ORGANOVO HOLDINGS, INC. Form 10-Q November 14, 2012 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# Form 10-Q

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

For the quarterly period ended September 30, 2012

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 000-54621

# Organovo Holdings, Inc.

(Exact name of registrant as specified in its charter)

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Delaware (State or other jurisdiction of 27-1488943 (I.R.S. Employer

incorporation or organization)

Identification No.)

6275 Nancy Ridge Drive, Suite 110,

San Diego, CA 92116 (Address of principal executive

(858) 550-9994 (Registrant s telephone number,

offices and zip code)

including area code)

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

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

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

Large accelerated filer "

Accelerated filer

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

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

As of September 30, 2012, a total of 46,969,141 shares of the Registrant s Common Stock, \$0.001 par value, were outstanding.

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Organovo Holdings Inc.

(A development stage company)

#### **Condensed Consolidated Balance Sheets**

Assets Current Assets Cash and cash equivalents Grants receivable Inventory Deferred financing costs Prepaid expenses and other current assets  Total current assets Fixed Assets - Net Restricted Cash Other Assets  Total assets  S  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accounts payable Accounted expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities  Capital lease obligation, net current portion  Total current liabilities  Capital lease obligation, net current portion  Warrant liabilities	7,675,918 95,477 312,182 144,515 8,228,092 605,920 88,321 120,890 9,043,223	\$ 339,607 291,881 318,843 79,874 1,030,205 278,208 100,419 1,408,832
Cash and cash equivalents Grants receivable Inventory Deferred financing costs Prepaid expenses and other current assets  Total current assets  Fixed Assets - Net Restricted Cash Other Assets  Total assets  \$  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable, current portion Total current liabilities Capital lease obligation, net current portion	95,477 312,182 144,515 8,228,092 605,920 88,321 120,890	291,881 318,843 79,874 1,030,205 278,208 100,419
Grants receivable Inventory Deferred financing costs Prepaid expenses and other current assets  Total current assets Fixed Assets - Net Restricted Cash Other Assets  Total assets  \$  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable, current portion Total current liabilities Capital lease obligation, net current portion	95,477 312,182 144,515 8,228,092 605,920 88,321 120,890	291,881 318,843 79,874 1,030,205 278,208 100,419
Inventory Deferred financing costs Prepaid expenses and other current assets  Total current assets Fixed Assets - Net Restricted Cash Other Assets  Total assets  \$  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable, current portion  Total current liabilities Capital lease obligation, net current portion	312,182 144,515 8,228,092 605,920 88,321 120,890	\$ 318,843 79,874 1,030,205 278,208 100,419
Deferred financing costs Prepaid expenses and other current assets  Total current assets Fixed Assets - Net Restricted Cash Other Assets  Total assets  \$  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable, current portion Total current liabilities Capital lease obligation, net current portion	144,515 8,228,092 605,920 88,321 120,890	\$ 318,843 79,874 1,030,205 278,208 100,419
Prepaid expenses and other current assets  Total current assets  Fixed Assets - Net  Restricted Cash  Other Assets  Total assets  \$  Liabilities and Stockholders Deficit  Current Liabilities  Accounts payable  Accrued expenses  Deferred revenue  Capital lease obligation, current portion  Accrued interest payable, current portion  Total current liabilities  Capital lease obligation, net current portion	8,228,092 605,920 88,321 120,890	\$ 79,874 1,030,205 278,208 100,419
Prepaid expenses and other current assets  Total current assets  Fixed Assets - Net  Restricted Cash  Other Assets  Total assets  \$  Liabilities and Stockholders Deficit  Current Liabilities  Accounts payable  Accrued expenses  Deferred revenue  Capital lease obligation, current portion  Accrued interest payable, current portion  Total current liabilities  Capital lease obligation, net current portion	8,228,092 605,920 88,321 120,890	\$ 1,030,205 278,208 100,419
Fixed Assets - Net Restricted Cash Other Assets  Total assets  \$  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion	605,920 88,321 120,890	\$ 278,208 100,419
Restricted Cash Other Assets  Total assets  \$  Liabilities and Stockholders Deficit Current Liabilities Accounts payable Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion	88,321 120,890	\$ 100,419
Other Assets  Total assets  \$  Liabilities and Stockholders Deficit  Current Liabilities  Accounts payable  Accrued expenses  Deferred revenue  Capital lease obligation, current portion  Accrued interest payable  Convertible notes payable, current portion  Total current liabilities  Capital lease obligation, net current portion	120,890	\$ ŕ
Total assets \$  Liabilities and Stockholders Deficit  Current Liabilities  Accounts payable \$  Accrued expenses  Deferred revenue  Capital lease obligation, current portion  Accrued interest payable  Convertible notes payable, current portion  Total current liabilities  Capital lease obligation, net current portion	·	\$ ŕ
Liabilities and Stockholders Deficit  Current Liabilities  Accounts payable \$ Accrued expenses  Deferred revenue  Capital lease obligation, current portion  Accrued interest payable  Convertible notes payable, current portion  Total current liabilities  Capital lease obligation, net current portion	9,043,223	\$ 1,408,832
Current Liabilities  Accounts payable \$ Accrued expenses  Deferred revenue  Capital lease obligation, current portion  Accrued interest payable  Convertible notes payable, current portion  Total current liabilities  Capital lease obligation, net current portion		
Accounts payable \$ Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion		
Accrued expenses Deferred revenue Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion		
Deferred revenue Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion	61,347	\$ 657,560
Capital lease obligation, current portion Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion	830,033	437,837
Accrued interest payable Convertible notes payable, current portion  Total current liabilities Capital lease obligation, net current portion	75,000	152,500
Convertible notes payable, current portion  Total current liabilities  Capital lease obligation, net current portion	9,845	
Total current liabilities  Capital lease obligation, net current portion		24,018
Capital lease obligation, net current portion		703,833
	976,225	1,975,748
Warrant liabilities	19,712	
Wallant natifices	35,471,527	1,266,869
Total liabilities \$	36,467,464	\$ 3,242,617
Commitments and Contingencies (Note 5)		
Stockholders Deficit		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 46,969,141 and		
22,445,254 issued and outstanding at September 30, 2012 and December 31, 2011,		
respectively	46,969	22,445
Additional paid-in capital	13,208,039	4,835,326
• •	(40,679,249)	(6,691,556)
Total stockholders deficit	(27,424,241)	(1,833,785)
Total Liabilities and Stockholders Deficit \$	9,043,223	\$ 1,408,832

