BioDelivery Sciences Provides Corporate Update and Reports Fourth Quarter and Full-Year 2015 Financial Results

March 10, 2016

- BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) prescriptions grow 66% in the fourth quarter over third quarter of 2015; addition of over 447 new prescribers in fourth quarter

- BELBUCA™ (buprenorphine) buccal film (CIII) for chronic pain approved in October and recently launched in the U.S.; Commercial partner, Endo Pharmaceuticals, projects BELBUCA sales to be >$250 million in 2019

- $50 million dollar payment received from Endo following NDA approval of BELBUCA

- Net revenue for the twelve months ended December 31, 2015, was $48.2 million, compared to $38.9 million in the corresponding period of 2014

- Net loss for the 12-months ended December 31, 2015, was $37.7 million, or ($0.72) per diluted share, compared to $54.2 million, or ($1.12) per diluted share, in the corresponding period of 2014

- Strong cash position of $83.6 million at end of 2015; runway to mid-2017

- Clonidine Topical Gel multi-center, randomized, double-blind, placebo-controlled study initiated for the treatment of painful diabetic neuropathy

- Buprenorphine 30 day Depot Injection being developed for opioid dependence and pain; readying for Phase I/II in second half of 2016

- Company to host conference call today at 5:00 PM ET

RALEIGH, N.C., March 10, 2016 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) reported financial results for the fourth quarter and full-year ended December 31, 2015, and reviewed its most significant recent accomplishments and upcoming milestones.

Net revenue for BUNAVAIL® (buprenorphine and naloxone) buccal film in the fourth quarter increased 29% to $1.5 million compared to the third quarter of 2015. BUNAVAIL net revenue for the 12-months ended December 31, 2015, was $4.2 million. BREAKYL® (brand name for ONSOLIS in the E.U.) revenue for the 12 month period was $1.4 million. BDSI net revenue for the 12-months ended December 31, 2015, was $48.2 million, compared to $38.9 million in the same period of 2014. This revenue increase was largely driven by the milestone payment received from Endo Pharmaceuticals upon the U.S. Food and Drug Administration (FDA) approval of BELBUCA™ (buprenorphine) buccal film, which generated $50 million in payments. Thirty ($30) million was attributed to the actual regulatory approval and was earned immediately while the additional $20 million was attributed to the extension of patent protection until 2027 from a patent granted in 2012 and payable on the FDA approval of BELBUCA. The latter aspect of the payment will be recognized over the patent extension period.

"We are pleased with our accomplishments in 2015, including the continued growth of BUNAVAIL prescriptions, and the approval of BELBUCA, our third FDA approved product, and the recently announced commercial launch in the United States," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "Looking ahead in 2016, we expect enhancements to our sales team, our recent agreement with Tennessee Medicaid, further commercial payer plan penetration and access, a pilot direct to consumer program, and certain government-driven initiatives, including the patient cap lift, to improve the growth trajectory of BUNAVAIL prescriptions. At the same time we will continue to explore strategic opportunities to maximize the value of that asset as well as our overall commercial infrastructure. In addition, we look forward to a strong BELBUCA launch from our partner Endo Pharmaceuticals and the continued advancement of our pipeline. With nearly $84 million in cash at the end of 2015, we continue to believe that BDSI has sufficient capital to support our current operating plan through approximately mid-2017."

Financial Highlights

Fourth Quarter 2015 Financial Results Overview

- Net revenue for the fourth quarter ended December 31, 2015, was $32.2 million, nearly all attributable to the $50 million BELBUCA-related FDA approval payment of which $30 million was recognized as revenue immediately. The remaining $20 million will be recognized as revenue over the patent extension period. Revenue for the corresponding period for 2014 was $2.5 million, primarily related to BREAKYL. BUNAVAIL revenue for the fourth quarter was $1.5 million, an increase of 29% over third quarter.
- Total operating expenses for the fourth quarter ended December 31, 2015, were $18.6 million, compared to $17.6 million in the corresponding period of 2014.
- Net income for the fourth quarter ended December 31, 2015, was $10.2 million, or $0.19 per diluted share, compared to a net loss of $17.6 million, or ($0.36) per diluted share, in the corresponding period of 2014.

