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 December 31, 2014

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 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 ☒ 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	☒
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 ☒

As of January 31, 2015, a total of 80,458,648 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

ORGANOVO HOLDINGS, INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets as of December 31, 2014 (Unaudited) and March 31, 2014 (Audited)	3
	Unaudited Condensed Consolidated Statements of Operations for the Three and Nine Months Ended December 31, 2014 and 2013	4
	Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2014 and 2013	5
	Notes to Unaudited Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	24
Item 4.	Controls and Procedures	25

PART II. OTHER INFORMATION

Item 1.	Legal Proceedings	26
Item 1A.	Risk Factors	26
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	38
Item 3.	Defaults Upon Senior Securities	38
Item 4.	Mine Safety Disclosure	38
Item 5.	Other Information	38
Item 6.	Exhibits	39

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	December 31, 2014 (Unaudited)	March 31, 2014 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 50,027	$ 48,167
Inventory	69	63
Prepaid expenses and other current assets	372	931
Total current assets	50,468	49,161
Fixed assets, net	1,440	857
Restricted cash	79	79
Other assets, net	83	89
Total assets	$ 52,070	$ 50,186
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 495	$ 326
Accrued expenses	2,028	822
Deferred rent	646	345
Deferred revenue	241	13
Capital lease obligation	8	10
Warrant liabilities	298	377
Total current liabilities	3,716	1,893
Deferred revenue, net of current portion	44	4
Capital lease obligation, net of current portion	-	5
Total liabilities	$ 3,760	$ 1,902
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 80,458,406 and 78,113,639 shares issued and outstanding at December 31, 2014 and March 31, 2014, respectively	80	78
Additional paid-in capital	162,727	140,419
Accumulated deficit	(114,497)	(92,213)
Total stockholders' equity	48,310	48,284
Total Liabilities and Stockholders' Equity	$ 52,070	$ 50,186

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 December 31, 2014	Three Months Ended December 31, 2013	Nine Months Ended December 31, 2014	Nine Months Ended December 31, 2013
Revenues				
Product and service	$ 139	—	$ 139	—
Collaborations	7	97	121	214
Grants	9	38	44	50
Total Revenues	155	135	304	264
Selling, general, and administrative expenses	3,878	2,379	13,350	8,740
Research and development expenses	3,238	2,382	9,281	5,487
Loss from Operations	(6,961)	(4,626)	(22,327)	(13,963)
Other Income (Expense)				
Change in fair value of warrant liabilities	(40)	(586)	24	(5,397)
Loss on disposals of fixed assets	—	—	(3)	(4)
Interest expense	—	—	—	(13)
Interest income	8	4	22	11
Total Other Income (Expense)	(32)	(582)	43	(5,403)
Net Loss	$ (6,993)	$ (5,208)	$ (22,284)	$ (19,366)
Net loss per common share—basic and diluted	$ (0.09)	$ (0.07)	$ (0.28)	$ (0.27)
Weighted average shares used in computing net loss per common share—basic and diluted	80,491,120	77,235,976	79,225,692	71,606,724

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)

	Nine Months Ended December 31, 2014	Nine Months Ended December 31, 2013
Cash Flows From Operating Activities		
Net loss	$ (22,284)	$ (19,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	3	4
Depreciation and amortization	334	288
Change in fair value of warrant liabilities	(24)	5,397
Expense associated with warrant modification	—	12
Stock-based compensation	5,215	2,840
Amortization of warrants issued for services	556	182
Increase (decrease) in cash resulting from changes in:		
Grants receivable	—	94
Inventory	(6)	6
Prepaid expenses and other assets	318	(25)
Accounts payable	169	(330)
Accrued expenses	1,206	779
Deferred rent	254	—
Deferred revenue	268	(42)
Net cash used in operating activities	(13,991)	(10,161)
Cash Flows From Investing Activities		
Deposits released from restriction	—	9
Purchases of fixed assets	(867)	(156)
Net cash used in investing activities	(867)	(147)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	16,512	44,310
Proceeds from exercise of stock options	213	195
Principal payments on capital lease obligations	(7)	(7)
Net cash provided by financing activities	16,718	44,498
Net Increase in Cash and Cash Equivalents	1,860	34,190
Cash and Cash Equivalents at Beginning of Period	48,167	15,628
Cash and Cash Equivalents at End of Period	$ 50,027	$ 49,818
Supplemental Disclosure of Cash Flow Information:		
Interest	$ —	$ —
Income Taxes	$ —	$ —

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

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

During the nine months ended December 31, 2014 and 2013, the warrant liability was reduced by approximately $55 and $10,522, respectively, as a result of warrant exercises and $0 and $767, respectively, for warrants reclassified as equity instruments.

During the nine months ended December 31, 2013, the Company issued 75,000 warrants to purchase shares of its common stock for consulting services. The warrants were valued at approximately $404.

During the nine months ended December 31, 2014, approximately $47 of leasehold improvements were funded by the Company's landlord as a lease incentive. The Company capitalized these costs as a fixed asset 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.

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. The Company is developing and commercializing functional three-dimensional (3D) 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.

Since its inception, the Company has devoted its efforts primarily to developing 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, 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. As of December 31, 2014, the Company has not yet realized significant revenues from its planned principal operations. The Company's activities are subject to significant risks and uncertainties including failing to secure additional funding to operationalize the Company's current technology and implement its business plan.

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, 2014 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 filed on Form 10-K for the year ended March 31, 2014 filed with the Securities and Exchange Commission (the "SEC") on June 10, 2014. Operating results for interim periods are not necessarily indicative of operating results for the Company's fiscal year ending March 31, 2015.

NYSE:MKT Listing

On July 9, 2013, the Company announced that its common stock had been approved for listing on the NYSE:MKT. Shares began trading on the New York Stock Exchange on July 11, 2013 under the symbol "ONVO". Prior to that time, the Company's shares were quoted on the OTC QX.

Liquidity

As of December 31, 2014, the Company had an accumulated deficit of approximately $114.5 million. The Company also had negative cash flows from operations of approximately $14.0 million during the nine months ended December 31, 2014.

Through December 31, 2014, the Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, the public offering of common stock, and through revenue derived from grants, product sales, collaborative research agreements and research service agreements. 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 grants, product sales, collaborative research agreements and research services 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.

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.

Financial instruments

For certain of the Company's financial instruments, including cash and cash equivalents, inventory, prepaid expenses and other current assets, accounts payable, accrued expenses, deferred revenue and capital lease obligations, the carrying amounts are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less to be cash equivalents.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency.

The Company reviews the terms of convertible debt and equity instruments it issues to determine whether there are derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where a host instrument contains more than one embedded derivative instrument, including a conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. Also, in connection with the sale of convertible debt and equity instruments, the Company may issue freestanding warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity.

Derivative instruments are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

The discount from the face value of the convertible debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to interest expense, using the effective interest method.

Restricted cash

As of December 31, 2014 and March 31, 2014, the Company had approximately $78,800 of restricted cash deposited with a financial institution. The entire amount is held in certificates of deposit to support a letter of credit agreement related to the Company's facility lease.

Inventory

Inventories are stated at the lower of the cost or market (first-in, first-out). Inventory consisted of approximately $69,000 and $63,000 in raw materials as of December 31, 2014 and March 31, 2014, respectively, net of reserves.

The Company provides inventory allowances based on excess or obsolete inventories determined based on anticipated use in the final product. The reserve for obsolete inventory at December 31, 2014 and March 31, 2014 was approximately $31,000.

Fixed assets and depreciation

Property and equipment are carried at cost. Expenditures that extend the life of the asset are capitalized and depreciated. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the remaining lease term. The estimated useful lives of the fixed assets range between two and seven years.

