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

May 10, 2016

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- *Strategic initiatives implemented to better align* BUNAVAIL® *expenses with revenue as part of ongoing efforts to preserve and enhance long-term value; changes expected to result in savings of approximately $20 million through 2017*
- *BUNAVAIL prescriptions increase 180% compared to first quarter of 2015; over 350 new prescribers added in first quarter of 2016*
- *BUNAVAIL net revenue increased 41% in first quarter compared to fourth quarter 2015*
- *BUNAVAIL revenue per prescription increased more than 20% in the first quarter compared to fourth quarter 2015*
- *Strong cash position of $69.4 million at March 31, 2016; cost cutting initiatives and loan revision extend cash runway to third quarter 2017*
- *BELBUCA™ for chronic pain launched in the U.S. in February 2016 by Endo Pharmaceuticals*
- *Over 50% of targeted number of patients have been enrolled in the Clonidine Topical Gel multi-center, randomized, double-blind, placebo-controlled Phase 2b study; top line data on target for first quarter 2017*

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) today reported financial results for the first quarter ended March 31, 2016, and provided an update on recent business highlights and upcoming milestones.

Net revenue for BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) in the first quarter increased 41% to $2.1 million, compared to $1.5 million in the fourth quarter of 2015. BDSI total net revenue for the three-months ended March 31, 2016, was $3.0 million.

BUNAVAIL prescription sales in the first quarter increased 180% year over year, and declined by 4% compared to the fourth quarter of 2015. The decline from the fourth quarter of 2015 is consistent with the decline in prescriptions for the overall market. Through the first quarter of 2016, over 3,000 physicians have prescribed BUNAVAIL with 350 new prescribers added during the first quarter.

Revenue per BUNAVAIL prescription increased by more than 20%, from less than $60 to over $72, in the first quarter from the fourth quarter 2015 as a result of the improved gross-to-net profile.

"BDSI continues to evolve, and we made progress in all areas of the business during the first quarter, despite facing challenges in prescription growth for BUNAVAIL," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "While prescription sales of BUNAVAIL were relatively flat in the first quarter compared to the fourth quarter of 2015, we improved BUNAVAIL's profitability generating a 41% increase in net revenue."

Dr. Sirgo continued, "We have also spent a considerable amount of time evaluating Bunavail to ensure we have the right strategy in place to enhance returns and shareholder value. We recognize that the sales trajectory for BUNAVAIL has not yielded results at the level we anticipated. In the near-term, we are taking decisive actions to better align costs with revenue and reduce spending, while preserving the value of the asset and positioning it for long-term growth. Specifically, we are strategically consolidating the sales force to focus our efforts on our most productive territories and reducing our marketing spend for a total savings of approximately $20 million through 2017. We will continue to act in a strategic and responsible manner as our value driving initiatives take hold. These initiatives include additional managed care contracts driven by a diversion platform, our direct to patient initiative, and activities associated with the implementation of the proposal from the Department of Health and Human Services to increase the patient cap. BDSI remains focused on creating long-term shareholder value through the commercialization of our marketed products, the growth of our development pipeline and disciplined capital management."

Financial Highlights

First Quarter 2016 Financial Results Overview

- Net revenue for the first quarter ended March 31, 2016, was $3.0 million, composed primarily of $2.1 million of BUNAVAIL revenue and $0.9 million of BREAKYL™ revenue, compared to $13.1 million in the first quarter of 2015, composed largely of $11.4 million in contract revenue including recognition of previously deferred revenue.
- Total operating expenses for the first quarter ended March 31, 2016, were $18.4 million, compared to $19.7 million in the same period of 2015.
- Net loss for the first quarter ended March 31, 2016, was $18.7 million, or ($0.36) per diluted share, compared to a net loss of $8.2 million, or ($0.16) per diluted share, in the same period of 2015.
- BDSI had cash and cash equivalents of approximately $69.4 million at March 31, 2016. This compares to cash and cash equivalents of approximately $83.6 million at December 31, 2015.

Corporate Update and Recent Accomplishments

BUNAVAIL (buprenorphine and naloxone) buccal film (CIII)

- BUNAVAIL prescriptions decreased 4% in the first quarter of 2016 vs the fourth quarter of 2015 and increased 180% versus the first quarter of 2015. Since launch, more than 100,000 BUNAVAIL prescriptions have been dispensed.
- BUNAVAIL net revenue per prescription was over $72 in the first quarter compared to less than $60 in the fourth quarter of 2015.
- BUNAVAIL prescriber base expanded to nearly 3,000 physicians, with 350 unique prescribers added during the first quarter.
- Market access continued to improve in the first quarter of 2016 with coverage now in over 180 million commercial lives and Medicaid coverage expanded to 26 states.
- Department of Health and Human Services (HHS) recently proposed to allow physicians to treat up to 200 patients from the current 100 level with buprenorphine for the treatment of opioid dependence. The HHS ruling is now open for a 60 day comment period prior to finalization and implementation.

