BioDelivery Sciences Provides Corporate Update and Reports Third Quarter 2016 Financial Results

November 9, 2016

Six BUNAVAIL® Managed Care Agreements Secured Since July; Additional Access to BUNAVAIL Provides Potential for Strong First Half 2017 Growth

Department of Health and Human Services Increases Patient Cap; Potential for Significant Increase in Patients Entering Treatment for Opioid Dependence

BDSI Meets Third Quarter Objective of Providing Stability to BUNAVAIL Prescription Sales Following Second Quarter Commercial Consolidation

BUNAVAIL Prescription Sales Up 68% Compared to Third Quarter 2015

Top-Line Phase 2b Data for Clonidine Topical Gel Expected in December

Buprenorphine 30-Day Injection IND Submission Expected by Year-End

RALEIGH, N.C., Nov. 9, 2016 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) today reported financial results for the third quarter ended September 30, 2016, and provided an update on recent business highlights and upcoming milestones.

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) net revenue for the three months ended September 30, 2016, was $2.0 million compared to $2.1 in the prior quarter and $1.2 million in the third quarter of 2015. BDSI believes that its goal of stabilizing BUNAVAIL revenue following the sales and marketing consolidation that was implemented in May 2016 is being achieved. As BDSI heads towards the first quarter of 2017, growth is now anticipated behind this consolidated commercial effort and will be driven by the six new managed care contracts recently secured.

Net revenue per BUNAVAIL prescription was relatively unchanged in the third quarter as compared to the second quarter of 2016. Cost of goods sold (COGS) decreased by 4% in the third quarter versus the second quarter of 2016 and is expected to improve an additional 30% by the end of 2017.

BDSI's total net revenue for the three-months ended September 30, 2016 was $3.6 millioncompared to $1.2 million for the same period last year and $5.0 million for the quarter ended June 30, 2016. The latter included a one-time recording of $2.5 million for the upfront payment from Collegium Pharmaceutical for the licensing rights to ONSOLIS® in the U.S.

Managed care contracts remain central to the future growth of BUNAVAIL and significant progress was achieved in the third quarter of this year. BDSI has secured six contracts since July that will provide BUNAVAIL potential increased access to approximately half a million prescriptions annually for buprenorphine products for opioid dependence. Four of the contracts provide access along with only one other branded buprenorphine/naloxone product and two of these contracts add BUNAVAIL alongside both branded products. While some contracts go into effect during the fourth quarter, three have an implementation date of January 1, 2017, including the managed care plan where Suboxone film will become non-preferred.

On August 8, 2016, the Department of Health and Human Services' (HHS) rule change increasing the number of patients an individual physician can treat with buprenorphine from 100 to 275 patients went into effect. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) in September, 1,665 clinicians applied for and were granted waivers to prescribe buprenorphine for the treatment of opioid dependence at the increased limit of 275. HHS had estimated that between 500 and 1,800 practitioners would request approval to treat up to 275 patients within the first year, resulting in an estimated range of 10,000 to 90,000 additional patients. This could result in BUNAVAIL having access to over half a million additional new prescriptions.

"We continue to achieve meaningful progress throughout our business, most importantly with managed care contracting for BUNAVAIL," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "During the third quarter, we achieved our goal of stabilizing the BUNAVAIL business behind the lowered cost structure that we implemented in the second quarter. Our focus now is on bringing BUNAVAIL to profitability by the end of 2017. We will achieve this objective by focusing first on increasing BUNAVAIL top-line sales, which will be driven by improved managed care access and formulary position and new patients entering treatment following the recent patient cap increase. These two factors alone have the potential to provide us with access to nearly 1 million new prescriptions over the next year that we did not have access to previously. Second, we will continue improving the bottom-line both through our reduced commercial expenses and an improved profit margin by reducing our COGS and improving our gross to net for BUNAVAIL."

"Looking at the remainder of our portfolio, our commercialization partner, Endo Pharmaceuticals, continues to progress with the launch of BELBUCA® while making important progress with commercial payers. In addition, last week, BELBUCA reached its highest prescription volume since launch, as sales continue to demonstrate the potential for growth, despite the current challenges around the use of opioids to treat pain," continued Dr. Sirgo. "In addition, we continue to expect the availability of top-line data for our Phase 2b study of Clonidine Topical Gel for the treatment of painful diabetic neuropathy in December. Finally, in regards to our 30-day buprenorphine injection, we are working diligently toward the submission of our IND before year-end. Overall, we remain enthusiastic around the opportunities with both our marketed and pipeline products over the remainder of 2016 and into 2017."

