ORGANOVO HOLDINGS, INC.
Form 10-Q
November 07, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

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

For the quarterly period ended September 30, 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 **(State or other jurisdiction of** **incorporation or organization)**	**27-1488943** **(I.R.S. Employer** **Identification No.)**
6275 Nancy Ridge Drive, Suite 110, **San Diego, CA 92121** **(Address of principal executive offices and zip code)**	**(858) 224-1000** **(Registrant s telephone number, including area code)**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

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

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

As of November 1, 2014, a total of 80,504,648 shares of the Registrant s Common Stock, $0.001 par value, were outstanding.

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Condensed Consolidated Balance Sheets

(in thousands except for share data)

	September 30, 2014 (Unaudited)	March 31, 2014 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 54,389	$ 48,167
Accounts receivable	30	
Inventory	70	63
Prepaid expenses and other current assets	616	931
Total current assets	55,105	49,161
Fixed assets, net	1,273	857
Restricted cash	79	79
Other assets, net	85	89
Total assets	$ 56,542	$ 50,186
Liabilities and Stockholders Equity		
Current Liabilities		
Accounts payable	$ 530	$ 326
Accrued expenses	1,559	822
Deferred rent	615	345
Deferred revenue	140	13
Capital lease obligation	10	10
Warrant liabilities	258	377
Total current liabilities	3,112	1,893
Deferred revenue, net of current portion	1	4
Capital lease obligation, net of current portion	1	5
Total liabilities	$ 3,114	$ 1,902
Commitments and Contingencies (Note 4)		
Stockholders Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 80,404,648 and 78,113,639 shares issued and outstanding at September 30, 2014 and March 31, 2014, respectively	80	78
Additional paid-in capital	160,852	140,419
Accumulated deficit	(107,504)	(92,213)
Total stockholders equity	53,428	48,284

Total Liabilities and Stockholders Equity	$	56,542	$	50,186

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

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Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands except share and per share data)

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Six Months Ended September 30, 2014	Six Months Ended September 30, 2013
Revenues				
Collaborations	$ 45	$ 23	$ 114	$ 117
Grants	5		35	12
Total Revenues	50	23	149	129
Selling, general, and administrative expenses	5,777	4,003	9,472	6,361
Research and development expenses	3,229	1,622	6,043	3,104
Loss from Operations	(8,956)	(5,602)	(15,366)	(9,336)
Other Income (Expense)				
Change in fair value of warrant liabilities	94	(4,787)	64	(4,811)
Loss on disposal of fixed assets	(3)		(3)	(4)
Interest expense				(13)
Interest income	7	3	14	7
Total Other Income (Expense)	98	(4,784)	75	(4,821)
Net Loss	$ (8,858)	$ (10,386)	$ (15,291)	$ (14,157)
Net loss per common share basic and diluted	$ (0.11)	$ (0.14)	$ (0.19)	$ (0.21)
Weighted average shares used in computing net loss per common share basic and diluted	78,933,884	72,716,031	78,589,521	68,776,718

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

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Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows (in thousands)

	Six Months Ended September 30, 2014	Six Months Ended September 30, 2013
Cash Flows From Operating Activities		
Net loss	$ (15,291)	$ (14,157)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	3	4
Depreciation and amortization	208	190
Change in fair value of warrant liabilities	(64)	4,811
Expense associated with warrant modification		12
Stock-based compensation	3,634	2,088
Amortization of warrants issued for services	469	72
Increase (decrease) in cash resulting from changes in:		
Grants receivable		101
Accounts receivable	(30)	
Inventory	(7)	14
Prepaid expenses and other assets	113	(49)
Accounts payable	204	(164)
Accrued expenses	737	833
Deferred rent	223	(30)
Deferred revenue	124	19
Net cash used in operating activities	(9,677)	(6,256)
Cash Flows From Investing Activities		
Deposits released from restriction		50
Purchases of fixed assets	(576)	(176)
Net cash used in investing activities	(576)	(126)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	16,291	44,096
Proceeds from exercise of stock options	188	20
Principal payments on capital lease obligation	(4)	(5)
Net cash provided by financing activities	16,475	44,111
Net Increase in Cash and Cash Equivalents	6,222	37,729
Cash and Cash Equivalents at Beginning of Period	48,167	15,628
Cash and Cash Equivalents at End of Period	$ 54,389	$ 53,357

