ORGANOVO HOLDINGS, INC.
Form 10-Q
August 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2016

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 (State or other jurisdiction of incorporation or organization)	27-1488943 (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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of August 1, 2016, a total of 92,655,870 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

ORGANOVO HOLDINGS, INC.

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PART I. FINANCIAL INFORMATION

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Organovo Holdings, Inc.

Condensed Consolidated Balance Sheets

(in thousands except for share data)

	June 30, 2016 (Unaudited)	March 31, 2016 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 53,538	$ 62,091
Accounts receivable	103	259
Inventory, net	512	334
Prepaid expenses and other current assets	1,028	968
Total current assets	55,181	63,652
Fixed assets, net	3,456	3,711
Restricted cash	79	79
Other assets, net	131	134
Total assets	$ 58,847	$ 67,576
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 481	$ 787
Accrued expenses	1,715	2,450
Deferred rent	140	139
Deferred revenue	791	1,110
Warrant liabilities	9	4
Total current liabilities	3,136	4,490
Deferred rent, net of current portion	868	905
Total liabilities	$ 4,004	$ 5,395
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 92,389,730 and 92,391,989 shares issued and outstanding at June 30, 2016 and March 31, 2016, respectively	92	92
Additional paid-in capital	224,388	222,959
Accumulated deficit	(169,637)	(160,870)
Total stockholders' equity	54,843	62,181
Total Liabilities and Stockholders' Equity	$ 58,847	$ 67,576

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

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands except share and per share data)

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015
Revenues		
Products and services	$ 674	$ 209
Collaborations	213	14
Grants	4	83
Total Revenues	891	306
Cost of revenues	168	—
Research and development expenses	4,444	4,142
Selling, general, and administrative expenses	5,056	4,622
Total costs and expenses	9,668	8,764
Loss from Operations	(8,777)	(8,458)
Other Income (Expense)		
Change in fair value of warrant liabilities	(5)	(38)
Interest income	37	8
Total Other Income (Expense)	32	(30)
Income Tax Expense	(22)	(3)
Net Loss	$ (8,767)	$ (8,491)
Net loss per common share—basic and diluted	$ (0.09)	$ (0.10)
Weighted average shares used in computing net loss per common share—basic and diluted	92,391,964	82,993,966

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

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Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015
Cash Flows From Operating Activities		
Net loss	$(8,767)	$(8,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	251	135
Change in fair value of warrant liabilities	5	38
Stock-based compensation	1,429	1,780
Amortization of warrants issued for services	—	(95)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	156	(132)
Inventory	(178)	(3)
Prepaid expenses and other assets	(41)	256
Accounts payable	(306)	(357)
Accrued expenses	(735)	(611)
Deferred rent	(36)	(8)
Deferred revenue	(319)	1,193
Net cash used in operating activities	(8,541)	(6,295)
Cash Flows From Investing Activities		
Purchases of fixed assets	(12)	(1,135)
Net cash used in investing activities	(12)	(1,135)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	—	43,214
Proceeds from exercise of stock options	—	77
Principal payments on capital lease obligations	—	(3)
Net cash provided by financing activities	—	43,288
Net Increase (Decrease) in Cash and Cash Equivalents	(8,553)	35,858
Cash and Cash Equivalents at Beginning of Period	62,091	50,142
Cash and Cash Equivalents at End of Period	$53,538	$86,000
Supplemental Disclosure of Cash Flow Information:		
Interest paid	$—	$—
Income taxes paid	$22	$3

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

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Supplemental Disclosure of Noncash Investing and Financing Activities ($ in thousands):

During the three months ended June 30, 2015, the warrant liability was reduced by approximately $138 as a result of warrant exercises.

During the three months ended June 30, 2015, approximately $337 of leasehold improvements were funded by the Company's landlord as a lease incentive. The Company capitalized these costs as property, plant and equipment, with a corresponding increase in deferred rent that will be amortized over the remaining lease term.

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

Organovo Holdings, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Description of Business and Summary of Significant Accounting Policies

Nature of operations and basis of presentation

References in these notes to the unaudited condensed consolidated financial statements to "Organovo Holdings, Inc.," "Organovo Holdings," "we," "us," "our," "the Company" and "our Company" refer to Organovo Holdings, Inc. and its consolidated subsidiaries. Our consolidated financial statements include the accounts of the Company as well as its wholly-owned subsidiaries, with all material intercompany accounts and transactions eliminated in consolidation. In December 2014, we established a wholly-owned subsidiary, Samsara Sciences, Inc., to focus on the acquisition of qualified cells in support of our commercial and research endeavors. In September 2015, we established another wholly-owned subsidiary in the United Kingdom, Organovo U.K., Ltd., for the primary purpose of establishing a sales presence in Europe.

Since its inception, the Company has devoted its efforts primarily to developing and commercializing a platform technology and functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company has also focused efforts on raising capital and building infrastructure. In November 2014, the Company announced the commercial release of its first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. The Company's activities are subject to significant risks and uncertainties including failing to successfully develop products and services based on its technology and to achieve the market acceptance necessary to generate sufficient revenues and to achieve and sustain profitability.