12-Months Ended December 31, 2015 Financial Results Overview

- Net revenue for the twelve months ended December 31, 2015, was $48.2 million, compared to $38.9 million in the

corresponding period of 2014.
- Total operating expenses for the twelve-month period ended December 31, 2015, were $75.3 million, compared to $72.7 million the same period of 2014.
- Net loss for the 12-months ended December 31, 2015, was $37.7 million, or ($0.72) per diluted share, compared to $54.2 million, or ($1.12) per diluted share, in the corresponding period of 2014.
- As of December 31, 2015, BDSI had $83.6 million in cash and cash equivalents, as compared to $70.5 million as of December 31, 2014.

Corporate Update and Recent Accomplishments

BUNAVAIL (buprenorphine and naloxone) buccal film (CIII)

- BUNAVAIL prescriptions continued to grow, with a 66% increase from the third to fourth quarter of 2015. Since launch, over 75,000 prescriptions have been dispensed for BUNAVAIL.
- BUNAVAIL prescriber base expanded to nearly 2,549 physicians, with 447 unique prescribers added during the fourth quarter.
- Exclusive preferred formulary status for BUNAVAIL with Tennessee Medicaid was a key growth driver and added nearly 300 new BUNAVAIL prescribers in the state of Tennesseeand over 7800 Medicaid prescriptions in the fourth quarter. BUNAVAIL prescription volume in Tennessee increased over 200% from the third quarter in the non-Medicaid segment (ie, commercial insurance and cash) as the Tennessee Medicaid formulary addition resulted in expanded BUNAVAIL use among other payer types.
- Market access improved through 2015 with coverage now in approximately 180 million commercial lives and Medicaid coverage expanded to 26 states.

BELBUCA (buprenorphine) buccal film (CIII)

- FDA approval for BELBUCA was received on October 23, 2015 resulting in a $50 millionNDA approval milestone payment received from Endo; BDSI is now eligible for a mid to upper-teen royalty on future U.S. net sales of BELBUCA and up to $55 million in potential sales milestones.
- Launched commercially in the U.S. on February 22, 2016; Commercial partner, Endo Pharmaceuticals, currently projects sales of BELBUCA to be >$250 million in 2019

Clonidine Topical Gel – Painful Diabetic Neuropathy

- Initiated multi-center, randomized, double-blind, placebo-controlled study, in fourth quarter of 2015. Study design incorporates significant learnings from two previously conducted studies where primary endpoints were not met and involves tightened and additional inclusion criteria.
- Expect last patient to complete the study before the end of 2016; data available in the first quarter of 2017.

Buprenorphine 30 Day Injection – Pain & Opioid Dependence

- Pre-IND meeting with the FDA held in fourth quarter 2015.
- BDSI will conduct one additional preclinical study to characterize the time for elimination of the formulation polymers at the injection site.
- IND submission targeted for the third quarter of this year.
- Anticipate initiating first in man study in the fourth quarter of 2016, with results expected by end of year.

Key Anticipated 2016 Milestones

- Results of a pilot direct to patient advertising program for BUNAVAIL anticipated in early third quarter, with national expansion, if successful.
- FDA approval of induction claim for BUNAVAIL anticipated in third quarter.
- Last patient completes Clonidine Topical Gel Phase IIB study by year-end; data expected in the first quarter of 2017.
- IND filing of Buprenorphine 30 Day Injection for the treatment of opioid dependence and chronic pain anticipated in third quarter 2016; single dose pharmacokinetic study results anticipated by year-end.

Conference Call & Webcast

Thursday, March 10th @ 5pm Eastern Time

Toll Free: 888-572-7025
International: 719-325-2323
Passcode: 6142703
Webcast: http://public.viavid.com/index.php?id=118491

Replays, available through March 24, 2016

Toll-Free: 877-870-5176
International: 858-384-5517
Conference ID: 6142703

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 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. BDSI's headquarters is located in Raleigh, North Carolina.

For more information, please visit or follow us:

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

BDSI markets BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and *ONSOLIS*®(fentanyl buccal soluble film) (CII). 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. 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 presentation described herein, 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(U.S. dollars, in thousands, except share and per share amounts)

	December 31,	
	2015	**2014**
ASSETS		
Current assets:		

