



## BioDelivery Sciences Reports Third Quarter 2017 Financial Results and Provides Corporate Update

November 9, 2017

**Third quarter net revenue of \$11.3 million; 29% increase over second quarter**  
**Third quarter earnings per share improved to (\$0.21) versus (\$0.27) in second quarter**  
**BELBUCA® third quarter prescriptions up 15% over second quarter**  
**All-time high in weekly and monthly BELBUCA total prescriptions achieved in October**  
**BELBUCA licensed to Purdue Pharma (Canada) for rights in Canada with launch anticipated in early 2018**  
**Finalized BUNAVAIL® Paragraph IV settlement agreement with Teva Pharmaceuticals**  
**BDSI qualifies for next \$15 million tranche as part of CRG loan**  
**Conference Call Today at 4:30 PM Eastern Time**

RALEIGH, N.C., Nov. 9, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) today reported financial results for the three and nine months ended September 30, 2017, and provided an update on recent business highlights and upcoming milestones.



"We continue to have strong sales momentum behind BELBUCA® since its reacquisition in January," said Dr. Mark A. Sirgo, Vice Chairman, President and Chief Executive Officer of BioDelivery Sciences. "Our solid performance in the third quarter continued the encouraging trend we have seen with BELBUCA, as we achieved prescription growth of 15% over the second quarter. The favorable trend continued into October as BELBUCA monthly total prescriptions reached an all-time high in excess of 8,000 based on preliminary sales data. Going forward, we anticipate continued growth of BELBUCA prescriptions behind our focused sales strategy, new and improved managed care coverage including Medicare, and efforts to continue our participatory role in working with government agencies and legislators to highlight the benefits of BELBUCA as part of the solution to the opioid crisis."

Dr. Sirgo continued, "This has been an extremely productive quarter, with not only strong BELBUCA prescription growth, but also the completion of an important licensing agreement with Purdue Pharma (Canada) for BELBUCA, with launch scheduled in early 2018, and the completion of the significant Paragraph IV patent settlement agreement with Teva regarding BUNAVAIL® that provides additional certainty to our patent portfolio. Finally, we also qualified for the next \$15 million-dollar tranche from our CRG loan agreement, and should we decide to exercise this option, it would provide us with capital given the current operating plan into 2019."

### Third Quarter 2017 Financial Highlights

Net revenue for the third quarter ended September 30, 2017, was approximately \$11.3 million, compared to \$8.7 million in the second quarter of 2017, an increase of 29%, and \$3.6 million in the third quarter of 2016.

Total net revenue for BELBUCA and BUNAVAIL in the third quarter was \$6.4 million and \$1.7 million respectively, versus \$6.6 million and \$1.3 million in the second quarter of 2017. This compares to BELBUCA (royalty) and BUNAVAIL revenue of \$2.3 million in the third quarter of 2016. BELBUCA net revenue in the third quarter was affected by a one-time cumulative gross to net adjustment secondary to commercial contract utilization that was higher than the original estimate which was carried over from Endo following the reacquisition.

Total operating expenses for the third quarter ended September 30, 2017, were \$16.9 million, compared to \$16.5 million in the third quarter of 2016.

Net loss for the third quarter ended September 30, 2017, was \$12.0 million, or (\$0.21) per diluted share, compared to a net loss of \$14.9 million, or (\$0.27) per diluted share in the second quarter. This compares to a loss of \$16.0 million or (\$0.30) per diluted share, in the same period of 2016. The decrease in net loss was attributable principally to net profitability from the reacquisition of BELBUCA in January 2017.

At September 30, 2017, BDSI had cash and cash equivalents of approximately \$19.7 million. This compares to cash and cash equivalents of approximately \$27.5 million at June 30, 2017. In the third quarter, BDSI met the financial requirements to access the next \$15 million tranche in its loan agreement with CRG. Should the company decide to execute this option, it would provide capital into 2019."

### Nine Months Ended June 30, 2017 Financial Highlights

Net revenue for the nine months ended September 30, 2017, was approximately \$49.5 million, compared to \$11.6 million in the same period of 2016. Total net sales of BELBUCA and BUNAVAIL in the first nine months of 2017 were \$17.6 million and \$6.2 million, respectively. Also recognized in net revenue for the nine months ended September 30, 2017, was \$20 million of deferred revenue for BELBUCA upon termination of the license with Endo.

Total operating expenses for the nine months ended September 30, 2017, were \$50.3 million, compared to \$51.4 million in the same period of 2016.