The accompanying interim condensed consolidated financial statements have been prepared by the Company, without audit, in accordance with the instructions to Form 10-Q and, therefore, do not necessarily include all information and footnotes necessary for a fair statement of its financial position, results of operations, stockholders' equity and cash flows in accordance with generally accepted accounting principles ("GAAP"). The balance sheet at March 31, 2016 is derived from the Company's audited balance sheet at that date.

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 financial statements should be read in conjunction with the financial statements included in the Company's Annual Report on Form 10-K for the year ended March 31, 2016, filed with the Securities and Exchange Commission (the "SEC") on June 9, 2016. Operating results for interim periods are not necessarily indicative of operating results for the Company's fiscal year ending March 31, 2017.

Liquidity

As of June 30, 2016, the Company had an accumulated deficit of approximately $169.6 million. The Company also had negative cash flows from operations of approximately $8.5 million during the three months ended June 30, 2016.

Through June 30, 2016, 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 offerings, and through revenue derived from product and research service-based agreements, collaborative research agreements, and grants. Based on

its current operating plan and available cash resources, the Company believes it has sufficient resources to fund its business for at least the next twelve months.

The Company will need additional capital to further fund the development and commercialization of its human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company intends to cover its future operating expenses through cash on hand, through revenue derived from research service agreements, product sales, collaborative research agreements, grants, 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.

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 raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Use of estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Significant estimates used in preparing the condensed consolidated financial statements include those assumed in computing the valuation of warrants, revenue recognized under the proportional performance model, the valuation of stock-based compensation expense, and the valuation allowance on deferred tax assets.

Fair value measurement

The Company has issued warrants, of which some are classified as derivative liabilities as a result of the terms in the warrants that provide for down-round protection in the event of a dilutive issuance. The Company uses Level 3 inputs (unobservable inputs that are supported by little or no market activity, and that are significant to the fair value of the assets or liabilities) for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions (see Note 2). The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any change in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of derivative liabilities. Various factors are considered in the pricing models the Company uses to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk-free interest rate. Future changes in these factors may have an impact on the computed fair value of the warrant liability.

The estimated fair values of the liabilities measured on a recurring basis are as follows:

Fair Value Measurements at June 30 and March 31, 2016 (in thousands):				
	Balance at June 30, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Warrant liability	$ 9	—	—	$ 9

	Balance at March 31, 2016	Quoted Prices in Active	Significant Other Observable Inputs	Significant Other Unobservable Inputs

	Markets (Level 1)	(Level 2)	(Level 3)
Warrant liability	$ 4	—	—	$ 4

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the three months ended June 30, 2016:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Derivative Liability (in thousands)
Balance at March 31, 2016	$ 4
Issuances	—
Adjustments to estimated fair value	5
Warrant liability removal due to settlements	—
Warrant liability reclassified to equity	—
Balance at June 30, 2016	$ 9

Revenue recognition

The Company’s revenues are derived from research service agreements, product sales, collaborative research agreements, and grants from the National Institutes of Health (“NIH”), U.S. Treasury Department and private not-for-profit organizations.

The Company recognizes revenue when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) services have been rendered or product has been delivered; (iii) price to the customer is fixed and determinable; and (iv) collection of the underlying receivable is reasonably assured.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of June 30, 2016 and March 31, 2016, the Company had approximately $791,000 and $1,110,000, respectively, in deferred revenue related to its grants, collaborative research programs and research service agreements.

Revenue arrangements with multiple deliverables

The Company follows ASC 605-25 Revenue Recognition – Multiple-Element Arrangements for revenue arrangements that contain multiple deliverables. Judgment is required to properly identify the accounting units of the multiple deliverable transactions and to determine the manner in which revenue should be allocated among the accounting units. Moreover, judgment is used in interpreting the commercial terms and determining when all criteria of revenue recognition have been met for each deliverable in order for revenue recognition to occur in the appropriate accounting period. For multiple deliverable agreements, consideration is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence (“VSOE”) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable.

While changes in the allocation of the arrangement consideration between the units of accounting will not affect the amount of total revenue recognized for a particular sales arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could affect the Company’s results of operations.

The Company periodically receives license fees for non-exclusive research licensing associated with funded research projects. License fees under these arrangements are recognized over the term of the contract or development period as it has been determined that such licenses do not have stand-alone value.

Revenue from research service agreements

For research service agreements that contain only a single or primary deliverable, the Company defers any up-front fees collected from customers, and recognizes revenue for the delivered element only when it determines there are no uncertainties regarding customer acceptance. For agreements that contain multiple deliverables, the Company follows ASC 605-25 as described above.

Research and development revenue under collaborative agreements

The Company’s collaboration revenue consists of license and collaboration agreements that contain multiple elements, which may include non-refundable up-front fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. The Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

The Company recognizes revenue from research funding under collaboration agreements when earned on a “proportional performance” basis as research services are provided or substantive milestones are achieved. We

recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered substantive when the consideration payable to us for the milestone (i) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (ii) relates solely to our past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

The Company initially defers revenue for any amounts billed or payments received in advance of the services being performed, and recognizes revenue pursuant to the related pattern of performance, using the appropriate method of revenue recognition based on its analysis of the related contractual element(s).

