

ORGANOVO HOLDINGS, INC.

Form 10-Q

February 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

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

For the quarterly period ended December 31, 2015

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)

6275 Nancy Ridge Drive, Suite 110,

San Diego, CA 92121

27-1488943
(I.R.S. Employer

Identification No.)

(858) 224-1000

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(Address of principal executive offices and zip code) (Registrant's telephone number, including area code)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

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

As of February 1, 2016, a total of 92,413,951 shares of the registrant's Common Stock, \$0.001 par value, were outstanding.

ORGANOVO HOLDINGS, INC.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Organovo Holdings, Inc.

Condensed Consolidated Balance Sheets

(in thousands except for share data)

	December 31, 2015 (Unaudited)	March 31, 2015 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 70,026	\$ 50,142
Accounts receivable	165	—
Inventory	71	66
Prepaid expenses and other current assets	483	1,054
Total current assets	70,745	51,262
Fixed assets, net	3,560	2,042
Restricted cash	79	79
Other assets, net	152	106
Total assets	\$ 74,536	\$ 53,489
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 466	\$ 1,387
Accrued expenses	2,494	2,257
Deferred rent	1,079	759
Deferred revenue	1,444	227
Capital lease obligation	—	5
Warrant liabilities	14	126
Total current liabilities	5,497	4,761
Deferred revenue, net of current portion	—	32
Total liabilities	\$ 5,497	\$ 4,793
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 92,413,951 and 81,536,724 shares issued and outstanding at December 31, 2015 and March 31, 2015, respectively	92	82
Additional paid-in capital	221,445	170,909
Accumulated deficit	(152,498)	(122,295)
Total stockholders' equity	69,039	48,696

Total Liabilities and Stockholders' Equity	\$ 74,536	\$ 53,489
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The accompanying notes are an integral part of these condensed consolidated financial statements.

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands except share and per share data)

	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014	Nine Months Ended December 31, 2015	Nine Months Ended December 31, 2014
Revenues				
Product and service	\$293	\$139	\$689	\$139
Collaborations	25	7	58	121
Grants	10	9	188	44
Total Revenues	328	155	935	304
Selling, general, and administrative expenses	6,212	3,878	17,680	13,350
Research and development expenses	4,586	3,238	13,467	9,281
Loss from Operations	(10,470)	(6,961)	(30,212)	(22,327)
Other Income (Expense)				
Change in fair value of warrant liabilities	2	(40)	(27)	24
Loss on disposals of fixed assets	—	—	—	(3)
Interest income	13	8	39	22
Total Other Income (Expense)	15	(32)	12	43
Income Tax Expense	—	—	(3)	—
Net Loss	\$(10,455)	\$(6,993)	\$(30,203)	\$(22,284)
Net loss per common share—basic and diluted	\$(0.11)	\$(0.09)	\$(0.34)	\$(0.28)
Weighted average shares used in computing net				
loss per common share—basic and diluted	92,396,358	80,491,120	90,026,158	79,225,692

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

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended December 31, 2015	Nine Months Ended December 31, 2014
Cash Flows From Operating Activities		
Net loss	\$ (30,203)	\$ (22,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	3
Depreciation and amortization	560	334
Change in fair value of warrant liabilities	27	(24)
Stock-based compensation	7,049	5,215
Amortization of warrants issued for services	(99)	556
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(165)	—
Inventory	(5)	(6)
Prepaid expenses and other assets	553	318
Accounts payable	(921)	169
Accrued expenses	237	1,206
Deferred rent	(54)	254
Deferred revenue	1,185	268
Net cash used in operating activities	(21,836)	(13,991)
Cash Flows From Investing Activities		
Purchases of fixed assets	(1,711)	(867)
Proceeds from disposals of fixed assets	14	—
Purchases of intangible assets	(35)	—
Net cash used in investing activities	(1,732)	(867)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	43,137	16,512
Proceeds from exercise of stock options	320	213
Principal payments on capital lease obligations	(5)	(7)
Net cash provided by financing activities	43,452	16,718
Net Increase in Cash and Cash Equivalents	19,884	1,860
Cash and Cash Equivalents at Beginning of Period	50,142	48,167
Cash and Cash Equivalents at End of Period	\$ 70,026	\$ 50,027
Supplemental Disclosure of Cash Flow Information:		
Interest	\$ —	\$ —
Income Taxes	\$ 3	\$ —

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

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

During the nine months ended December 31, 2015 and 2014, the warrant liability was reduced by approximately \$139 and \$55, respectively, as a result of warrant exercises.

During the nine months ended December 31, 2015 and 2014, approximately \$374 and \$47, respectively, of leasehold improvements were funded by the Company's landlord as a lease incentive. The Company capitalized these costs as property, plant and equipment, with a corresponding increase in deferred rent that will be amortized over the remaining lease term.

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

Organovo Holdings, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

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

Nature of operations and basis of presentation

References in these notes to the unaudited condensed consolidated financial statements to “Organovo Holdings, Inc.,” “Organovo Holdings,” “we,” “us,” “our,” “the Company” and “our Company” refer to Organovo Holdings, Inc. and its consolidated subsidiaries. The Company is an early commercial stage company, focused on developing and commercializing functional three-dimensional (3D) human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs.

Since its inception, the Company has devoted its efforts primarily to developing and commercializing a platform technology and functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company has also focused efforts on raising capital and building infrastructure. In November 2014, the Company announced the commercial release of its first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. As of December 31, 2015, the Company had not yet realized significant revenues from its planned principal operations. The Company’s activities are subject to significant risks and uncertainties including failing to successfully develop products and services based on its technology and to achieve the market acceptance necessary to generate sufficient revenues and to achieve and sustain profitability.

