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 September 30, 2018

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)**

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 November 1, 2018, a total of 115,890,335 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 data)

	September 30, 2018 (Unaudited)	March 31, 2018 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 37,355	$ 43,726
Accounts receivable	475	883
Grant receivable	453	145
Inventory, net	1,036	842
Prepaid expenses and other current assets	798	1,164
Total current assets	40,117	46,760
Fixed assets, net	2,236	2,788
Restricted cash	127	127
Other assets, net	145	152
Total assets	$ 42,625	$ 49,827
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 449	$ 464
Accrued expenses	2,026	3,341
Deferred revenue	619	668
Deferred rent	197	185
Total current liabilities	3,291	4,658
Deferred revenue, net of current portion	—	19
Deferred rent, net of current portion	464	564
Total liabilities	3,755	5,241
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 115,200,421 and 111,032,957 shares issued and outstanding at September 30, 2018 and March 31, 2018, respectively	115	111
Additional paid-in capital	286,128	278,595
Accumulated deficit	(247,373)	(234,120)
Total stockholders' equity	38,870	44,586
Total Liabilities and Stockholders' Equity	$ 42,625	$ 49,827

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 September 30, 2018	Three Months Ended September 30, 2017	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Revenues				
Products and services	$ 493	$ 946	$ 1,039	$ 1,890
Collaborations and licenses	42	260	85	306
Grants	408	149	508	149
Total Revenues	943	1,355	1,632	2,345
Cost of revenues	125	254	245	555
Research and development expenses	3,187	4,944	6,566	9,977
Selling, general and administrative expenses	3,640	5,736	8,407	11,592
Total costs and expenses	6,952	10,934	15,218	22,124
Loss from Operations	(6,009)	(9,579)	(13,586)	(19,779)
Other Income (Expense)				
Gain (loss) on fixed asset disposals	—	—	2	—
Interest income	172	118	334	216
Total Other Income	172	118	336	216
Income Tax Expense	—	—	(3)	—
Net Loss	$ (5,837)	$ (9,461)	$ (13,253)	$ (19,563)
Currency Translation Adjustment	$ —	$ —	$ —	$ (11)
Comprehensive Loss	$ (5,837)	$ (9,461)	$ (13,253)	$ (19,574)
Net loss per common share—basic and diluted	$ (0.05)	$ (0.09)	$ (0.12)	$ (0.19)
Weighted average shares used in computing net loss per common share—basic and diluted	113,993,237	106,297,699	112,732,767	105,497,939

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)

	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Cash Flows From Operating Activities		
Net loss	$ (13,253)	$ (19,563)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of fixed assets	(2)	—
Depreciation and amortization	570	647
Stock-based compensation	2,553	4,350
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	408	(386)
Grants receivable	(308)	(149)
Inventory	(194)	54
Prepaid expenses and other assets	366	210
Accounts payable	(15)	(694)
Accrued expenses	(1,315)	(1,280)
Deferred revenue	(68)	81
Deferred rent	(88)	(72)
Net cash used in operating activities	(11,346)	(16,802)
Cash Flows From Investing Activities		
Purchases of fixed assets	(11)	(56)
Proceeds from disposals of fixed assets	2	—
Purchases of intangible assets	—	(70)
Net cash used in investing activities	(9)	(126)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	5,129	4,135
Employee taxes paid related to net share settlement of equity awards	(145)	(51)
Proceeds from exercise of stock options	—	825
Net cash provided by financing activities	4,984	4,909
Net decrease in cash, cash equivalents, and restricted cash	(6,371)	(12,019)
Cash, cash equivalents, and restricted cash at beginning of period	43,853	62,878
Cash, cash equivalents, and restricted cash at end of period	$ 37,482	$ 50,859
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	37,355	50,732
Restricted cash	127	127
Total cash, cash equivalent and restricted cash	37,482	50,859
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," and collectively with its subsidiaries, "the Company") is a biotechnology company pioneering a unique set of therapeutic and drug profiling capabilities based on its revolutionary ability to 3D bioprint liver tissues that emulate human biology and disease. The Company is developing its *in vivo* liver tissues to treat a range of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. The Company's program focused on an orphan disease known as Alpha-1-antitrypsin deficiency ("A1AT"), received the U.S. Food and Drug Administration's ("FDA") orphan drug designation in December 2017 and is targeted for an Initial New Drug Application ("IND") filing in calendar-year 2020. Organovo Holdings is also capitalizing on its foundational ability to characterize highly specialized human cells and to build robust, functional human tissues by creating a range of novel *in vitro* disease modeling platforms, including a broad set of non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH") conditions.

Except where specifically noted or the context otherwise requires, references to "Organovo Holdings," "the Company," "we," "our," and "us" in these notes to the condensed consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc., Samsara Sciences, Inc., and Organovo U.K., Ltd. In March 2018, the U.K. operations were combined with Organovo, Inc.'s operations.

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, 2018 is derived from the Company's audited balance sheet at that date.

The 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, 2018, 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, 2019.

Reclassification of prior year presentation

As a result of the adoption of the new accounting standard associated with clarifying presentation and classification in the statement of cash flows, certain reclassifications have been made to the prior period financial statements to conform with the current period presentation. These reclassifications did not have any effect on previously reported cash flows, net loss, or financial position.

