

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 10-Q

May 15, 2017

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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 March 31, 2017

**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	35-2089858 (I.R.S. Employer
incorporation or organization)	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
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 15, 2017, there were 55,341,463 shares of company Common Stock issued and 55,325,972 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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	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	\$ 35,219	\$ 32,019
Accounts receivable, net	7,102	3,569
Inventory	8,145	3,368
Prepaid expenses and other current assets	3,942	4,136
Total current assets	54,408	43,092
Property and equipment, net	4,549	4,230
Goodwill	2,715	2,715
BELBUCA® license and distribution rights intangible	45,000	
Other intangible assets, net	918	2,285
Total assets	\$ 107,590	\$ 52,322
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 30,521	\$ 18,174
Deferred revenue, current		1,716
Total current liabilities	30,521	19,890
Notes payable, less current maturities, net	34,800	29,272
Deferred revenue, long-term		20,000
Other long-term liabilities	4,050	825
Total liabilities	69,371	69,987
Commitments and contingencies (Notes 11 and 14)		
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 both March 31, 2017 and December 31, 2016, respectively.	2	2
Common Stock, \$.001 par value; 75,000,000 shares authorized; 55,341,463 and 54,133,511 shares issued; 55,325,972 and 54,118,020 shares outstanding at	55	54

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March 31, 2017 and December 31, 2016, respectively.

Additional paid-in capital	300,225	292,667
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(262,016)	(310,341)
Total stockholders' equity (deficit)	38,219	(17,665)
Total liabilities and stockholders' equity (deficit)	\$ 107,590	\$ 52,322

See notes to condensed consolidated financial statements

Table of Contents**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 March 31,	
	2017	2016
Revenues:		
Product sales	\$ 7,795	\$ 2,102
Product royalty revenues	1,661	934
Research and development reimbursements	22	4
Contract revenues	20,000	
Total Revenues:	29,478	3,040
Cost of sales	5,645	2,550
Expenses:		
Research and development	2,671	5,377
Selling, general and administrative	13,259	13,055
Total Expenses:	15,930	18,432
Income (loss) from operations	7,903	(17,942)
Interest expense, net	(2,886)	(778)
Other expense, net		(13)
Bargain purchase gain	27,336	
Income (loss)	\$ 32,353	\$ (18,733)
Income tax benefit	15,972	
Net income (loss) attributable to common stockholders	\$ 48,325	\$ (18,733)
Basic		
Basic income (loss) per share:	\$ 0.89	\$ (0.36)
Weighted average common stock shares outstanding:	54,519,574	52,230,648
Diluted		
Diluted income (loss) per share:	\$ 0.87	\$ (0.36)

Diluted weighted average common stock shares outstanding:	55,431,628	52,230,648
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See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)
(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balances, January 1, 2017	2,093,155	\$ 2	54,133,511	\$ 54	\$ 292,667	\$ (47)	\$ (310,341)	\$ (17,665)
Stock-based compensation					3,070			3,070
Restricted stock awards			1,207,952	1	(1)			
Issuance of warrants					4,489			4,489
Net income							48,325	48,325
Balances, March 31, 2017	2,093,155	\$ 2	55,341,463	\$ 55	\$ 300,225	\$ (47)	\$ (262,016)	\$ 38,219

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)**

	Three months ended	
	March 31,	
	2017	2016
Operating activities:		
Net income (loss)	\$ 48,325	\$(18,733)
Depreciation	111	86
Accretion of debt discount and loan costs	1,040	99
Amortization of intangible assets	1,369	243
Stock-based compensation expense	3,070	4,111
Deferred income taxes	(15,972)	
Bargain purchase gain	(27,336)	
Changes in assets and liabilities:		
Accounts receivable	(3,531)	356
Inventories, net of effect of acquisition	633	(2,263)
Prepaid expenses and other assets	194	118
Accounts payable and accrued expenses, net of effect of acquisition	4,811	(438)
Deferred revenue	(21,716)	(235)
Net cash flows from operating activities	(9,002)	(16,656)
Investing activities:		
Purchase of equipment		(236)
Net cash flows from investing activities		(236)
Financing activities:		
Proceeds from notes payable	45,000	
Payment of notes payable	(30,000)	
Payment of deferred financing fees	(2,798)	
Equity financing costs		40
Proceeds from exercise of stock options		225
Proceeds from issuance of common stock		2,460
Net cash flows from financing activities	12,202	2,725
Net change in cash and cash equivalents	3,200	(14,167)
Cash and cash equivalents at beginning of year	32,019	83,560

Cash and cash equivalents at end of period	\$ 35,219	\$ 69,393
Cash paid for interest	\$ 946	\$ 679

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SUPPLEMENTAL CASH FLOW INFORMATION

(U.S. DOLLARS IN THOUSANDS EXCEPT SHARE DATA)

Non-cash Financing and Investing Activities:

The Company recorded the fair value of the bargain purchase price of the BELBUCA® acquisition totaling \$27.3 million to income during the three months ended March 31, 2017 in accordance with US GAAP (note 7).

The Company recorded the fair value of warrants totaling \$4.5 million to equity with an offsetting amount to Notes payable in connection with the CRG term loan during the three months ended March 31, 2017 in accordance with US GAAP (note 12).

See notes to 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 developing and commercializing, either on its own or in partnerships with third parties, new applications of approved therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. 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, 2016 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, 2016. 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, 2016.

Operating results for the three month periods ended March 31, 2017 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.

Principles of consolidation

The condensed consolidated financial statements include the accounts of the Company, Arius Pharmaceuticals, Inc. (Arius), Arius Two, Inc. (Arius Two) and Bioral Nutrient Delivery, LLC (BND). For each period presented BND has been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Use of estimates in financial statements

The preparation of the accompanying condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. The Company reviews all significant estimates affecting the consolidated financial statements on a recurring basis and records the effect of any necessary adjustments prior to their issuance. Significant estimates of the Company include: revenue

recognition, sales allowances such as returns of product sold, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, stock-based compensation, determination of fair values of assets and liabilities in connection with business combinations, and deferred income taxes.

Reacquisition of BELBUCA®

On December 7, 2016, the Company entered into an agreement (the Termination Agreement) with Endo Pharmaceuticals, Inc. (Endo) terminating Endo's licensing of rights to the Company's BELBUCA® (buprenorphine) buccal film product (BELBUCA®). The closing of the Termination Agreement, and the formal termination of the BELBUCA® license to Endo and closing of the transactions further described below occurred on January 6, 2017 (see note 7, Business Combinations and Asset Acquisitions).

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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 (continued):

Inventory

Other than the inventory purchased from Endo which is stated at fair value, inventories are stated at the lower of cost or net realized value with costs determined for each batch under the first-in, first-out method and specifically al