Impairment of long-lived assets

In accordance with authoritative guidance, the Company reviews its long-lived assets, including property and equipment and other assets, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. To determine recoverability of its long-lived assets, the Company evaluates whether future undiscounted net cash flows will be less than the carrying amount of the assets and adjusts the carrying amount of its assets to fair value. Management has determined that no impairment of long-lived assets has occurred through December 31, 2014.

Fair value measurement

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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 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 decrease or increase 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 a significant 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 December 31 and March 31, 2014 (in thousands):			
	Balance at December 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Warrant liability	$ 298	—	—	$ 298

	Balance at March 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Warrant liability	$ 377	—	—	$ 377

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the nine months ended December 31, 2014:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Derivative Liability (in thousands)
Balance at March 31, 2014	$ 377
Issuances	—
Adjustments to estimated fair value	(24)
Warrant liability removal due to settlements	(55)
Warrant liability reclassified to equity	—
Balance at December 31, 2014	$ 298

Research and development

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs, as well as costs associated with sponsored research and development. Research and development costs are expensed as incurred.

Income taxes

Deferred income taxes are recognized for the tax consequences in future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the year and the change during the year in deferred tax assets and liabilities.

Revenue recognition

The Company's revenues are derived from research service agreements, product sales, collaborative research agreements, and grants from the National Institute 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 December 31, 2014 and March 31, 2014, the Company had approximately $285,000 and $17,000, respectively, in deferred revenue related to its grants, collaborative research programs and research service agreements.

Research and Development Revenue Under Collaborative Agreements

The Company's collaboration revenue consists of license and collaboration agreements that contain multiple elements, including 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 hours are incurred. The Company performs services as specified in each respective agreement on a best-efforts basis, and is reimbursed based on labor hours incurred on each contract. 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, based on total labor hours incurred relative to total labor hours estimated under the contract.

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.

Revenue Arrangements with Multiple Deliverables

The Company periodically enters into 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 expects to periodically receive 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.

Grant Revenues

During 2012, the NIH awarded the Company a research grant totaling approximately $290,000. Revenue from the NIH grant is based upon internal and subcontractor costs incurred that are specifically covered by the grant, and an additional facilities and administrative rate that provides funding for overhead expenses. This revenue is recognized when expenses have been incurred by subcontractors and as the Company incurs internal expenses that are related to the grants. Activities under this grant concluded in April 2013. Revenue recognized under the grant was approximately $0 and $12,000 for the three and nine months, respectively, ended December 31, 2013.

During August of 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 $9,000 and $44,000 for the three and nine months, respectively, ended December 31, 2014.

During September of 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 will be recognized upon completion of those milestones. Grant activities did not commence until the third quarter of fiscal 2015, and the first milestone had not yet been met as of December 31, 2014. Therefore no revenue has been recognized under this grant as of December 31, 2014.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board's ("FASB") ASC Topic 718, *Compensation — Stock Compensation*, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is

re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). For the three and nine months ended December 31, 2014 and 2013, 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 and nine months ended December 31, 2014 and 2013, 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 8.2 million for the three and nine months ended December 31, 2014, respectively, and 6.4 million for the three and nine months ended December 31, 2013, respectively.

Reclassifications

Certain reclassifications were made to the Condensed Consolidated Balance Sheet as of March 31, 2014 and the Unaudited Condensed Consolidated Statement of Operations for the three and nine months ended December 31, 2013 in order to conform to the presentation of the Condensed Consolidated Balance Sheet as of December 31, 2014 and the Condensed Consolidated Statement of Operations for the three and nine months ended December 31, 2014. The reclassifications did not have any effect on previously reported net loss or financial position.

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 $0.3 million and $0.4 million as of December 31, 2014 and March 31, 2014, respectively. The changes in fair value of the derivative liabilities were increases of approximately $40,000 and $0.6 million for the three months ended December 31, 2014 and 2013, respectively, and were approximately a $24,000 decrease and a $5.4 million increase for the nine months ended December 31, 2014 and 2013, respectively, and are included in other income (expense) in the statements of operations.

During the three months ended December 31, 2014 and 2013, 0 and 60,176 warrants, respectively, that were classified as derivative liabilities were exercised. During the nine months ended December 31, 2014 and 2013, 8,647 and 1,878,104 warrants, respectively, that were classified as derivative liabilities were exercised. The warrants were revalued as of the settlement dates, and the change in fair value was recognized to earnings. In addition, during the nine months ended December 31, 2013, the Company entered into amendment agreements with certain of the warrant holders, which removed the down-round pricing protection provisions, resulting in 269,657 of these warrants being reclassified from liability instruments to equity instruments. The Company also recognized a reduction in the warrant liability based on the fair value as of the settlement date for the warrants exercised and as of the modification date for the warrants that were amended, with a corresponding increase in additional paid-in capital.

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

	December 31, 2014	March 31, 2014	December 31, 2013
Closing price per share of common stock	$ 7.25	$ 7.64	$ 11.07
Exercise price per share	$ 1.00	$ 1.00	$ 1.00
Expected volatility	76.5%	76.5%	82.3%
Risk-free interest rate	0.67%	0.90%	0.78%
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	2.21	2.96	3.20

Note 3. Stockholders' Equity

Common stock

A shelf registration statement on Form S-3 (File No. 333-189995), or shelf, was filed 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, 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 shelf was declared effective by the SEC on July 26, 2013.

On August 2, 2013, the Company, entered into an Underwriting Agreement (the "Underwriting Agreement") with Lazard Capital Markets LLC, acting as representative of the underwriters named in the Underwriting Agreement (the "Underwriters") and joint book-runner with Oppenheimer & Co. Inc., relating to the issuance and sale of 10,350,000 shares of the Company's common stock, which includes the issuance and sale of 1,350,000 shares pursuant to an overallotment option exercised by the Underwriters on August 5, 2013 (the "Offering"). JMP Securities LLC and Maxim Group LLC each acted as co-managers for the Offering. The price to the public in the Offering was $4.50 per share, and the Underwriters purchased the shares from the Company pursuant to the Underwriting Agreement at a price of $4.23 per share. The net proceeds to the Company from the Offering were approximately $43.4 million, after deducting underwriting discounts and commissions and other offering expenses of $3.2 million payable by the Company, including the Underwriters' exercise of the overallotment option. The transactions contemplated by the Underwriting Agreement closed on August 7, 2013.

In November 2013, the Company entered into an equity distribution agreement with an investment banking firm. Under the terms of the distribution agreement, the Company may offer and sell up to 4,000,000 shares of its common stock, from time to time, through the investment bank in "at the market" offerings, as defined by the SEC, and pursuant to the Company's effective shelf registration statement previously filed with the SEC. During the year ended March 31, 2014, the Company issued 334,412 shares of common stock in at the market offerings under the distribution agreement with net proceeds of $3.5 million. During the three and nine months ended December 31, 2014, the Company issued 0 and 2,197,768 shares of common stock in at the market offerings under the distribution agreement with net proceeds of $0 and $16.1 million, respectively.

In December 2014, the Company entered into an equity offering sales agreement with another investment banking firm. Under the terms of the 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, as defined by the SEC, and pursuant to the Company's effective shelf registration statement previously filed with the SEC. As of December 31, 2014, the Company has not sold any shares of common stock in at the market offerings under the sales agreement. The Company intends to use the net proceeds raised through any "at-the-market" sales for general corporate purposes, including research and development, the commercialization of the Company's products, general administrative expenses, and working capital and capital expenditures.

The Company will limit future sales under the 2013 distribution agreement and the 2014 sales agreement to ensure that it does not exceed the maximum amount available for sale under its effective shelf registration statement previously filed with the SEC. Based on its use of the shelf registration statement through December 31, 2014, the Company cannot sell more than an aggregate of $33,210,335 in shares of common stock under the 2013 distribution agreement and the 2014 sales agreement.