In November 2014, the Company entered into a collaborative nonexclusive 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 surgical transplantation research. The Company has recorded $12,500 for each of the three months ended June 30, 2016 and 2015 in revenue related to this collaboration in recognition of the proportional performance achieved.

In April 2015, the Company entered into a research collaboration agreement with a third party to develop custom tissue models for fixed fees. Based on the proportional performance achieved under this agreement, no collaboration revenue was recorded for the three months ended June 30, 2016 or 2015. Approximately $352,000 in collaboration revenue has been recognized to date under this agreement as of June 30, 2016.

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. Approximately $200,000 and $0 were recorded as revenue in recognition of the proportional performance achieved under this agreement during the three months ended June 30, 2016 and 2015, respectively.

In June 2016, the Company announced it had entered into another collaborative nonexclusive 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 has initially been recorded as deferred revenue. No revenue has been recorded under this agreement as of June 30, 2016.

Product revenue

The Company recognizes product revenue at the time of shipment to the customer, provided all other revenue recognition criteria have been met. To date, the Company has not recognized significant revenue from commercial product sales.

As our commercial sales increase, we expect to establish a reserve for estimated product returns that will be recorded as a reduction to revenue. This reserve will be maintained to account for future return of products sold in the current period. The reserve will be reviewed quarterly and will be estimated based on an analysis of our historical experience related to product returns.

Grant revenues

During August 2013, the Company was awarded a research grant by a private, not-for-profit organization for up to $251,700, contingent on go/no-go decisions made by the grantor at the completion of each stage of research as outlined in the grant award. Revenues from the 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 when the Company incurs expenses that are related to the grant. Revenue recognized under this grant was approximately $4,000 for the three months ended June 30, 2016. Revenue recognized under this grant was approximately $9,000 for the three months ended June 30, 2015.

During September 2014, the NIH awarded the Company a research grant totaling approximately $222,000. The grant provides for fixed payments based on the achievement of certain milestones. As such, revenue is recognized upon completion of substantive milestones. Revenue recognized under this grant was approximately $74,000 for the three months ended June 30, 2015. The full amount of this grant has been recognized as revenue as of September 30, 2015.

Cost of revenues

We reported $0.2 million in cost of revenues for the three months ended June 30, 2016. This is our first period reporting this expense line item, which captures all of our costs related to manufacturing and delivering our product and service revenue. Cost of revenues for the three months ended June 30, 2015 was minimal and was included in research and development expense.

Comprehensive income (loss)

For the three months ended June 30, 2016 and 2015, respectively, the comprehensive loss was equal to the net loss.

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, the assumed release of restriction of restricted stock units, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the three months ended June 30, 2016 or 2015, 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 11.6 million for the three months ended June 30, 2016, and 10.2 million for the three months ended June 30, 2015.

Note 2. Derivative Liability

During 2011 and 2012, the Company issued five-year warrants to purchase its common stock. For certain of these warrants, the exercise price is protected against down-round financing throughout the term of the warrant. Pursuant to ASC 815-15 and ASC 815-40, the fair value of the warrants was recorded as a derivative liability on the issuance dates.

The Company revalues the warrants classified as derivative liabilities as of the end of each reporting period. The estimated fair value of the outstanding warrant liabilities was approximately $9,000 and $4,000 as of June 30, 2016 and March 31, 2016, respectively. The changes in fair value of the derivative liabilities were increases of approximately $5,000 and $38,000 for the three months ended June 30, 2016 and 2015, respectively, and are included in other income (expense) in the statements of operations.

During the three months ended June 30, 2016 and 2015, 0 and 38,234 warrants, respectively, that were classified as derivative liabilities were exercised. The warrants were revalued as of the applicable settlement dates, and the change in fair value was recognized to earnings.

The derivative liabilities were valued at the end of each reporting period using a Monte Carlo valuation model with the following assumptions:

	June 30, 2016	March 31, 2016
Closing price per share of common stock	$3.72	$2.17
Exercise price per share	$1.00	$1.00
Expected volatility	72.10%	73.35%
Risk-free interest rate	0.45 %	0.59 %
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.71	0.96

Note 3. Stockholders' Equity

Common stock

In May 2008, the Board of Directors of the Company approved the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan authorized the issuance of up to 1,521,584 common shares for awards of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock award units, and stock appreciation rights. The 2008 Plan terminates on July 1, 2018. No shares have been issued under the 2008 Plan since 2011, and the Company does not intend to issue any additional shares from the 2008 Plan in the future.

In January 2012, the Board of Directors of the Company approved the 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan authorized the issuance of up to 6,553,986 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares, and other stock or cash awards. The Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan in August 2013 to increase the number of shares of common stock that may be issued under the 2012 Plan by 5,000,000 shares. In addition, the Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan in August 2015 to further increase the number of shares of common stock that may be issued under the 2012 Plan by 6,000,000 shares, bringing the aggregate shares issuable under the 2012 Plan to 17,553,986. The 2012 Plan as amended and restated became effective on August 20, 2015 and terminates ten years after such date. As of June 30, 2016, 5,575,475 shares remain available for issuance under the 2012 plan.

