BioDelivery Sciences Provides Corporate Update and Reports Third Quarter 2015 Financial Results

November 9, 2015

Company to host conference call today at 8:00 AM ET
BELBUCA™ (buprenorphine HCl) buccal film for chronic pain received U.S. Food and Drug Administration (FDA) approval; triggering $50M milestone payment to BDSI from partner Endo Pharmaceuticals
BUNAVAIL® (buprenorphine and naloxone) buccal film prescriptions grow 26% over second quarter; addition of over 460 new prescribers
BUNAVAIL received exclusive preferred formulary status from Tennessee Medicaid
U.S. Department of Health and Human Services and Obama administration announced important new steps to increase access to treatments for opioid dependence and prevention of opioid overdose
Third quarter ended with a strong cash position of $54.4 million, exclusive of the $50 million milestone payment associated with the approval of BELBUCA

RALEIGH, N.C., Nov. 9, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) today reported financial results for the third quarter ended September 30, 2015, and reviewed its most significant recent accomplishments and upcoming milestones.

Net revenue for BUNAVAIL increased 39% to $1.2 million compared to the second quarter. Net revenue for the nine months ended September 30, 2015, was $16.0 million, compared to $36.4 million in the same period of 2014. The nine month revenue for 2014 includes two milestone payments totaling $20 million for database locks for the two BELBUCA Phase 3 studies and $12.1 million of R&D reimbursable expenses for BELBUCA, while the 2015 revenue for the same period includes the milestone payment of $10 million for the FDA acceptance of the NDA for BELBUCA in the first quarter.

"We continued our operational achievements while working to contain expenses and maintain our cash burn rate according to our operating plan over the first nine months of the year," said Ernest De Paolantonio, Chief Financial Officer of BDSI. "The recently earned $50 million milestone from Endo Pharmaceuticals, triggered by the FDA approval of BELBUCA, combined with our cash on hand at September 30th, provides us with sufficient capital to operate our business, based on our current plan to approximately the middle of 2017. In addition, with BELBUCA anticipated to become commercially available in the U.S. in the first quarter of 2016, we expect to receive additional revenue from our mid-teen percent royalty on net sales."

Financial Highlights

Third Quarter 2015 Financial Results Overview

- Net revenue for the third quarter ended September 30, 2015, was $1.2 million, nearly all attributed to BUNAVAIL product sales, compared to $1.8 million in the corresponding period of 2014 which included royalties received from BREAKYL and R&D reimbursement revenue under our licensing agreement with Endo.
- Total operating expenses for the third quarter ended September 30, 2015, were $19.2 million, compared to $20.4 million in the corresponding period of 2014.
- Net loss for the third quarter ended September 30, 2015, was $20.4 million, or $0.39 per diluted share, compared to $25.3 million, or $0.51 per diluted share, in the corresponding period of 2014 due primarily to a derivative loss in 2014.

Nine Months Ended September 30, 2015 Financial Results Overview

- Net revenue for the nine months ended September 30, 2015, was $16.0 million, compared to $36.4 million in the corresponding period of 2014.
- Total operating expenses for the nine month period ended September 30, 2015, were $56.7 million, compared to $54.9 million the same period of 2014.
- Net loss for the nine months ended September 30, 2015, was $47.8 million, or $0.92 per diluted share, compared to $36.6 million, or $0.77 per diluted share, in the corresponding period of 2014 due primarily to greater milestone income.
- As of September 30, 2015, BDSI had $54.4 million in cash and cash equivalents, as compared to $70.5 million as of December 31, 2014. The September 30, 2015 cash position does not include the $50 million milestone payment from Endo, which will be received during the fourth quarter.

Corporate Update and Recent Accomplishments

BUNAVAIL (buprenorphine and naloxone) buccal film (CIII)

- Nearly 18,000 prescriptions dispensed for BUNAVAIL during the third quarter 2015, representing a 26% increase over second quarter.
- BUNAVAIL prescriber base expanded to nearly 2,300 physicians, with 463 new prescribers added during the third quarter.
- Exclusive preferred formulary status secured for BUNAVAIL with Tennessee Medicaid

    - All Medicaid patients presenting a buprenorphine/naloxone prescription are to receive BUNAVAIL.
    - Tennessee represents one of the largest states in the country for buprenorphine/naloxone-related Medicaid prescriptions.
- Enhanced sales force and managed markets leadership including the hiring of a new head of sales, Scott Plesha, who joined BDSI with over 25 years of sales and sales management experience, most recently as Senior Vice President, GI Sales Force and Training for Salix Pharmaceuticals. BDSI also added, Mike Bullock, formerly head of managed markets from Salix, along with four Salix regional sales managers.
- U.S. Department of Health and Human Services (HHS) announced that they plan to implement important new steps to increase access to treatments for opioid dependence and prevention of opioid overdose.
    - Revised regulations that limit the prescribing of buprenorphine to treat opioid dependence would expand access to medication assisted treatment (MAT).
    - Plan to double the number of physicians certified to prescribe buprenorphine from the approximately 30,000 to 60,000 over the next three years.