Liquidity

As of September 30, 2018, the Company had cash, cash equivalents, and restricted cash of approximately $37.5 million, consisting of cash and cash equivalents of $37.4 million and restricted cash of $0.1 million. The restricted cash was pledged as collateral for two letters of credit the Company is required to maintain as security deposits under the terms of the leases of its facilities. The Company had an accumulated deficit of approximately $247.4 million. The Company also had negative cash flows from operations of approximately $11.3 million during the six months ended September 30, 2018.

Through September 30, 2018, the Company has financed its operations primarily through the sale of convertible notes, 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 six months ended September 30, 2018, the Company issued 3,762,130 shares of its common stock through its ATM facility and received net proceeds of approximately $5.1 million.

Based on its current operating plan and available cash resources, the Company has sufficient resources to fund its business for at least the next twelve months from the financial statement issuance date.

The Company will need additional capital to further fund the development of its therapeutic tissues focusing on critical unmet medical needs in the liver disease space and to fund the development and commercialization of its proprietary platform to produce and study living tissues that emulate key aspects of human biology and disease that can be used to facilitate drug discovery and development. The Company intends to cover its future operating expenses through cash on hand, through revenue derived from research service agreements, product sales, collaborative agreements, grants and license payments, and through the issuance of additional equity or debt securities. Depending on market conditions, the Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to it or to its stockholders.

Having insufficient funds may require the Company to delay, scale back, or eliminate some or all of its development programs or relinquish rights to its technology on less favorable terms than it would otherwise choose. Failure to obtain adequate financing could eventually adversely affect its ability to operate as a going concern. If the Company continues to raise additional funds from the issuance of equity securities, there will be substantial dilution to its existing stockholders. If the Company raises 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 its ability to operate its business.

Use of estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Actual results could differ from those estimates. Significant estimates used in preparing the condensed consolidated financial statements include those assumed in revenue recognition, 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.

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 September 30, 2018 and March 31, 2018, the Company had approximately $619,000 and $687,000, respectively, in deferred revenue related to its research service agreements, collaborative agreements, and licenses within the scope of Topic 606. In the six months ended September 30, 2018 the Company recognized revenue on approximately $93,000 that had been recorded as deferred revenue at March 31, 2018.

Effective April 1, 2018, the Company adopted the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 606, *Revenue from Contracts with Customers* (“Topic 606”). Under Topic 606, the Company recognizes revenue 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.

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 six months ended September 30, 2018, 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 National Institutes of Health ("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 ASC 606.

Revenue recognized under this grant was approximately $408,000 and $508,000 for the three and six months ended September 30, 2018, respectively. Revenue recognized under this grant was approximately $149,000 for the three and six months ended September 30, 2017.

Cost of revenues

The Company reported approximately $0.1 million and $0.2 million in cost of revenues for the three and six months ended September 30, 2018, respectively. The Company reported approximately $0.3 million and $0.6 million in cost of revenues for the three and six months ended September 30, 2017, respectively. 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, 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 and six months ended September 30, 2018 or 2017, 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 17.8 million at September 30, 2018, and 15.4 million at September 30, 2017.

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 May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("Topic 606"), which supersedes most existing revenue recognition guidance in U.S. generally accepted accounting principles ("GAAP"), including most industry-specific guidance. The standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard was originally effective for public companies for annual reporting periods beginning after December 15, 2016, with no early application permitted. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers*, which deferred by one year the effective date for all entities, with application permitted as of the original effective date. The standard allows for either a full retrospective or modified retrospective method of adoption. The Company adopted this standard on its effective date, April 1, 2018, under the modified retrospective method of adoption. Under this method, entities recognize the cumulative impact of applying the new standard at the date of adoption without restatement of prior periods presented. The cumulative effect of applying the new standard to contracts that were not completed as of April 1, 2018 did not have a material impact on the Company's consolidated financial position, results of operations, or cash flows.

The new standard also requires enhanced disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. See “Note 2. Summary of Significant Accounting Policies” for further discussion. Topic 606 supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition* (“Topic 605”). While results for reporting periods beginning after April 1, 2018 are presented under Topic 606, all prior period amounts are not adjusted and continue to be reported under the accounting standards in effect during these prior periods. The accounting policies for revenue recognition for periods prior to April 1, 2018 are described in “Note 1. Description of Business and Summary of Significant Accounting Policies” of the Notes to the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K for the year ended March 31, 2018. Adoption of this ASC did not have a material impact on the Company’s condensed consolidated financial statements. Refer to the revenue recognition disclosure above.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* (Topic 230): *Restricted Cash*. The standard clarifies the presentation of restricted cash and cash equivalents and requires companies to include restricted cash and cash equivalents in the beginning and ending balances of cash and cash equivalents on the statement of cash flows. The standard also requires additional disclosures to describe the amount and detail of the restriction by balance sheet line item. The new standard was effective for the Company on April 1, 2018. The Company adopted this standard using the retrospective transition method by restating its condensed consolidated statements of cash flows to include restricted cash of $0.1 million in the beginning and ending cash, cash equivalents, and restricted cash balance. Net cash flows for the six months ended September 30, 2017, did not change as a result of including restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts presented on the statements of cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation* (Topic 718): *Scope of Modification Accounting*, which provides clarity and guidance around which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting. The new standard was effective for annual reporting periods beginning after April 1, 2018, and interim periods within those annual reporting periods. The adoption of this guidance had no impact on the Company’s financial statements.