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

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Organovo Holdings, Inc.

(A development stage company)

#### **Unaudited Condensed Consolidated Statements of Operations**

	Three Months September 2012			Months Ended otember 30, 2011		e Months Ended tember 30, 2012		Months Ended ember 30, 2011	A	Period from pril 19, 2007 (Inception) through tember 30, 2012
Revenues										
Product	\$		\$		\$		\$	100,000	\$	223,500
Collaborations		3,761		231,974		752,736		449,213		1,515,824
Grants	95	5,477				95,477		56,925		759,589
<b>Total Revenues</b>	469	,238		231,974		848,213		606,138		2,498,913
Cost of product revenue				,		·		50,584		133,607
Selling, general, and										
administrative expenses	2,981	,481		550,157		4,939,403		1,129,597		7,605,440
Research and development										
expenses	1,105	5,456		304,251		2,305,311		1,013,981		5,503,699
Loss from Operations	(3,617	,699)		(622,434)		(6,396,501)		(1,588,024)		(10,743,833)
Other Income (Expense)										
Fair value of warrant liabilities in										
excess of proceeds received						(19,019,422)				(19,019,422)
Change in fair value of warrant										
liabilities	42,252	2,357				(5,190,637)				(5,197,206)
Financing transaction costs in										
excess of proceeds received						(2,129,500)				(2,129,500)
Loss on disposal of fixed assets	(158	3,366)				(158,366)				(158,366)
Interest expense		(203)		(182,320)		(1,087,656)		(294,245)		(3,406,098)
Interest income	1	,358				3,342				5,348
Other income (expense)		596		(488)		(8,953)		(2,038)		(30,172)
<b>Total Other Income (Expense)</b>	42,095	5,742		(182,808)		(27,591,192)		(296,283)		(29,935,416)
Net Income (Loss)	\$ 38,478	3,043	\$	(805,242)	\$	(33,987,693)	\$	(1,884,307)	\$	(40,679,249)
	,					,				,
Net income (loss) per common										
share - basic	\$	0.87	\$	(0.07)	\$	(0.86)	\$	(0.16)	\$	
Net income (loss) per common	Ť		7	(0.07)	Ψ	(0.00)	Ψ	(0.10)	¥	
share - diluted	\$	0.69	\$	(0.07)	\$	(0.86)	\$	(0.16)	\$	
Weighted average shares used in				(1117)		(2.70)		(3. 4)		
computing net income (loss) per										
common share - basic	44,099	.554		12,262,691		39,349,681		11,537,879		
Weighted average shares used in	,522	,		,,		,. ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		<i>yy</i>		
computing net income (loss) per										
common share - diluted	55,849	.360		12,262,691		39,349,681		11,537,879		
	,	,		, - ,		. , ,		,,		

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

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Organovo Holdings, Inc.