BELBUCA (buprenorphine HCl) buccal film (CIII)

- FDA approval received on October 23, 2015
- U.S. commercial launch anticipated to occur in first quarter of 2016 by partner Endo Pharmaceuticals, Inc.
- $50 million NDA approval milestone payment earned from Endo
- Mid to upper-teen royalty on future net sales of BELBUCA
- $55 million in potential sales milestones

"We are beginning to gain meaningful traction with the BUNAVAIL launch, as third quarter prescriptions for the product grew 26 percent over the second quarter," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "In addition, we are now beginning to see positive impact of having recently received exclusive preferred formulary status for BUNAVAIL from Tennessee Medicaid. We expect this growth momentum to continue in the fourth quarter and into 2016 based on this agreement and other accomplishments such as continued improved managed care access on the Medicaid front and our strengthened sales management team. Other market factors, such as the expected increase in access to buprenorphine treatment from initiatives including the lifting of the patient prescribing cap should also support this momentum. Importantly, the recent FDA approval of BELBUCA represents another significant value driver for BDSI. We have already earned a $50 millionmilestone payment from Endo triggered by the approval of BELBUCA and are eligible to receive royalties on net sales and sales-related milestone payments in the future. Also it magnifies the development capability within BDSI as BELBUCA was the third product approval in the company's short history."

Dr. Sirgo continued, "With the BUNAVAIL launch gaining strong momentum, the downstream benefits of the recent FDA approval of BELBUCA, the continued development of our pipeline, and a solid cash position that is expected to support our current operating plan to mid-2017, we believe that BDSI is well-positioned for future growth."

Key Anticipated Remaining 2015 and Early 2016 Milestones

- Buprenorphine Depot Injection (maintenance treatment of opioid dependence/chronic pain)
    - Pre-IND meeting in November
- Clonidine Topical Gel (treatment of painful diabetic neuropathy)
    - Phase 2B study planned to begin by the end of 2015
- Launch of BELBUCA by partner Endo Pharmaceuticals anticipated in the first quarter of 2016

Conference Call & Webcast	
Monday, November 9, 2015 @ 8:00 am Eastern Time	
Domestic:	888-510-1785
International:	719-457-2664
Passcode:	343795
Webcast:	http://public.viavid.com/player/index.php?id=116872
Replays available through November 23rd:	
Domestic:	877-870-5176

International:	858-384-5517
Conference ID:	343795

BDSI markets BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and *ONSOLIS*®(fentanyl buccal soluble film) (CII). BELBUCA™ (buprenorphine) buccal film (CIII) will be commercialized in the U.S. by Endo Pharmaceuticals pursuant to the worldwide licensing and development agreement between BDSI and Endo. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS and BELBUCA, 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.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc., headquartered in Raleigh, North Carolina, 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 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 particular 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.

For more information, please visit or follow us:

Internet:	www.bdsi.com
Facebook:	Facebook.com/BioDeliverySI
Twitter:	@BioDeliverySI

Cautionary Note on Forward-Looking Statements

This press release, the conference call described herein, and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, at the presentations 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 the commercial launches of BUNAVAIL and BELBUCA and the Company's clinical trials for, and FDA 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.

BioDelivery Sciences International

Condensed Consolidated Statements of Operations

(in thousands, except share data)

Statement of Profits and Losses	**Three Months Ended**	**Nine Months Ended**

	9/30/2015	9/30/2014	9/30/2015	9/30/2014
Revenues:				
Net Revenues	**$**1,235	$1,823	**$**16,022	$36,397
Costs and Expenses:				
Cost of Goods Sold	1,699	463	5,443	1,875
Research & Development	4,473	6,770	15,527	29,376
Selling, General and Administrative	14,715	13,648	41,185	25,533
Total Expenses	19,188	20,418	56,712	54,909
(Loss) / Income From Operations	(19,652)	(19,058)	(46,133)	(20,387)
Interest (expense) income net	(785)	(515)	(1,732)	(1,589)
Derivative (loss) gain	-	(5,685)	-	(14,631)
Other (expenses) income, net	(2)	2	21	35
(Loss) / Income before taxes	(20,439)	(25,256)	(47,844)	(36,572)
Income tax expense	-	-	-	-
Net (loss)/ income	**$(20,439)**	**$(25,256)**	**$(47,844)**	**$(36,572)**
(Loss)/ income per share, basic	**$(0.39)**	**$(0.51)**	**$(0.92)**	**$(0.77)**
(Loss)/ income per share, diluted	**$(0.39)**	**$(0.51)**	**$(0.92)**	**$(0.77)**
Shares used in computing net income/(loss) per share, basic	**52,542,715**	**49,555,815**	**52,286,757**	**47,391,040**
Shares used in computing net income/(loss) per share, diluted	**52,542,715**	**49,555,815**	**52,286,757**	**47,391,040**

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Condensed Consolidated Statements of Operations

(in thousands)

Balance Sheet	**9/30/2015**	12/31/2014
Assets		

Cash and cash equivalents	$ 54,429	$ 70,472
Accounts receivable, net	1,406	3,141
Inventory	1,887	1,828
other assets	14,693	13,870
Total Assets	**$ 72,415**	**$ 89,311**
Liabilities and Stockholders' Equity:		
Accounts Payable and other liabilities	$ 23,034	$ 22,742
Notes payable short and long term	29,679	12,173
Total Liabilities and Notes Payable	52,713	34,915
Preferred Stock	2	2
Common Stock	53	52
Additional paid-in capital	273,069	259,920
Treasury Stock at cost	(47)	(47)
Accumulated Deficit	(253,375)	(205,531)
Total stockholder' equity	19,702	54,396
Total liabilities and stockholders' equity (deficit)	**$ 72,415**	**$ 89,311**

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SOURCE BioDelivery Sciences International, Inc.

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