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

(Mark One)

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 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)

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Delaware (State or other jurisdiction of

35-2089858 (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 "

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 filer "

Accelerated filer

X

Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company " Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No x

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

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)

	June 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:				
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 52,730,799 shares issued; 53,594,979 and 52,715,308 shares outstanding at June 30, 2016 and December 31, 2015, respectively

Additional paid-in capital	285,072	274,891
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(278,422)	(243,203)
Total stockholders equity	6,659	31,696
Total liabilities and stockholders equity	\$ 77,695	\$ 102,772

See notes to condensed consolidated financial statements.

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 Ju 2016 20			d June 30, 2015	Six Months Er 2016		nded 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	
Cost of sales		1,001		2,021		0,011		3,7 13	
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	
T. C.		(15.504)		(10 (01)		(22.526)		(0(100)	
Loss from operations		(15,594)		(18,681)		(33,536)		(26,480)	
Interest expense, net		(914)		(527)		(1,691)		(947)	
Derivative gain		22		(2)		22		22	
Other (expense) income, net				(3)		(14)		23	
Net loss	\$	(16,486)	\$	(19,211)	\$	(35,219)	\$	(27,404)	
1,001	Ψ	(10,100)	Ψ	(12,=11)	Ψ	(00,21))	Ψ	(=1,101)	
Basic and diluted loss per share:	\$	(0.31)	\$	(0.37)	\$	(0.66)	\$	(0.53)	
Weighted average common stock shares									
outstanding:		53,594,979		52,401,747		53,412,813		52,156,657	

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	tock Amount	Additional Paid-In Capital	sury ock	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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

	Six months ended		
	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