Net income for the nine months ended September 30, 2017, was \$21.5 million, or \$0.38 per diluted share, compared to a net loss of \$51.2 million, or (\$0.96) per diluted share, in the same period of 2016. The increase in net income was attributable principally to BELBUCA net profitability, favorable valuation of the licensing and distribution agreement for BELBUCA and recognition of deferred revenue associated with the license termination and reacquisition of BELBUCA.

## **Recent Company Milestones**

### Commercial

- Solid BELBUCA growth in the third quarter, with total prescription sales increasing 15% over the prior quarter. BELBUCA total prescriptions reached their highest monthly total to date in October based on preliminary sales data, with well over 8,000 prescriptions. Additionally, weekly prescription sales also hit an all-time high in October and are now approaching 2,000 per week.
- BELBUCA sales metrics continue to show noteworthy first year improvement since reacquisition, with monthly prescriptions (in September) up 30% over January.
- Recently secured Medicare contracts, representing up to 40% of claims, go into effect on January 1, 2018.
- A recently announced exclusive licensing, distribution, marketing and sales agreement with Purdue Pharma (Canada) for BELBUCA in Canada.
  - In return for the licensing and distribution rights to BELBUCA in Canada, BDSI is eligible to receive upfront and potential milestones of up to CAD \$4.5 million, as well as royalties on net sales.
  - Received market authorization to formally transfer the Drug Identification Number ownership of BELBUCA in Canada to Purdue Pharma, triggering a milestone payment to BDSI.
- Presented data on BELBUCA at PainWeek 2017 Conference
  - Review of the adverse event data from 16 clinical trials, representing a total of 2,458 subjects, indicated that BELBUCA's safety profile was consistent with the ceiling effect of buprenorphine on respiratory depression that has been described in scientific literature.
  - Evaluation of potential economic effects of the use of buprenorphine for pain, and found that its use may reduce the need for additional medical services, and could potentially provide cost savings to payers and patients.

### Corporate

- Participated in a round table meeting convened by the U.S. Department of Health and Human Services to discuss solutions to the opioid crisis.

### Intellectual Property

- BDSI resolved its previously reported BUNAVAIL Paragraph IV patent litigation against Teva Pharmaceuticals USA, Inc., Actavis Laboratories UT, Inc. and Teva Pharmaceuticals Industries, Ltd. (collectively "Teva").
  - BDSI entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL the US on July 23, 2028 or earlier under certain circumstances.

### Key Anticipated Milestones

- Continued prescription and revenue growth of BELBUCA
- Opportunity behind recently awarded BELBUCA Medicare and commercial contracts beginning on January 1, 2018
- Opportunities for new managed care contracts for BUNAVAIL and BELBUCA in 2018
- BELBUCA launch in Canada in early 2018 by Purdue (Canada)
- Opportunity to execute additional commercial transactions for ex-U.S. rights to BELBUCA
- Planned regulatory submission to qualify the new manufacturer for ONSOLIS, facilitating a potential return of the product to market in 2018

### **Conference Call & Webcast**

#### **Thursday, November 9 @ 4:30 PM Eastern Time**

Domestic: 888-378-4361

International: 719-325-2456

Passcode: 2745956

Webcast: <http://public.viavid.com/index.php?id=126438>

Replays available through November 23rd:

Domestic: 844-512-2921  
International: 412-317-6671  
Conference ID: 2745956

## 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<sup>®</sup>) 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 marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: [www.bdsi.com](http://www.bdsi.com)  
Facebook: [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI)  
Twitter: @BioDeliverySI

**BUNAVAIL<sup>®</sup> (buprenorphine and naloxone) buccal film (CIII) and BELBUCA<sup>®</sup> (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. ONSOLIS<sup>®</sup> (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](http://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](http://www.belbuca.com) and for full prescribing and safety information on BUNAVAIL, please visit [www.bunavail.com](http://www.bunavail.com).**

## Cautionary Note on Forward-Looking Statements

This press release, the investor conference call described herein, and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto 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 the Company's commercialization programs for BELBUCA, BUNAVAIL and ONSOLIS) may differ significantly from those set forth or implied 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)

	September 30, <u>2017</u>	December 31, <u>2016</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,746	\$ 32,019
Accounts receivable	10,791	3,569
Inventory	6,466	3,368
Prepaid expenses and other current assets	2,310	4,136
Total current assets	<u>39,313</u>	<u>43,092</u>
Property and equipment, net	4,202	4,230
Goodwill	2,715	2,715
BELBUCA <sup>®</sup> license and distribution rights intangible	41,625	-
Other intangible assets, net	1,558	2,285
Total assets	<u>\$ 89,413</u>	<u>\$ 52,322</u>

## LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

Current liabilities:

Accounts payable and accrued liabilities	\$	30,807	\$	18,174
Deferred revenue, current		-		1,716
Total current liabilities		30,807		19,890
Notes payable, net of discount and loan costs		35,701		29,272
Deferred revenue, long-term		-		20,000
Other long-term liabilities		4,050		825
Total liabilities		70,558		69,987
Commitments and contingencies				
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 September 30, 2017 and December 31, 2016, respectively.		2		2
Common Stock, \$.001 par value; 75,000,000 shares authorized; 55,852,926 and 54,133,511 shares issued; 55,837,435 and 54,118,020 shares outstanding at September 30, 2017 and December 31, 2016, respectively.		56		54
Additional paid-in capital		307,690		292,667
Treasury stock, at cost, 15,491 shares		(47)		(47)
Accumulated deficit		(288,846)		(310,341)
Total stockholders' equity (deficit)		18,855		(17,665)
Total liabilities and stockholders' equity (deficit)	\$	89,413	\$	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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<b>Revenues:</b>				
Product sales	\$ 8,118	\$ 2,009	\$ 23,798	\$ 6,221
Product royalty revenues	1,409	1,065	3,682	2,393
Research and development reimbursements	532	497	799	501
Contract revenue	1,194	-	21,194	2,500
Total Revenues:	11,253	3,571	49,473	11,615
Cost of sales	4,445	2,314	14,261	8,958
<b>Expenses:</b>				
Research and development:	1,986	4,402	6,246	13,786
Sales, general and administrative	14,867	12,054	44,094	37,606
Total Expenses:	16,853	16,456	50,340	51,392
Loss from operations	(10,045)	(15,199)	(15,128)	(48,735)
Interest expense	(1,893)	(786)	(6,657)	(2,477)
Derivative gain	-	14	-	36
Other expense, net	(13)	(6)	(28)	(20)
Bargain purchase gain	-	-	27,336	-
(Loss) income before income taxes	\$ (11,951)	\$ (15,977)	\$ 5,523	\$ (51,196)
Income tax benefit	\$ -	\$ -	\$ 15,972	\$ -
Net (loss) income attributable to common stockholders	\$ (11,951)	\$ (15,977)	\$ 21,495	\$ (51,196)
<b>Basic:</b>				
Basic (loss) income per share:	\$ (0.21)	\$ (0.30)	\$ 0.39	\$ (0.96)
Weighted average common stock shares outstanding:	55,604,708	53,767,099	55,170,569	53,531,770
<b>Diluted:</b>				
Diluted (loss) income per share:	\$ (0.21)	\$ (0.30)	\$ 0.38	\$ (0.96)
Weighted average common stock shares outstanding:	55,604,708	53,767,099	56,204,358	53,531,770

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

	<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Operating activities:</b>		
Net income (loss)	\$ 21,495	\$ (51,196)
Depreciation	465	325
Accretion of debt discount and loan costs	1,941	297
Amortization of Intangible Assets	4,103	728
Derivative liability	-	100
Stock-based compensation expense	10,223	11,600
Deferred income taxes	(15,972)	-
Bargain purchase gain	(27,336)	-
<b>Changes in assets and liabilities:</b>		
Accounts receivable	(7,222)	(601)
Inventories, net of effect of acquisition	2,314	(1,460)
Prepaid expenses and other assets	1,826	(537)
Accounts payable and accrued expenses, net of effect of acquisition	8,998	(662)
Deferred Revenue	(21,716)	47
<b>Net cash flows from operating activities</b>	<b>(20,881)</b>	<b>(41,359)</b>
<b>Investing activities:</b>		
BELBUCA <sup>®</sup> acquisition	(3,902)	-
Purchase of equipment	(5)	(316)
<b>Net cash flows from investing activities</b>	<b>(3,907)</b>	<b>(316)</b>
<b>Financing activities:</b>		
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	313	297
Proceeds from issuance of common stock	-	2,460
<b>Net cash flows from financing activities</b>	<b>12,515</b>	<b>2,797</b>
<b>Net change in cash and cash equivalents</b>	<b>(12,273)</b>	<b>(38,878)</b>
Cash and cash equivalents at beginning of year	32,019	83,560
<b>Cash and cash equivalents at end of year</b>	<b>\$ 19,746</b>	<b>\$ 44,682</b>
Cash paid for interest	\$ 3,816	\$ 2,045

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