully pursue and complete a strategic transaction depends in part on our ability to retain our key medical, clinical, scientific, technical, and managerial personnel required to pursue and evaluate our strategic alternatives. Our success will also 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. As a result, the loss of any of our executive officers or other key personnel could adversely impact our ability to successfully pursue and complete a strategic transaction.

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 harms, result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and/or cause reputational harm.

If our laboratory facilities become inoperable, we will lose access to our 3D bioprinters and tissues, and our ability to conduct our business and comply with our contractual obligations will be harmed.

We manufacture our NovoGen Bioprinters® and our 3D Human Liver Tissues at our laboratory facilities in San Diego, California. We also provide research services to our customers and collaboration partners and conduct our product research and development activities at our laboratory facilities in San Diego, California. We do not currently have redundant laboratory facilities. Our San Diego, California laboratory facilities are situated near active earthquake fault lines. Our facilities may be harmed or rendered inoperable by natural or manmade disasters, including earthquakes, flooding, fires, power outages and contamination, which may render it difficult or impossible for us to continue to provide our products and services and engage in our research and development activities for some period of time. Even if our facilities are inoperable for a short period of time, we may suffer the loss of our existing tissue and cell inventory, and the loss of any research services and activities currently in process. Accordingly, any disruption to operations at our laboratory facilities in San Diego, California would materially affect our business, prospects and results of operations.

We are subject to risks associated with doing business outside the United States.

We do business with customers outside the United States. There are a number of risks arising from our international business, including those related to:

- foreign currency exchange rate fluctuations, potentially reducing the United States dollars we receive for sales denominated in foreign currency;

- general economic and political conditions in the markets we operate in;
- potential increased costs associated with overlapping tax structures;
- potential trade restrictions and exchange controls;
- more limited protection for intellectual property rights in some countries;
- difficulties and costs associated with staffing and managing foreign operations;
- unexpected changes in regulatory requirements;
- the difficulties of compliance with a wide variety of foreign laws and regulations; and
- longer accounts receivable cycles in certain foreign countries, whether due to cultural differences, exchange rate fluctuation or other factors.

These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition. For example, we are subject to compliance with the United States Foreign Corrupt Practices Act and similar anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. While our employees are required to comply with these laws, we cannot be sure that our internal policies and procedures will always protect us from violations of these laws, despite our commitment to legal compliance and corporate ethics. The occurrence or allegation of these types of risks may adversely affect our business, performance, prospects, value, financial condition, and results of operations.

Risks Related to Our Common Stock and Liquidity Risks

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 Global 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. 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 of 2002 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 "Act") requires that we evaluate and determine the effectiveness of our internal control over financial reporting and requires an attestation and report by our external auditing firm on our internal control over financial reporting. We believe our system and process evaluation and testing comply with the management certification and auditor attestation 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, especially as we grow our business. 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 or our independent registered public accounting firm identifies 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 regarding the status of our strategic alternatives process, including the announcement of any potential strategic transaction;

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors, including new product and service offerings;
- results of our preclinical studies and regulatory actions regarding our therapeutic products;
- reduced government funding for research and development activities;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- 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, 2019, there were an aggregate of 159,103,375 shares of our common stock issued and outstanding on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 27,490,194 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, 1,188,718 shares of common stock that may be issued through our Employee Stock Purchase Plan ("ESPP"), and 145,000 shares of our common stock that may be issued upon the exercise of outstanding warrants.

In the future, we may issue additional authorized but previously unissued equity securities to raise funds to support our continued operations. 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 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 Global 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. Our future dividend policy will be based on the results of our strategic alternatives process. 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 the 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 *In Vitro* Tissues Business

Our in vitro tissues business depends on new and unproven technology and approaches, and we have been 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. Our commercial products reflect a novel approach to preclinical testing of drug compounds and disease modeling, and there is no assurance that they will perform as expected or as required by our customers. To date, 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, have not resulted in our development of a profitable, standalone business. In addition, some of our customers may continue to require unique features, cell sourcing, validation data, or greater degrees of reproducibility than we have been 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. If our drug discovery and biological research tools do not assist in the discovery and development of such therapeutic products or to model diseases, our current and potential customers may lose confidence in our *in vitro* products and services, and our ability to achieve or maintain commercial acceptance for those products and services may adversely affect our business, financial condition and results of operations. Further, there is no assurance that we will be successful in entering into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vitro* tissues business 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.

Our ability to successfully commercialize our in vitro products and services is subject to a variety of risks.

The commercialization of our *in vitro* products and services is 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 any of these or any other risks and uncertainties 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 existing business and proprietary technology and may not enhance stockholder value.

The near and long-term viability of our in vitro products and services will depend on our ability to successfully establish new strategic relationships.