In addition, during the three months ended December 31, 2014 and 2013, the Company issued 100,000 and 533,533 shares of common stock upon exercise of 100,000 and 600,306 warrants, respectively. During the nine months ended December 31, 2014 and 2013, the Company issued 210,600 and 2,404,519 shares of common stock upon exercise of 211,647 and 2,878,863 warrants, respectively.

Finally, during the three and nine months ended December 31, 2014, the Company issued 9,961 and 98,707 shares of common stock upon exercise of 10,612 and 99,358 stock options, respectively. During the three and nine months ended December 31, 2013, the Company issued 76,501 and 83,801 shares of common stock upon exercise of 76,501 and 83,801 stock options, respectively.

Restricted stock awards

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, for an aggregate of 11,553,986 shares issuable under the 2012 Plan. The 2012 Plan terminates ten years after its adoption.

During the nine months ended December 31, 2013, the Company issued an aggregate of 60,000 restricted stock units with immediate vesting to a consultant. No restricted stock units were awarded during the nine months ended December 31, 2014.

During the three months ended December 31, 2014 and 2013, there were 3,703 and 3,703 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 8,750 and 8,750 restricted stock units, respectively. During the nine months ended December 31, 2014 and 2013, there were 109,808 and 164,243 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 205,000 and 305,000 restricted stock units, 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.

On August 6, 2012, 200,000 restricted stock awards were issued to a member of senior management, the vesting of which was performance based with achievement to be measured at December 31, 2014 or earlier if the metric was achieved. As of December 31, 2014, the Company had determined that three of the four target metrics had been achieved with the fourth performance metric criteria not met resulting in 150,000 shares of restricted stock vested and the remaining 50,000 restricted stock awards surrendered back to the Company unvested. The Company recognized the related stock-based compensation expense over the requisite service period ending on December 31, 2014.

A summary of the Company's restricted stock award activity from March 31, 2014 through December 31, 2014 is as follows:

	Number of Shares
Unvested at March 31, 2014	573,495
Granted	—
Vested	(205,000)
Canceled / forfeited	(52,500)
Unvested at December 31, 2014	315,995

The fair value of each restricted common 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 operating expenses for employees and non-employees of approximately $48,000 and $148,000 for the three months ended December 31, 2014 and 2013, respectively, and approximately $315,000 and $681,000 for the nine months ended December 31, 2014 and 2013, respectively. Stock-based compensation expense included in research and development was $4,000 and $4,000 for the three months ended December 31, 2014 and 2013, respectively, and $12,000 and $12,000 for the nine months ended December 31, 2014 and 2013, respectively. Stock-based compensation expense included in general and administrative expense was $44,000 and $144,000 for the three months ended December 31, 2014 and 2013, respectively, and $303,000 and $669,000 for the nine months ended December 31, 2014 and 2013, respectively.

As of December 31, 2014, total unrecognized restricted stock-based compensation expense was approximately $328,000, which will be recognized over a weighted average period of 0.83 years.

Stock options

Under the 2012 Plan, 310,203 and 91,203 stock options were issued during the three months ended December 31, 2014 and 2013, respectively, and 867,058 and 665,743 stock options were issued during the nine months ended December 31, 2014 and 2013, respectively, at various exercise prices. The stock options generally vest on the one year anniversary of the grant date, quarterly over a three year period, or over a four-year period, with a quarter 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 36 month terms.

A summary of the Company's stock option activity for the nine months ended December 31, 2014 is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2014	5,935,888	$ 4.87	$ 20,482,823
Options granted	867,058	$ 7.23	
Options canceled	(35,443)	$ 7.25	
Options exercised	(99,358)	$ 2.18	$ 462,948
Outstanding at December 31, 2014	6,668,145	$ 5.21	$ 18,539,044
Vested and Exercisable at December 31, 2014	2,559,635	$ 3.01	$ 11,124,896

The weighted-average remaining contractual term of options exercisable and outstanding at December 31, 2014 was approximately 7.82 years and 8.36 years, respectively.

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 December 31, 2014	Three Months Ended December 31, 2013	Nine Months Ended December 31, 2014	Nine Months Ended December 31, 2013
Dividend yield	—	—	—	—
Volatility	77.0%	82.3%	77.1%	83.9%
Risk-free interest rate	1.67%	0.78%	1.64%	0.82%
Expected life of options	6.00 years	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	$ 4.49	$ 5.54	$ 4.86	$ 4.00

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 $1,533,000 and $605,000 for the three months ended December 31, 2014 and 2013, respectively, and $4,900,000 and $2,160,000 for the nine months ended December 31, 2014 and 2013, respectively. Expense included in research and development was $327,000 and $129,000 for the three months ended December 31, 2014 and 2013, respectively, and $856,000 and $262,000 for the nine months ended December 31, 2014 and 2013, respectively. Expense included in general and administrative was $1,206,000 and $476,000 for the three months ended December 31, 2014 and 2013, respectively and $4,044,000 and $1,898,000 for the nine months ended December 31, 2014 and 2013, respectively.

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2014 was approximately $15,100,000 and the weighted average period over which these grants are expected to vest is 2.84 years.

Warrants

During the three months ended December 31, 2014 and 2013, 0 and 450,176 warrants, respectively, were exercised through a cashless exercise provision for issuance of 0 and 383,403 shares of common stock, respectively. During the nine months ended December 31, 2014 and 2013, 8,647 and 2,485,233 warrants, respectively, were exercised through a cashless exercise provision for issuance of 7,600 and 2,010,889 shares of common stock, respectively. During the three and nine months ended December 31, 2014, 100,000 and 203,000 warrants, respectively, were exercised at prices ranging from $1.00 to $2.21 for total proceeds of $221,000 and $445,000, respectively and during the three and nine months ended December 31, 2013, 150,130 and 393,630 warrants, respectively, were exercised at prices ranging from $1.00 and $3.24 for total proceeds of $284,696 and $935,876.

Of the warrants exercised during the three months ended December 31, 2014 and 2013, 0 and 60,176, respectively, were derivative liabilities and were valued at the settlement date. Of the warrants exercised during the nine months ended December 31, 2014 and 2013, 8,647 and 1,878,104, respectively, were derivative liabilities and were valued at the settlement date. For the three months ended December 31, 2014 and 2013, and the nine months ended December 31, 2014 and 2013, respectively, approximately $0, $375,000, $55,000, and $10,522,000, of the warrant liability was removed due to the exercise of these warrants. (See Note 2).

During April 2013, the Company entered into amendment agreements for 269,657 warrants to purchase common stock which reduced the exercise price of the warrants from $1.00 to $0.85 and removed the down-round price protection provision of the warrant agreement related to the adjustment of exercise price upon issuance of additional shares of common stock. As a result of the removal of the down-round price protection provision, the warrants were reclassified from liability to equity instruments at their fair value of $767,000. The Company determined the incremental expense associated with the modification based on the fair value of the awards prior to and subsequent to the modification. The fair value of the awards subsequent to modification was calculated using the Black-Scholes model. The incremental expense associated with the modification of approximately $12,000 was recognized as interest expense for the nine months ended December 31, 2013.

During the year ended December 31, 2012, the Company entered into four agreements with consultants for services. In connection with the agreements, the Company issued a total of 650,000 warrants to purchase common stock, at prices ranging from $1.70 to $3.24, with lives ranging from two to five years, to be earned over service periods of up to six months. The fair value of the warrants was estimated to be approximately $890,000, which was recognized as a prepaid asset and was amortized over the term of the consulting agreements. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using volatility rates ranging from 79.8% to 103.8% and risk-free interest rate factors ranging from 0.24% to 0.63%, were used to determine the value. The value has been amortized over the term of the agreements. The Company recognized approximately $72,000 during the nine months ended December 31, 2013 related to these services.