The accompanying interim condensed consolidated financial statements have been prepared by the Company, without audit, in accordance with the instructions to Form 10-Q and, therefore, do not necessarily include all information and footnotes necessary for a fair statement of its financial position, results of operations, stockholders’ equity and cash flows in accordance with generally accepted accounting principles (“GAAP”). The balance sheet at March 31, 2015 is derived from the Company’s audited balance sheet at that date.

In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of the Company’s financial position, results of operations, stockholders’ equity and cash flows. These financial statements should be read in conjunction with the financial statements included in the Company’s Annual Report filed on Form 10-K for the year ended March 31, 2015 filed with the Securities and Exchange Commission (the “SEC”) on June 9, 2015. Operating results for interim periods are not necessarily indicative of operating results for the Company’s fiscal year ending March 31, 2016.

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 NYSE MKT on July 11, 2013 under the symbol “ONVO”. Prior to that time, the Company’s shares were quoted on the OTC QX.

Liquidity

As of December 31, 2015, the Company had an accumulated deficit of approximately \$152.5 million. The Company also had negative cash flows from operations of approximately \$21.8 million during the nine months ended December 31, 2015.

Through December 31, 2015, the Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, the public offering of common stock, and through revenue derived from grants, product sales, collaborative research agreements and research service agreements. Based on its current operating plan and available cash resources, the Company has sufficient resources to fund its business for at least the next twelve months.

The Company intends to cover its future operating expenses through cash on hand, through revenue derived from grants, product sales, collaborative research agreements and research services agreements and through the issuance of additional equity or debt securities. Depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Use of estimates

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

Fair value measurement

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

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

Fair Value Measurements at December 31 and March 31, 2015 (in thousands):				
		Quoted		
		Prices in Active Markets	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Balance at				
December 31, 2015		(Level 1)	(Level 2)	(Level 3)
Warrant liability	\$ 14	—	—	\$ 14
Balance at		Quoted	Significant	Significant

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March 31, 2015				
	Prices in		Other	Other
			Observable	Unobservable
	Active		Inputs	Inputs
	Markets		(Level 2)	(Level 3)
	(Level 1)			
Warrant liability	\$	126	—	\$ 126

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the nine months ended December 31, 2015:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant
	Derivative
	Liability
	(in thousands)
Balance at March 31, 2015	\$ 126
Issuances	—
Adjustments to estimated fair value	27
Warrant liability removal due to settlements	(139)
Warrant liability reclassified to equity	—
Balance at December 31, 2015	\$ 14

Revenue recognition

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

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

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of December 31, 2015 and March 31, 2015, the Company had approximately \$1,444,000 and \$259,000, respectively, in deferred revenue related to its grants, collaborative research programs and research service agreements.

Revenue arrangements with multiple deliverables

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

selling price for the deliverable.

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

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

Product revenue

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

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

Revenue from research service agreements

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

Research and development revenue under collaborative agreements

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

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

Grant revenues

During August 2013, the Company was awarded a research grant by a private, not-for-profit organization for up to \$251,700, contingent on go/no-go decisions made by the grantor at the completion of each stage of research as outlined in the grant award. Revenues from the grant are based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue is recognized when the Company incurs expenses that are related to the grant. Revenue recognized under this grant was approximately \$10,000 and \$40,000 for the three and nine months ended December 31, 2015, respectively. Revenue recognized under this grant was approximately \$9,000 and \$44,000 for the three and nine months ended December 31, 2014, respectively.

During September 2014, the NIH awarded the Company a research grant totaling approximately \$222,000. The grant provides for fixed payments based on the achievement of certain milestones. As such, revenue is recognized upon completion of substantive milestones. Revenue recognized under this grant was approximately \$0 and \$148,000 for the three and nine months ended December 31, 2015, respectively. The full amount of this grant has been recognized as revenue as of December 31, 2015. Grant activities did not commence until the third quarter of fiscal 2015 and the first milestone had not yet been met as of December 31, 2014. Therefore no revenue was recognized under this grant

as of December 31, 2014.

Comprehensive income (loss)

For the three and nine months ended December 31, 2015 and 2014, respectively, the comprehensive loss was equal to the net loss.

Net loss per share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and warrants, the assumed release of restriction of restricted stock units, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the three and nine months ended December 31, 2015 or 2014, 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 10.5 million for the three and nine months ended December 31, 2015, and 8.2 million for the three and nine months ended December 31, 2014.

Note 2. Derivative Liability

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

The Company revalues the warrants classified as derivative liabilities as of the end of each reporting period. The estimated fair value of the outstanding warrant liabilities was approximately \$14,000 and \$126,000 as of December 31, 2015 and March 31, 2015, respectively. The changes in fair value of the derivative liabilities were a decrease of approximately \$2,000 and an increase of approximately \$40,000 for the three months ended December 31, 2015 and 2014, respectively, and an increase of approximately \$27,000 and a decrease of approximately \$24,000 for the nine months ended December 31, 2015 and 2014, respectively, and are included in other income (expense) in the statements of operations.

During the three months ended December 31, 2015 and 2014, no warrants that were classified as derivative liabilities were exercised. During the nine months ended December 31, 2015 and 2014, 38,234 and 8,647 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.