In December 2017, the United States (“U.S.”) enacted the Tax Cuts and Jobs Act (the “2017 Act”), which changes existing U.S. tax law and includes various provisions that are expected to affect public companies. The 2017 Act (i) changes U.S. corporate tax rates, (ii) generally reduces a company’s ability to utilize accumulated net operating losses, and (iii) requires the calculation of a one-time transition tax on certain previously unrepatriated foreign earnings and profits (“E&P”). The 2017 Act will also impact estimates of a company’s deferred tax assets and liabilities. The Company is currently in the early stages of evaluating the financial statement impact of the 2017 Act. Based on initial assessments, the Company expects significant adjustments to its gross deferred tax assets and liabilities; however, it also expects to record a corresponding offset to its estimated full valuation allowance against its net deferred tax assets, which should result in minimal net effect to its provision for income taxes. In accordance with SEC issued guidance under Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (“SAB 118”), the Company anticipates a minimal impact to its financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases*, which requires an entity to recognize lease assets and lease liabilities on the balance sheet for leases with terms of more than 12 months and to disclose key information about leasing arrangements. This new guidance is effective for the Company on April 1, 2019, with early adoption permitted in any interim or annual period. The Company is currently evaluating the impact that this guidance will have on its financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share* (Topic 260); *Distinguishing Liabilities from Equity* (Topic 480); *Derivatives and Hedging* (Topic 815): *(Part I) Accounting for Certain Financial Instruments with Down Round Features*, (Part II) *Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature) and will also recognize the effect of the trigger within equity. This standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The adoption of this guidance will have no impact on the Company’s financial statements as the Company’s only derivative liabilities were all exercised or expired as of March 31, 2017.

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 is effective for the Company on April 1, 2019. The requirements of ASU 2018-02 are not expected to have a significant impact on the Company's financial statements.

Note 3. Stockholders' Equity

Stock-based compensation expense and valuation information

Stock-based awards include (i) stock options and (ii) restricted stock units under the 2012 Equity Incentive Plan ("2012 Plan"), (iii) performance-based restricted stock units under an Incentive Award Performance-Based Restricted Stock Unit Agreement, and (iv) 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 September 30, 2018	Three Months Ended September 30, 2017	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Research and development	$ 229	$ 384	$ 431	$ 715
General and administrative	$ 1,045	$ 1,914	$ 2,122	$ 3,635
Total	$ 1,274	$ 2,298	$ 2,553	$ 4,350

The total unrecognized compensation cost related to unvested stock option grants as of September 30, 2018 was approximately $10,231,536 and the weighted average period over which these grants are expected to vest is 3.14 years.

The total unrecognized compensation cost related to unvested restricted stock units (not including performance-based restricted stock units) as of September 30, 2018 was approximately $4,585,160, which will be recognized over a weighted average period of 2.82 years.

The total unrecognized compensation cost related to unvested performance-based restricted stock units as of September 30, 2018 was approximately $166,075, which will be recognized over a weighted average period of 1.98 years.

The total unrecognized stock-based compensation cost related to unvested employee stock purchase plan shares as of September 30, 2018 was approximately $14,000, which will be recognized over a period of 5 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 September 30, 2018	Three Months Ended September 30, 2017	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Dividend yield	—	—	—	—
Volatility	73.19%	70.97%	72.98%	76.58%
Risk-free interest rate	2.74%	1.78%	2.75%	1.81%
Expected life of options	6.00 years	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	$ 0.73	$ 1.25	$ 0.84	$ 1.73

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Considering the expected life of these options, the Company determined that a blend of historical volatility and implied volatility of comparable companies whose share prices are publicly available is more reflective of market conditions and a better indicator of expected volatility than using purely Company-specific historical 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. Certain options granted to consultants are subject to variable accounting treatment and are required to be revalued until vested.

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 September 30, 2018	Three Months Ended September 30, 2017	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Dividend yield	—	—	—	—
Volatility	61.35 - 80.23%	43.03 - 74.70%	61.35 - 80.23%	43.03 - 74.70%
Risk-free interest rate	1.85 - 2.29%	0.79 - 1.10%	1.85 - 2.29%	0.79 - 1.10%
Expected term	6 months	6 months	6 months	6 months
Grant date fair value	$0.30 - $0.45	$0.52 - $1.04	$0.30 - $0.45	$0.52 - $1.04

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. For the first full year of ESPP offering periods, beginning September 1, 2016, the Company determined that a blend of historical volatility and implied volatility of comparable companies whose share prices are publicly available was more reflective of market conditions and a better indicator of expected volatility than using purely Company-specific historical volatility. As of September 1, 2017 and the beginning of the second year of ESPP offering periods, the Company is using the Company-specific historical volatility rate as the 6-month historical volatility is now a better 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

In December 2014, the Company entered into an equity offering sales agreement (the "2014 Sales Agreement") with an investment banking firm. In July 2016, the Company registered the sale of up to $26.6 million of common stock under the 2014 Sales Agreement pursuant to its shelf registration statement on Form S-3 (File No. 333-202382) filed with the SEC on February 27, 2015 (the "2015 Shelf") that expired on March 17, 2018. Prior to its expiration, the Company sold an aggregate of 7,304,286 shares of common stock in at-the-market offerings under the 2014 Sales Agreement, with net proceeds of approximately $19.9 million.

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, as supplemented by a prospectus supplement, dated March 16, 2018 (the "2018 Shelf"), that expires on February 22, 2021.

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"), 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 issued pursuant to the Company's 2018 Shelf.

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.