Supplemental Disclosure of Cash Flow Information:

Interest	$	$
Income Taxes	$	$

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

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

During the six months ended September 30, 2014 and 2013, the warrant liability was reduced by approximately $55 and $10,147, respectively, as a result of warrant exercises and $0 and $767, respectively, for warrants reclassified as equity instruments.

During the six months ended September 30, 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.

Organovo Holdings, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

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 consolidated subsidiary Organovo, Inc. 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.

As of September 30, 2014, the Company has devoted its efforts primarily to developing a platform technology for the generation of 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. 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 before another company develops similar technology or products.

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 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 September 30, 2014, the Company had an accumulated deficit of approximately $107.5 million. The Company also had negative cash flows from operations of approximately $9.7 million during the six months ended September 30, 2014.

Through September 30, 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 or collaborative research agreements. Based on its current operating plan and available cash resources, the Company has sufficient resources to fund its business for at least the next twelve months.

The Company will need additional capital to further fund product 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 additional financing from existing and prospective investors, from revenue derived from grants and collaborative research agreements, and revenue from the commercialization of products and services. However, we may not be successful in obtaining sufficient funding to support our operations from new or existing collaborative research agreements or the commercialization of products and services. In addition, 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. Further, we cannot assure you that we will receive 100% of the potential funding under existing grants, and we may not be successful in securing additional grants in the future.

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.

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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, accounts receivable, 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 September 30, 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 $70,000 and $63,000 in raw materials as of September 30, 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 September 30, 2014 and March 31, 2014 was approximately $31,000.

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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 September 30, 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 will 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 September 30 and March 31, 2014 (in thousands):

	Balance at September 30, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Warrant liability	$ 258			$ 258

	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

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The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the six months ended September 30, 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	(64)
Warrant liability removal due to settlements	(55)
Warrant liability reclassified to equity	
Balance at September 30, 2014	$ 258

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 collaborative research agreements, 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 September 30, 2014 and March 31, 2014, the Company had approximately $141,000 and $17,000, respectively, in deferred revenue related to its grants and collaborative research programs.

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 Arrangements with Multiple Deliverables

The Company occasionally 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.

The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance. 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 six months, respectively, ended September 30, 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 $5,000 and $35,000 for the three and six months, respectively, ended September 30, 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 therefore no revenue has been recognized under this grant as of September 30, 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.

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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 six months ended September 30, 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 six months ended September 30, 2014 or 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 7.9 million for the three and six months ended September 30, 2014, respectively, and 6.9 million for the three and six months ended September 30, 2013, respectively.

Reclassifications

Certain reclassifications were made to the Condensed Consolidated Balance Sheet as of March 31, 2014 and the Condensed Consolidated Statement of Operations for the three and six months ended September 30, 2013 in order to conform to the presentation of the Condensed Consolidated Balance Sheet as of September 30, 2014 and the Condensed Consolidated Statement of Operations for the three and six months ended September 30, 2014. The reclassifications did not have any effect on previously reported net loss or financial position.

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 September 30, 2014 and March 31, 2014, respectively. The changes in fair value of the derivative liabilities were approximately a $94,000 decrease and a $4.8 million increase for the three months ended September 30, 2014 and 2013, respectively, and were approximately a $64,000 decrease and a $4.8 million increase for the six months ended September 30, 2014 and 2013, respectively, and are included in other income (expense) in the statement of operations.