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

	December 31, 2015	March 31, 2015	December 31, 2014
Closing price per share of common stock	\$ 2.49	\$3.54	\$ 7.25
Exercise price per share	\$ 1.00	\$1.00	\$ 1.00
Expected volatility	71.90 %	76.80%	76.50 %
Risk-free interest rate	0.65 %	0.56 %	0.67 %
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	1.21	1.96	2.21

Note 3. Stockholders' Equity

Common stock

In May 2008, the Board of Directors of the Company approved the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan authorized the issuance of up to 1,521,584 common shares for awards of incentive stock options,

non-statutory stock options, restricted stock awards, restricted stock award units, and stock appreciation rights. The 2008 Plan terminates on July 1, 2018. No shares have been issued under the 2008 Plan since 2011, and the Company does not intend to issue any additional shares from the 2008 Plan in the future.

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

The Company filed a shelf registration statement on Form S-3 (File No. 333-189995), or the 2013 Shelf, with the SEC on July 17, 2013 authorizing the offer and sale in one or more offerings of up to \$100,000,000 in aggregate of common stock, preferred stock, debt securities, or warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities. This 2013 Shelf was declared effective by the SEC on July 26, 2013.

On August 2, 2013, the Company, entered into an Underwriting Agreement with Lazard Capital Markets LLC, acting as representative of the underwriters named in the Underwriting Agreement 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 "2013 Offering"). JMP Securities LLC and Maxim Group LLC each acted as co-managers for the 2013 Offering. The price to the public in the 2013 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 2013 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 2013 Shelf. During the three and nine months ended December 31, 2015, the Company issued no shares of common stock in at the market offerings under the distribution agreement. During the three and nine months ended December 31, 2014, the Company issued 0 and 2,197,768 shares of common stock, respectively, in at the market offerings under the distribution agreement with net proceeds of \$0 and \$16.1 million, respectively. As of December 31, 2015, the Company has issued 2,532,180 shares of common stock in at the market offerings under the distribution agreement, with net proceeds of \$19.6 million.

In December 2014, the Company entered into an equity offering sales agreement with another investment banking firm. Under the terms of the sales agreement, the Company may offer and sell shares of its common stock, from time to time, through the investment bank in "at the market" offerings, as defined by the SEC, and pursuant to the 2013 Shelf. During the three and nine months ended December 31, 2015 and 2014, the Company issued no shares of common stock in at the market offerings under the sales agreement. As of December 31, 2015, the Company sold 1,000,000 shares of common stock in at the market offerings under the sales agreement, with net proceeds of approximately \$6.2 million.

The Company will limit future sales under the 2013 distribution agreement and the 2014 sales agreement to ensure that it does not exceed the maximum amount available for sale under its 2013 Shelf. Based on its use of the 2013 Shelf through December 31, 2015, the Company cannot sell more than an aggregate of \$26,777,785 in shares of common stock under the 2013 distribution agreement and the 2014 sales agreement.

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

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

over-allotment option, with net proceeds of approximately \$43.1 million, after deducting underwriting discounts and commissions and expenses payable by the Company. The shares were issued pursuant to the 2015 Shelf.

During the three months ended December 31, 2015 and 2014, the Company issued 0 and 100,000 shares of common stock upon the exercise of 0 and 100,000 warrants, respectively. During the nine months ended December 31, 2015 and 2014, the Company issued 30,186 and 210,600 shares of common stock upon the exercise of 38,234 and 211,647 warrants, respectively.

Finally, during the three months ended December 31, 2015 and 2014, the Company issued 88,438 and 9,961 shares of common stock upon the exercise of 88,438 and 10,612 stock options, respectively. During the nine months ended December 31, 2015 and 2014, the Company issued 116,001 and 98,707 shares of common stock upon the exercise of 116,001 and 99,358 stock options, respectively.

Restricted stock awards

During the three months ended December 31, 2015 and 2014, there were 2,259 and 3,703 shares of restricted stock, respectively, cancelled related to shares of common stock returned to the Company, at the option of the holders, to cover the tax liability related to the vesting of 6,250 and 8,750 restricted stock units, respectively. During the nine months ended December 31, 2015 and 2014, there were 105,210 and 109,808 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 200,000 and 205,000 restricted stock units, respectively. Upon the return of the common stock, an equal number of stock options with immediate vesting were granted to the individuals at the vesting date market value strike price. A summary of the Company's restricted stock award activity from March 31, 2015 through December 31, 2015 is as follows:

	Number of Shares
Unvested at March 31, 2015	258,750
Granted	—
Vested	(200,000)
Canceled / forfeited	(2,500)
Unvested at December 31, 2015	56,250

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 \$26,000 and \$48,000 for the three months ended December 31, 2015 and 2014, respectively, and approximately \$203,000 and \$315,000 for the nine months ended December 31, 2015 and 2014, respectively. Stock-based compensation expense included in research and development was \$2,000 and \$4,000 for the three months ended December 31, 2015 and 2014, respectively, and \$5,000 and \$12,000 for the nine months ended December 31, 2015 and 2014, respectively. Stock-based compensation expense included in general and administrative expense was \$24,000 and \$44,000 for the three months ended December 31, 2015 and 2014, respectively and \$198,000 and \$303,000 for the nine months ended December 31, 2015 and 2014, respectively.

As of December 31, 2015, total unrecognized restricted stock-based compensation expense was approximately \$15,000, which will be recognized over a weighted average period of 0.25 years.

Stock options

Under the 2012 Plan, 167,239 and 310,203 stock options were issued during the three months ended December 31, 2015 and 2014, respectively, and 2,621,972 and 867,058 stock options were issued during the nine months ended December 31, 2015 and 2014, respectively, at various exercise prices. The stock options generally vest (i) on the one year anniversary of the grant date, (ii) quarterly over a three year period, or (iii) over a four-year period, with 25% vesting on either the one year anniversary of employment or the one year anniversary of the vesting commencement date, and the remainder vesting ratably over the remaining term.