The Company filed a shelf registration statement on Form S-3 (File No. 333-189995), or the 2013 Shelf, with the SEC on July 17, 2013 authorizing the offer and sale in one or more offerings of up to $100,000,000 in aggregate of common stock, preferred stock,

debt securities, or warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities. This 2013 Shelf was declared effective by the SEC on July 26, 2013. On July 20, 2016, the Company filed a post-effective amendment to the 2013 Shelf to deregister the $26,777,784 of common stock remaining unsold as of such date under the 2013 Shelf. As a result of the post-effective amendment, no further shares of common stock may be issued pursuant to the 2013 Shelf.

The Company filed a second shelf registration statement on Form S-3 (File No. 333-202382), or the 2015 Shelf, with the SEC on February 27, 2015 authorizing the offer and sale in one or more offerings of up to $190,000,000 in aggregate of common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units compromised one or more of the other securities. This shelf was declared effective by the SEC on March 17, 2015.

On June 18, 2015, the Company entered into an Underwriting Agreement with Jefferies LLC and Piper Jaffray & Co., acting as representatives of the underwriters named in the 2015 Underwriting Agreement and as joint book-running managers, relating to the issuance and sale of 9,425,000 shares of the Company's common stock, par value $0.001 per share (the "2015 Offering"). The price to the public in the 2015 Offering was $4.25 per share, and the Underwriters agreed to purchase the shares from the Company pursuant to the 2015 Underwriting Agreement at a price of $3.995 per share. Under the terms of the 2015 Underwriting Agreement, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 1,413,750 shares. The Company issued 10,838,750 shares of common stock pursuant to the 2015 Underwriting Agreement, including shares issuable upon the exercise of the over-allotment option, with net proceeds of approximately $43.1 million, after deducting underwriting discounts and commissions and expenses payable by the Company. The shares were issued pursuant to the 2015 Shelf.

In December 2014, the Company entered into an equity offering sales agreement, or the 2014 Sales Agreement, with Cantor Fitzgerald. Under the terms of the 2014 Sales Agreement, the Company may offer and sell shares of its common stock, from time to time, through the investment bank in at-the-market offerings and pursuant to the 2013 Shelf. During the three months ended June 30, 2016 and 2015, the Company issued no shares of common stock in at-the-market offerings under the 2014 Sales Agreement. As of June 30, 2016, the Company sold 1,000,000 shares of common stock in at-the-market offerings under the 2014 Sales Agreement, with net proceeds of approximately $6.2 million. On July 20, 2016, the Company filed a prospectus supplement to move the remaining $26,560,000 of the shares of common stock that previously could have been sold pursuant to the 2014 Sales Agreement under the 2013 Shelf to the 2015 Shelf, which does not expire until March 17, 2018.

During the three months ended June 30, 2016 and 2015, the Company issued 0 and 30,186 shares of common stock upon the exercise of 0 and 38,234 warrants, respectively.

Finally, during the three months ended June 30, 2016 and 2015, the Company issued 0 and 25,503 shares of common stock upon the exercise of 0 and 25,503 stock options, respectively.

Restricted stock awards

During the three months ended June 30, 2016 and 2015, there were 2,259 and 2,259 shares of restricted stock, respectively, cancelled related to shares of common stock returned to the Company, at the option of the holders, to cover the tax liability related to the vesting of 6,250 and 6,250 restricted stock awards, respectively. Upon the return of the common stock, an equal number of stock options with immediate vesting were granted to the individuals at the vesting date market value strike price. A summary of the Company's restricted stock award activity from March 31, 2016 through June 30, 2016 is as follows:

	Number of Shares
Unvested at March 31, 2016	6,250
Granted	—
Vested	(6,250)
Canceled / forfeited	—
Unvested at June 30, 2016	—

The fair value of each restricted stock award is recognized as stock-based compensation expense over the vesting term of the award. The Company recorded restricted stock-based compensation expense in general and administrative expenses for employees and non-employees of approximately $3,000 and $103,000 for the three months ended June 30, 2016 and 2015, respectively.

As of June 30, 2016, there was no unrecognized stock-based compensation expense for restricted stock awards.

Restricted stock units

During the three months ended June 30, 2016 the Company issued restricted stock units for an aggregate of 519,850 shares of common stock to its employees. These shares of common will be issued upon vesting of the restricted stock units. Vesting will occur quarterly over a four year period. A summary of the Company's restricted stock unit activity from March 31, 2016 through June 30, 2016 is as follows:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2016	—	$ —
Granted	519,850	$ 3.21
Vested	—	$ —
Canceled / forfeited	—	$ —
Unvested at June 30, 2016	519,850	$ 3.21

The fair value of each restricted common 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 recorded restricted stock-based compensation expense in operating expenses for employees of approximately $21,000 for the three months ended June 30, 2016. Stock-based compensation expense included in research and development was $18,000 for the three months ended June 30, 2016. Stock-based compensation expense included in general and administrative expense was $3,000 for the three months ended June 30, 2016.

As of June 30, 2016, total unrecognized stock-based compensation expense related to restricted stock units was approximately $1,647,000, which will be recognized over a weighted average period of 3.15 years.