Initiatives to reduce spending by approximately $20 million by the end of 2017 and more prudently align expenses with revenue:

- Consolidating the sales force size and adapting the structure to focus efforts on the most productive areas of the country.
- Reducing originally planned marketing spend through 2017 by focusing resources on marketing initiatives that will deliver the greatest return.
- Initiatives extend cash runway to the third quarter of 2017.

BELBUCA® (buprenorphine) buccal film (CIII)

- Launched commercially in the U.S. on February 22, 2016; Commercial partner, Endo Pharmaceuticals reports favorable early healthcare provider feedback that pain control needs are being met and positive patient experience with regard to efficacy, tolerability and the buccal film formulation
- BDSI is 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

Clonidine Topical Gel – Painful Diabetic Neuropathy

- Initiated multi-center, randomized, double-blind, placebo-controlled Phase 2b study, in fourth quarter of 2015. Study design incorporates significant learnings from two previously conducted studies and involves additional and tightened inclusion criteria.
- More than 50% of the targeted number of patients have been randomized to date.
- Expect last patient to complete the study before the end of 2016 with data available the first quarter of 2017.

Buprenorphine 30 Day Injection – Pain & Opioid Dependence

- Will conduct a pre-clinical study to characterize the time for elimination of the formulation polymers at the injection site beyond the 30-day period for buprenorphine exposure.
- IND submission targeted for the third quarter of this year.
- Anticipate first-in-man trial in fourth quarter of 2016, with data by year-end.

Modification of MidCap Loan

- BDSI announced that it has very recently worked with its senior lender MidCap Financial to extend the interest only period of BDSI's loan through the end of 2016 in order to preserve cash resources. BDSI issued MidCap 84,986 warrants to purchase BDSI common stock at an exercise price of $3.53 in connection with this loan modification.

Key Anticipated 2016-2017 Milestones

- FDA approval of induction claim for BUNAVAIL anticipated in third quarter.
- Last patient completes Clonidine Topical Gel Phase 2b 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
Tuesday, May 10 @ 8:00 AM Eastern Time

Domestic: 888-500-6950
International: 719-325-2491
Passcode: 2412873
Webcast: http://public.viavid.com/index.php?id=119222

Replays available through May 24th:

Domestic: 877-870-5176

International: 858-384-5517
Conference ID: 2412873

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.

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Condensed Consolidated Statements of Operations

(in thousands)

Balance Sheet	3/31/2016	12/31/2015
Assets		
Cash and cash equivalents	$69,393	$83,560
Accounts receivable, net	2,132	2,488

Inventory	4,821	2,558
other assets	13,955	14,166
Total Assets	**$90,301**	**$102,772**
Liabilities and Stockholders' Equity:		
Accounts Payable and other liabilities	$41,528	$42,201
Notes payable short and long term	28,974	28,875
Total Liabilities and Notes Payable	70,502	71,076
Preferred Stock	2	2
Common Stock	54	53
Additional paid-in capital	281,726	274,891
Treasury Stock at cost	(47)	(47)
Accumulated Deficit	(261,936)	(243,203)
Total stockholder' equity	19,799	31,696
Total liabilities and stockholders' equity (deficit)	**$90,301**	**$102,772**
	90,301	**$102,772**

BioDelivery Sciences International

Condensed Consolidated Statements of Operations

(in thousands, except share data)

Statement of Profits and Losses	**Three Months Ended**	
	3/31/2016	**3/31/2015**
Revenues:		
Bunavail	2,102	677
Royalty & Other Revenue	938	12,377
Net Revenues	$3,040	$13,054
Costs and Expenses:		

Cost of Goods Sold	2,550	1,124
Research & Development	5,377	6,549
Selling, General and Administrative	13,055	13,181
Total Expenses	18,432	19,730
(Loss) / Income From Operations	(17,942)	(7,800)
Interest (expense) income net	(778)	(420)
Derivative (loss) gain	-	-
Other (expenses) income, net	(13)	27
(Loss) / Income before taxes	(18,733)	(8,193)
Income tax expense	-	-
Net (loss)/ income	**$(18,733)**	**$(8,193)**
(Loss)/ income per share, basic	**$(0.36)**	**$(0.16)**
(Loss)/ income per share, diluted	**$(0.36)**	**$(0.16)**
Shares used in computing net income/(loss) per share, basic	**52,230,648**	**51,908,844**
Shares used in computing net income/(loss) per share, diluted	**52,230,648**	**51,908,844**

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