

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
August 07, 2014
Table of Contents

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, 2014

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.)

801 Corporate Center Drive, Suite #210

Raleigh, NC
(Address of principal executive offices)

27607
(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 August 5, 2014, there were 49,315,401 shares of company Common Stock issued and 49,299,910 shares of company Common Stock outstanding.

Table of Contents

BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

TABLE OF CONTENTS

	Page
Part I. Financial Information	
Item 1. Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013</u>	1
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2014 and 2013</u>	2
<u>Condensed Consolidated Statement of Stockholders' Equity (Deficit) for the six months ended June 30, 2014</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2014 and 2013</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	24
<u>Cautionary Note on Forward Looking Statements</u>	25
Part II. Other Information	
<u>Item 1. Legal Proceedings</u>	25
<u>Item 5. Other Information</u>	28
<u>Item 6. Exhibits</u>	28
<u>Signatures</u>	S-1
Certifications	

Table of Contents**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****AS OF JUNE 30, 2014 AND DECEMBER 31, 2013**

	June 30, 2014 (unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 78,364,276	\$ 23,175,809
Accounts receivable	12,639,549	2,794,040
Inventory	795,374	
Prepaid expenses and other current assets	600,998	630,657
Total current assets	92,400,197	26,600,506
Equipment, net	237,908	178,168
Idle equipment, net (note 1)	3,462,926	2,844,718
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	9,050,000	9,050,000
Accumulated amortization	(6,238,680)	(5,753,502)
Total other intangible assets	4,711,320	5,196,498
Other assets	313,690	470,535
Total assets	\$ 103,841,041	\$ 38,005,425
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 9,496,763	\$ 10,415,981
Notes payable, current maturities	7,333,334	7,333,333
Deferred revenue, current (notes 3 and 4)	1,302,766	2,927,088
Derivative liabilities (note 8)	10,761,692	4,315,183
Total current liabilities	28,894,555	24,991,585
Notes payable, less current maturities	8,009,099	11,844,706
Deferred revenue, long-term	4,440,889	1,281,485
Other long-term liabilities	700,000	700,000
Total liabilities	42,044,543	38,817,776
Commitments and contingencies (note 10)		
Stockholders' equity (deficit):		
	2,139	2,709

Preferred Stock, \$.001 par value; 5,000,000 shares authorized; 2,139,000 and 2,709,300 shares of Series A Non-Voting Convertible Preferred Stock outstanding in 2014 and 2013, respectively.

Common Stock, \$.001 par value; 75,000,000 shares authorized; 49,125,877 and 38,204,384 shares issued; 49,110,386 and 38,188,893 shares outstanding in 2014 and 2013, respectively

	49,126	38,204
Additional paid-in capital	224,421,204	150,506,927
Treasury stock, at cost, 15,491 shares	(47,183)	(47,183)
Accumulated deficit	(162,628,788)	(151,313,008)
Total stockholders' equity (deficit)	61,796,498	(812,351)
Total liabilities and stockholders' equity (deficit)	\$ 103,841,041	\$ 38,005,425

See notes to condensed consolidated financial statements

Table of Contents**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2014 AND 2013****(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Product royalties	\$ 892,098	\$ 855,101	\$ 1,846,088	\$ 855,101
Research and development reimbursements	2,317,584		10,769,563	
Contract revenues	10,674,895	1,908,949	21,958,728	3,530,926
Total Revenues:	13,884,577	2,764,050	34,574,379	4,386,027
Cost of product royalty revenues	686,966	690,207	1,412,563	1,065,207
Expenses:				
Research and development	7,982,976	12,758,215	22,606,197	24,790,383
General and administrative	7,249,960	3,110,754	11,871,984	6,021,010
Related party general and administrative, net	6,000	13,000	12,000	29,500
Total Expenses:	15,238,936	15,881,969	34,490,181	30,840,893
Loss from operations	(2,041,325)	(13,808,126)	(1,328,365)	(27,520,073)
Interest (expense) income, net	(518,773)	96,006	(1,074,018)	168,516
Derivative (loss) gain	(4,120,324)	392,586	(8,945,782)	1,417,537
Other income (expense), net	9,053	(95,477)	32,385	(118,631)
Net loss before taxes	(6,671,369)	(13,415,011)	(11,315,780)	(26,052,651)
Income tax expense				(85,000)
Net loss attributable to common stockholders	(6,671,369)	\$ (13,415,011)	(11,315,780)	\$ (26,137,651)
Basic earnings per share:	\$ (0.14)	\$ (0.35)	\$ (0.24)	\$ (0.69)
Diluted earnings per share:	\$ (0.14)	\$ (0.35)	\$ (0.24)	\$ (0.69)
Weighted average common stock shares outstanding:	48,521,351	37,998,610	46,290,712	37,756,309

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)
FOR THE SIX MONTHS ENDED JUNE 30, 2014
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
	Series A Shares	Amount	Shares	Amount				
Balances, January 1, 2014	2,709,300	\$ 2,709	38,204,384	\$ 38,204	\$ 150,506,927	\$ (47,183)	\$ (151,313,008)	\$ (812,351)
Stock-based compensation					2,479,256			2,479,256
Restricted stock awards			363,893	364	(364)			
Exercise of stock options			932,391	932	2,831,602			2,832,534
Exercise of warrants			798,871	799	3,993,557			3,994,356
Cashless exercise of warrants			97,549	98	(98)			
Shares issued pursuant to registered direct offering, net			7,500,000	7,500	58,173,672			58,181,172
Shares issued pursuant to an at the market offering, net			658,489	659	3,855,042			3,855,701
Warrant derivative liability reclassified to equity					2,499,273			2,499,273
Short swing profit return					82,337			82,337
Conversion of preferred shares to common shares	(570,300)	(570)	570,300	570				

Net loss (11,315,780) (11,315,780)

Balances,
June 30, 2014 2,139,000 \$ 2,139 49,125,877 \$ 49,126 \$ 224,421,204 \$(47,183) \$(162,628,788) \$ 61,796,498

See notes to condensed consolidated financial statements

Table of Contents**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013****(Unaudited)**

	Six months Ended June 30,	
	2014	2013
Operating activities:		
Net loss	\$ (11,315,780)	\$ (26,137,651)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	509,741	685,759
Debt costs	321,240	
Derivative loss (gain)	8,945,782	(1,417,537)
Purchase of Arcion license with common stock		2,072,136
Stock-based compensation expense	2,479,256	1,365,259
Changes in assets and liabilities:		
Accounts receivable	(9,845,509)	11,796
Inventory	(795,374)	
Prepaid expenses and other assets	29,659	(21,672)
Accounts payable and accrued liabilities	(601,493)	1,121,820
Income tax payable		85,000
Deferred revenue	1,535,082	(3,530,926)
Net cash flows from operating activities	(8,737,396)	(25,766,016)
Investing activities:		
Purchase of equipment	(1,020,237)	(1,648)
Net cash flows from investing activities	(1,020,237)	(1,648)
Financing activities:		
Proceeds from sale of securities	62,036,873	
Proceeds from exercise of stock options	2,832,534	9,235
Proceeds from exercise of common stock warrants	3,994,356	
Payment of notes payable	(4,000,000)	
Return of short swing profits	82,337	
Net cash flows from financing activities	64,946,100	9,235
Net change in cash and cash equivalents	55,188,467	(25,758,429)
Cash and cash equivalents at beginning of period	23,175,809	63,189,307