A summary of the Company's stock option activity for the nine months ended December 31, 2015 is as follows:

	Options	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2015	7,113,548	\$ 5.21	\$4,969,499
Options granted	2,621,972	\$ 4.08	
Options canceled / forfeited	(305,530)	\$ 6.13	
Options exercised	(116,001)	\$ 2.76	\$112,441
Outstanding at December 31, 2015	9,313,989	\$ 4.88	\$2,777,141
Vested and Exercisable at December 31, 2015	4,845,925	\$ 4.39	\$2,469,941

The weighted-average remaining contractual term of options exercisable and outstanding at December 31, 2015 was approximately 6.24 years.

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

	Three Months Ended December 31, 2015		Three Months Ended December 31, 2014		Nine Months Ended December 31, 2015		Nine Months Ended December 31, 2014	
Dividend yield	—		—		—		—	
Volatility	71.90	%	77.0	%	74.10	%	77.1	%
Risk-free interest rate	1.64	%	1.67	%	1.61	%	1.64	%
Expected life of options	6.00 years		6.00 years		6.00 years		6.00 years	
Weighted average grant date fair value	\$ 2.16		\$ 4.49		\$ 2.67		\$ 4.86	

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 \$3,072,000 and \$1,533,000 for the three months ended December 31, 2015 and 2014, respectively, and \$6,846,000 and \$4,900,000 for the nine months ended December 31, 2015 and 2014, respectively. Expense included in research and development was \$309,000 and \$327,000 for the three months ended December 31, 2015 and 2014, respectively, and \$935,000 and \$856,000 for the nine months ended December 31, 2015 and 2014, respectively. Expense included in general and administrative was \$2,763,000 and \$1,206,000 for the three months ended December 31, 2015 and 2014, respectively, and \$5,911,000 and \$4,044,000 for the nine months ended December 31, 2015 and 2014, respectively.

Included in total stock option-based compensation for the three months ended December 31, 2015 is additional expense resulting from acceleration of the vesting schedule to fully vest options held by a terminated executive as pursuant to the 2012 Equity Incentive Plan. Additionally, as part of the severance agreement, a modification was made to extend the exercise period of the fully vested options, resulting in an incremental expense.

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2015 was approximately \$14,455,000 and the weighted average period over which these grants are expected to vest is 2.64 years.

Warrants

During the three months ended December 31, 2015 and 2014, there were no cashless warrant exercises. During the nine months ended December 31, 2015 and 2014, 38,234 and 8,647 warrants, respectively, were exercised through a cashless exercise provision for issuance of 30,186 and 7,600 shares of common stock, respectively. During the three and nine months ended December 31, 2014, 100,000 and 203,000 warrants, respectively, were exercised at prices ranging from \$1.00 to \$2.21 for total proceeds of \$221,000 and \$445,000, respectively. In addition, during the nine months ended December 31, 2015, a warrant that was previously expected to be issued to a service provider and had been expensed in prior periods at its approximate value of \$130,000 was cancelled, and the amount was reversed

against operating expense during the period.

Of the warrants exercised during the nine months ended December 31, 2015 and 2014, 38,234 and 8,647, respectively, were derivative liabilities and were valued at the settlement date. For the nine months ended December 31, 2015 and 2014, respectively, approximately \$139,000 and \$55,000, respectively, of the warrant liability was extinguished due to the exercise of these warrants. (See Note 2).

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

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. As of December 31, 2014, the full amount of the warrants related to these services, approximately \$273,000, had been recognized.

During November 2014 the Company entered into an agreement with a consultant for services. In connection with the agreement, the Company issued 145,000 warrants to purchase common stock, at a price of \$6.84, with a life of five years, to be earned over a seventeen month service period ending on March 31, 2016. The final number of vested warrant shares will be determined, at the discretion of management, based on management's judgment of the satisfaction of specific performance metrics prior to the earlier to occur of March 31, 2016 or the termination of the consulting arrangement with the Company. The initial fair value of the warrants was estimated to be approximately \$309,000, which is being revalued and amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 76.78% and a risk-free interest rate factor of 1.37%, was used to determine the value. The Company recognized expense of approximately \$6,000 and \$31,000 during the three and nine months ended December 31, 2015 and approximately \$35,000 during the three and nine months ended December 31, 2014, respectively, related to these services.

The following table summarizes warrant activity for the nine months ended December 31, 2015:

	Warrants	Weighted-Average Exercise Price
Balance at March 31, 2015	1,178,109	\$ 2.59
Granted	—	\$ —
Exercised	(38,234)	\$ 1.00
Cancelled	(37,500)	\$ 7.36
Balance at December 31, 2015	1,102,375	\$ 2.49

The warrants outstanding at December 31, 2015 are exercisable at prices between \$0.85 and \$7.62 per share, and have a weighted average remaining term of approximately 1.63 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at December 31, 2015:

Common stock warrants outstanding	1,102,375
Common stock options outstanding under the 2008 Plan	622,192
Common stock options outstanding and reserved under the 2012 Plan	15,404,481

Total

17,129,048

Preferred stock

The Company is authorized to issue 25,000,000 shares of preferred stock. There are no shares of preferred stock currently outstanding, and the Company has no present plans to issue shares of preferred stock.