During the three months ended September 30, 2014 and 2013, 0 and 1,782,928 warrants, respectively, that were classified as derivative liabilities were exercised. During the six months ended September 30, 2014 and 2013, 8,647 and 1,817,928 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 six months ended September 30, 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 closing dates of the Private Placement and the end of each reporting period using a Monte Carlo valuation model with the following assumptions:

	September 30, 2014		March 31, 2014		September 30, 2013	
Closing price per share of common stock	$	6.37	$	7.64	$	5.77
Exercise price per share	$	1.00	$	1.00	$	1.00
Expected volatility		76.5%		76.5%		82.6%
Risk-free interest rate		0.58%		0.90%		0.63%
Dividend yield						
Remaining expected term of underlying securities (years)		2.46		2.96		3.44

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 six months ended September 30, 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.

In addition, during the three months ended September 30, 2014 and 2013, the Company issued 0 and 1,670,851 shares of common stock upon exercise of 0 and 2,026,428 warrants, respectively. During the six months ended September 30, 2014 and 2013, the Company issued 110,600 and 1,870,986 shares of common stock upon exercise of 111,647 and 2,278,557 warrants, respectively.

Finally, during the three and six months ended September 30, 2014, the Company issued 28,224 and 88,746 shares of common stock upon exercise of 28,224 and 88,746 stock options, respectively. During the three and six months ended September 30, 2013, the Company issued 7,300 shares of common stock upon exercise of 7,300 stock options.

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 six months ended September 30, 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 six months ended

September 30, 2014.

During the three months ended September 30, 2014 and 2013, there were 103,804 and 160,540 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 190,000 and 296,250 restricted stock units, respectively. During the six months ended September 30, 2014 and 2013, there were 106,105 and 163,083 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 196,250 and 302,500 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.

There are 200,000 of restricted stock awards that were issued to a member of senior management in a prior year, the vesting of which is performance based. As of September 30, 2014, the Company believed the financial targets would be met, and accordingly is recognizing the related stock-based compensation expense over the requisite service period.

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A summary of the Company s restricted stock award activity from March 31, 2014 through September 30, 2014 is as follows:

	Number of Shares
Unvested at March 31, 2014	573,495
Granted	
Vested	(196,250)
Canceled / forfeited	
Unvested at September 30, 2014	377,245

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 $134,000 and $131,000 for the three months ended September 30, 2014 and 2013, respectively, and approximately $267,000 and $533,000 for the six months ended September 30, 2014 and 2013, respectively. Stock-based compensation expense included in research and development was $4,000 and $4,000 for the three months ended September 30, 2014 and 2013, respectively, and $8,000 and $8,000 for the six months ended September 30, 2014 and 2013, respectively. Stock-based compensation expense included in general and administrative expense was $130,000 and $127,000 for the three months ended September 30, 2014 and 2013, respectively, and $259,000 and $525,000 for the six months ended September 30, 2014 and 2013, respectively.

As of September 30, 2014, total unrecognized restricted stock-based compensation expense was approximately $466,000, which will be recognized over a weighted average period of 1.02 years.

Stock options

Under the 2012 Plan, 290,054 and 475,540 stock options were issued during the three months ended September 30, 2014 and 2013, respectively, and 556,855 and 572,540 stock options were issued during the six months ended September 30, 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 six months ended September 30, 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	556,855	$ 7.53	
Options canceled	(22,125)	$ 7.22	
Options exercised	(88,746)	$ 2.12	$ 425,156
Outstanding at September 30, 2014	6,381,872	$ 5.14	$ 14,989,496

Vested and Exercisable at September 30, 2014	2,349,427	$	2.95	$ 8,414,477

The weighted-average remaining contractual term of options exercisable and outstanding at September 30, 2014 was approximately 8.07 years and 8.55 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 September 30, 2014	**Three Months Ended September 30, 2013**	**Six Months Ended September 30, 2014**	**Six Months Ended September 30, 2013**
Dividend yield				
Volatility	76.3%	82.6%	77.1%	84.8%
Risk-free interest rate	1.66%	0.63%	1.61%	0.84%
Expected life of options	6.00 years	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	$ 5.16	$ 4.00	$ 5.06	$ 3.81