(A development stage company)

#### Unaudited Condensed Consolidated Statements of Stockholders Deficit

Period from April 19, 2007 (Inception) through September 30, 2012

	Common Shares	Stock Amount		Additional id-in Capital	]	Deficit ccumulated During the evelopment Stage		Total
Balance at Inception (April 19, 2007)	Situres	\$	\$		\$		\$	
Issuance of Common stock								
Stock-based compensation expense								
Net Loss								
Balance at December 31, 2007		\$	\$		\$		\$	
Issuance of Common stock to founders	1,729,532	1,730		(1,730)				
Issuance of restricted Common stock	12,627,697	12,628		(12,628)				
Stock-based compensation expense				1,742				1,742
Net Loss						(97,559)		(97,559)
Balance at December 31, 2008	14,357,229	\$ 14,358	\$	(12,616)	\$	(97,559)	\$	(95,817)
Issuance of restricted Common stock	130,422	130		(130)				
Stock-based compensation expense				2,336				2,336
Net Loss						(872,041)		(872,041)
Balance at December 31, 2009	14,487,651	\$ 14,488	\$	(10,410)	\$	(969,600)	\$	(965,522)
Issuance of restricted Common stock	219,369	219		(219)				
Stock-based compensation expense				3,856				3,856
Net Loss						(1,338,694)		(1,338,694)
Balance at December 31, 2010	14,707,020	\$ 14,707	\$	(6,773)	\$	(2,308,294)	\$	(2,300,360)
Issuance of Common stock through conversion of notes								
payable	7,676,828	7,677		3,482,081				3,489,758
Issuance of restricted Common stock	61,406	61		(61)				
Warrants issued with convertible notes and conversion of								
notes				1,111,364				1,111,364
Beneficial conversion feature of convertible notes payable				239,700				239,700
Stock-based compensation expense				9,015				9,015
Net Loss						(4,383,262)		(4,383,262)
Balance at December 31, 2011	22,445,254	\$ 22,445	\$	4,835,326	\$	(6,691,556)	4	(1,833,785)
Issuance of Common stock in connection with the merger	6,000,000	6,000	φ	(6,000)	φ	(0,031,330)	φ	(1,033,703)
Issuance of Common stock through private placements in	0,000,000	0,000		(0,000)				
connection with the merger	13,722,600	13,723		13,708,877				13,722,600
Costs associated with the merger	12,722,000	10,720	(	(13,722,600)				(13,722,600)
Issuance of Common stock through conversion of notes				(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				(==,,,==,,000)
payable and accrued interest in connection with the merger	1,525,387	1,525		1,523,862				1,525,387
Issuance of warrants to consultant	-,- 20,007	-,020		72,919				72,919
Issuance of Common stock from warrant exercises	1,810,831	1,811		1,766,665				1,768,476

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Warrant liability removed due to exercise of warrants			3,728,001		3,728,001
Issuance of Common stock from stock option exercises	224,064	224	17,701		17,925
Issuance of restricted common stock	1,380,000	1,380	(1,380)		
Restricted stock forfeitures	(138,995)	(139)	139		
Stock-based compensation expense			1,284,529		1,284,529
Net Loss				(33,987,693)	(33,987,693)
Balance at September 30, 2012	46,969,141	\$ 46,969	\$ 13,208,039	\$ (40,679,249)	\$ (27,424,241)

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

Organovo Holdings, Inc.

(A development stage company)