Note 4. Commitments and Contingencies

Operating leases

The Company leases office and laboratory space under a non-cancelable operating lease which was entered into in February 2012 and amended in December 2013 and March 2015, a non-cancelable operating lease entered into on January 9, 2015, and a non-cancelable operating lease entered into on December 28, 2015, with the future minimum lease payments from the leases included below. The Company records rent expense on a straight-line basis over the life of the leases and records the excess of expense over the amounts paid as deferred rent. In addition, one of the leases provides for certain improvements made for the Company's benefit to be funded by the landlord. Such costs, totaling approximately \$518,000 to date, have been capitalized as fixed assets and included in deferred rent.

Rent expense was approximately \$254,000 and \$235,000 for the three months ended December 31, 2015 and 2014, respectively, and \$803,000 and \$705,000 for the nine months ended December 31, 2015 and 2014, respectively.

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

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

On March 12, 2015, the Company entered into a Second Amendment to the Original Lease (the “Second Amendment”), to adjust the square footage covered by Amended Lease and an additional portion of the building containing approximately 335 rentable square feet (“Second Expansion Premises”). This square footage adjustment was the result of the re-measurement of each suite and the building overall. The net adjustment to overall leased space was an increase of 88 square feet with a corresponding increase in monthly rental payments at the same rate per square foot as the Expansion Premises.

On January 9, 2015, the Company entered into an agreement to lease a second facility consisting of 5,803 rentable square feet of office and lab space located at 6310 Nancy Ridge Drive, San Diego, CA 92121. The term of the lease is 36 months, beginning on February 1, 2015 and ending on January 31, 2018, with monthly rental payments of approximately \$12,000 commencing on April 1, 2015. In addition, there are annual rent escalations of 3.0% on each 12-month anniversary of the lease commencement date.

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

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2015, are as follows (in thousands):

Fiscal year ended March 31, 2016	\$319
Fiscal year ended March 31, 2017	1,307

Fiscal year ended March 31, 2018	1,145
Fiscal year ended March 31, 2019	1,041
Fiscal year ended March 31, 2020	1,072
Thereafter	1,572
Total	\$6,456

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 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. Moreover, as of the end of the period presented, the Company does not believe that the outcome of any pending legal actions will have a material adverse effect on its financial condition, results of operations or cash flows.

Note 5. Concentrations

Credit risk

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

Note 6. Recent Accounting Pronouncements

In May 2014, the FASB 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 was originally effective for public companies for annual reporting periods beginning after December 15, 2016, with no early application permitted. In August 2015, the FASB issued ASU No. 2015-14 that defers by one year the effective date for all entities, with application permitted as of the original effective date. The updated standard becomes effective for us on April 1, 2018, with early adoption permitted as of April 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that 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 August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern—Disclosures of Uncertainties about an entity’s Ability to Continue as a Going Concern (“ASU 2014-15”). ASU 2014-15 provides new guidance related to management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards and to provide related footnote disclosures. This new guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The requirements of ASU 2014-15 are not expected to have a significant impact on our consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. The new guidance was issued to more closely align the measurement of inventory in U.S. GAAP with the measurement of

inventory in International Financial Reporting Standards. The core principle of this updated guidance is that an entity should measure inventory at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in ASU 2015-11 apply to inventory that is measured using the first-in, first-out or average cost methods. ASU 2015-11 is effective for annual and interim reporting periods ending after December 15, 2016, including interim periods within those fiscal years and should be applied prospectively. Early adoption is permitted as of the beginning of an interim or annual reporting period. The requirements of ASU 2015-11 are not expected to have a significant impact on our consolidated financial statements.

Note 7. Subsequent Events

None.

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

The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with the Company's historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2015. 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 "will," "may," "could," "should," or similar expressions, identify certain of these forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties, including those described in "Item 1A—Risk Factors" of this Quarterly Report on Form 10-Q that could cause our actual results or events to differ materially from those expressed or implied by such forward-looking statements. Except to the limited extent required by applicable law, the Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report.

Basis of Presentation

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

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

Organovo, Inc. was founded in Delaware in April 2007. Activities since Organovo, Inc.'s inception through December 31, 2015 have been devoted primarily to technology and product development, raising capital and building infrastructure. As of December 31, 2015, Organovo, Inc. has not realized significant revenues from its planned principal operations.

In December 2014, we established a wholly-owned subsidiary, Samsara Sciences, Inc. ("Samsara") for the purpose of providing high-quality primary human liver cells for a wide variety of in vivo and in vitro research applications. Samsara is expected to serve as a key source of primary human liver cells for the Company's needs in the preclinical safety and therapeutic tissue markets, allowing the Company to optimize its supply chain and operating expenses related to cell sourcing and procurement. We also established Samsara as a cell provider in part to support our needs for a high-quality cell supply for use in the research and development of bioprinted liver tissue as a potential therapeutic product. Samsara will also provide human liver cells beyond Organovo's requirements to life science customers through typical commercial channels. Samsara launched commercial operations in January 2016.

In addition, in September 2015, we established a wholly-owned subsidiary, Organovo UK, Ltd., to establish a sales presence in Europe. As of December 31, 2015, there has been no significant activity related to this subsidiary.