During the three and six months ended September 30, 2018, the Company issued 1,676,590 and 3,762,130 shares of common stock, respectively, for net proceeds of $2.1 million and $5.1 million, respectively, in at-the-market offerings under the 2018 Sales Agreement. During the three and six months ended September 30, 2017, the Company issued 398,728 and 1,538,217 shares of common stock, respectively, for net proceeds of $1.0 million and $4.0 million, respectively, under the 2014 Sales Agreement.

As of September 30, 2018, the Company has sold an aggregate of 3,762,130 shares of common stock in at-the-market offerings under the 2018 Sales Agreement, with net proceeds of approximately $5.1 million. Based on these sales, the Company cannot raise more than an aggregate of $94.8 million in future offerings under the 2018 Shelf, including the $44.8 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.

Restricted stock units

On August 15, 2018 in connection with the appointment of a new Chief Medical Officer ("CMO"), the Company allocated 160,714 Restricted Stock Units ("RSUs") outside of the 2012 Plan. The Company intends for these to be "inducement awards" 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.

A summary of the Company's restricted stock unit (not including performance-based restricted stock units) activity from March 31, 2018 through September 30, 2018 is as follows:

	Number of Shares		Weighted Average Price
Unvested at March 31, 2018	2,035,345	$	2.89
Granted	1,759,520	$	1.18
Vested	(412,368)	$	2.63
Cancelled / forfeited	(772,732)	$	2.38
Unvested at September 30, 2018	2,609,765	$	1.94

Performance-based restricted stock units

On April 24, 2017, in connection with the appointment of a new Chief Executive Officer ("CEO"), the Company allocated 208,822 Performance-Based Restricted Stock Units ("PBRSUs") outside of the 2012 Plan. The Company intends for these to be "inducement awards" 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 generally 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 PBRSUs allocated by the Company on April 24, 2017. The units are divided into five separate tranches each with independent vesting criteria. The first four tranches have 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 has 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. As of September 30, 2018, 100% of the Negative Adjusted EBITDA tranche had vested and the additional 20% overachievement is expected to vest in a future year. As of September 30, 2018, no other tranches are currently expected to vest in fiscal year 2019.

The grant date fair values of the PBRSU was $393,000 of which one-fifth is being recognized over each tranches' service period. The Company began recording stock-based compensation expense for these tranches after the August 23, 2017 grant date when the financial performance goals were established and approved.

A summary of the Company's performance-based restricted stock unit activity from March 31, 2018 through September 30, 2018 is as follows:

	Number of Shares	Maximum Number of Shares Eligible to be Issued		Weighted Average Price
Unvested at March 31, 2018	167,058	200,470	$	1.88
Granted	—	—	$	—
Vested	(41,764)	(41,764)	$	1.88
Cancelled / forfeited	—	—	$	—
Unvested at September 30, 2018	125,294	158,706	$	1.88

Stock options

On April 24, 2017, in connection with the appointment of a new CEO, the Company granted 2,088,212 stock options outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of NASDAQ Marketplace Rule 5635(c)(4). While granted 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 15, 2018 in connection with the appointment of a new CMO, the Company allocated 974,694 stock options outside of the 2012 Plan. The Company intends for these to be "inducement awards" 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. These stock options vest over a four-year period, with a quarter of the option shares vesting on the one-year anniversary of the vesting commencement date and the remaining options shares vesting in equal quarterly installments over the next 12 quarterly periods.

A summary of the Company's stock option activity from March 31, 2018 to September 30, 2018 is as follows:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2018	10,132,312	$ 4.01	$ 591,082
Options granted	7,947,694	$ 1.29	$ —
Options cancelled / forfeited	(3,246,759)	$ 5.12	$ —
Options exercised	—	$ —	$ —
Outstanding at September 30, 2018	14,833,247	$ 2.31	$ 769,236
Vested and Exercisable at September 30, 2018	4,904,840	$ 3.66	$ 665,745

The weighted average remaining contractual term of options exercisable and outstanding at September 30, 2018 was approximately 6.05 years.

Employee Stock Purchase Plan

The Company reserved 1,500,000 shares of common stock for issuance under the ESPP. 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 the lower of $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 September 30, 2018, there were 1,230,735 shares available for purchase under the ESPP.

Warrants

The following table summarizes warrant activity for the six months ended September 30, 2018:

	Warrants	Weighted Average Exercise Price
Balance at March 31, 2018	220,000	$ 7.19
Granted	—	$ —
Exercised	—	$ —
Cancelled	—	$ —
Balance at September 30, 2018	220,000	$ 7.19

The warrants outstanding at September 30, 2018 are exercisable at prices between $6.84 and $7.62 per share and have a weighted average remaining term of approximately 0.71 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at September 30, 2018:

Common stock warrants outstanding	220,000
Common stock options outstanding under the 2008 Plan	622,192
Common stock options outstanding and reserved under the 2012 Plan	11,148,149
Common stock reserved under the 2012 Plan	11,042,706
Common stock reserved under the 2016 Employee Stock Purchase Plan	1,230,735
Restricted stock units outstanding under the 2012 Plan	2,449,051
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 September 30, 2018	30,095,159

Note 4. Collaborative Research, Development, and License Agreements

In April 2015, the Company entered into a research collaboration agreement with a third party to develop custom tissue models for fixed fees. No revenue was recorded under this agreement during the three and six months ended September 30, 2018. Collaboration revenue of $150,000 was recorded for the three and six months ended September 30, 2017. The Company completed its obligations under this agreement in September 2017.