FINANCIAL HIGHLIGHTS

Third Quarter Ended September 30, 2016 Financial Results Overview

- Net revenue for the third quarter ended September 30, 2016, was $3.6 million, comprised primarily of $2.0 million of BUNAVAIL revenue, compared to $1.2 million in the same period of 2015.
- Total operating expenses for the third quarter ended September 30, 2016, were $16.5 million, compared to $19.2 million in the third quarter of 2015.
- Net loss for the third quarter ended September 30, 2016, was $16.0 million, or ($0.30) per diluted share, compared to a net loss of $20.4 million, or ($0.39) per diluted share in the same period of 2015.

Nine Months Ended September 30, 2016 Financial Results Overview

- Total revenue for the nine months ended September 30, 2016, was $11.6 million, compared to $16.0 million in the same period of 2015.
- Total operating expenses for the nine months ended September 30, 2016, were $51.4 million, compared to $56.7 million in the same period of 2015.
- Net loss for the nine months ended September 30, 2016, was $51.2 million, or ($0.96) per diluted share, compared to a net loss of $47.8 million, or ($0.92) per diluted share, in the same period of 2015.
- BDSI had cash and cash equivalents of approximately $44.7 million at September 30, 2016.

CORPORATE UPDATE AND RECENT ACCOMPLISHMENTS

BUNAVAIL (buprenorphine and naloxone) buccal film (CIII)

- BUNAVAIL prescription sales in the third quarter increased slightly from the second quarter of 2016, with an increase of 68% over the same period last year.
- Third quarter marked the first full quarter since BDSI completed a comprehensive salesforce restructuring.
    - Current sales force now covers 85% of the overall market.
    - Changes are expected to reduce commercial expenses by approximately $20 millionthrough the end of 2017.
- Secured six new managed care wins since July.
    - Contracts will provide BUNAVAIL potential access to an additional 500,000 prescriptions annually for buprenorphine products for opioid dependence, according to data from Symphony Health.
    - Four of the contracts provide access along with only one other branded buprenorphine/naloxone product, and in one plan, Suboxone film will move to non-preferred status in January. The other two contracts add BUNAVAIL alongside both branded products.
    - While two contracts go into effect during the fourth quarter, three have an implementation date of January 1, 2017.

BELBUCA (buprenorphine) buccal film (CIII)

- The third quarter represented BDSI's first quarter of recognizing royalty revenue paid by Endo from sales of BELBUCA.
- Last week, BELBUCA prescription sales reached its highest point since launch, according to data from Symphony Health, as sales continue to demonstrate the potential for growth despite the current challenges in the opioid market.

Clonidine Topical Gel – Painful Diabetic Neuropathy

- Phase 2b clinical study completed enrollment and randomization ahead of schedule.
- Top-line data expected to be available in December.

Buprenorphine 30-Day Injection – Pain & Opioid Dependence

- Currently expect to submit an Investigational New Drug Application (IND) before year-end.
- Continued activities to support initiation of the first-in-man study, which BDSI expects to begin during the first quarter of 2017.

Appointed Timothy C. Tyson to Board of Directors

- Appointed as an independent director.
- Corporate career spans over 30 years in the pharmaceutical industry, including leadership positions at GlaxoSmithKline, Valeant Pharmaceuticals and Bristol-Myers.
- Currently Chairman and CEO of Avara Pharmaceutical Services and Chairman at Icagen Inc., and recently served as Chairman and CEO of Aptuit LLC.

KEY ANTICIPATED LATE 2016 – EARLY 2017 MILESTONES

- Implementation of recently awarded BUNAVAIL managed care contracts.
- Continued BELBUCA prescription growth.
- Clonidine Topical Gel Phase 2b study preliminary results in December.
- IND filing of Buprenorphine 30-day injection for the treatment of opioid dependence by end of year, followed by initiation of

a single-dose pharmacokinetic study.

CONFERENCE CALL AND WEBCAST

Wednesday, November 9th @ 8am Eastern Time	
Domestic:	**888-778-9064**
International:	**913-312-0417**
Conference ID:	**6212819**
Webcast:	**http://public.viavid.com/index.php?id=121503**
Replay, available through November 23rd:	
Toll-Free:	**844-512-2921**
International:	**412-317-6671**

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
Twitter:	@BioDeliverySI

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) is marketed in the U.S. by BioDelivery Sciences. BELBUCA™ (buprenorphine) buccal film (CIII) is commercialized in the U.S. by Endo Pharmaceuticals pursuant to the worldwide licensing and development agreement between BDSI and Endo. *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.