The condensed consolidated financial statements included in this Form 10-Q have been prepared in accordance with the Securities and Exchange Commission (the "SEC") instructions to Quarterly Reports on Form 10-Q. Accordingly, the condensed consolidated financial statements presented elsewhere in this Form 10-Q and discussed below are unaudited and do not contain all the information required by U.S. generally accepted accounting principles ("GAAP") to be included in a full set of financial statements. The audited financial statements for the year ended March 31, 2015, filed with the SEC on Form 10-K on June 9, 2015 include a summary of our significant accounting policies and

should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Overview

We are an early commercial stage company focused on developing and commercializing functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We intend to introduce a paradigm shift in the generation of three-dimensional (“3D”) human tissues, by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition, architecture, and function. We intend to leverage our unique 3D human tissue models to improve the current industry standard cell-based and animal model testing approaches to drug discovery and development by creating 3D tissues constructed solely of human cells. We believe our foundational approach to the 3D printing of living tissues, as disclosed in peer-reviewed scientific publications,

and the continuous evolution of our core bioengineering technology platform combine to provide us with the opportunity to fill many critical gaps in commercially available preclinical human tissue modeling and tissue transplantation. In November 2014, we announced the commercial release of our first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. Initial revenues derived from the product have been and will continue to be predominantly through our research service model, which involves testing compounds provided to us for analysis by our customers. Prior to initiating the service, our technical staff assists customers in determining the extent of testing to be conducted utilizing our exVive3D Human Liver Tissue. Testing may include the analysis of one or multiple compounds under various dosing and duration protocols to determine toxicity and metabolic effects of the test compounds on the tissue model. Projects may involve multiple deliverables which are clearly defined and based on pricing as stated in the related customer agreements. Consistent with our revenue recognition policies, revenue related to each deliverable will be recognized when delivered and the period of customer acceptance has been met. Revenue from projects without multiple deliverables will be recognized when the data package has been delivered to the customer and the term of customer acceptance has been met. In general, project duration is in the four to six month range.

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

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to revenue recognition, valuation of long-lived assets and warrant liability, stock-based compensation and the timing of the achievement of collaboration milestones. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known. Besides the estimates identified above that are considered critical, we make many other accounting estimates in preparing our financial statements and related disclosures. All estimates, whether or not deemed critical, affect reported amounts of assets, liabilities, revenues and expenses, as well as disclosures of contingent assets and liabilities. These estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known, even for estimates and judgments that are not deemed critical.

For further information, refer to the Company's audited financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended March 31, 2015, filed with the SEC on June 9, 2015.

Results of Operations

Comparison of the three months ended December 31, 2015 and 2014

Revenues

For the three months ended December 31, 2015, total revenue of \$328,000 was \$173,000 or approximately 112% higher than total revenue for the three months ended December 31, 2014. Product and service revenue of \$293,000 for the third quarter of fiscal 2016 versus \$139,000 in the third quarter of fiscal 2015 relates to exVive3D Human Liver Tissue product and research services, which were launched commercially in November 2014. The majority of

revenues for the third quarter of fiscal 2016 and 2015 were derived from research service agreements related to the exVive3D Human Liver Tissue.

Operating Expenses

Overview

Operating expenses increased approximately \$3.7 million, or 52%, from approximately \$7.1 million for the three months ended December 31, 2014 to \$10.8 million for the three months ended December 31, 2015. Of this increase, approximately \$1.4 million related to increased investment in research and development, while the other \$2.3 million related to increased selling, general and administrative expense. These increases can be attributed to the Company's continued implementation of its business plan, including hiring additional staff to support research and development initiatives, incremental investments associated with strategic growth and commercialization project initiatives associated with the commercial launch of its exVive3D Human Liver Tissue in November 2014, expenses related to operating as a publicly traded corporation, and the expansion of its facility.

Research and Development Expenses

More specifically, research and development expenses increased 42% from approximately \$3.2 million for the three months ended December 31, 2014 to \$4.6 million for the three months ended December 31, 2015, as the Company increased its research staff to support its obligations under existing collaborative research agreements and to expand its product development team and activities to support sales of its commercial research services. Full-time research and development staffing increased from an average of forty-seven full-time employees for the three months ended December 31, 2014 to an average of sixty-eight full-time employees for the three months ended December 31, 2015, resulting in an increase in staffing expense of approximately \$0.7 million, an increase in facility costs of approximately \$0.4 million, an increase in lab supply costs of \$0.2 million, and an increase in consulting services of \$0.1 million.

Selling, General and Administrative Expenses

For the three months ended December 31, 2015, selling, general and administrative expenses were approximately \$6.2 million, an increase of \$2.3 million, or 60%, over expenses in the prior year period of approximately \$3.9 million. This increase was primarily related to an increase in staffing expense of \$0.6 million due to an increase in average administrative headcount from sixteen full-time employees to twenty-eight full-time employees to provide strategic infrastructure in developing collaborative relationships and the commercialization of research-derived product introductions, an increase in non-cash stock-based compensation of \$1.5 million, \$1.3 million of which is related to the acceleration of vesting and modification to extend the exercise period of options for an employee who terminated employment due to Disability (as defined in the Company's Amended and Restated 2-12 Equity Plan), an increase in facility costs of \$0.2 million, and an increase in strategic consulting costs of \$0.1 million, partially offset by a decrease in legal fees due to the settlement of a lawsuit in the second quarter of fiscal 2016.

Other Income (Expense)

Other income was less than \$0.1 million for the three months ended December 31, 2015 and consisted primarily of interest income, which increased from the same period of fiscal 2015 due to higher average yields and investment balances. Other expense was less than \$0.1 million for the three months ended December 31, 2014 and consisted primarily of losses related to revaluation of warrant derivative liabilities.

Comparison of the Nine Months Ended December 31, 2015 and 2014

Revenues

For the nine months ended December 31, 2015, total revenue of \$0.9 million was \$0.6 million, or approximately 208% higher than total revenue for the nine months ended December 31, 2014. \$0.5 million of this increase is comprised of product and service revenue related to the exVive3D Human Liver Tissue, which was launched commercially in the third quarter of fiscal 2015. Grant revenue also increased by more than \$0.1 million due primarily to the completion of activities under the Company's NIH grant, under which activities commenced during the third quarter of fiscal 2015 and completed in the second quarter of fiscal 2016.