Also in April 2015, the Company entered into a multi-year research agreement with a third party to develop multiple custom tissue models for use in drug development. No revenue was recorded under this agreement during the three and six months ended September 30, 2018 and 2017.

In June 2016, the Company entered into 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 bioprinted tissues for skeletal disease research. The Company received an up-front payment in June 2016, which was initially recorded as deferred revenue. No revenue was recorded under this agreement during the three and six months ended September 30, 2018. Revenue of $18,000 and $35,000 was recorded under this agreement during the three and six months ended September 30, 2017, respectively. The Company does not anticipate recording any further revenue under this agreement.

In December 2016, the Company signed another 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 an architecturally correct kidney for potential therapeutic applications. The Company received up-front payments in January and March 2017, which were initially recorded as deferred revenue. Revenue of $10,000 and $19,000 was recorded under this agreement for the three and six months ended September 30, 2018, respectively. Revenue of $9,000 and $19,000 has been recorded under this agreement for the three and six months ended September 30, 2017, respectively.

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 initially recorded as deferred revenue. Revenue of approximately $14,000 and $29,000 has been recorded under this agreement for the three and six months ended September 30, 2018, respectively. Revenue of approximately $14,000 has been recorded under this agreement for the three and six months ended September 30, 2017, beginning subsequent to the installation of the printer in July 2017. 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 April 2018, which were initially recorded as deferred revenue. Revenue of $19,000 and $38,000 has been recorded under this agreement for the three and six months ended September 30, 2018, respectively. Revenue of $18,750 and $37,500 was recorded under this agreement for the three and six months ended September 30, 2017, respectively.

In September 2017, the Company entered into an agreement with a company, under which the Company received a one-time non-refundable payment of $50,000 for limited use of a Company patent in reference to four bioprinters developed and placed at research and academic facilities. The Company recorded no revenue under this agreement for the three and six months ended September 30, 2018. The Company recorded $50,000 for the three and six months ended September 30, 2017.

Note 5. Commitments and Contingencies

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 and 2016, consists of approximately 45,580 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are currently approximately $120,000 per month 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 . The remainder of the total rentable square footage under the lease expires on September 1, 2021, unless the Company exercises its option to terminate the lease on or after September 1, 2019 with 9 months prior written notice.

The Company also previously leased a second facility from February 1, 2015 through January 31, 2018, consisting of 5,803 rentable square feet of office and lab space located at 6310 Nancy Ridge Drive, San Diego, California 92121, with a monthly rent of approximately $12,000 commencing on April 1, 2015, which increased be 3% each 12-month anniversary of the 36 month lease.

The Company records rent expense on a straight-line basis over the life of the leases and records the excess of expense over the amounts paid as deferred rent. In addition, one of the leases provides for certain improvements made for the Company's benefit to be funded by the landlord. Such costs, totaling approximately $518,000 to date, have been capitalized as fixed assets and included in deferred rent.

Rent expense was approximately $326,000 and $651,000 for the three and six months ended September 30, 2018, respectively, and $365,000 and $731,000 for the three and six months ended September 30, 2017, respectively.

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of September 30, 2018, are as follows (in thousands):

Fiscal year ended March 31, 2019	$	565,411
Fiscal year ended March 31, 2020		1,073,027
Fiscal year ended March 31, 2021		1,104,070
Fiscal year ended March 31, 2022		467,594
Fiscal year ended March 31, 2023		—
Thereafter		—
Total	$	3,210,102

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 highly 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.

Note 6. 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. 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 September 30, 2018.

Note 7. 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 services agreement with Cirius Therapeutics, Inc. ("Cirius"), an entity for which Robert Baltera, Jr., a director of the Company, serves as Chief Executive Officer. Under this agreement and its amendments, the Company has provided ExVive™ Liver Tissue Services for Cirius in the amount of $255,000 to date, of which $52,000 and $94,000 was recognized as revenue in the three and six months ended September 30, 2018, respectively. The Company has provided ExVive™ Liver Tissue Services for Cirius in the amount of $50,000 in the three and six months ended September 30, 2017. The agreement contains an additional $27,000 of ExVive™ Liver Tissue Services to be completed in the third quarter of Fiscal 2019.

During the fiscal year, the Company sold study materials and products to Viscient Biosciences ("Viscient"), an entity which Keith Murphy, a former director and Chief Executive Officer of the Company, serves as Chief Executive Officer. Viscient purchased study materials from Organovo in the amount of $2,000 to date, pursuant to the terms of a Quote which was entered into on September 11, 2018, of which $2,000 was recognized as revenue in the three and six months ended September 30, 2018. Viscient also purchased primary human cell-based products from our subsidiary, Samsara, in the amount of $3,000 to date, pursuant to the terms of multiple Quotes entered into throughout the fiscal year, of which $1,000 and $3,000 was recognized as revenue in the three and six months ended September 30, 2018, respectively. There were no sales to Viscient during the three and six months ended September 30, 2017. Subsequent to September 30, 2018, Viscient executed a Quote to purchase an RNAseq data set and primary human cell-based products from Samsara in the amount of $130,000 which will be recognized in the third quarter of Fiscal 2019.

Note 8. Subsequent Events

Between October 1, 2018 and the date of filing, the Company issued 741,298 shares of its common stock pursuant to its at-the-market ("ATM") facility for net proceeds of approximately $0.8 million.