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 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)

	September 30,	**December 31,**
ASSETS	**2016**	**2015**
Current assets:		
Cash and cash equivalents	44,682	83,560
Accounts receivable	3,089	2,488
Inventory	4,018	2,558
Prepaid expenses and other current assets	4,470	3,933
	56,259	92,539
Property and equipment, net	4,253	4,262
Goodwill	2,715	2,715
Other intangible assets, net	2,528	3,256
Total assets	$ 65,755	$ 102,772
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	18,839	19,501
Notes Payable, current	11,446	6,707

Deferred revenue, current	1,922	1,875
Derivative liability	100	-
Total current liabilities	32,307	28,083
Notes payable, less current maturities	17,726	22,168
Deferred revenue, long term	20,000	20,000
Other Long Term liabilities	825	825
Total liabilities	70,858	71,076
Commitments and contingencies (Notes 7 and 12)	-	-
Stockholders' (deficit) 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 September 30, 2016 and December 31, 2015	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 54,133,511 and 52,730,799 shares issued; 54,118,020 and 52,715,308 shares outstanding at September 30, 2016 and December 31, 2015, respectively	54	53
Additional paid-in capital	289,287	274,891
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(294,399)	(243,203)
Total stockholders' (deficit) equity	(5,103)	31,696
Total liabilities and stockholders' (deficit) equity	$ 65,755	$ 102,772

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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,	
	2016	**2015**	**2016**	**2015**
Product sales	$ 2,009	$ 1,155	$ 6,221	$ 2,665
Product royalty revenues	1,065	25	2,393	689
Research and development reimbursements	497	55	501	909
Contract revenues	-	-	2,500	11,759
Total Revenues	3,571	1,235	11,615	16,022
Cost of sales	2,314	1,699	8,958	5,443
Expenses:				
Research and development:	4,402	4,473	13,786	15,527
Selling, general and administrative	12,054	14,715	37,606	41,185
Total expenses	16,456	19,188	51,392	56,712
Loss from operations	(15,199)	(19,652)	(48,735)	(46,133)
Interest expense, net	(786)	(785)	(2,477)	(1,732)
Derivative gain	14	-	36	-
Other (expense) income, net	(6)	(2)	(20)	21
Net loss	$ (15,977)	$ (20,439)	$ (51,196)	$ (47,844)
Basic and diluted loss per share:	$ (0.30)	$ (0.39)	$ (0.96)	$ (0.92)
Weighted average common stock shares outstanding, basic and diluted:	53,767,099	52,542,715	53,531,770	52,286,757

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars, in thousands)

(Unaudited)

	Nine months ended September 30,	
	2016	**2015**
Operating activities:		
Net loss	$ (51,196)	$ (47,844)
Depreciation	325	248
Accretion of discount	297	400
Amortization of Intangible Assets	728	728
Derivative liability	100	-
Stock-based compensation expense	11,600	12,703
Changes in assets and liabilities:		
Accounts receivable	(601)	1,734
Inventories	(1,460)	(59)
Prepaid expenses and other assets	(537)	(727)
Accounts payable and accrued expenses	(662)	477
Deferred Revenue	47	(377)
Net cash flows from operating activities	(41,359)	(32,717)
Investing activities:		
Purchase of equipment	(316)	(619)
Net cash flows from investing activities	(316)	(619)
Financing activities:		
Equity Financing costs	40	(40)
Proceeds from exercise of stock options	297	480
Proceeds from issuance of common stock	2,460	-
Proceeds from exercise of common stock warrants	-	1
Payment on note payable	-	(3,335)

Proceeds from Notes Payable	-	20,667
Deferred Financing fees	-	(486)
Return on short swing profits	-	6
Net cash flows from financing activities	2,797	17,293
Net change in cash and cash equivalents	(38,878)	(16,043)
Cash and cash equivalents at beginning of year	83,560	70,472
Cash and cash equivalents at end of year	**$ 44,682**	**$ 54,429**
Cash paid for interest	$ 2,045	$ 1,201

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SOURCE BioDelivery Sciences International, Inc.

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