Operating Expenses

Overview

Operating expenses increased approximately \$8.5 million, or 38%, from approximately \$22.6 million for the nine months ended December 31, 2014 to \$31.1 million for the nine months ended December 31, 2015. Of this increase,

approximately \$4.3 million is related to increased selling, general and administrative expense while the other \$4.2 million relates to increased investment in research and development. These increases are attributed to the Company's continued implementation of its business plan, including hiring additional staff to support research and development initiatives, incremental investments associated with strategic growth and commercialization project initiatives associated with the commercial launch of our exVive3D Human Liver Tissue in November 2014, expenses related to operating as a publicly traded corporation, and expansion of its facility.

Research and Development Expenses

Research and development expenses increased by approximately \$4.2 million, or 45%, from approximately \$9.3 million for the nine months ended December 31, 2014 to approximately \$13.5 million for the nine months ended December 31, 2015, as the Company increased its research staff to support its obligations under existing collaborative research agreements and to expand its product development team and activities commensurate with launching commercial research services associated with the commercial launch of the Company's first product in the third quarter of fiscal 2015. Full-time research and development staffing increased from an average of forty-one full-time employees for the nine months ended December 31, 2014 to an average of sixty-three full-time

employees for the nine months ended December 31, 2015. In addition to increases in staffing expense of approximately \$2.0 million and stock-based compensation expense of \$0.1 million, the Company increased its spending on lab supplies and contract services by \$0.8 million and \$0.4 million, respectively, in proportion to its increased research activities. Finally, facilities charges allocated to research and development increased by approximately \$0.9 million due to the expansion of the Company's facilities and increased occupancy rates.

Selling, General and Administrative Expenses

For the nine months ended December 31, 2015, selling, general and administrative expenses were approximately \$17.7 million, an increase of \$4.3 million, or 32%, over expenses in the same period of fiscal 2015 of approximately \$13.4 million. This increase was primarily driven by an increase in staffing-related expenses of approximately \$2.0 million due to an increase in average administrative headcount from fifteen full-time employees to twenty-six full-time employees to provide strategic infrastructure in developing collaborative relationships and the commercialization of research-derived product introductions, and a \$1.8 million increase in non-cash stock-based compensation expense, \$1.3 million of which is related to the acceleration of vesting and modification to extend the exercise period of options for an employee who terminated employment due to Disability (as defined in the Company's Amended and Restated 2-12 Equity Plan) in addition to new grants during the period. In addition, consulting costs increased approximately \$0.5 million due to additional strategic review and planning performed during the nine months ended December 31, 2015, facilities costs increased \$0.4 million due to expansion of the Company's facilities and increased occupancy rates, patent-related costs increased \$0.2 million due to an expanding portfolio of intellectual property, and other corporate expenses increased approximately \$0.2 million due to an overall increase in oversight activities. Partially mitigating these increases was a \$0.8 million decrease in expense related to vendor warrants due to fewer warrants issued and outstanding during the nine months ended December 31, 2015.

Other Income (Expense)

Other income was less than \$0.1 million for the nine months ended December 31, 2015 and 2014, and consisted primarily of interest income and changes in fair value related to the revaluation of warrant derivative liabilities.

Financial Condition, Liquidity and Capital Resources

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

Since inception, the Company has incurred negative cash flows from operations. As of December 31, 2015, the Company had cash and cash equivalents of approximately \$70.0 million and an accumulated deficit of \$152.5 million. The Company also had negative cash flow from operations of \$21.8 million during the nine months ended December 31, 2015. At March 31, 2015, the Company had cash and cash equivalents of approximately \$50.1 million and an accumulated deficit of \$122.3 million.

At December 31, 2015, the Company had total current assets of approximately \$70.7 million and current liabilities of approximately \$5.5 million, resulting in working capital of \$65.2 million. At March 31, 2015, we had total current assets of approximately \$51.3 million and current liabilities of approximately \$4.8 million, resulting in working capital of \$46.5 million.

Net cash used by operating activities for the nine months ended December 31, 2015 was approximately \$21.8 million as compared to \$14.0 million used in operating activities for the nine months ended December 31, 2014. This \$7.8 million increase in cash usage can be attributed to an \$8.5 million increase in operating expenses as well as changes in working capital.

Net cash used in investing activities was approximately \$1.7 million and \$0.9 million for the nine months ended December 31, 2015 and 2014, respectively. This increase can be attributed to increased capital spending as the company built out its facility space to expand its research capabilities.

Net cash provided by financing activities increased from \$16.7 million provided during the nine months ended December 31, 2014 to \$43.5 million provided during the nine months ended December 31, 2015 due primarily to the public offering of common stock in June 2015 that yielded net proceeds of approximately \$43.1 million.

We believe our cash and cash equivalents on hand as of December 31, 2015, together with amounts to be received from our collaborative research agreements and our commercial products and services, will be sufficient to fund our ongoing operations as currently planned for at least the next twelve months. Through December 31, 2015, we have financed our operations primarily through the sale of convertible notes, the private placement of equity securities, the sale of common stock through public offerings, and from revenue derived from grants, collaborative research agreements, product sales and research-based services.