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 the Company's 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, 2018. 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, 2018, filed with the Securities and Exchange Commission on May 31, 2018, 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, 2018, filed with the SEC on Form 10-K on May 31, 2018 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 a unique set of therapeutic and drug profiling capabilities based on our revolutionary ability to 3D bioprint liver tissues that emulate human biology and disease. We are developing our *in vivo* liver tissues to treat a range of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. Our program focused on an orphan disease known as Alpha-1-antitrypsin deficiency ("A1AT"), received the U.S. Food and Drug Administration's ("FDA") orphan drug designation in December 2017 and is targeted for an Initial New Drug Application ("IND") filing in calendar-year 2020. We are also capitalizing on our foundational ability to characterize highly specialized human cells and to build robust, functional human tissues by creating a range of novel *in vitro* disease modeling platforms, including a broad set of non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH") conditions.

We aim to generate revenue through product sales and fee-based service agreements and collaborations for our invitro tissues to provide a portion of the required cash flow to support our therapeutics development program. Our *in vitro* and *in vivo* tissues are both built upon the same proprietary 3D bioprinting technology and our highly specialized primary human cells, providing valuable synergies in advancing each of our businesses. We are striving to change the face of medicine by enabling more relevant and translational drug discovery and by launching novel approaches to treating disease.

In the near-term, we will focus on several value-driving inflection points including:

- Holding a pre-IND meeting with the FDA for our first liver therapeutic tissue indication and commencing IND-enabling studies;
- Pursuing orphan designation for a second rare disease indication, which we expect to receive in the first half of calendar 2019; Generate revenue to support its therapeutic research mission through client agreements aimed at developing its NASH profiling platform;
- Growing our Samsara division's cell-based product revenue, as well as continuing to generate revenue from grant and licensing agreements; and
- Continuing to present and publish major scientific findings of our tissue platform.

Over the long-term, we will focus on achieving the following key milestones:

- One or more successful IND submissions, leading to the initiation of Phase I clinical studies involving implantation and functional evaluation of our liver therapeutic tissue patch in target disease patients;
- Achieving key FDA designations associated with tissue-based approaches that address serious unmet medical needs in orphan disease indications, which can include Regenerative Medicine Advanced Therapy ("RMAT"), Orphan Disease, Fast Track and Breakthrough designations;
- Achieving operational breakeven profitability for our commercial business by securing significant revenue-generating fee-based service agreements and collaborations and creating business opportunities which may lead to valuable spin-out and/or partnering opportunities; and
- Continuing academic, partner and internal research programs to generate additional, high value tissue applications and therapeutics pipeline opportunities in other organ and disease areas.

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, valuation of long-lived assets, stock-based compensation and the timing of the achievement of collaboration milestones. 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, 2018, with the exception of changes made upon adoption of ASU No. 2014-09 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, 2018, filed with the SEC on May 31, 2018. For a description of accounting policy changes resulting from the adoption of ASU No. 2014-09 and the related supplemental ASUs, refer to Note 2 to our condensed financial statements contained in this quarterly report on Form 10-Q.

Results of Operations

Comparison of the three months ended September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017 (in thousands):

	Three months ended September 30,		Increase (decrease)	
	2018	**2017**	**$**	**%**
Revenues	$ 943	$ 1,355	$ (412)	(30%)
Cost of revenues	$ 125	$ 254	$ (129)	(51%)
Research and development	$ 3,187	$ 4,944	$ (1,757)	(36%)
Selling, general and administrative	$ 3,640	$ 5,736	$ (2,096)	(37%)
Other income	$ 172	$ 118	$ 54	46%

Revenues

For the three months ended September 30, 2018, total revenue was $0.9 million, a decrease of $0.4 million or 30% from the three months ended September 30, 2017. Product and service revenue of approximately $0.5 million for the three months ended September 30, 2018 decreased 48% from the prior-year period. This decrease was primarily driven by fewer contracts for liver tissue research services. Collaboration revenue and licensing revenue of less than $0.1 million for the three months ended September 30, 2018

decreased 84% from the prior-year period due to the absence of revenue from both a collaboration agreement that concluded, and a one-time license fee that was recorded during the second quarter of fiscal 2018. Grant revenue increased by approximately $0.3 million for the three months ended September 30, 2018 due to a higher level of activity under our National Institutes of Health ("NIH") grant during the second quarter of fiscal 2019.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services was $0.1 million for the three months ended September 30, 2018, compared to $0.3 million for the three months ended September 30, 2017. The decrease was primarily due to lower sales from liver tissue research services versus the prior year period.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2018 and 2017 (in thousands):

	Three months ended September 30, 2018	% of total	Three months ended September 30, 2017	% of total	Increase (decrease) $	Increase (decrease) %
Research and development	$ 2,818	89%	$ 4,396	89%	$ (1,578)	(36%)
Non-cash stock-based compensation	$ 229	7%	$ 384	8%	$ (155)	(40%)
Depreciation and amortization	$ 140	4%	$ 164	3%	$ (24)	(15%)
Total research and development expenses	**$ 3,187**	**100%**	**$ 4,944**	**100%**	**$ (1,757)**	**(36%)**

