



BioDelivery Sciences Reports First Quarter 2017 Financial Results and Provides Corporate Update

May 15, 2017

Product Related Net Revenue of \$9.5 Million in 1Q 2017 vs \$3.3 Million in 4Q 2016

BELBUCA® Q1 Net Revenue of \$4.6 Million Drives Commercial Business Unit to Profitability in March 2017

BELBUCA Net Revenue Hits All Time High in March

First Quarter BDSI Net Revenue of \$29.5 Million (Including \$20 Million of Deferred Revenue) and \$43.3 Million from BELBUCA Reacquisition Provide EPS of \$0.87 vs (\$0.30) in 4Q 2016

Conference Call on Monday, May 15 @ 4:30pm Eastern Time

RALEIGH, N.C., May 15, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) today reported financial results for the first quarter ended March 31, 2017 and provided a corporate update.

"We are very pleased with the financial results of the first quarter, particularly what we were able to accomplish with BELBUCA® in our hands," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "We completed a swift and effective transition of BELBUCA following the early January close of the transaction with Endo Pharmaceuticals (Endo), and by the end of the quarter, we were generating sufficient product revenue to offset the expense of our commercial business unit. In fact, we recorded the highest net sales revenue for BELBUCA since the product was launched over a year ago, and albeit early in the relaunch, it appears our focused selling approach and commercial strategy are working. These efforts led to first quarter sales of \$4.6 million in comparison to what would have been approximately \$640 thousand in royalties had we not reacquired the product. Importantly, the impact of the BELBUCA license termination and reacquisition has resulted in \$43.3 million in value that is added to BDSI's balance sheet. This gain in value arises out of the very favorable terms on which BDSI reacquired BELBUCA. In addition, we are vigorously pursuing potential licensing agreements and remain focused on securing up to two ex-U.S. partnerships for BELBUCA in the coming months."

"As for BUNAVAIL®, we will continue to focus our efforts on our current prescribers while working to secure new managed contracts where BUNAVAIL is in a favorable position. BUNAVAIL generated \$3.2 million in revenue for the quarter."

"Finally, to support our currently planned activities into the second half of 2018, we recently completed a debt financing for a total of up to \$75 million, \$45 million of which was funded in February 2017. We believe this has allowed us to take the appropriate steps, in a non-dilutive fashion, to strengthen our balance sheet, which allows us to now put our full attention on growing the business."

First Quarter 2017 Financial Highlights

Net revenue for the first quarter ended March 31, 2017, was approximately \$29.5 million. Total net sales of BELBUCA (buprenorphine) buccal film (CIII) and BUNAVAIL (buprenorphine and naloxone) buccal film (CIII) in the first quarter were \$4.6 million and \$3.2 million, respectively. This compares to BUNAVAIL total net revenue of approximately \$2.1 million in the first quarter of 2016. The \$20 million of contract revenues recorded in the three months ended March 31, 2017, is related to the release of deferred revenue for BELBUCA upon the reacquisition from Endo. This deferred revenue was part of the \$50 million NDA approval milestone payment received by BDSI from Endo. The \$20 million had been deferred because it was tied to the entry of any generic competition between 2020 and 2027.

Total operating expenses for the first quarter ended March 31, 2017, were \$15.9 million, compared to \$18.4 million in the first quarter of 2016, with the reduction in operating expenses being attributable to reduced research and development spending.

Net income for the first quarter ended March 31, 2017 was \$48.3 million, or \$0.89 per basic and \$0.87 per diluted share, compared to a net loss of \$18.7 million, or (\$0.36) per basic and diluted share, in the same period of 2016. The increase in net income was attributable principally to the impact of the valuation of the licensing and distribution agreement for BELBUCA and recognition of deferred revenue associated with the license termination and reacquisition of BELBUCA.

BDSI had cash and cash equivalents of approximately \$35.2 million at March 31, 2017, including net proceeds of \$13.7 million from the initial funding under the CRG facility in February 2017. This compares to cash and cash equivalents of approximately \$32.0 million at December 31, 2016.

