BIODELIVERY SCIENCES INTERNATIONAL INC Form 10-Q August 09, 2016 Table of Contents

## **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

# " 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 001-31361

**BioDelivery Sciences International, Inc.** 

(Exact name of registrant as specified in its charter)

Delaware	35-2089858
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
4131 ParkLake Ave., Suite 225	
Raleigh, NC	27612
(Address of principal executive offices)	(Zip Code)
Registrant s telephone number (including	area code): 919-582-9050

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  $\ddot{}$ 

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, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filerAccelerated filerxNon-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"

As of August 5, 2016, there were 53,655,470 shares of company Common Stock issued and 53,639,979 shares of company Common Stock outstanding.

Act). Yes " No x

# **BioDelivery Sciences International, Inc. and Subsidiaries**

## **Quarterly Report on Form 10-Q**

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# **BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

# CONDENSED CONSOLIDATED BALANCE SHEETS

# (U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

		une 30, 2016	December 31, 2015		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	57,464	\$	83,560	
Accounts receivable, net		2,408		2,488	
Inventory		4,426		2,558	
Prepaid expenses and other current assets		3,612		3,933	
Total current assets		67,910		92,539	
Property and equipment, net		4,299		4,262	
Goodwill		2,715		2,715	
Other intangible assets, net		2,771		3,256	
Total assets	\$	77,695	\$	102,772	
LIABILITIES AND STOCKHOLDERS EQUITY					
Current liabilities:	<i>•</i>	10.050	<b>.</b>		
Accounts payable and accrued liabilities	\$	19,059	\$	19,501	
Notes payable, current maturities, net		7,533		6,707	
Deferred revenue, current		1,965		1,875	
Derivative liability		114			
Total current liabilities		28,671		28,083	
Notes payable, less current maturities, net		21,540		22,168	
Deferred revenue, long-term		20,000		20,000	
Other long-term liabilities		825		825	
Total liabilities		71,036		71,076	
Commitments and contingencies (Notes 7 and 12)					
· · · · · · · · · · · · · · · · · · ·					
Stockholders equity:					
Preferred Stock, \$.001 par value; 5,000,000 shares authorized; 2,093,155 shares of Series A Non-Voting Convertible Preferred Stock outstanding at June 30, 2016					
and December 31, 2015		2		2	
		54		53	

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Common Stock, \$.001 par value; 75,000,000 shares authorized; 53,610,470 and<br/>52,730,799 shares issued; 53,594,979 and 52,715,308 shares outstanding at June<br/>30, 2016 and December 31, 2015, respectively285,072Additional paid-in capital285,072Treasury stock, at cost, 15,491 shares(47)Accumulated deficit(278,422)Total stockholders equity6,659Total liabilities and stockholders equity\$ 77,695

See notes to condensed consolidated financial statements.

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274,891

(243,203)

31,696

102,772

\$

(47)

# **BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

# (U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

#### (Unaudited)

	Three Months Ended June 30, 2016 2015			Six Months Ende 2016			ed June 30, 2015	
Revenues:								
Product sales	\$	2,110	\$	833	\$	4,212	\$	1,510
Product royalty revenues		394		469		1,328		663
Research and development reimbursements				80		4		855
Contract revenues		2,500		351		2,500		11,759
Total Revenues:		5,004		1,733		8,044		14,787
Cost of sales		4,094		2,621		6,644		3,745
Expenses:								
Research and development		4,008		4,506		9,385		11,054
Selling, general and administrative		12,496		13,287		25,551		26,468
Total Expenses:		16,504		17,793		34,936		37,522
Loss from operations		(15,594)		(18,681)		(33,536)		(26,480)
Interest expense, net		(914)		(527)		(1,691)		(947)
Derivative gain		22				22		
Other (expense) income, net				(3)		(14)		23
Net loss	\$	(16,486)	\$	(19,211)	\$	(35,219)	\$	(27,404)
Basic and diluted loss per share:	\$	(0.31)	\$	(0.37)	\$	(0.66)	\$	(0.53)
Weighted average common stock shares outstanding:	5	3,594,979	5	52,401,747	5	3,412,813	5	2,156,657

See notes to condensed consolidated financial statements.

## **BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

# CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

# (U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

	Preferred Series Shares		Common S Shares	Stock Amount	Additional Paid-In Capital	Treas Sto	•	AccumulatedS Deficit	Total tockholders Equity
Balances,									
January 1, 2016	2,093,155	\$ 2	52,730,799	\$ 53	\$ 274,891	\$	(47)	\$ (243,203)	\$ 31,696
Stock-based									
compensation					7,457				7,457
Exercise of stock									
options			112,425		225				225
Vesting of									
restricted stock									
awards			104,025						
Common stock									
issuance upon									
retirement			663,221	1	2,459				2,460
Equity financing									
costs					40				40
Net loss								(35,219)	(35,219)
Balances, June 30, 2016	2,093,155	\$ 2	53,610,470	\$ 54	\$ 285,072	\$	(47)	\$ (278,422)	\$ 6,659

See notes to condensed consolidated financial statements.

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# **BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

#### Six months ended

	June	June 30,		
	2016	2015		
Operating activities:				
Net loss	\$ (35,219)	\$(27,404)		
Depreciation	212	167		
Accretion of debt discount	198	278		
Amortization of intangible assets	485	485		
Derivative liability	114			
Stock-based compensation expense	7,457	7,658		
Changes in assets and liabilities:				
Accounts receivable	80	1,614		
Inventories	(1,868)	295		
Prepaid expenses and other assets	321	133		
Accounts payable and accrued expenses	(441)	(2,210)		
Deferred revenue	90	(366)		
Net cash flows from operating activities	(28,571)	(19,350)		
Investing activities:				
Purchase of equipment	(249)	(583)		
Net cash flows from investing activities	(249)	(583)		
Financing activities:				
Proceeds from issuance of common stock	2,459			
Equity financing costs	40	(40)		
Proceeds from exercise of stock options	225	303		
Proceeds from exercise of common stock warrants		1		
Payment on note payable		(3,335)		
Proceeds from notes payable		20,667		
Payment of deferred financing fees		(486)		
Return of short swing profits		6		
Net cash flows from financing activities	2,724	17,116		
Net change in cash and cash equivalents	(26,096)	(2,817)		

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Cash and cash equivalents at beginning of year	83,560	70,472
Cash and cash equivalents at end of year	\$ 57,464	\$ 67,655
Cash paid for interest	\$ 1,358	\$ 491

See notes to condensed consolidated financial statements.

## **BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### (U.S. DOLLARS, IN THOUSANDS)

#### (Unaudited)

# 1. Organization, basis of presentation and summary of significant policies: *Overview*

BioDelivery Sciences International, Inc., together with its subsidiaries (collectively, the Company or BDSI) is a specialty pharmaceutical company that is developing and commercializing, either on its own or in partnerships with third parties, new applications of approved therapeutics to address important unmet medica