Research and development expenses were approximately $3.2 million, a decrease of $1.8 million, or 36%, from the prior year period. The decrease was primarily due to a $1.0 million decrease in personnel related costs, a $0.5 million decrease in lab services and supply costs, and a $0.3 million decrease in all other costs. The decrease in personnel related costs was driven by a reduction in staffing from the Company's restructuring and a reduction of stock-based compensation. The Company's average full-time research and development staff decreased from an average of seventy-eight full-time employees for the three months ended September 30, 2017 to an average of forty-five full-time employees for the three months ended September 30, 2018.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended September 30, 2018 and 2017 (in thousands):

	Three months ended September 30, 2018	% of total	Three months ended September 30, 2017	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 2,453	67%	$ 3,655	64%	$ (1,202)	(33%)
Non-cash stock-based compensation	$ 1,045	29%	$ 1,914	33%	$ (869)	(45%)
Depreciation and amortization	$ 142	4%	$ 167	3%	$ (25)	(15%)
Total selling, general and administrative expenses	**$ 3,640**	**100%**	**$ 5,736**	**100%**	**$ (2,096)**	**(37%)**

For the three months ended September 30, 2018, selling, general and administrative expenses were approximately $3.6 million, a decrease of $2.1 million, or 37%, over the prior year period of approximately $5.7 million. This decrease was largely due to a $1.8 million decrease in personnel related costs, and a $0.3 million decrease in consulting costs. The decrease in personnel related costs was driven by a reduction in staffing from our restructuring. Our average selling, general and administrative headcount was twenty-three full-time employees for the three months ended September 30, 2018 compared to thirty-six full-time employees in the prior year period.

Other Income (Expense)

Other income was approximately $0.2 million for the three months ended September 30, 2018 and consisted primarily of interest income. For the three months ended September 30, 2017, other income of approximately $0.1 million consisted primarily of interest income. Interest income increased from the same period of fiscal 2018 due to higher average yields on short-term investment balances.

Comparison of the six months ended September 30, 2018 and 2017

The following table summarizes our results of operations for the six months ended September 30, 2018 and 2017 (in thousands):

	Six months ended September 31,		Increase (decrease)	
	2018	2017	$	%
Revenues	$ 1,632	$ 2,345	$ (713)	(30%)
Cost of revenues	$ 245	$ 555	$ (310)	(56%)
Research and development	$ 6,566	$ 9,977	$ (3,411)	(34%)
Selling, general and administrative	$ 8,407	$ 11,592	$ (3,185)	(27%)
Other income	$ 336	$ 216	$ 120	56%

Revenues

For the six months ended September 30, 2018, total revenue was $1.6 million, a decrease of $0.7 million or 30% from the six months ended September 30, 2017. Product and service revenue of approximately $1.0 million for the six months ended September 30, 2018 decreased 45% from the prior-year period. This decrease was primarily driven by fewer contracts for liver tissue research services, which was partially offset by higher sales of primary human liver cells. Collaboration revenue and licensing revenue of $0.1 million for the six months ended September 30, 2018 decreased 72% from the prior-year period due to the absence of revenue from both a collaboration agreement that concluded, and a one-time license fee that was recorded during the second quarter of fiscal 2018. Grant revenue increased by approximately $0.4 million for the six months ended September 30, 2018 due to a higher level of activity under our National Institutes of Health (“NIH”) grant during the second quarter of fiscal 2019.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services was $0.2 million for the six months ended September 30, 2018, compared to $0.6 million for the six months ended September 30, 2017. The decrease was primarily due to lower sales from liver tissue research services versus the prior year period.

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended September 30, 2018 and 2017 (in thousands):

	Six months ended September 30, 2018	% of total	Six months ended September 30, 2017	% of total	Increase (decrease) $	Increase (decrease) %
Research and development	$ 5,853	89%	$ 8,927	90%	$ (3,074)	(34%)
Non-cash stock-based compensation	$ 431	7%	$ 715	7%	$ (284)	(40%)
Depreciation and amortization	$ 282	4%	$ 335	3%	$ (53)	(16%)
Total research and development expenses	**$ 6,566**	**100%**	**$ 9,977**	**100%**	**$ (3,411)**	**(34%)**

Research and development expenses were approximately $6.6 million, a decrease of $3.4 million, or 34%, from the prior year period. The decrease was primarily due to a $1.8 million decrease in personnel related costs, a $1.0 million decrease in lab services and supply costs, a $0.4 million decrease in facilities and allocated overhead costs, and a $0.2 million decrease in all other costs. The decrease in personnel related costs was driven by a reduction in staffing from our restructuring and a reduction of stock-based compensation. Our average full-time research and development staff decreased from an average of seventy-eight full-time employees for the six months ended September 30, 2017 to an average of forty-seven full-time employees for the six months ended September 30, 2018.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the six months ended September 30, 2018 and 2017 (in thousands):

	Six months ended September 30, 2018	% of total	Six months ended September 30, 2017	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 5,997	72%	$ 7,645	66%	$ (1,648)	(22%)
Non-cash stock-based compensation	$ 2,122	25%	$ 3,635	31%	$ (1,513)	(42%)
Depreciation and amortization	$ 288	3%	$ 312	3%	$ (24)	(8%)
Total selling, general and administrative expenses	**$ 8,407**	**100%**	**$ 11,592**	**100%**	**$ (3,185)**	**(27%)**

For the six months ended September 30, 2018, selling, general and administrative expenses were approximately $8.4 million, a decrease of $3.2 million, or 27%, over the prior year period of approximately $11.6 million. This decrease was largely due to a $2.7 million decrease in personnel related costs, a $0.6 million decrease in consulting costs, and a $0.3 million decrease in other costs, which offset a $0.4 million increase in facilities and allocated overhead costs. The decrease in personnel related costs was driven by a reduction in staffing from our restructuring. Our average selling, general and administrative headcount was twenty-four full-time employees for the six months ended September 30, 2018 compared to thirty-six full-time employees in the prior year period.