The near and long-term viability of our *in vitro* products and services will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our technology or product offerings or our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of new collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further commercialization efforts. Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any *in vitro* product or service candidates for several reasons both within and outside of our control.

We 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. We have 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 do:

- 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. Even 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 our competitors.

We will require access to a constant, steady, reliable supply of human cells to successfully develop and commercialize our in vitro products and services.

We require a reliable supply of qualified human cells for our commercial products and services and for our research and product development activities. We purchase 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 utilize in our business. 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 work closely with Samsara and our third-party suppliers to assure adequate supply while maintaining high quality and reliability. If demand for our products and services grows significantly, we may 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. Any failure to obtain a reliable supply of sufficient human cells or a supply at cost effective prices will harm our business and our results of operations and could cause us to be unable to comply with the contractual obligations we owe to our customers and collaboration partners.

We may not be successful in establishing Samsara as a profitable commercial business.

In January 2016, we announced that our wholly-owned subsidiary, Samsara, commenced commercial operations. We formed Samsara to serve as a key source of certain of the primary human cells we utilize in our products and services and in the development of our therapeutic tissue candidates. In addition to supplying human cells for our business requirements, we believe there is an opportunity for Samsara to operate as a commercial business by selling human cells to other pharmaceutical, biotech and research organizations. Samsara has begun selling its human cell offerings to end users both directly and through distribution partners. Operating and developing Samsara's business is subject to a number of risks and uncertainties, including:

- failing to source a sufficient supply of high-quality human organs or cells;
- failing to achieve market acceptance for its human cell offerings;
- failing to demonstrate the quality and reliability of its human cell offerings;
- failing to be both cost effective and competitive with the products offered by third parties;
- failing to obtain any necessary regulatory approvals;
- failing to be able to produce its human cell offerings on a large enough scale;
- failing to establish and maintain distribution relationships with reliable third parties;
- failing to hire and retain qualified personnel; and
- infringing the proprietary rights of third parties.

If any of these or any other risks and uncertainties occur, our efforts to establish Samsara as a commercial business 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 Samsara business 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.

A significant portion of any future sales of in vitro products and services would be dependent upon our customers' capital spending policies and research and development budgets, and government funding of research and development programs at universities and other organizations, which are each subject to significant and unexpected decrease.

Our prospective customers for our *in vitro* products and services include pharmaceutical and biotechnology companies, academic institutions, government laboratories, and private research foundations. Fluctuations in the research and development budgets at these organizations could have a significant effect on the demand for our products and services. Research and development budgets fluctuate due to changes in available resources, patent expirations, mergers of pharmaceutical and biotechnology companies, spending priorities, general economic conditions, and institutional and governmental budgetary policies, including but not limited to reductions in grants for research by federal and state agencies as a result of the current budget crises and budget reduction measures. In addition, our business could be seriously damaged by any significant decrease in life sciences research and development expenditures by pharmaceutical and biotechnology companies, academic institutions, government laboratories, or private foundations.

The timing and amount of revenues from customers that rely on government funding of research may vary significantly due to factors that can be difficult to forecast. Research funding for life science research has increased more slowly during the past several years compared to the previous years and has declined in some countries, and some grants have been frozen for extended periods of time or otherwise become unavailable to various institutions, sometimes without advance notice. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. Other programs, such as homeland security or defense, or general efforts to reduce the federal budget deficit could be viewed by the United States government as a higher priority. These budgetary pressures may result in reduced allocations to government agencies that fund research and development activities. National Institute of Health and other research and development allocations have been diminished in recent years by federal budget control efforts. The prolonged or increased shift away from the funding of life sciences research and development or delays surrounding the approval of government budget proposals may cause our customers to delay or forego purchases of our products or services, which could seriously damage our *in vitro* products and services business.

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 collaborators or customers use our products in the manufacturing or testing processes for their 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 (CMS) 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. However, we may agree to comply with certain requirements, and, if we fail to do so, we could lose sales and our collaborators or customers and be exposed to regulatory delays or objections and potential product liability claims. In addition, our customers may require that our 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 we will be able to comply with GLP requirements on the timetable required by our customers. As a result, the violation of government regulations or failure to comply with quality requirements could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.

Any therapeutic tissues we elect to develop would be subject to extensive, lengthy and uncertain regulatory requirements, which could adversely affect our ability to obtain regulatory approval in a timely manner, or at all.