In November 2013, the Company entered into an equity distribution agreement with an investment banking firm. Under the terms of the distribution agreement, the Company may offer and sell up to 4,000,000 shares of its common stock, from time to time, through the investment bank in “at the market” offerings, as defined by the SEC, and pursuant to the Company’s effective shelf registration statement previously filed with the SEC in July 2013 (the “2013 Shelf”). Through December 31, 2015, the Company issued 2,532,180 shares of common stock in at the market offerings under the distribution agreement with net proceeds of approximately \$19.6 million. The net proceeds from these offerings have been used for general corporate purposes, including research and development, the commercialization of our products, general administrative expenses, and working capital and capital expenditures.

In December 2014, the Company entered into an equity offering sales agreement with another investment banking firm. Under the terms of the sales agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$33,000,000, from time to time, through the investment bank in “at the market” offerings, as defined by the SEC, and pursuant to the 2013 Shelf. As of December 31, 2015, the Company has sold 1,000,000 shares of common stock in at the market offerings under the sales agreement, with net proceeds of approximately \$6.2 million. The Company has used the net proceeds raised through these “at-the-market” sales for general corporate purposes, including research and development, the commercialization of the Company’s products, general administrative expenses, and working capital and capital expenditures.

The Company will limit future sales under the 2013 distribution agreement and the 2014 sales agreement to ensure that it does not exceed the maximum amount available for sale under the 2013 Shelf. Based on its use of the 2013 Shelf registration statement through December 31, 2015, the Company cannot sell more than an aggregate of \$26,777,785 in shares of common stock under the 2013 distribution agreement and the 2014 sales agreement.

The Company’s future capital needs will depend on the revenues it generates through its commercialization efforts and the resources it elects to spend to pursue its product development efforts and implement its business plan. As a result, the Company cannot predict with certainty when it may be required to secure additional capital to fund its future operations.

The Company intends to cover its future operating expenses through cash on hand, revenue derived from grants, product sales, collaborative research agreements and research services agreements and through the issuance of additional equity or debt securities. Depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

As of December 31, 2015, the Company had 92,413,951 total issued and outstanding shares of common stock, and five-year warrants for the opportunity to purchase an additional 831,005 shares of common stock at exercise prices between \$0.85 and \$1.00 per share and 271,370 warrants with terms between two and five years and exercise prices between \$2.28 and \$7.62 per share. If all warrants were exercised on a cash basis, the Company would realize approximately \$2.7 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 17,553,986 shares, or

approximately 20% 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 109,542,999 shares of common stock as of December 31, 2015.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We have certain warrants and options outstanding but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the underlying securities are registered, and/or all restrictions on trading, if any, are removed, and in either case the trading price of our common stock is significantly greater than the applicable exercise prices of the options and warrants.

Effect of Inflation and Changes in Prices

Management does not believe that inflation and changes in price will have a material effect on the Company's operations.

Contractual Obligations

In the normal course of business, we enter into contracts and commitments that obligate us to make payments in the future. The table below sets forth our significant contractual obligations and related scheduled payments as of December 31, 2015 (in thousands):

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligations (A)	6,456	1,320	2,229	2,160	747
Total	6,456	1,320	2,229	2,160	747

(A) Operating lease obligations are primarily comprised of remaining payments due under the Company's facility leases.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the quarterly period covered by this report were effective.

Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 4 of the Notes to the Unaudited Condensed Consolidated Financial Statements within this Form 10-Q for a discussion of our legal proceedings and contingencies.

ITEM 1A. RISK FACTORS

In evaluating us and our common stock, we urge you to carefully consider the risks and other information in this Quarterly Report on Form 10-Q as well as the risk factors disclosed in our Annual Report on Form 10-K for the year ended March 31, 2015, filed with the Securities and Exchange Commission on June 9, 2015. There have been no material changes from the risk factors as previously disclosed in our Annual Report on Form 10-K. Any of the risks discussed in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our results of operations or financial condition.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit

No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of February 8, 2012, by and among Organovo Holdings, Inc. a Delaware corporation, Organovo Acquisition Corp., a Delaware corporation and Organovo, Inc., a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
2.2	Certificate of Merger as filed with the Delaware Secretary of State effective February 8, 2012 (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
2.3	Articles of Merger as filed with the Nevada Secretary of State effective December 28, 2011 (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission (the "SEC") on February 3, 2012 (the "February 2012 Form 8-K"))
2.4	Agreement and Plan of Merger, dated as of December 28, 2011, by and between Real Estate Restoration and Rental, Inc. and Organovo Holdings, Inc. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2012)
2.5	Certificate of Merger as filed with the Delaware Secretary of State effective January 30, 2012 (incorporated by reference from Exhibit 2.3 to the February 2012 Form 8-K)
2.6	Agreement and Plan of Merger, dated as of January 30, 2012, by and between Organovo Holdings, Inc. (Nevada) and Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 2.2 to the February 2012 Form 8-K)
2.7	Articles of Merger as filed with the Nevada Secretary of State effective January 30, 2012 (incorporated by reference from Exhibit 2.4 to the February 2012 Form 8-K)
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the February 2012 Form 8-K)
3.2	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the February 2012 Form 8-K)
4.1	Form of Bridge Warrant of Organovo, Inc. (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
4.2	Form of Warrant of Organovo, 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.

#Designates management contracts and compensation plans.

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SIGNATURES

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

ORGANOVO HOLDINGS, INC.

Date: February 8, 2016 By: /s/ Keith Murphy
Name: Keith Murphy
Title: Chairman, Chief Executive Officer and President

(Principal Executive Officer)

Date: February 8, 2016 By: /s/ Barry D. Michaels
Name: Barry D. Michaels
Title: Chief Financial Officer

(Principal Financial and Accounting Officer)