Stock options

Under the 2012 Plan, 416,640 and 1,762,641 stock options were issued during the three months ended June 30, 2016 and 2015, respectively, at various exercise prices based on the closing market price of the Company's common stock on the NYSE MKT on the date of the grant. The stock options generally vest (i) on the one year anniversary of the grant date, (ii) quarterly over a three year period, (iii) quarterly over a four year period, or (iv) over a four-year period, with 25% vesting on either the one year anniversary of employment or the one year anniversary of the vesting commencement date, and the remainder vesting ratably over the remaining term.

A summary of the Company's stock option activity for the three months ended June 30, 2016 is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value

Outstanding at March 31, 2016	9,614,627	$ 4.79	$1,927,137
Options granted	416,640	$ 3.21	
Options canceled / forfeited	(22,970)	$ 3.64	
Options exercised	—	$ —	$—
Outstanding at June 30, 2016	10,008,297	$ 4.72	$7,092,419
Vested and Exercisable at June 30, 2016	5,862,904	$ 4.55	$5,416,930

The weighted-average remaining contractual term of options exercisable and outstanding at June 30, 2016 was approximately 6.18 years.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. Stock-based compensation expense is recognized over the vesting period using the straight-line method. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015
Dividend yield	—	—
Volatility	71.30 %	74.25 %
Risk-free interest rate	1.20 %	1.65 %
Expected life of options	6.00 years	6.00 years
Weighted average grant date fair value	$ 2.03	$ 3.22

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Due to the Company's limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the 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 total stock option-based compensation recorded as operating expense was approximately $1,405,000 and $1,677,000 for the three months ended June 30, 2016 and 2015, respectively. Expense included in research and development was $390,000 and $349,000 for the three months ended June 30, 2016 and 2015, respectively. Expense included in general and administrative was $1,015,000 and $1,328,000 for the three months ended June 30, 2016 and 2015, respectively.

The total unrecognized compensation cost related to unvested stock option grants as of June 30, 2016 was approximately $11,840,000 and the weighted average period over which these grants are expected to vest is 2.42 years.

Warrants

During the three months ended June 30, 2016 there were no warrant exercises. During the three months ended June 30, 2015, 38,234 warrants were exercised through a cashless exercise provision for issuance of 30,186 shares of common stock. In addition, during the three months ended June 30, 2015, a warrant that was previously expected to be issued to a service provider and had been expensed in prior periods at its approximate value of $130,000, was cancelled, and the amount was reversed against operating expense during the quarter.

Of the warrants exercised during the three months ended June 30, 2016 and 2015, 0 and 38,234, respectively, were derivative liabilities and were valued at the settlement date. For the three months ended June 30, 2016 and 2015, respectively, approximately $0 and $138,000, respectively, of the warrant liability was extinguished due to the exercise of these warrants. (See Note 2).

During November 2014 the Company entered into an agreement with a consultant for services. In connection with the agreement, the Company issued 145,000 warrants to purchase common stock, at a price of $6.84, with a life of five

years, to be earned over a seventeen month service period ending on March 31, 2016. The final number of vested warrant shares was 95,000, based on management's judgment of the satisfaction of specific performance metrics. The fair value of the warrants was estimated to be approximately $74,000, which was revalued and amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they did not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 73.4% and a risk-free interest rate factor of 1.21%, was used to determine the value as of March 31, 2016. The Company recognized expense of approximately $34,000 during the three months ended June 30, 2015, related to these services. As of March 31, 2016, these warrants were fully expensed.

The following table summarizes warrant activity for the three months ended June 30, 2016:

	Warrants	Weighted-Average Exercise Price
Balance at March 31, 2016	1,046,813	$ 2.29
Granted	—	$ —
Exercised	—	$ —
Cancelled	—	$ —
Balance at June 30, 2016	1,046,813	$ 2.29

The warrants outstanding at June 30, 2016 are exercisable at prices between $0.85 and $7.62 per share, and have a weighted average remaining term of approximately 1.03 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at June 30, 2016:

Common stock warrants outstanding	1,046,813
Common stock options outstanding under the 2008 Plan	622,192
Common stock options outstanding and reserved under the 2012 Plan	14,961,580
Restricted stock units outstanding under the 2012 Plan	519,850
Total	17,150,435

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.

Note 4. Commitments and Contingencies

Operating leases

The Company leases laboratory and office space in San Diego, California under three non-cancelable leases as described below.

Since July 2012, the Company has leased its main facilities at 6275 Nancy Ridge Drive, San Diego, CA 92121. The lease, as amended in 2013 and 2015, consists of approximately 30,895 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are currently approximately $83,000 per month with 3% annual escalators. The lease term expires September 1, 2021 with the option to terminate on or after September 1, 2019. The Company also has a right of first refusal on adjacent additional premises of approximately 14,500 square feet.

On January 9, 2015, the Company entered into an agreement to lease a second facility consisting of 5,803 rentable square feet of office and lab space located at 6310 Nancy Ridge Drive, San Diego, CA 92121. The term of the lease is 36 months, beginning on February 1, 2015 and ending on January 31, 2018, with monthly rental payments of approximately $12,000 commencing on April 1, 2015. In addition, there are annual rent escalations of 3% on each 12-month anniversary of the lease commencement date.