During November 2013 the Company entered into an agreement with a consultant for services. In connection with the agreement, the Company issued 75,000 warrants to purchase common stock, at a price of $7.36, with a life of five years, to be earned over a twelve month service period. The fair value of the warrants was estimated to be approximately $404,000, which was recognized as a prepaid asset and has been amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 96.90% and a risk-free interest rate factor of 0.60%, was used to determine the value. The Company recognized approximately $39,000 and $241,000 during the three and nine months ended December 31, 2014, respectively, related to these services.

Additionally, during September 2014, the Company issued 50,000 warrants to a consultant in recognition of services previously provided. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Company recognized approximately $0 and $273,000 during the three and nine months ended December 31, 2014, respectively, related to these services.

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 will be determined, at the discretion of management, based on management’s judgment of the satisfaction of specific performance metrics prior to the earliest to occur of March 31, 2016 or the termination of the consulting arrangement with the Company. The initial fair value of the warrants was estimated to be approximately $309,000, which is being revalued and amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 76.50% and a risk-free interest rate factor of 1.65%, was used to determine the value. The Company recognized approximately $35,000 during the three and nine months ended December 31, 2014, respectively, related to these services.

The following table summarizes warrant activity for the nine months ended December 31, 2014:

	Warrants	Weighted-Average Exercise Price
Balance at March 31, 2014	1,194,756	$ 1.79
Granted	195,000	$ 7.04
Exercised	(211,647)	$ 2.14
Balance at December 31, 2014	1,178,109	$ 2.59

The warrants outstanding at December 31, 2014 are exercisable at prices between $0.85 and $7.62 per share, and have a weighted average remaining term of approximately 2.63 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at December 31, 2014:

Common stock warrants outstanding	1,178,109
Common stock options outstanding under the 2008 Plan	672,192
Common stock options outstanding and reserved under the 2012 Plan	9,403,590
Total	11,253,891

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 present plans to issue shares of preferred stock.

Note 4. Commitments and Contingencies

Operating leases

The Company leases office and laboratory space under a non-cancelable operating lease which was entered into in February 2012 and amended in December 2013, with the future minimum lease payments from the lease included below. The Company records rent expense on a straight-line basis over the life of the lease and records the excess of expense over the amounts paid as deferred rent. In addition, the lease provides for certain improvements made for the Company’s benefit to be funded by the landlord. Such costs, totaling approximately $47,000 to date, have been capitalized as fixed assets and included in deferred rent.

Rent expense was approximately $235,000 and $112,000 for the three months ended December 31, 2014 and 2013, respectively, and $705,000 and $322,000 for the nine months ended December 31, 2014 and 2013, respectively.

On February 27, 2012, the Company entered into a facilities lease at 6275 Nancy Ridge Drive (the “Original Lease”), San Diego, CA 92121, with occupancy as of July 15, 2012. The base rent under the lease was approximately $38,800 per month with 3% annual escalators. The lease term was 48 months with an option for the Company to extend the lease at the end of the lease term.

On December 5, 2013, the Company entered into a First Amendment (the "Amendment") to the Original Lease, together with the Amendment, (the "Amended Lease"). Pursuant to the Amendment, the Company expanded the size of its facility by approximately 15,268 square feet (the "Expansion Premises") from approximately 15,539 square feet (the "Original Premises") for a total of approximately 30,807 square feet. The Amended Lease provides for base rent (i) on the Original Premises to continue at approximately $38,800 per month, with annual escalators, until August 1, 2016, at which point the base rent shall be payable at the same rate per rentable square foot as the Expansion Premises and (ii) on the Expansion Premises of approximately $38,934 per month, with 3% annual escalators, not to commence until two months after the earlier of (A) the date that the landlord delivers possession of the Expansion Premises to the Company with the work in the Expansion Lab Premises (as defined in the Amendment) substantially complete and (B) the date the landlord could have delivered the Expansion Premises with the work in the Expansion Lab Premises (as defined in the Amendment) substantially complete but for certain delays of the Company. Additionally, the Company has a right of first refusal on adjacent additional premises of approximately 14,500 square feet. The term of the Amended Lease expires on the seven-year anniversary of the earlier of (A) the date that the landlord delivers possession of the Expansion Premises to the Company and (B) the date the landlord could have delivered the Expansion Premises but for certain delays of the Company (the "Expansion Premises Commencement Date"). The Expansion Premises Commencement Date was September 1, 2014. The Company also has the option to terminate the Amended Lease on the 5-year anniversary of the Expansion Premises Commencement Date. The Expansion Premises contains office, laboratory, and clean room areas.

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2014, are as follows (in thousands):

Fiscal year ended March 31, 2015	$	242
Fiscal year ended March 31, 2016		979
Fiscal year ended March 31, 2017		984
Fiscal year ended March 31, 2018		1,001
Fiscal year ended March 31, 2019		1,031
Thereafter		2,527
Total	$	6,764

Legal Matters

In addition to commitments and obligations in the ordinary course of business, the Company is subject 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.

Spencer Trask Matter. In June 2013, the Company filed a declaratory relief action against Spencer Trask Ventures ("STV") in the Supreme Court of New York (case #652305/2013) following claims by STV that it was entitled to additional compensation arising from a warrant tender offer the Company completed in December 2012. The Company is seeking a declaration that a Warrant Solicitation Agency Agreement (the "WSAA") between the parties is a valid and enforceable agreement; the Company believes that under the terms of this agreement and the Placement Agent Agreement (the "PAA") it entered into with STV in connection with the private placement financings the Company completed in February and March 2012, STV is not entitled to the additional compensation it is seeking.

Also in June, 2013, STV initiated an arbitration in which it is alleging (1) breach of contract, and (2) breach of confidentiality obligations under the terms of the PAA. STV is seeking compensation (including a cash fee and warrants to purchase common stock) as a result of the Company's warrant tender offer in December 2012 and its warrant redemption in 2013, and damages for breach of confidentiality provisions in relation to the contacting of warrant holders who participated in the warrant tender offer. The Company believes there was no breach of confidentiality, as the Company's tender offer was made to warrant holders of record relating to warrants already owned by them and whose identity was public information via a Registration Statement on Form S-1 the Company was required to file to register the resale of the shares underlying their warrants.

In January 2014, the Supreme Court of New York stayed the New York litigation, finding that the arbitrator should determine in the first instance which disputes between the Company and STV should proceed in the Arbitration and which disputes between the Company and STV should proceed in the New York Court. The parties are proceeding in the Arbitration and the Company has reserved its right to file a summary disposition motion with regard to the proper venue for its claims under the WSAA. The Arbitration has been scheduled for July, 2015. The Company believes that the assertions made against it by STV are without merit and the Company intends to continue to vigorously defend against the claims made by STV.

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 in San Diego. 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.

Note 6. Recent Accounting Pronouncements

In May 2014, the Financial Accountings Standards Board issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, 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 is effective for us on April 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 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 the standard on our ongoing financial reporting.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities*, which eliminated certain financial reporting requirements under Topic 915 for entities considered to be in the development stage. This standard becomes effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015, with earlier application permitted. The Company adopted this standard prospectively as of April 1, 2014. This adoption had no effect on current or previously reported amounts, but eliminated the need to present inception-to-date financial information that was previously required under Topic 915.

Note 7. Subsequent Events

None.

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

The following management's discussion and analysis 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, 2014. The management's discussion and analysis contains forward-looking statements, such as statements of 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 "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 December 31, 2014 have been devoted primarily to technology and product development, raising capital and building infrastructure. As of December 31, 2014, Organovo, Inc. has not realized significant revenues from its planned principal operations.

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, 2014, filed with the SEC on Form 10-K on June 10, 2014 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 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 believe we can introduce a paradigm shift in the approach to the generation of three-dimensional human tissues, by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition and architecture. We believe we will improve the current industry standard cell-based 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 full 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 will predominantly be 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 will be 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.

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, 2014, filed with the SEC on June 10, 2014 and the Company's Supplemental Prospectus filed with the SEC on December 30, 2014.