Other Income (Expense)

Other income was approximately $0.3 million for the six months ended September 30, 2018 and consisted primarily of interest income. For the six months ended September 30, 2017, other income of approximately $0.2 million consisted primarily of interest income. Interest income increased from the same period of fiscal 2018 due to higher average yields on short-term 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 September 30, 2018, we had cash and cash equivalents of approximately $37.4 million and an accumulated deficit of $247.4 million. We also had negative cash flow from operations of $11.4 million during the six months ended September 30, 2018. At March 31, 2018, we had cash and cash equivalents of approximately $43.7 million and an accumulated deficit of $234.1 million.

At September 30, 2018, we had total current assets of approximately $40.1 million and current liabilities of approximately $3.3 million, resulting in working capital of $36.8 million. At March 31, 2018, we had total current assets of approximately $46.8 million and current liabilities of approximately $4.7 million, resulting in working capital of $42.1 million.

The following table sets forth a summary of the primary sources and uses of cash for the six months ended September 30, 2018 and 2017 (in thousands):

	Six months ended September 30, 2018	Six months ended September 30, 2017
Net cash (used in) provided by:		
Operating activities	$ (11.4)	$ (16.8)
Investing activities	$ -	$ (0.1)
Financing activities	$ 5.0	$ 4.9
Net increase (decrease) in cash and cash equivalents	$ (6.4)	$ (12.0)

Operating activities

Net cash used by operating activities for the six months ended September 30, 2018 was approximately $11.4 million as compared to $16.8 million used in operating activities for the six months ended September 30, 2017. This $5.4 million decrease in operating cash usage can be attributed primarily to a $4.4 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 $1.0 million reduction in the change in working capital.

Investing activities

Net cash used in investing activities was less than $0.1 million and $0.1 million for the six months ended September 30, 2018 and 2017, respectively. This slight decrease can be attributed to reduced capital spending, combined with the absence of an investment in patent related intangible assets during the six months ended September 30, 2018.

Financing activities

Net cash provided by financing activities was approximately $5.0 million during the six months ended September 30, 2018 compared to $4.9 million during the six months ended September 30, 2017. Financing in both periods was driven by the sale of common stock through at-the-market ("ATM") offerings.

Operations funding requirements

Through September 30, 2018, 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 at-the-market ("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.

We will need additional capital to further fund the development of our therapeutic tissues and the implementation of our business plan. We intend to cover our future operating expenses through cash on hand, revenue derived from research service agreements, product sales, grants, and collaborative research agreements and through the issuance of additional equity or debt securities. 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. As of March 31, 2018, we are authorized to offer and sell under the 2018 Shelf, in one or more offerings, common stock, preferred stock, warrants to purchase common stock, preferred stock, or any combination of the foregoing, either individually or as units compromised one or more of the other securities. 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 six months ended September 30, 2018, we sold 3,762,130 shares of common stock in at-the-market offerings, with net proceeds of approximately $5.1 million under the 2018 Shelf. Based on our use of the 2018 Shelf through September 30, 2018, we can offer an aggregate of $94.8 million in future offerings under the 2018 Shelf, including the $44.8 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.

As of September 30, 2018, we had 115,200,421 total issued and outstanding shares of common stock, and five-year warrants to purchase an additional 220,000 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 11,042,706 shares remain available for issuance as of September 30, 2018, 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, 1,500,000 shares of common stock have been reserved 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 145,295,580 shares of common stock out of the 200,000,000 shares of common stock authorized for issuance as of September 30, 2018.

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.

Effect of Inflation and Changes in Prices

Management does not believe that inflation and changes in price will have a material effect on our operations.

Contractual Obligations

In the normal course of business, we enter into contracts and commitments that obligate us to make payments in the future. The table below sets forth our significant contractual obligations and related scheduled payments as of September 30, 2018 (in thousands):

	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations (A)	$ 565,411	$ 2,177,097	$ 467,594	$ —
Total	$ 565,411	$ 2,177,097	$ 467,594	$ —

(A) Operating lease obligations are primarily comprised of remaining payments due under our facility leases.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital for the purpose of funding our operations. To achieve this objective, our investment policy allows us to maintain a portfolio of cash, cash equivalents, and short-term investments in a variety of securities, including money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are comprised of cash and cash equivalents. We currently do not hedge interest rate exposure. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We have limited foreign currency risk exposure as our business operates primarily in U.S. dollars. We do not have any significant foreign currency or other derivative financial instruments.

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

In evaluating the Company and an investment in our common stock, we urge you to carefully consider the risks and other information in this Quarterly Report on Form 10-Q as well as the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2018, filed with the Securities and Exchange Commission on May 31, 2018. There have been no material changes from the risk factors as previously disclosed in our Annual Report on Form 10-K. Any of the risks discussed in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our results of operations or financial condition.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the February 2012 Form 8-K)
3.2	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the February 2012 Form 8-K)
3.3	Certificate of Amendment 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)
10.1	Amended and Restated 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018)
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: November 8, 2018

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

Date: November 8, 2018

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: November 8, 2018

/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: November 8, 2018

/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 September 30, 2018, 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: November 8, 2018

/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.