On December 28, 2015, the Company entered into an agreement to lease a third facility consisting of 12,088 rentable square feet of office space located at 6166 Nancy Ridge Drive, San Diego, CA 92121. The term of the lease is 12 months, beginning on February 1, 2016 and ending on January 31, 2017, with monthly rental payments of $15,000 commencing on February 1, 2016.

Rent expense was approximately $303,000 and $277,000 for the three months ended June 30, 2016 and 2015, 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 June 30, 2016, are as follows (in thousands):

Fiscal year ended March 31, 2017	$976
Fiscal year ended March 31, 2018	1,148
Fiscal year ended March 31, 2019	1,044
Fiscal year ended March 31, 2020	1,072
Fiscal year ended March 31, 2021	1,104
Thereafter	468
Total	$5,812

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 5. Concentrations

Credit risk

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

cash and cash equivalents.

The Company is also potentially subject to concentrations of credit risk in its revenues and accounts receivable. Because it is in the early commercial stage, the Company's revenues to date have been derived from a relatively small number of customers and collaborators. However, the Company has not historically experienced any accounts receivable write-downs and management does not believe significant credit risk exists as of June 30, 2016.

Note 6. Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, which 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 standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. 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 that defers by one year the effective date for all entities, with application permitted as of the original effective date. The updated standard becomes effective for us on April 1, 2018, with early adoption permitted as of April 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that these updates will have on our consolidated financial statements and related disclosures. We have not yet selected a transition method nor have we determined the effect of these standards on our ongoing financial reporting.

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 us 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.

Note 7. Subsequent Events

On July 11, 2016, the Compensation Committee of the Board of Directors authorized the annual equity grants for the Company's executive officers for fiscal 2017. In connection therewith, the Company awarded certain executive officers an aggregate of 900,000 stock options and 450,500 restricted stock units, which vest on a quarterly basis over a four year period.

In addition, the Company has received approval to move its stock exchange listing from the NYSE MKT to the NASDAQ Global Market, with trading on the NYSE MKT to cease at the market close on August 5, 2016 and trading to commence on the NASDAQ Global Market at the market open on August 8, 2016. Its shares of common stock will continue to trade under the "ONVO" ticker symbol.

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, 2016. 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 "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 "Item 1A—Risk Factors" of this Quarterly Report on Form 10-Q 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

References in this section to "Organovo Holdings, Inc.," "Organovo Holdings," "we," "us," "our," "the Company" and "our Company" refer to Organovo Holdings, Inc. and its consolidated subsidiaries.

On February 8, 2012, Organovo, Inc., a privately held Delaware corporation, merged with and into Organovo Acquisition Corp., a wholly-owned subsidiary of the Company, with Organovo, Inc. surviving the merger as a wholly-owned subsidiary of the Company (the "Merger"). As a result of the Merger, the Company acquired the business of Organovo, Inc., and has continued the business operations of Organovo, Inc.

Organovo, Inc. was founded in Delaware in April 2007. Activities since Organovo, Inc.'s inception through June 30, 2016 have been devoted primarily to technology and product development, raising capital and building infrastructure.

In January 2016, we announced that our wholly-owned subsidiary, Samsara, commenced commercial operations. We formed Samsara to serve as a key source of certain of the primary human cells that we utilize in our products and services and in the development of therapeutic products. In addition to serving as one of our key suppliers, Samsara offers human cells for use by life science customers, both directly or through distribution partners.

In addition, in September 2015, we established a wholly-owned subsidiary, Organovo UK, Ltd., to establish a sales presence in Europe. As of June 30, 2016, there has been no significant activity related to this subsidiary.

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, 2016, filed with the SEC on Form 10-K on June 9, 2016 include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Overview

We are an early commercial stage company focused on developing and commercializing functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We are introducing a paradigm shift in the generation of three-dimensional ("3D") human tissues, by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition, architecture, and function. We leverage our unique 3D human tissue models to improve the current industry standard cell-based and animal model testing approaches to drug discovery and development by creating 3D tissues constructed solely of human cells. We believe our foundational approach to the 3D printing of living tissues, as disclosed in peer-reviewed scientific publications, and the continuous evolution of our core bioengineering technology platform combine to provide us with the opportunity to fill many critical gaps in commercially available preclinical human tissue modeling and tissue transplantation. In November 2014, we announced the commercial release of our first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. Initial revenues derived from the product have been and will continue to be predominantly through our research service model, which

involves testing compounds provided to us for analysis by our customers. Prior to initiating the service, our technical staff assists customers in determining the extent of testing to be conducted utilizing our exVive3D Human Liver Tissue. Testing may include the analysis of one or multiple compounds under various dosing and duration protocols to determine toxicity and metabolic effects of the test compounds on the tissue model. Projects may involve multiple deliverables which are clearly defined and based on pricing as stated in the related customer agreements. Consistent with our revenue recognition policies, revenue related to each deliverable will be recognized when delivered and the period of customer acceptance has been met. Revenue from projects without multiple deliverables will be recognized when the data package has been delivered to the customer and the term of customer acceptance has been met. In general, project duration is in the four- to six-month range.

In addition to our exVive3D Human Liver Tissue, we have entered into collaborative research agreements with pharmaceutical corporations and academic medical centers. We have also secured federal grants, including Small Business Innovation Research grants, to support the development of our technology.