Results of Operations

Comparison of the three months ended December 31, 2014 and 2013

Revenues

For the three months ended December 31, 2014, total revenue of $155,000 was $20,000 or approximately 15% higher than total revenue for the three months ended December 31, 2013. Product and service revenue of $139,000 for the third quarter of fiscal 2015 versus $0 in the third quarter of fiscal 2014 represents initial revenue from the initial shipment of exVive3D™ Human Liver Tissue product and from exVive3D™ Human Liver Tissue research services. The Company announced the commercial launch of its exVive3D™ Human Liver Tissue in November 2014. The majority of revenues for the third quarter of fiscal 2015 were derived from research service agreements related to the exVive3D™ Human Liver Tissue, whereas revenues for the third quarter of fiscal 2014 were derived mainly from existing collaborations and from research funded by grants.

Operating Expenses

Overview

Operating expenses increased approximately $2.3 million, or 48%, from approximately $4.8 million for the three months ended December 31, 2013 to $7.1 million for the three months ended December 31, 2014. Of this increase, $1.5 million relates to increased selling, general and administrative expense while the other $0.8 million relates to increased investment in research and development. 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 project initiatives associated with the commercial launch of our exVive3D™ Human Liver Tissue in November 2014, expenses related to operating as a publicly traded corporation, expansion of its facility, and increased stock compensation expense relative to employees and certain consulting services.

Research and Development Expenses

Research and development expenses increased 36% from approximately $2.4 million for the three months ended December 31, 2013 to $3.2 million for the three months ended December 31, 2014, as the Company increased its research staff to support its obligations under existing collaborative research agreements and to expand its product development efforts in preparation for commercial research services associated with the commercial launch of the Company's first product in the third quarter of fiscal 2015. Full-time research and development staffing increased from twenty-six full-time employees as of December 31, 2013 to forty-nine full-time employees as of December 31, 2014, resulting in an increase in staffing expense of approximately $0.5 million, an increase in stock-based compensation of $0.2 million and an increase in facility costs of approximately $0.4 million. Partially offsetting these increases was a decrease in bioprinter development costs of approximately $0.3 million as compared to the same

quarter of the previous year. In fiscal 2014, the Company began an initiative to advance its bioprinting technology; however, the most significant of these expenditures had already been incurred prior to the third quarter of fiscal 2015.

General and Administrative Expenses

For the three months ended December 31, 2014, general and administrative expenses were approximately $3.9 million, an increase of $1.5 million, or 63%, over expenses in the same period of the previous year of approximately $2.4 million. This increase was related to an increase in staffing expense of $0.4 million due to an increase in administrative headcount from thirteen full-time employees to eighteen full-time employees to provide strategic infrastructure in developing collaborative relationships and preparation for commercialization of research-derived product introductions as well as an increase in stock-based compensation of $0.6 million due to additional grants. In addition, legal and other corporate expenses increased $0.5 million.

Other Income (Expense)

Other expense was less than $0.1 million for the three months ended December 31, 2014 and consisted primarily of a loss related to the revaluation of warrant derivative liabilities. This loss was caused by an increasing stock price during the quarter that increased the value of the derivative liability. For the three months ended December 31, 2013, other expense consisted primarily of a $0.6 million loss related to the revaluation of the warrant derivative liability due to rising stock prices during the period that caused an increase in the value of the derivative liability. In addition, the majority of the underlying warrants to which the derivative relates were exercised or converted to equity instruments during fiscal 2014, significantly lessening the impact of subsequent changes in our stock price.

Comparison of the nine months ended December 31, 2014 and 2013

Revenues

For the nine months ended December 31, 2014 and 2013, total revenues were approximately $0.3 million. Despite relatively flat revenue on a period-to-period comparative basis, there was a substantial change in the source of revenues as prior year revenue was primarily sourced from collaborations, whereas nearly half of the current year-to-date revenues reflect pre-launch shipments of exVive3DTM Human Liver Tissue product and from exVive3DTM Human Liver Tissue services. The Company announced the commercial launch of its exVive3DTM Human Liver Tissue in November 2014, post-launch revenues are expected to be primarily derived from service agreements and product sales, and the respective revenues therefrom are not expected to be recognized on the Company's statement of income for approximately four to six months after the work on each respective project is started.

Operating Expenses

Overview

Operating expenses increased approximately $8.4 million, or 59%, from approximately $14.2 million for the nine months ended December 31, 2013 to $22.6 million for the nine months ended December 31, 2014. Of this increase, $4.7 million is related to increased selling, general and administrative expense while the other $3.8 million relates to increased investment in research and development. These increases are 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 project initiatives associated with the commercial launch of our exVive3D™ Human Liver Tissue in November 2014, expenses related to operating as a publicly traded corporation, expansion of its facility, and increased stock compensation expense relative to employees and certain consulting services.

Research and Development Expenses

Research and development expenses increased by approximately $3.8 million, or 69%, from approximately $5.5 million for the nine months ended December 31, 2013 to approximately $9.3 million for the nine months ended December 31, 2014, as the Company increased its research staff to support its obligations under certain collaborative research agreements and to expand its product development efforts in preparation for research-derived revenues. Full-time research and development staffing increased from twenty-six full-time employees as of December 31, 2013 to forty-nine full-time employees as of December 31, 2014. In addition to increases in staffing expense of approximately $1.2 million and an increase in stock-based compensation of $0.6 million resulting from increased headcount and additional grants, the Company increased its spending on recruiting, lab equipment, supplies and contracted services in proportion to its increased research activities.

General and Administrative Expenses

For the nine months ended December 31, 2014, general and administrative expenses were approximately $13.3 million, an increase of $4.7 million, or 54%, over expenses in the same period of 2013 of approximately $8.7 million. Stock-based compensation increased $1.8 million due to additional grants and increasing stock prices from December 31, 2013 to December 31, 2014. Staffing expense increased $1.0 million due to an increase in administrative headcount from thirteen full-time employees to eighteen full-time employees to provide strategic infrastructure in developing collaborative relationships and preparation for commercialization of research-derived product introductions. In addition, the Company incurred additional expenses for investor outreach initiatives, consulting and legal activities in the nine months ended December 31, 2014 as compared to the nine months ended December 31, 2013.

Other Income (Expense)

Other income was less than $0.1 million for the nine months ended December 31, 2014 and consisted primarily of interest income and a gain related to the revaluation of warrant derivative liabilities. This gain was caused by a declining stock price during the period that decreased the value of the derivative liability. For the nine months ended December 31, 2013, other expense consisted primarily of a $5.4 million loss related to the revaluation of the warrant derivative liability due to rising stock prices during the period that caused an increase in the value of the derivative liability. In addition, the majority of the underlying warrants to which the derivative relates were exercised or converted to equity instruments during fiscal 2014, significantly lessening the impact of subsequent changes in our stock price.

Financial Condition, Liquidity and Capital Resources

Since its inception, the Company has primarily devoted its efforts to technology and product development, raising capital and building infrastructure. The Company has not realized significant revenue from its planned principal operations.

Since inception, the Company incurred negative cash flows from operations. As of December 31, 2014, the Company had cash and cash equivalents of approximately $50.0 million and an accumulated deficit of $114.5 million. The Company also had negative cash flow from operations of $14.0 million during the nine months ended December 31, 2014. At March 31, 2014, the Company had cash and cash equivalents of approximately $48.2 million and an accumulated deficit of $92.2 million.

At December 31, 2014, the Company had total current assets of approximately $50.5 million and current liabilities of approximately $3.7 million, resulting in working capital of $46.8 million. At March 31, 2014, we had total current assets of approximately $49.2 million and current liabilities of approximately $1.9 million, resulting in working capital of $47.3 million.

Net cash used by operating activities for the nine months ended December 31, 2014 was approximately $14.0 million as compared to $10.2 million used in operating activities for the nine months ended December 31, 2013. This $3.8 million increase in cash usage can be attributed to an $8.4 million increase in operating expenses, partially offset by an overall increase of $2.8 million of non-cash expenses included in operations, including stock-based compensation, depreciation and amortization, as well as changes in working capital.