Cash and cash equivalents	$ 83,560	$ 70,472
Accounts receivable, net	2,488	3,141
Inventory	2,558	1,828
Prepaid expenses and other current assets	3,933	2,568
Total current assets	92,539	78,009
Property and Equipment, net	4,262	3,890
Goodwill	2,715	2,715
Other Intangible assets, net	3,256	4,226
Total assets	$ 102,772	$ 88,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 19,501	$ 14,429
Notes payable, current maturities	6,707	8,000
Deferred revenue, current	1,875	6,772
Total current liabilities	28,083	29,201
Notes payable, less current maturities, net	22,168	3,702
Deferred revenue, long-term	20,000	841
Other long-term liabilities	825	700
Total liabilities	71,076	34,444
Commitments and contingencies (Notes 7 and 14)	—	—
Stockholders' equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 and 2,139,000 shares of Series A Non-Voting Convertible Preferred Stock outstanding at December 31, 2015 and 2014, respectively.	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 52,730,799 and 51,603,070 shares issued; 52,715,308 and 51,587,579 shares outstanding at December 31, 2015 and 2014, respectively	53	52
Additional paid-in capital	274,891	259,920

Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(243,203)	(205,531)
Total stockholders' equity	31,696	54,396
Total liabilities and stockholders' equity	$ 102,772	$ 88,840

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars, in thousands, except per share amounts)

	Year Ended December 31,		
	2015	**2014**	**2013**
Revenues:			
Product sales	$ 4,157	$ 76	$ —
Product royalty revenues	1,406	3,407	1,773
Research and development reimbursements	909	12,712	2,783
Contract revenue	41,759	22,749	6,800
Total revenues	48,231	38,944	11,356
Cost of sales	8,101	4,939	2,082
Expenses:			
Research and development	20,624	34,285	53,327
Selling, general and administrative	54,685	38,460	12,349
Total expenses	75,309	72,745	65,676
Loss from operations	(35,179)	(38,740)	(56,402)
Interest expense, net	(2,518)	(2,016)	(903)
Derivative (loss) gain	—	(13,167)	121

Other income (expense), net	25	(295)	(210)
Net loss	$ (37,672)	$ (54,218)	$ (57,394)
Basic and diluted loss per share	$ (0.72)	$ (1.12)	$ (1.51)
Weighted average common stock shares outstanding	52,384,876	48,355,200	37,941,044

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars, in thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Operating activities:			
Net loss	$ (37,672)	$ (54,218)	$ (57,394)
Adjustments to reconcile net loss to net cash flows from operating activities			
Depreciation	329	123	207
Accretion of debt discount	500	642	164
Amortization of intangible assets	970	972	1,140
Derivative loss (gain)	—	13,167	(121)
Impairment loss on assets	—	295	—
Stock-based compensation expense	14,249	6,883	3,327
Purchase of Arcion license with common stock	—	—	2,072
Changes in assets and liabilities:			
Accounts receivable	653	(347)	(2,273)
Inventories	(730)	(1,828)	—
Prepaid expenses and other assets	(1,365)	(2,252)	(68)
Accounts payable and accrued expenses	5,072	4,325	(656)
Deferred revenue	14,262	3,405	(6,500)

Net cash flows from operating activities	(3,732)	(28,833)	(60,102)
Investing activities:			
Purchase of equipment	(701)	(1,603)	(77)
Net cash flows from investing activities	(701)	(1,603)	(77)
Financing activities:			
Proceeds from sales of securities	(40)	72,662	—
Proceeds from exercise of stock options	755	4,580	357
Proceeds from exercise of common stock warrants	1	7,741	50
Payment on note payable	(3,335)	(7,333)	—
Proceeds from notes payable and warrants	20,667	—	20,000
Return of short swing profits	6	82	—
Payment of deferred financing fees	(533)	—	(241)
Net cash flows from financing activities	17,521	77,732	20,166
Net change in cash and cash equivalents	13,088	47,296	(40,013)
Cash and cash equivalents at beginning of year	70,472	23,176	63,189
Cash and cash equivalents at end of year	**$ 83,560**	**$ 70,472**	**$ 23,176**
Cash paid for interest	$ 1,885	$ 1,386	$ 742
Cash paid for taxes	$ —	$ —	$ 80

Logo - http://photos.prnewswire.com/prnh/20110217/CL49801LOGO

SOURCE BioDelivery Sciences International, Inc.

For further information: Investors: Matthew P. Duffy, Managing Director, LifeSci Advisors, LLC, 212-915-0685, matthew@lifesciadvisors.com or Al Medwar, Senior Vice President, Corporate and Business Development, BioDelivery Sciences International, Inc., 919-582-9050, amedwar@bdsi.com; Media: Susan Forman/Laura Radocaj, Dian Griesel Int'l., 212-825-3210, sforman@dgicomm.com, lradocaj@dgicomm.com