We continuously engage in research and development to enhance our platform technology, to develop new product and service offerings and to pursue our therapeutic initiatives. Our research and development efforts include internal initiatives as well as collaborative development opportunities with third parties. Our second commercial product under development is our 3D Human Kidney Tissue. Similar to our 3D Human Liver Tissue, we are designing our 3D Human Kidney Tissue to be used for predictive preclinical testing of drug compounds.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with 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 and warrant liability, 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.

For further information, refer to the Company’s audited financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended March 31, 2016, filed with the SEC on June 9, 2016.

Results of Operations

Comparison of the three months ended June 30, 2016 and 2015

Revenues

For the three months ended June 30, 2016, total revenue of $0.9 million was $0.6 million, or approximately 191%, higher than total revenue for the three months ended June 30, 2015. Product and service revenue of approximately $0.7 million for the first quarter of fiscal 2017 increased 222% over product and service revenue of $0.2 million in the

first quarter of fiscal 2016. This increase was primarily driven by increasing customer adoption of the exVive3D Human Liver Tissue product and research services, which were launched commercially in November 2014. In addition, collaboration revenue increased approximately $0.2 million as compared to the first quarter of fiscal 2016. This increase was driven by a substantial milestone achievement under a collaboration agreement with a pharmaceutical corporation to develop multiple custom tissue models.

Operating Expenses

Overview

Operating expenses increased approximately $0.9 million, or 10%, from approximately $8.8 million for the three months ended June 30, 2015 to $9.7 million for the three months ended June 30, 2016. Of this increase, approximately $0.4 million is related to increased selling, general and administrative expense, $0.3 million is related to increased investment in research and development, and $0.2 million is related to cost of revenues. These increases can be attributed to the Company’s continued implementation of its business plan, including hiring additional staff to support research and development initiatives, incremental investments associated

with strategic growth and commercialization of its exVive3D Human Liver Tissue, expenses related to operating as a publicly traded corporation, and the expansion of its facilities.

Cost of Revenues

We reported $0.2 million in cost of revenues for the three months ended June 30, 2016. This is our first period reporting this expense line item, which captures all of our costs related to manufacturing and delivering our product and service revenue. Cost of revenues for the three months ended June 30, 2015 was minimal and was included in research and development expense.

Research and Development Expenses

More specifically, research and development expenses increased 7% from approximately $4.1 million for the three months ended June 30, 2015 to $4.4 million for the three months ended June 30, 2016, as the Company increased its research staff to support its obligations under existing collaborative research agreements and to expand its product development team and activities to support sales of its commercial research services. Full-time research and development staffing increased from an average of fifty-seven full-time employees for the three months ended June 30, 2015 to an average of eighty full-time employees for the three months ended June 30, 2016, resulting in an increase in staffing expense of approximately $0.6 million, partially offset by a decrease in outsourced services.

Selling, General and Administrative Expenses

For the three months ended June 30, 2016, selling, general and administrative expenses were approximately $5.0 million, an increase of $0.4 million, or 9%, over the prior year period of approximately $4.6 million. This increase was primarily related to an increase in staffing expense of $0.5 million due to an increase in administrative headcount from an average of twenty-three full-time employees to an average of thirty-four full-time employees to provide strategic infrastructure in developing collaborative relationships and the commercialization of research-derived product introductions. This was partially offset by a decrease of approximately $0.4 million in stock compensation expense, primarily as a result of mark-to-market adjustment to an employee’s grants upon transition to non-employee status during fiscal year 2017, the departure of an executive officer in mid-fiscal 2016, and a decrease in expense related to restricted stock awards due to prior awards becoming fully vested in fiscal 2016.

Other Income (Expense)

Other income was less than $0.1 million for the three months ended June 30, 2016 and consisted primarily of interest income, which increased from the same period of fiscal 2016 due to higher average yields and investment balances. Other expense was less than $0.1 million for the three months ended June 30, 2015 and consisted primarily of losses related to revaluation of warrant derivative liabilities.

Financial Condition, Liquidity and Capital Resources

The Company has primarily devoted its efforts to technology and product development, raising capital and building infrastructure. In November 2014, the Company announced the full commercial release of its first product, the exVive3D Human Liver Tissue for use in toxicology and other preclinical drug testing, and has built a sales and marketing and research and development infrastructure to support the commercialization of research services for the

exVive3D Human Liver Tissue.

The Company has incurred negative cash flows from operations. As of June 30, 2016, the Company had cash and cash equivalents of approximately $53.5 million and an accumulated deficit of $169.6 million. The Company also had negative cash flow from operations of $8.5 million during the three months ended June 30, 2016. At March 31, 2016, the Company had cash and cash equivalents of approximately $62.1 million and an accumulated deficit of $160.9 million.

At June 30, 2016, the Company had total current assets of approximately $55.2 million and current liabilities of approximately $3.1 million, resulting in working capital of $52.1 million. At March 31, 2016, we had total current assets of approximately $63.7 million and current liabilities of approximately $4.5 million, resulting in working capital of $59.2 million.