Net cash used in investing activities was approximately $0.9 million and $0.1 million for the nine months ended December 31, 2014 and 2013, respectively. This increase can be attributed to increased capital spending as the company increased its facility space to expand its research capabilities.

Net cash provided by financing activities decreased from $44.5 million provided during the nine months ended December 31, 2013 to $16.7 million provided during the nine months ended December 31, 2014 due to lower net proceeds from the issuance of common stock during the nine months ended December 31, 2014.

We believe our cash and cash equivalents on hand as of December 31, 2014, together with amounts to be received from our collaborative research agreements and our commercial products and services, should be sufficient to fund our ongoing operations as currently planned for at least the next twelve months. Through December 31, 2014, 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.

In November 2013, the Company entered into an equity distribution agreement with an investment banking firm. Under the terms of the distribution agreement, the Company may offer and sell up to 4,000,000 shares of its common stock, from time to time, through the investment bank in “at the market” offerings, as defined by the SEC, and pursuant to the Company’s effective shelf registration statement previously filed with the SEC. During the three and nine months ended December 31, 2014, the Company issued 2,197,768 shares of common stock in at the market offerings under the distribution agreement with net proceeds of $16.1

million. The net proceeds from these offerings have been used for general corporate purposes, including research and development, the commercialization of our products, general administrative expenses, and working capital and capital expenditures.

In December 2014, the Company entered into an equity offering sales agreement with another investment banking firm. Under the terms of the sales agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $33,000,000, from time to time, through the investment bank in “at the market” offerings, as defined by the SEC, and pursuant to the Company’s effective shelf registration statement previously filed with the SEC. As of December 31, 2014, the Company has not sold any shares of common stock in at the market offerings under the sales agreement. The Company intends to use the net proceeds raised through any “at-the-market” sales for general corporate purposes, including research and development, the commercialization of the Company’s products, general administrative expenses, and working capital and capital expenditures.

The Company will limit future sales under the 2013 distribution agreement and the 2014 sales agreement to ensure that it does not exceed the maximum amount available for sale under its effective shelf registration statement previously filed with the SEC. Based on its use of the shelf registration statement through December 31, 2014, the Company cannot sell more than an aggregate of $33,210,335 in shares of common stock under the 2013 distribution agreement and the 2014 sales agreement.

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 services agreements, product sales, grants, 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.

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 December 31, 2014, the Company had 80,458,406 total issued and outstanding shares of Common Stock, and five year warrants for the opportunity to purchase an additional 869,239 shares of Common Stock at exercise prices between $0.85 and $1.00 per share and 308,870 warrants with terms between two and five years and exercise prices between $2.21 and $7.62 per share. If all warrants were exercised on a cash basis, the Company would realize approximately $3.1 million additional gross proceeds.

The 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 11,553,986 shares, or approximately 15% of our outstanding 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 reserved for the 2008 and 2012 incentive plans total 91,712,297 shares of common stock as of December 31, 2014.

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.

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 commercial paper and 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 foreign currency or other derivative financial instruments.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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 effective.

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 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 us and our common stock, we urge you to carefully consider the risks and other information in this Quarterly Report on Form 10-Q. We updated our "Risk Factors" section in connection with preparing and filing a prospectus supplement with the Securities and Exchange Commission on December 30, 2014 to our Registration Statement on Form S-3 (No. 333-189995). We are providing that same updated "Risk Factors" section in this Quarterly Report on Form 10-Q. This "Risk Factor" section includes two new risk factors identified with an "" below and provides updated information in certain areas, but we do not believe those updates have materially changed the type or magnitude of the risks we face in comparison to the disclosure provided in our most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2014. Any of the risks discussed in this Quarterly Report on Form 10-Q, 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.*

Risks Related to Our Business and Our Industry

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

We were incorporated in 2007, and opened our laboratories in San Diego, California in January 2009. Since our incorporation, we have focused primarily on the development of our platform technology and the development of our biological research, drug discovery and therapeutic products and services based on that technology. In April 2014, we announced that we had begun to sign contracts for research services using our 3D Human Liver Tissue product, and in November 2014, we announced the full commercial release of our first product, the exVive3D ™ Human Liver Tissue for use in toxicology and other preclinical drug testing. As a result, as of December 31, 2014, we had not generated significant revenues from our planned principal operation. Because of our limited operating history, there is limited historical financial or other information upon which to base an evaluation of our performance and future prospects. Our future prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations and competing in new and rapidly developing technology areas. We have generated operating losses since we began operations, including $20.6 million, $9.3 million and $2.3 million for the years ended March 31, 2014, December 31, 2012 and December 31, 2011, respectively, and $4.0 million and $1.3 million for the three months ended March 31, 2013 and March 31, 2012, respectively. Additionally, we have generated operating losses of $6.9 million and $4.6 million for the three months ended December 31, 2014 and December 31, 2013, respectively, and $22.3 million and $13.9 million for the nine months ended December 31, 2014 and December 31, 2013, respectively. As of March 31, 2014, we had incurred cumulative operating losses of $38.3 million and cumulative net losses totaling $92.2 million. We expect to incur substantial additional operating losses over the next several years as our research, development, and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, successfully developing drug discovery, biological research and therapeutic tools and products that are more effective than existing technologies; entering into collaborative relationships with strategic partners; obtaining any necessary regulatory approval for our drug discovery, biological research and therapeutic tools and products; entering into successful manufacturing, sales and marketing arrangements with third parties or developing an effective sales and marketing infrastructure to commercialize any future tools and products; and raising sufficient funds to finance our activities and business plan. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations will be materially adversely affected.

We are an early-stage company with an unproven business strategy, and may never achieve profitability.

We are in the early stages of using our proprietary platform technology to develop and commercialize functional human tissues that can be employed in drug discovery and development, biological research, and potentially as therapeutic implants for the treatment of damaged or degenerating tissues and organs. Our success will depend upon the commercial viability of our platform technology, as well as on our ability to determine which drug discovery, biological research and therapeutic tools and products can be successfully developed with our platform technology. Our success will also depend on our ability to obtain any necessary regulatory approvals for our tools and products, to enter into additional collaboration agreements on favorable terms and to select an appropriate commercialization strategy for the tools and products we or our collaborators choose to pursue. If we are not successful in implementing our development and commercialization strategies, which are new and unproven, and/or if we under-price or overrun

our cost estimates for our contracts, we may never achieve profitability, or if we achieve profitability, be able to maintain or increase our profitability.

We may not be able to correctly estimate our future revenues and operating expenses, which could lead to cash shortfalls, and we may need to secure additional financing.

We may not correctly predict the amount or timing of future revenues and our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- our expectations regarding revenues from sales of our tools and products and from collaborations with third parties;
- the time and resources required to develop our drug discovery, biological research and therapeutic tools and products;
- the time and cost of obtaining any necessary regulatory approvals;
- the cost to create effective sales and marketing capabilities;
- the expenses we incur to maintain and improve our platform technology;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

In addition, our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our tools and products and from collaborations with third parties. However, we may not correctly predict the amount or timing of future revenues. In addition, we may not be able to adjust our operations in a timely manner to compensate for any unexpected shortfall in our revenues. As a result, a significant shortfall in our planned revenues could have an immediate and material adverse effect on our business and financial condition. In such case, we may be required to issue additional equity or debt securities or enter into other commercial arrangements, including relationships with corporate and other partners, to secure the additional financial resources to support our development efforts and future operations. Depending upon market conditions, we may not be successful in raising sufficient additional capital on a timely basis, or at all. If we fail to obtain sufficient additional financing, or enter into relationships with others that provide additional financial resources, we will not be able to develop our technology and products on our planned timeline, or at all, and we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products. In such event, our business, prospects, financial condition and results of operations would be adversely affected.