Any therapeutic and other life science products we elect to develop would be subject to extensive, lengthy and uncertain regulatory approval process by the Food and Drug Administration (FDA) and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and clinical studies is lengthy, expensive and uncertain. We may not be able to obtain FDA approvals for any therapeutic products we elect to develop in a timely manner, or at all. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technologies and have not been the subject of extensive laboratory testing and clinical studies. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by the FDA and other foreign governmental regulatory authorities that could prevent or delay approval in the United States and any other foreign country. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

In addition, the manufacture and marketing of any products we elect to pursue would be subject to government regulation in the United States and other countries. In the United States and most foreign countries, we would be required to complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. The steps required by the FDA before our proposed products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an IND, NDA (New Drug Application), or BLA (Biologic License Application) which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; and performance of a consistent and reproducible manufacturing process intended for commercial use.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of any products to the satisfaction of such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are outside of our control. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to our distribution. Expanded or additional indications for approved devices or drugs may not be approved, which could limit our revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our tissue candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our products are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

Even if a product gains regulatory approval, such approval is likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or our manufacturer are subsequently discovered, and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

If restrictions on reimbursements and health care reform limit our or our collaborators' actual or potential financial returns on therapeutic products that we or they develop based on our platform technology, we may not be able to recover our research and development costs and our collaborators may reduce or terminate their collaborations with us.

Our ability to recover our research and development costs and successfully commercialize any therapeutic products we elect to develop and our collaborators' abilities to successfully commercialize the therapeutic and other life science products they develop through the research tools or services that we provide them may depend in part on the extent to which coverage and adequate payments for these products will be available from government payers, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payers. These payers are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved therapeutic and other life science products, and coverage and adequate payments may not be available for these products.

In recent years, officials have made numerous proposals to change the health care system in the U.S. These proposals included measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of pharmaceuticals and other medical products to government control. Government and other third-party payers increasingly attempt to contain health care costs by limiting both coverage and the level of payments of newly approved health care products. In some cases, they may also refuse to provide any coverage of uses of approved products for disease indications other than those for which the FDA has granted marketing approval. Governments may adopt future legislative proposals and federal, state or private payers for healthcare goods and services may take action to limit their payments for goods and services. Any of these events could reduce the demand for our products and services by our collaboration partners, reduce the proceeds we receive from our arrangements with our collaboration partners based on future sales of their therapeutic products or limit our ability to recover our research and development costs and successfully commercialize any therapeutic products we develop.

We use 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 involve 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 are 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 require that environmental permits and approvals be issued by applicable government agencies. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts. If we fail 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 Intellectual Property

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

If we do not protect our intellectual property adequately, competitors may be able to use our technologies and the value of our business would be harmed. 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.

Any strategic transaction we elect to pursue 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.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and potential products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for these breaches. Alternatively, if a third party alleges that any of our employees or consultants has breached confidentiality obligations to our benefit, we may have to defend against allegations of trade secret misappropriation.

Enforcing or defending a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We rely in part on trademarks to distinguish our products and services from those of other entities. Trademarks may be opposed or cancelled, and we may be involved in lawsuits or other proceedings to protect or enforce our trademarks.

We rely on trademarks, in the United States and in certain foreign jurisdictions, to distinguish our products and services in the minds of consumers and our business partners from those of other entities. Third parties may challenge our pending trademark applications through opposition proceedings in the U.S., or comparable proceedings in foreign jurisdictions, in which they seek to prevent registration of a mark. Our registered trademarks may be subject to cancellation proceedings in the U.S., or comparable proceedings in foreign jurisdictions, in which a third party seeks to cancel an existing registration. To enforce our trademark rights, we may be involved in lawsuits or other proceedings which could be expensive, time-consuming and uncertain.

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

Costs Associated with Exit or Disposal Activities.

On August 7, 2019, we undertook a business restructuring to better focus and align resources, reducing approximately 40 positions, or 69% of our overall workforce. This restructuring allows us to manage resources and extend our cash runway as we 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, and our financial assets. As a result, we expect to record a restructuring charge in the fiscal second quarter of approximately $1.3 million, primarily related to employee severance and benefits costs. The actions associated with the restructuring announcement are anticipated to be complete by the end of fiscal second quarter 2020, with liabilities anticipated to be paid by the end of fiscal second quarter 2020 and yield approximately $5.3 million of annual savings to employee costs.

In accordance with ASC 360-10, we record 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). On August 7, 2019, events and circumstances relating to a forecast of operating cash flow losses and the expectation that, more likely than not, an asset group will be sold or disposed of significantly before the end of its previously estimated useful life indicated that long-lived assets of approximately $5.9 million might be impaired. We performed an asset impairment analysis on our long-lived asset group, consisting of our property, plant and equipment, leases, and intangibles, which concluded that the carrying amount is not recoverable. Further, our analysis indicated that the carrying amount of the asset group does not exceed its fair value. Thus, 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. We will continue to monitor assets for impairment.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
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).
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 8, 2019

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

Date: August 8, 2019

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 8, 2019

/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 8, 2019

/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, 2019, 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 8, 2019

/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.