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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 $1,962,000 and $1,155,000 for the three months ended September 30, 2014 and 2013, respectively, and $3,367,000 and $1,555,000 for the six months ended September 30, 2014 and 2013, respectively. Expense included in research and development was $281,000 and $66,000 for the three months ended September 30, 2014 and 2013, respectively, and $529,000 and $133,000 for the six months ended September 30, 2014 and 2013, respectively. Expense included in general and administrative was $1,681,000 and $1,089,000 for the three months ended September 30, 2014 and 2013, respectively and $2,838,000 and $1,422,000 for the six months ended September 30, 2014 and 2013, respectively.

The total unrecognized compensation cost related to unvested stock option grants as of September 30, 2014 was approximately $15,400,000 and the weighted average period over which these grants are expected to vest is 3.03 years.

Warrants

During the three months ended September 30, 2014 and 2013, 0 and 1,782,928 warrants, respectively, were exercised through a cashless exercise provision for issuance of 0 and 1,427,351 shares of common stock, respectively. During the six months ended September 30, 2014 and 2013, 8,647 and 2,035,057 warrants, respectively, were exercised through a cashless exercise provision for issuance of 7,600 and 1,627,486 shares of common stock, respectively. During the three and six months ended September 30, 2014, 0 and 103,000 warrants, respectively, were exercised at prices ranging from $1.00 to $2.21 for total proceeds of $0 and $224,000, respectively and during the three and six months ended September 30, 2013, 243,500 warrants were exercised at prices ranging from $2.28 and $3.24 for total proceeds of $651,180.

Of the warrants exercised during the three months ended September 30, 2014 and 2013, 0 and 1,782,928, respectively, were derivative liabilities and were valued at the settlement date. Of the warrants exercised during the six months ended September 30, 2014 and 2013, 8,647 and 1,817,928, respectively, were derivative liabilities and were valued at the settlement date. For the three months ended September 30, 2014 and 2013, and the six months ended September 30, 2014 and 2013, respectively, approximately $0, $10,018,000, $55,000, and $10,147,000, 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 six months ended September 30, 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 six months ended September 30, 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 is being 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 $101,000 and $202,000 during the three and six months ended September 30, 2014, respectively, related to these services.

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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 following table summarizes warrant activity for the six months ended September 30, 2014:

	Warrants	Weighted-Average Exercise Price	
Balance at March 31, 2014	1,194,756	$	1.79
Granted	50,000	$	7.62
Exercised	(111,647)	$	2.08
Balance at September 30, 2014	1,133,109	$	2.02

The warrants outstanding at September 30, 2014 are immediately exercisable at prices between $0.85 and $7.62 per share, and have a weighted average remaining term of approximately 2.34 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at September 30, 2014:

Common stock warrants outstanding	1,133,109
Common stock options outstanding under the 2008 Plan	672,192
Common stock options outstanding and reserved under the 2012 Plan	9,502,348
Total	11,307,649

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.

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 $105,000 for the three months ended September 30, 2014 and 2013, respectively, and $470,000 and $210,000 for the six months ended September 30, 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

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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 September 30, 2014, are as follows (in thousands):

Fiscal year ended March 31, 2015	$ 444
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	$ 6,966

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 this agreement, 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 a confidentiality agreement. 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 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.

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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.

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.

7. Subsequent Events

In October 2014, we executed an amendment to our existing Research Agreement with United Therapeutics Corporation (Unither) to expand the scope of research we are conducting using the NovoGen Bioprinter technology. The term of our extended Research Agreement with Unither now runs through December 2015.

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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 and our Annual Report on Form 10-K for the fiscal year ended March 31, 2014 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 subsidiary Organovo, Inc.