Our platform technology and our drug discovery, biological research and therapeutic tools and products are new and unproven.

Our platform technology, as well as our drug discovery, biological research and therapeutic tools and products, involve new and unproven models and approaches. We have not proven that our platform technology will enable us or our collaborators to develop effective or competitive drug discovery and biological research tools and products. Nor have we proven that any of our existing or planned tools or products will enable our customers to conduct drug discovery and biological research more effectively than through the use of existing technologies. Our success depends on commercial acceptance of our drug discovery and biological research tools and products. Even if we or our collaborators are successful in our respective efforts, we or our collaborators may not be able to discover or develop commercially viable therapeutics or other products therefrom. To date, no one has developed or commercialized any therapeutic or other life science products based on our drug discovery and biological research tools and products. If our drug discovery and biological research products and tools do not assist in the discovery and development of such therapeutic or life science products, our current and potential collaborators may lose confidence in us and our drug discovery and biological research tools and products. Our inability to successfully develop effective and competitive drug discovery, biological research and therapeutic tools and products and achieve and maintain commercial acceptance for those tools and products would materially adversely affect our business, financial condition and results of operations.

Our technology, tools and products are subject to the risks associated with new and rapidly evolving technologies and industries.

Our proprietary tissue creation technology and our drug discovery, biological research and therapeutic tools and products are subject to the risks associated with new, rapidly evolving technologies and industries. We may experience unforeseen technical complications, unrecognized defects and limitations in the development and commercialization of our tools and products. These

complications could materially delay or limit the use of those tools and products, substantially increase the anticipated cost of manufacturing them or prevent us or our collaborators from implementing their drug discovery or biological research projects successfully or at all. In addition, the process of developing new technologies, tools and products is complex, and if we are unable to develop enhancements to, and new features for, our existing tools and products or acceptable new tools and products that keep pace with technological developments or industry standards, our tools and products may become obsolete, less marketable and less competitive.

Our ability to successfully commercialize any drug discovery, biological research or therapeutic tools or products we develop is subject to a variety of risks.

The commercialization of our drug discovery and biological research tools and products are subject to risks and uncertainties, including:

- failing to develop tools or products that are effective and competitive;
- failing to demonstrate the commercial and technical viability of any tools or products that we successfully develop or otherwise failing to achieve market acceptance of such tools or products;
- failing to be cost effective;
- failing to obtain any necessary regulatory approvals;
- being difficult or impossible to manufacture on a large scale;
- being unable to establish and maintain supply and manufacturing relationships with reliable third parties;
- failing to develop our tools and products before the successful marketing of similar tools and products by competitors;
- being unable to hire and retain qualified personnel; and
- infringing the proprietary rights of third parties or competing with superior products marketed by third parties.

If any of these or any other risks and uncertainties occur, our efforts to commercialize our drug discovery and biological research tools and products may be unsuccessful, which would harm our business and results of operations.

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

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

We cannot control our collaborators' allocation of resources or the amount of time that our collaborators devote to developing our programs or potential products, which may have a material adverse effect on our business.

Our existing research and collaboration agreements typically allow our collaborators to obtain the options to license or exclusive rights to negotiate licenses to our new technologies. Our collaborators may have significant discretion in electing whether to pursue product development, regulatory approval, manufacturing and marketing of the products they may develop with the help of our technology. We cannot control the amount and timing of resources our collaborators may devote to our programs or potential products. As a result, we cannot be certain that our collaborators will choose to develop and commercialize these products or that we will realize any future milestone payments, royalties and other payments provided for in the agreements with our collaborators. In addition, if a collaborator is involved in a business combination, such as a merger or acquisition, or if a collaborator changes its business focus, its performance pursuant to its agreement with us may suffer. As a result, we may not generate any revenues from royalty, milestone and similar provisions that may be included in our collaborative agreements.

In addition, our collaborative partners or other customers that utilize our research tools will be required to submit their research for regulatory review in order to proceed with human testing of drug candidates. This review by the FDA and other regulatory agencies may result in timeline setbacks or complete rejection of an application to begin human studies, such as an

Investigative New Drug (IND) application, or the ultimate failure to receive the regulatory approval required to commercialize the drug candidate or product. Should our collaborative partners or other customers face such setbacks, we would be at risk of not earning any future milestone or royalty payments.

Any termination or breach by or conflict with our collaborators or licensees could harm our business.

If we or any of our existing or future collaborators or licensees fail to renew or terminate any of our collaboration or license agreements, or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could lose significant sources of revenue, which could result in volatility in our future revenues. In addition, our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply or commercialization of certain products, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to our intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations or license agreements may prove to be unsuccessful.

Our collaborators could develop competing research, reducing the available pool of potential collaborators and increasing competition, which may adversely affect our business and revenues.

Our collaborators and potential collaborators could develop research tools similar to our own, reducing our pool of possible collaborative parties and increasing competition. Any of these developments could harm our product and technology development efforts, which could seriously harm our business. In addition, we may pursue opportunities in fields that could conflict with those of our collaborators. Developing products that compete with our collaborators' or potential collaborators' products could preclude us from entering into future collaborations with our collaborators or potential collaborators. Any of these developments could harm our product development efforts and could adversely affect our business and revenues.

We face intense competition which could result in reduced acceptance and demand for our research tools and products.

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

- research and technology development;
- product identification and development;
- regulatory processes and approvals;
- production and manufacturing;
- securing government contracts and grants to support their research and development efforts; and
- sales and marketing of products and technologies.

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

In order to effectively compete, we will need to make substantial investments in our research and technology development, product identification and development, testing and regulatory approval, manufacturing and sales and marketing activities. There is no assurance that we will be successful in commercializing and gaining significant market share for any products developed in part through use of our technology. Our technologies, products and services also may be rendered obsolete or noncompetitive as a result of products and services introduced by our competitors.

We may have product liability exposure from the sale of our research tools and therapeutic products or the services we provide.

We may have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. There can be no assurance that our existing insurance coverage will extend to other products in the future. Our product liability

insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

We may be dependent on third-party research organizations to conduct some of our future laboratory testing, animal and human studies.

We may be dependent on third-party research organizations to conduct some of our laboratory testing, animal and human studies with respect to therapeutic tissues and other life science products that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we so request. We may not be able to secure and maintain suitable research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our future product candidates.

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

Commercialization of our tools and products will require that we have access to a constant, steady and reliable supply of human cells. We will also require access to, or development of, facilities to manufacture a sufficient supply of our tools and products. If we are unable to manufacture our products in commercial quantities, our business and future results will suffer.

We may rely on third-party suppliers for some of our materials.

We may rely on third-party suppliers and vendors for some of the materials we require in our drug discovery and biological research products and tool businesses as well as for the manufacture of any therapeutic product candidates that we may develop in the future. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

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

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

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

allocations. The prolonged or increased shift away from the funding of life sciences research and development or delays surrounding the approval of government budget proposals may cause our customers to delay or forego purchases of our products or services, which could seriously damage our business.

An inability to manage our planned growth or expansion of our operations could adversely affect our business, financial condition or results of operations.

Our business has grown rapidly, and we expect this growth to continue as we expand our ability to develop and commercialize functional human tissues. The rapid expansion of our business and addition of new personnel may place a strain on our management and operational systems. To effectively manage our operations and growth, we must continue to expend funds to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. In addition, our management will need to continue to successfully:

- expand and our research and product development efforts;
- implement and expand our sales, marketing and customer support programs;
- expand, train and manage our employee base; and
- effectively address new issues related to our growth as they arise.

We may not manage our planned growth and expansion successfully, which could adversely affect our business, financial condition or results of operations.