Net cash used by operating activities for the three months ended June 30, 2016 was approximately $8.5 million as compared to $6.3 million used in operating activities for the three months ended June 30, 2015. This $2.2 million increase in cash usage can be attributed primarily to a $0.9 million increase in operating expenses and changes in deferred revenue.

Net cash used in investing activities was less than $0.1 million and approximately $1.1 million for the three months ended June 30, 2016 and 2015, respectively. This decrease can be attributed to reduced capital spending during the three months ended June 30, 2016.

Net cash provided by financing activities decreased from $43.3 million provided during the three months ended June 30, 2015 to $0 provided during the three months ended June 30, 2016 due primarily to the timing of the closing of the Company's public offering of common stock in June 2015 that yielded net proceeds of approximately $43.1 million.

Through June 30, 2016, 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 offerings, and from revenue derived from grants, collaborative research 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.

The Company will need additional capital to further fund the development and commercialization of its human tissues that can be employed in drug discovery and development, biological research and as therapeutic implants for the treatment of damages or degenerating tissues and organs. The Company intends to cover its 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.

The Company has an effective shelf registration statement on Form S-3 (File No. 333-202382), or the 2015 Shelf, that expires on March 17, 2018. As of June 30, 2016, the Company is authorized to offer and sell under the 2015 Shelf, in one or more offerings, common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units compromised one or more of the other securities. On July 20, 2016, the Company filed a prospectus supplement to the 2015 Shelf to register the sale of up to $26,560,000 of shares of its common stock in "at-the-market" offerings pursuant to an equity offering sales agreement it had entered into with an investment banking firm in December 2014.

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 raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

As of June 30, 2016, the Company had 92,389,730 total issued and outstanding shares of common stock, and five-year warrants for the opportunity to purchase an additional 825,443 shares of common stock at exercise prices between $0.85 and $1.00 per share and 221,370 warrants with terms between two and five years and exercise prices between $2.28 and $7.62 per share.

In addition, the Company's 2008 Equity Incentive Plan provides for the issuance of up to 896,256 shares of its outstanding common stock and the 2012 Equity Incentive Plan, as amended, provides for the issuance of up to 17,553,986 shares of its common stock, to executive officers, directors, advisory board members, employees and consultants. 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 total 109,540,165 shares of common stock as of June 30, 2016.

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 the Company’s 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 June 30, 2016 (in thousands):

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligations (A)	$5,812	$ 1,266	$ 2,166	$ 2,192	$ 188
Total	$5,812	$ 1,266	$ 2,166	$ 2,192	$ 188

(A) Operating lease obligations are primarily comprised of remaining payments due under the Company's 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 these objectives, 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 Principal 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 Principal 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 effective.

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 Principal 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 4 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, 2016, filed with the Securities and Exchange Commission on June 9, 2016. 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
2.1	Agreement and Plan of Merger and Reorganization, dated as of February 8, 2012, by and among Organovo Holdings, Inc. a Delaware corporation, Organovo Acquisition Corp., a Delaware corporation and Organovo, Inc., a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
2.2	Certificate of Merger as filed with the Delaware Secretary of State effective February 8, 2012 (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
2.3	Articles of Merger as filed with the Nevada Secretary of State effective December 28, 2011 (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission (the "SEC") on February 3, 2012 (the "February 2012 Form 8-K")
2.4	Agreement and Plan of Merger, dated as of December 28, 2011, by and between Real Estate Restoration and Rental, Inc. and Organovo Holdings, Inc. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2012)
2.5	Certificate of Merger as filed with the Delaware Secretary of State effective January 30, 2012 (incorporated by reference from Exhibit 2.3 to the February 2012 Form 8-K)
2.6	Agreement and Plan of Merger, dated as of January 30, 2012, by and between Organovo Holdings, Inc. (Nevada) and Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 2.2 to the February 2012 Form 8-K)
2.7	Articles of Merger as filed with the Nevada Secretary of State effective January 30, 2012 (incorporated by reference from Exhibit 2.4 to the February 2012 Form 8-K)
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)
4.1	Form of Bridge Warrant of Organovo, Inc. (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
4.2	Form of Warrant of Organovo Holdings, Inc. ($1.00 exercise price) issued to Placement Agent (incorporated by reference from Exhibit 4.2(i) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)

4.3	Form of Warrant of Organovo Holdings, Inc. ($1.00 exercise price) issued to Placement Agent in exchange for Organovo, Inc. warrant issued to Selling Agent (incorporated by reference from Exhibit 4.2(iii) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)
10.1	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement (Retention Form) under 2012 Equity Incentive Plan*#
10.2	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement (Executive Form) under 2012 Equity Incentive Plan *#
10.3	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement (Employee Form) under 2012 Equity Incentive Plan *#
10.4	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement (Non-employee Director Form) under 2012 Equity Incentive Plan *#
31.1	Certification of Chief Executive Officer and Principal 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.
#Designates management contracts and compensation plans.
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SIGNATURES

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

ORGANOVO HOLDINGS, INC.

Date: August 4, 2016 By: /s/ Keith Murphy
Name: Keith Murphy
Title: Chairman of the Board,

Chief Executive Officer and President

(Principal Executive Officer and Principal Financial and Accounting Officer)

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