The condensed consolidated financial statements included in this Form 10-Q have been prepared in accordance with 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

Organovo, Inc. was founded in Delaware in April 2007. Activities since Organovo, Inc. s inception through September 30, 2014 were devoted primarily to developing 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. As of September 30, 2014, Organovo, Inc. has devoted substantially all of its efforts to product development, raising capital and building infrastructure. Organovo, Inc. has not, as of that date, realized significant revenues from its planned principal operations.

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 will continue the existing business operations of Organovo, Inc.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with accounting principles that are generally accepted in the United States. 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.

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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 Securities and Exchange Commission (the SEC) on June 10, 2014.

Results of Operations

Comparison of the three months ended September 30, 2014 and 2013

Revenues

For the three months ended September 30, 2014, total revenues of $50,000 were $27,000 or 117% above the $23,000 in revenues for the same period in 2013. For both periods, the majority of revenues were derived from collaborative research agreements.

Operating Expenses

Overview

Operating expenses increased approximately $3.4 million, or 61%, from approximately $5.6 million for the three months ended September 30, 2013 to $9.0 million for the three months ended September 30, 2014. Of this increase, $1.8 million relates to increased selling, general and administrative expense while the other $1.6 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, 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 nearly 100% from approximately $1.6 million for the three months ended September 30, 2013 to $3.2 million for the three months ended September 30, 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-four full-time employees as of September 30, 2013 to forty-four full-time employees as of September 30, 2014. In addition to an increase in staffing expense of approximately $0.5 million and an increase in stock-based compensation of $0.2 million resulting from increased headcount and increasing stock prices from September 30, 2013 to September 30, 2014, the Company increased its spending on recruiting, lab equipment and supplies in proportion to its increased research activities. In addition, the Company has continued to invest additional resources to advance its bioprinting technology during the period.

General and Administrative Expenses

For the three months ended September 30, 2014, general and administrative expenses were approximately $5.8 million, an increase of $1.8 million, or 44%, over expenses in the same period of 2013 of approximately $4.0 million. Stock-based compensation increased $0.6 million due to additional grants and increasing stock prices from September 30, 2013 to September 30, 2014. Staffing expense increased $0.4 million due to an increase in administrative headcount from twelve full-time employees to sixteen 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 and consulting activities in the three months ended September 30, 2014 as compared to the three months ended September 30, 2013.

Other Income (Expense)

Other income was less than $0.1 million for the three months ended September 30, 2014 and consisted primarily of a gain related to the revaluation of warrant derivative liabilities. This gain was caused by a declining stock price during the quarter that decreased the value of the derivative liability. For the three months ended September 30, 2013, other expense consisted primarily of a $4.8 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.

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Comparison of the six months ended September 30, 2014 and 2013

Revenues

For the six months ended September 30, 2014, total revenues of $0.1 million were consistent with the $0.1 million in revenues for the same period in 2013. For both periods, the majority of revenues were derived from collaborative research agreements.

Operating Expenses

Overview

Operating expenses increased approximately $6.0 million, or 64%, from approximately $9.5 million for the six months ended September 30, 2013 to $15.5 million for the six months ended September 30, 2014. Of this increase, $3.1 million is related to increased selling, general and administrative expense while the other $2.9 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, 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 $2.9 million, or 95%, from approximately $3.1 million for the six months ended September 30, 2013 to approximately $6.0 million for the six months ended September 30, 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-four full-time employees as of September 30, 2013 to forty-four full-time employees as of September 30, 2014. In addition to increases in staffing expense of approximately $0.9 million and an increase in stock-based compensation of $0.4 million resulting from increased headcount and increasing stock prices from September 30, 2013 to September 30, 2014, the Company increased its spending on recruiting, lab equipment, supplies and contracted services in proportion to its increased research activities. In addition, the Company has continued to invest additional resources to advance its bioprinting technology during the period.

General and Administrative Expenses

For the six months ended September 30, 2014, general and administrative expenses were approximately $9.5 million, an increase of $3.1 million, or 49%, over expenses in the same period of 2013 of approximately $6.4 million. Stock-based compensation increased $1.1 million due to additional grants and increasing stock prices from September 30, 2013 to September 30, 2014. Staffing expense increased $0.7 million due to an increase in administrative headcount from twelve full-time employees to sixteen 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 six months ended September 30, 2014 as compared to the six months ended September 30, 2013.