Our business will be adversely impacted if we are unable to successfully attract and hire key additional employees or if we are unable to retain our executive officers and other key personnel.*

In connection with the commercial release of the exVive 3D ™ Human Liver Tissue for use in toxicology and other preclinical drug testing and to pursue our research and development plans, we need to significantly expand our employee headcount. As a result, our future success depends in part on our ability to timely attract and hire highly skilled technical, managerial and sales and marketing personnel. Our success will also depend to a significant degree upon the continued contributions of our key personnel, especially our executive officers. We do not currently have long-term employment agreements with our executive officers or our other key personnel, and there is no guarantee that our executive officers or key personnel will remain employed with us. Moreover, we have not obtained key man life insurance that would provide us with proceeds in the event of the death, disability or incapacity of any of our executive officers or other key personnel. Further, the process of attracting and retaining suitable replacements for any executive officers and other key personnel we lose in the future would result in transition costs and would divert the attention of other members of our senior management from our existing operations. Additionally, such a loss could be negatively perceived in the capital markets. As a result, the loss of any of our executive officers or other key personnel or our inability to timely attract and hire qualified personnel in the future (in particular skilled technical, managerial and sales and marketing personnel) will adversely impact our ability to meet our key commercial and technical goals and successfully implement our business plan.

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

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

Risks Related to Government Regulation

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

To the extent that our collaborators or customers use our products in the manufacturing or testing processes for their drug and medical device products, such end-products or services may be regulated by the FDA under Quality System Regulations (QSR) or

the Centers for Medicare & Medicaid Services (CMS) under Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) regulations. The customer is ultimately responsible for QSR, CLIA'88 and other compliance requirements for their products. However, we may agree to comply with certain requirements, and, if we fail to do so, we could lose sales and our collaborators or customers and be exposed to product liability claims. In addition, our platform technology is subject to the requirements of Good Laboratory Practice (GLP) to provide suitable data for INDs and other regulatory filings. No regulatory review of data from our platform technology has yet been conducted and there is no guarantee that our technology will be acceptable under GLP. As a result, the violation of government regulations or quality programs could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.

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

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

As we continue to adapt and develop parts of our product line in the future, including tissue-based products in the field of regenerative medicine, the manufacture and marketing of our products will become subject to government regulation in the United States and other countries. In the United States and most foreign countries, we will be required to complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. The steps required by the FDA before our proposed products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an IDE (Investigational Device Exemption), NDA (New Drug Application), or BLA (Biologic License Application) which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; Pre-Market Approval Application (PMA); and FDA approval of the PMA before any commercial sale or shipment of the product.

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

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

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or our manufacturer are subsequently discovered and we cannot provide assurance

that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

If restrictions on reimbursements and health care reform limit our collaborators' actual or potential financial returns on therapeutic products that they develop based on our platform technology, our collaborators may reduce or terminate their collaborations with us.

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

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

We are subject to various environmental, health and safety laws.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

Risks Related to Our Intellectual Property

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

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

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

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

- the patents of others will not have an adverse effect on our business; or
- as issued patents expire, we will not lose some competitive advantage.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock and Liquidity Risks

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

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

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

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

If we fail to comply with the rules of Section 404 of the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, we may be subject to sanctions by regulatory authorities and our stock price could decline.

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

We may have undisclosed liabilities and any such liabilities could harm our revenues, business, prospects, financial condition and results of operations.

Prior to our reverse merger in February 2012, the assets and liabilities of the public company shell we eventually merged into were transferred in a split-off transaction (the "Split-Off") to a separate entity (the "Split-Off Entity") owned by the then outstanding stockholders of the public company shell (the "Split-Off Stockholders"). Even though the pre-merger assets and liabilities were transferred to the Split-Off Entity in the Split-Off, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities that survived our reverse merger could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities. The transfer of the operating assets and liabilities to Split-Off Entity, coupled with the Split-Off, will result in taxable income to us in an amount equal to the difference between the fair market value of the assets transferred and the pre-merger tax basis of the assets. Any gain recognized, to the extent not offset by our net operating loss carryforward, if any, will be subject to federal income tax at regular corporate income tax rates.

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

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

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

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

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

We are authorized to issue 150,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of December 31, 2014, there were an aggregate of 91,712,297 shares of our common stock issued and outstanding on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 10,075,782 shares of our common stock that may be issued upon the exercise of outstanding stock options or is available for issuance under our equity incentive plans, and 1,178,109 shares of our common stock that may be issued upon the exercise of outstanding warrants.

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with presently outstanding warrants, hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on the NYSE MKT.

Our common stock is subject to trading risks created by the influence of third party investor websites.

Our common stock is widely traded and held by retail investors, and these investors are subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet. This information has become influential because it is widely distributed and links to it appear as top company headlines on commonly used stock quote and finance websites, or through services such as Google alerts. These emerging information distribution models are a consequence of the emergence of the internet. Some information and content distribution is by individuals through platforms that mainly serve as hosts seeking advertising revenue. As such, we believe an incentive exists for these sites to increase advertising revenue by increasing page views, and for them to post or allow to be posted inflammatory information to achieve this end. It has been our experience that a significant portion of the information on these websites or distributed by independent authors about our Company is false or misleading, and occasionally, we believe, purposefully misleading. These sites and internet distribution strategies also create opportunity for individuals to pursue both “pump and dump” and “short and distort” strategies. We believe that many of these websites have little or no requirements for authors to have professional qualifications. While these sites sometimes require disclosure of stock positions by authors, as far as we are aware these sites do not audit the accuracy of such conflict of interest disclosures. We believe that many of these websites have few or lax editorial standards, and thin or non-existent editorial staffs. Despite our best efforts, we have not and may not be able in the future to obtain corrections to information provided on these websites about our Company, including both positive and negative information, and any corrections that are obtained may not be achieved prior to the majority of audience impressions being formed for a given article. These conditions create volatility and risk for holders of our common stock and should be considered by investors. We can make no guarantees that regulatory authorities will take action on these types of activities, and we cannot guarantee that legislators will act responsively, or ever act at all, to appropriately restrict the activities of these websites and authors.

Our common stock is controlled by insiders.

Our current executive officers and directors beneficially own approximately 11.8% of our outstanding shares of common stock, as of December 31, 2014. Although we are not aware of any voting arrangements between our officers and directors, such concentrated control may adversely affect the price of our common stock. Investors who acquire our common stock may have no effective voice in the management of our operations.

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

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

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

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

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

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

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, Inc. issued to former holders of Organovo, Inc. promissory notes (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
4.3	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)
4.4	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	Controlled Equity Offering^{SM} Sales Agreement, dated December 30, 2014, by and between Organovo Holdings, Inc. and Cantor Fitzgerald & Co. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 30, 2014)
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	Certifications 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: February 6, 2015

By: */s/ Keith Murphy*
Name: Keith Murphy
Title: Chairman, Chief Executive Officer and President
(Principal Executive Officer)

Date: February 6, 2015

By: */s/ Barry D. Michaels*
Name: Barry D. Michaels
Title: Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION
PURSUANT TO SECTION 302 OR THE
SARBANES-OXLEY
ACT OF 2002

I, Keith Murphy, 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 circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officers 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.

Date: February 6, 2015

By: */s/ Keith Murphy*
Name: Keith Murphy
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
PURSUANT TO SECTION 302 OR THE
SARBANES-OXLEY
ACT OF 2002

I, Barry D. Michaels, 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 circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officers 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.

Date: February 6, 2015

By: */s/ Barry D. Michaels*
Name: Barry D. Michaels
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Quarterly Report of Organovo Holdings, Inc. (the "Corporation") on Form 10-Q for the period ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith Murphy, President and Chief Executive Officer and I, Barry D. Michaels, Chief Financial Officer, of the Corporation, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Corporation.

Date: February 6, 2015

By: */s/ Keith Murphy*
Name: Keith Murphy
Title: President and Chief Executive Officer

Date: February 6, 2015

By: */s/ Barry D. Michaels*
Name: Barry D. Michaels
Title: Chief 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.