BDSI also began recognizing revenue using the sell-in method, which records sales based on product sold to wholesalers versus sell-through method previously. As such, we recognized \$1.7 million of the \$3.2 million of BUNAVAIL sales for product shipped to wholesalers prior to January 1, 2017.

Recent Company Milestones

Commercial

- Closed on an agreement with Endo Pharmaceuticals, terminating Endo's licensing of rights for BELBUCA and returning worldwide rights to the product back to BDSI.

- Generated total product revenue of \$9.5 million in the first quarter of 2017
 - Achieved the highest net sales level for BELBUCA since the product was launched.
 - Achieved profitability in commercial business unit in the month of March, although not full enterprise profitability.

Regulatory

- Received approval from the U.S. Food and Drug Administration's (FDA) for a Supplemental New Drug Application (sNDA) expanding the indication for BUNAVAIL to include induction of buprenorphine treatment for opioid dependence. Induction is the first step to assist a patient in discontinuing or markedly reducing their use of opioids.
- Received FDA acceptance of the Investigational New Drug (IND) for Sustained Release Buprenorphine Injection, allowing initiation of the clinical development program.

Intellectual Property

- Strengthened the intellectual property surrounding BELBUCA, BUNAVAIL and ONSOLIS®, with the granting of two new patents listed in FDA's Orange Book

Corporate

- Secured a \$75 million senior credit facility with affiliates of CRG LP, a healthcare-focused investment firm, to retire existing credit facility and provide additional working capital into the second half of 2018.

Key Anticipated 2017 Milestones

- Opportunity to execute up to two commercial transactions for ex-U.S. rights to BELBUCA in the coming months.
- Anticipated approval of BELBUCA in Canada in June 2017.
- Initiation of, and initial results from, an ascending, single dose pharmacokinetic study of sustained release buprenorphine injection. Results from the first dosing cohort expected to be available in the fourth quarter.
- Planned regulatory submission later this year to qualify the new manufacturer for ONSOLIS (product licensed to Collegium Pharmaceutical) and, if approved, allows the product to return to market early in the first half of 2018.

Conference Call & Webcast

Monday, May 15 @ 4:30 PM Eastern Time

Domestic: 888-437-9364

International: 719-325-2133

Passcode: 7698100

Webcast: <http://public.viavid.com/index.php?id=124144>

Replays available through May 29th:

Domestic: 844-512-2921

International: 412-317-6671

Conference ID: 7698100

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology and other drug delivery technologies to

develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs.

BDSI's development strategy focuses on the utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: www.bdsi.com

Facebook: [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI)

Twitter: @BioDeliverySI

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and BELBUCA® (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. ONSOLIS® (fentanyl buccal soluble film) (CII) is licensed in the U.S. to Collegium Pharmaceutical pursuant to the U.S. licensing and development agreement between BDSI and Collegium. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS, please visit www.bdsi.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit www.belbuca.com and for full prescribing and safety information on BUNAVAIL, please visit www.bunavail.com.

Cautionary Note on Forward-Looking Statements

This press release and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, at the presentation described herein) contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results of commercialization efforts for the Company's approved products and the clinical trials for, and regulatory review of, the Company's products in development) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

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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)

	March 31,	December 31,
	2017	2016

ASSETS

Current assets:

Cash and cash equivalents	\$	35,219	\$	32,019
Accounts receivable		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, 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 and 2,093,155

shares of Series A Non-Voting Convertible Preferred Stock outstanding at both March 31, 2017 and December 31, 2016 and 2015, respectively.

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

	55	54
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Additional paid-in capital		300,225		292,667
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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

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 revenue	20,000	-
Total Revenues:	29,478	3,040
Cost of sales	5,645	2,550
Expenses:		
Research and development:	2,671	5,377
Sales, 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)
Weighted average common stock shares outstanding	55,431,628	52,230,648	

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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 year	\$	35,219	\$ 69,392
Cash paid for interest	\$	946	679

SOURCE BioDelivery Sciences International, Inc.

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