#### **Unaudited Condensed Consolidated Statements of Cash Flows**

	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Period from April 19, 2007 (Inception) through September 30, 2012
Cash Flows From Operating Activities	Φ (22.007.602)	Φ (1.004.207)	Φ (40 (70 <b>2</b> 40)
Net loss	\$ (33,987,693)	\$ (1,884,307)	\$ (40,679,249)
Adjustments to reconcile net loss to net cash used in operating			
activities:	210.042		429.206
Amortization of deferred financing costs	318,843 158,366		438,296 158,366
Loss on disposal of fixed assets  Depreciation and amortization	116,828	49,929	273,156
Amortization of debt discount	896,167	97,565	2,083,735
Interest accrued on convertible notes payable	11,616	196,680	495,392
Fair value of warrant liabilities in excess of proceeds	19,019,422	190,000	19,019,422
Change in fair value of warrant liabilities	5,190,637		5,197,206
Stock-based compensation	1,284,529	2,596	1,301,478
Amortization of warrants issued for services	36,054	2,370	36,054
Warrants issued in connection with exchange agreement	30,034		527,629
Increase (decrease) in cash resulting from changes in:			321,02)
mercuse (decrease) in cush resulting from changes in.			
Grants receivable	(95,477)	59,744	(95,477)
Inventory	(327,993)	(212,395)	(619,874)
Prepaid expenses and other assets	(53,490)	1,044	(146,496)
Accounts payable	(596,213)	374,973	61,347
Accrued expenses	392,196	260,031	830,033
Deferred revenue	(77,500)	95,075	75,000
Net cash used in operating activities	(7,713,708)	(959,065)	(11,043,982)
Cook Flour From Lungating Astinities			
Cash Flows From Investing Activities Restricted cash deposits	(00 221)		(00 221)
Purchases of fixed assets	(88,321) (255,750)	(16,290)	(88,321) (682,573)
Purchases of intagible assets	(233,730)	(65,000)	(95,000)
i dichases of intaligible assets		(03,000)	(93,000)
Net cash used in investing activities	(344,071)	(81,290)	(865,894)
Cash Flows From Financing Activities			
Proceeds from issuance of convertible notes payable		1,042,500	4,630,000
Proceeds from issuance of common stock and warrants	15,491,075		15,491,075
Proceeds from exercise of stock options	17,925		17,925
Proceeds from issuance of related party notes payable		225,000	250,000
Principal payments on capital lease obligations	(4,663)		(4,663)
Repayment of related party notes payable		(250,000)	(250,000)
Repayment of convertible notes and interest payable	(110,247)		(110,247)
Deferred financing costs		(205,984)	(438,296)
Net cash provided by financing activities	15,394,090	811,516	19,585,794

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Net Increase (Decrease) in Cash and Cash Equivalents Cash and Cash Equivalents at Beginning of Period	7,336,311 339,607	(228,839) 285,308	7,675,918
Cash and Cash Equivalents at End of Period	\$ 7,675,918	\$ 56,469	\$ 7,675,918
Supplemental Disclosure of Cash Flow Information:			
Interest	\$ 10,247	\$	\$ 10,247
Income Taxes	\$ 800	\$ 2,400	\$ 3,200

#### Supplemental Disclosure of Noncash Investing and Financing Activities:

During 2008, the Company issued 1,729,532 shares of Common stock to its founders.

During 2011 and 2010 and for the period from April 19, 2007 (Inception) through December 31, 2011, the Company issued 61,406, 219,369 and 13,038,894, respectively, shares of restricted Common stock to certain employees, advisors and consultants of the Company.

During 2011 and for the period from April 19, 2007 (Inception) through December 31, 2011, the Company issued certain convertible notes payable that included warrants. The warrants and the related beneficial conversion feature, valued at \$823,435 were classified as equity instruments and recorded as a discount to the carrying value of the related debt.

During 2011 and for the period from April 19, 2007 (Inception) through December 31, 2011, the Company issued warrants, valued at approximately \$1,260,000, in connection with certain convertible notes payable. The warrants were recorded as a warrant liability and recorded as a discount to the carrying value related to debt.

During 2011, the Company issued 7,676,828 shares of Common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$3,030,000 and accrued interest totaling \$459,758.

During 2012, the Company issued 1,525,387 shares of Common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$1,500,000 and accrued interest totaling \$25,387.

During 2012, the Company issued warrants, valued at approximately \$32,743,000, in connection with the Reverse Merger and the Private Placement. The warrants were recognized as a derivative liability.

During 2012, the Company purchased equipment valued at \$34,220 through a capital lease.

During 2012, the Company transferred approximately \$307,700 of inventory to fixed assets.

During 2012, the Company issued 100,000 warrants to purchase shares of our common stock for consulting services. The warrants were valued at approximately \$73,000.

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

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Organovo Holdings, Inc.

(A development stage company)

**Notes to Condensed Consolidated Financial Statements** 

#### 1. Summary of Significant Accounting Policies

Nature of operations and basis of

presentation

References in these notes to the unaudited condensed financial statements to Organovo Holdings, Inc., Organovo Holdings, we, us, our, the Company and our Company refer to Organovo Holding Inc. and its consolidated subsidiary Organovo, Inc.

The Company has developed and is commercializing a platform technology for the generation of three-dimensional (3D) human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs.

As of September 30, 2012, the Company has devoted substantially all of its efforts to product development, raising capital, and building infrastructure. The Company has not realized significant revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

The accompanying interim condensed 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 and cash flows in accordance with generally accepted accounting principles ( GAAP ). The balance sheet at December 31, 2011 is derived from the audited balance sheet at that date.

In the opinion of management, the unaudited financial information for the inter