

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
August 10, 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 June 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)

4131 ParkLake Ave., Suite 225

Raleigh, NC
(Address of principal executive offices)

Registrant's telephone number (including area code): 919-582-9050

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

27612
(Zip 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, 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 August 7, 2015, there were 52,476,926 shares of company Common Stock issued and 52,461,435 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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	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,655	\$ 70,472
Accounts receivable, net	1,526	3,141
Inventory	1,533	1,828
Prepaid expenses and other current assets	2,749	2,882
Total current assets	73,463	78,323
Property and equipment, net	4,305	3,890
Goodwill	2,715	2,715
Other intangible assets, net	3,741	4,226
Other assets	684	157
Total assets	\$ 84,908	\$ 89,311
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 12,263	\$ 14,429
Notes payable, current maturities	1,000	8,000
Deferred revenue, current	7,247	6,772
Total current liabilities	20,510	29,201
Notes payable, less current maturities, net	28,653	4,173
Deferred revenue, long-term		841
Other long-term liabilities	825	700
Total liabilities	49,988	34,915
Commitments and contingencies (Notes 6 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 June 30, 2015 and December 31, 2014, respectively	2	2
Common Stock, \$.001 par value; 75,000,000 shares authorized; 52,436,926 and	53	52

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51,603,070 shares issued; 52,421,435 and 51,587,579 shares outstanding at June 30, 2015 and December 31, 2014, respectively

Additional paid-in capital	267,847	259,920
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(232,935)	(205,531)
Total stockholders' equity	34,920	54,396
Total liabilities and stockholders' equity	\$ 84,908	\$ 89,311

See notes to condensed consolidated financial statements

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues:				
Product sales	\$ 833	\$	\$ 1,510	\$
Product royalty revenues	469	892	663	1,846
Research and development reimbursements	80	2,318	855	10,770
Contract revenues	351	10,675	11,759	21,959
Total Revenues:	1,733	13,885	14,787	34,575
Cost of sales	2,621	687	3,745	1,413
Expenses:				
Research and development	4,506	7,983	11,054	22,606
General and administrative	13,287	7,256	26,468	11,884
Total Expenses:	17,793	15,239	37,522	34,490
Loss from operations	(18,681)	(2,041)	(26,480)	(1,328)
Interest expense, net	(527)	(519)	(947)	(1,074)
Derivative loss		(4,120)		(8,946)
Other (expense) income, net	(3)	9	23	32
Net loss	\$ (19,211)	\$ (6,671)	\$ (27,404)	\$ (11,316)
Basic and diluted loss per share:	\$ (0.37)	\$ (0.14)	\$ (0.53)	\$ (0.24)
Weighted average common stock shares outstanding:	52,401,747	48,521,351	52,156,657	46,290,712

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				Paid-In	Stock	Deficit	Stockholders
	Shares	Amount	Shares	Amount	Capital			Equity
Balances, January 1, 2015	2,139,000	\$ 2	51,603,070	\$ 52	\$ 259,920	\$ (47)	\$ (205,531)	\$ 54,396
Stock-based compensation					7,658			7,658
Restricted stock awards			712,677	1	(1)			
Exercise of stock options			75,050		303			303
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							(27,404)	(27,404)
Balances, June 30, 2015	2,093,155	\$ 2	52,436,926	\$ 53	\$ 267,847	\$ (47)	\$ (232,935)	\$ 34,920

See notes to condensed consolidated financial statements

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	Six months ended	
	June 30,	
	2015	2014
Operating activities:		
Net loss	\$ (27,404)	\$ (11,316)
Depreciation	167	25
Accretion of debt discount	278	321
Amortization of intangible assets	485	485
Derivative loss		8,946
Stock-based compensation expense	7,658	2,479
Changes in assets and liabilities:		
Accounts receivable	1,614	(9,846)
Inventories	295	(795)
Prepaid expenses and other assets	133	30
Accounts payable and accrued expenses	(2,210)	(602)
Deferred revenue	(366)	1,535
Net cash flows from operating activities	(19,350)	(8,738)
Investing activities:		
Purchase of equipment	(583)	(1,020)
Net cash flows from investing activities	(583)	(1,020)
Financing activities:		
Proceeds from sales of securities		62,037
Equity financing costs	(40)	
Proceeds from exercise of stock options	303	2,833
Proceeds from exercise of common stock warrants	1	3,994
Payment on note payable	(3,335)	(4,000)
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	17,116	64,946
Net change in cash and cash equivalents	(2,817)	55,188

Cash and cash equivalents at beginning of year	70,472	23,176
Cash and cash equivalents at end of year	\$ 67,655	\$ 78,364
Cash paid for interest	\$ 491	\$ 824

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. The Company has reclassified certain amounts within expenses in the Statements of Operations for the three and six month periods ended June 30, 2014 to conform to the current year presentation. These reclassifications had no effect on the measurement of total expenses, loss from operations, or net loss. We also made certain reclassifications in a footnote table for the year ending December 31, 2014 to conform to the current period presentation.

Operating results for the three and six month period ended June 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 Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. There were no allowances recorded at June 30, 2015.

Deferred revenue

Consistent with the Company's revenue recognition policy, deferred revenue represents cash received in advance for licensing fees, consulting, research and development services, related supply agreements and product sales. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)