

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 10-Q

November 09, 2015

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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
(State or other jurisdiction of
incorporation or organization)

35-2089858
(I.R.S. Employer
Identification No.)

4131 ParkLake Ave., Suite 225

Raleigh, NC
(Address of principal executive offices)

27612
(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 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, 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

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 November 6, 2015, there were 52,680,799 shares of company Common Stock issued and 52,665,308 shares of company Common Stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

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	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,429	\$ 70,472
Accounts receivable, net	1,406	3,141
Inventory	1,887	1,828
Prepaid expenses and other current assets	3,609	2,882
Total current assets	61,331	78,323
Property and equipment, net	4,261	3,890
Goodwill	2,715	2,715
Other intangible assets, net	3,498	4,226
Other assets	610	157
Total assets	\$ 72,415	\$ 89,311
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 14,973	\$ 14,429
Notes payable, current maturities	4,000	8,000
Deferred revenue, current	7,236	6,772
Total current liabilities	26,209	29,201
Notes payable, less current maturities, net	25,679	4,173
Deferred revenue, long-term		841
Other long-term liabilities	825	700
Total liabilities	52,713	34,915
Commitments and contingencies (Notes 6, 7 and 10)		
Stockholders equity:		
Preferred Stock, \$.001 par value; 5,000,000 shares authorized; 2,093,155 and 2,139,000 shares of Series A Non-Voting Convertible Preferred Stock outstanding at September 30, 2015 and December 31, 2014, respectively	2	2

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Common Stock, \$.001 par value; 75,000,000 shares authorized; 52,655,369 and 51,603,070 shares issued; 52,639,878 and 51,587,579 shares outstanding at September 30, 2015 and December 31, 2014, respectively	53	52
Additional paid-in capital	273,069	259,920
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(253,375)	(205,531)
Total stockholders' equity	19,702	54,396
Total liabilities and stockholders' equity	\$ 72,415	\$ 89,311

See notes to condensed consolidated financial statements

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Product sales	\$ 1,155	\$	\$ 2,665	\$
Product royalty revenues	25	12	689	1,858
Research and development reimbursements	55	1,298	909	12,067
Contract revenues		513	11,759	22,472
Total Revenues:	1,235	1,823	16,022	36,397
Cost of sales	1,699	463	5,443	1,875
Expenses:				
Research and development	4,473	6,770	15,527	29,376
General and administrative	14,715	13,648	41,185	25,533
Total Expenses:	19,188	20,418	56,712	54,909
Loss from operations	(19,652)	(19,058)	(46,133)	(20,387)
Interest expense, net	(785)	(515)	(1,732)	(1,589)
Derivative loss		(5,685)		(14,631)
Other (expense) income, net	(2)	2	21	35
Net loss	\$ (20,439)	\$ (25,256)	\$ (47,844)	\$ (36,572)
Basic and diluted loss per share:	\$ (0.39)	\$ (0.51)	\$ (0.92)	\$ (0.77)
Weighted average common stock shares outstanding:	52,542,715	49,555,815	52,286,757	47,391,040

See notes to condensed consolidated financial statements

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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 Stock		Common Stock		Additional	Treasury	Accumulated	Total
	Series A Shares	Amount	Shares	Amount	Paid-In Capital	Stock	Deficit	Stockholders Equity
Balances, January 1, 2015	2,139,000	\$ 2	51,603,070	\$ 52	\$ 259,920	\$ (47)	\$ (205,531)	\$ 54,396
Stock-based compensation					12,703			12,703
Restricted stock awards			857,677	1	(1)			
Exercise of stock options			148,493		480			480
Exercise of warrants			284		1			1
Short swing profit return					6			6
Conversion of preferred shares to common shares	(45,845)		45,845					
Equity financing costs					(40)			(40)
Net loss							(47,844)	(47,844)
Balances, September 30, 2015	2,093,155	\$ 2	52,655,369	\$ 53	\$ 273,069	\$ (47)	\$ (253,375)	\$ 19,702

See notes to condensed consolidated financial statements

Table of Contents**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(U.S. DOLLARS, IN THOUSANDS)****(Unaudited)**

	Nine months ended	
	September 30,	
	2015	2014
Operating activities:		
Net loss	\$ (47,844)	\$ (36,572)
Depreciation	248	55
Accretion of debt discount	400	482
Amortization of intangible assets	728	728
Derivative loss		14,631
Stock-based compensation expense	12,703	4,857
Changes in assets and liabilities:		
Accounts receivable	1,734	2,589
Inventories	(59)	(2,024)
Prepaid expenses and other assets	(727)	(805)
Accounts payable and accrued expenses	477	2,978
Deferred revenue	(377)	2,282
Net cash flows from operating activities	(32,717)	(10,799)
Investing activities:		
Purchase of equipment	(619)	(1,554)
Net cash flows from investing activities	(619)	(1,554)
Financing activities:		
Proceeds from sales of securities		70,718
Equity financing costs	(40)	
Proceeds from exercise of stock options	480	4,573
Proceeds from exercise of common stock warrants	1	4,931
Payment on note payable	(3,335)	(5,333)
Proceeds from notes payable	20,667	
Payment of deferred financing fees	(486)	
Return of short swing profits	6	82
Net cash flows from financing activities	17,293	74,971
Net change in cash and cash equivalents	(16,043)	62,618

Cash and cash equivalents at beginning of year	70,472	23,176
Cash and cash equivalents at end of period	\$ 54,429	\$ 85,794
Cash paid for interest	\$ 1,201	\$ 1,065

See notes to condensed consolidated financial statements

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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 leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. The Company is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

The accompanying unaudited condensed consolidated financial statements include all adjustments (consisting of normal and recurring adjustments) necessary for a fair presentation of these financial statements. The condensed consolidated balance sheet at December 31, 2014 has been derived from the Company's audited consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2014. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP) have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. It is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2014.

Operating results for the three and nine month period ended September 30, 2015 are not necessarily indicative of results for the full year or any other future periods.

As used herein, the Company's common stock, par value \$.001 per share, is referred to as the Common Stock.

Use of estimates in financial statements

The preparation of the accompanying condensed consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

Inventory

Inventories are stated at the lower of cost or market value with costs determined on the first-in, first-out method. Inventory consists of raw materials, work in process and finished goods. Raw materials include active pharmaceutical ingredient for a product to be manufactured, work in process includes the bulk inventory of laminate prior to being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale.

On a quarterly basis, the