Other Income (Expense)

Other income was less than $0.1 million for the six months ended September 30, 2014 and consisted primarily of 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 six months ended September 30, 2013, other expense consisted primarily of a $4.8 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 research and development, business planning, raising capital, recruiting management and technical staff, and acquiring operating assets. The Company has not commenced principal operations or realized significant revenue therefrom.

Since inception, the Company incurred negative cash flows from operations. As of September 30, 2014, the Company had cash and cash equivalents of approximately $54.4 million and an accumulated deficit of $107.5 million. The Company also had negative cash flow from operations of $9.7 million during the six months ended September 30, 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 September 30, 2014, the Company had total current assets of approximately $55.1 million and current liabilities of approximately $3.1 million, resulting in working capital of $52.0 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 six months ended September 30, 2014 was approximately $9.7 million as compared to $6.3 million used in operating activities for the six months ended September 30, 2013. This $3.4 million increase in cash usage can be attributed to a $6.0 million increase in operating expenses, partially offset by an overall increase of $2.0 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 $0.6 million and $0.1 million for the six months ended September 30, 2014 and 2013, respectively. This increase can be attributed to increased capital spending as the company expands its research capabilities.

Net cash provided by financing activities decreased from $44.1 million provided during the six months ended September 30, 2013 to $16.5 million provided during the six months ended September 30, 2014. This decrease is primarily due to the inclusion of $43.4 million in net proceeds from the issuance of common stock during the six months ended September 30, 2013, as compared to $16.1 million in net proceeds from the issuance of common stock during the six months ended September 30, 2014.

We believe our cash and cash equivalents on hand as of September 30, 2014, together with amounts to be received from our collaborative research agreements and the commercialization of our products and services, should be sufficient to fund our ongoing operations as currently planned for at least the next twelve months. Through September 30, 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 or collaborative research agreements.

In addition, 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 six months ended September 30, 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. We intend to use the net proceeds from these offerings for general corporate purposes, including research and development, the development and commercialization of our products, general administrative expenses, license or technology acquisitions, and working capital and capital expenditures. We may also use the net proceeds to repay any debts and/or invest in or acquire complementary businesses, products or technologies, although we have no current commitments or agreements with respect to any such investments or acquisitions as of the date of this Quarterly Report on Form 10-Q.

The Company will need additional capital to further fund product 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 additional financing from existing and prospective investors, from revenue derived from grants and collaborative research agreements, and revenue from the commercialization of products and services. However, we may not be successful in obtaining sufficient funding to support our operations from new or existing collaborative research agreements or the commercialization of products and services. In addition, 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. Further, we cannot assure you that we will receive 100% of the potential funding under existing grants, and we may not be successful in securing additional grants in the future.

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 September 30, 2014, the Company had 80,404,648 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 263,870 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 $2.3 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 16% 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 September 30, 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.

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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, as well as the risk factors disclosed in Item 1A. to Part I of our Annual Report on Form 10-K for the fiscal year ended March 31, 2014 (our 2014 Form 10-K), and filed with the Securities and Exchange Commission on June 10, 2014. Except as set forth below, there have been no material changes from the risk factors as previously disclosed in our 2014 Form 10-K. Any of the risks discussed in this Quarterly Report on Form 10-Q or any of the risks disclosed in Item 1A. to Part I of our 2014 Form 10-K, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our results of operations or financial condition.

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.

To prepare for the commercial launch of our first product 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.

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

(a) 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)
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.

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SIGNATURES

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

ORGANOVO HOLDINGS, INC.

Date: November 7, 2014

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

(Principal Executive Officer)

/s/ Barry D. Michaels
Name: Barry D. Michaels
Title: Chief Financial Officer and Secretary

(Principal Financial and Accounting Officer)