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

August 9, 2016

BDSI targeting BUNAVAIL® profitability by end of 2017 following commercial restructuring, managed care wins and improved operating margins

Two significant managed care agreements secured providing preferred access to BUNAVAIL

BUNAVAIL net revenue per prescription increased for the second consecutive quarter

BUNAVAIL cost of goods declined 16% versus first quarter 2016

BUNAVAIL gross profit increased by nearly 200% versus first quarter 2016

BELBUCA™ weekly prescriptions continue to grow reaching a high to date of >1,300

Top-line Phase 2b data for Clonidine Topical Gel study expected by end of year

Licensing agreement signed with Collegium Pharmaceutical for exclusive rights to develop and commercialize ONSOLIS® in U.S.

Strong Cash Position of $57.5 million at June 30, 2016; cash runway to third quarter 2017

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

BDSI's total net revenue for the three-months ended June 30, 2016, was $5.0 million, an increase of 65% over the first quarter of 2016 and an increase of 189% over last year's corresponding quarter. BUNAVAIL (buprenorphine and naloxone) buccal film (CIII) net revenue for the three months-ended June 30, 2016 was $2.1 million.

BUNAVAIL prescription sales remained stable in the second quarter from the prior quarter despite BDSI's previously announced sales force consolidation and restructuring in May, while overall unit (film) sales increased 2%.

Net revenue per BUNAVAIL prescription increased in the second quarter over the first quarter of 2016, which is expected to continue through 2017. Cost of goods (COGS) decreased 16% due to the transition to a high-speed packaging line in May and are expected to improve an additional 30% by the end of 2017. As a result of the aforementioned improvements, the gross profit for BUNAVAIL improved by nearly 200% in the second quarter versus the first quarter.

Operating expenses decreased by $1.9 million from $18.4 million in the first quarter to $16.5 million in the second quarter. BUNAVAIL commercial costs remained comparable between quarters due to one-time expenses related to the consolidation and transition of the sales force from Quintiles to BDSI in May. However, savings of approximately $3 million per quarter are expected to be realized beginning with the third quarter of this year.

Managed care contracts remain central to the future growth of BUNAVAIL, and two important new agreements were finalized recently. As announced in July, BDSI secured access to a commercial plan that will allow BUNAVAIL to move from its current non-formulary position to a preferred formulary position within this plan, while the current market leader is made non-preferred. The other branded buprenorphine/naloxone product will share preferred status with BUNAVAIL. This contract will go into effect on January 1, 2017, though the transition may begin sooner for some plans under the agreement. Additionally, and not previously announced, BUNAVAIL has been added to a second plan where it will replace Zubsolv and share preferred status with Suboxone film. BDSI did not previously have access within either plan.

Progress was made this past quarter in enacting important legislation increasing patient access to treatment for opioid dependence, which began with the final ruling by the Department of Health and Human Services (HHS) which increased the cap from 100 to 275 *patients* an individual physician can treat with buprenorphine. This ruling went into effect yesterday. HHS estimates that this could expand access to up to 90,000 additional patients in the first year following implementation which could translate into over half a million additional prescriptions. It is anticipated that participating doctors will begin having an impact on the prescription market starting in the fourth quarter of this year. Additionally, the President recently signed new legislation, referred to as the Comprehensive Addiction and Recovery Act, or CARA, which further expands access to care including allowing nurse practitioners and physician assistants to prescribe buprenorphine and provides funding for grants to expand access to medication assisted treatment.

"We are focused on bringing BUNAVAIL to profitability by the end of 2017 and made significant advances in that regard during the quarter," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "Our plan for bringing our commercial expenses more in line with our revenue began with the restructuring and consolidation of the sales force in May around high performing and future growth territories. This will result in the elimination of approximately $20 million in expenses through the end of 2017. We are actively seeking to drive BUNAVAIL prescription growth by improving our position on or securing additional managed care contracts as well as initiatives focused on driving more patients to BUNAVAIL in conjunction with the lifting of the patient cap and our direct to patient program. Simultaneously, we will continue efforts to improve our operating margins as we strive to achieve our goal of bringing BUNAVAIL to profitability by the end of 2017."

Dr. Sirgo concluded, "Regarding the rest of our portfolio, we continue to be optimistic about the long-term success of BELBUCA based on both the considerable commercial and post-marketing effort that our partner Endo is putting behind the launch and initial favorable reports from healthcare providers and patients. BELBUCA also has favorable managed care receptivity and coverage. Further driving our optimism, BELBUCA hit a high to date of over 1300 prescriptions last week. Separately, we continue to make significant progress with our product development pipeline. Our Phase 2b study of Clonidine Topical Gel for the treatment of painful diabetic neuropathy has reached its target enrollment, and we now anticipate top-line results ahead of schedule and before the end of this year, and our buprenorphine 30-day injection continues to progress toward IND submission and the start of our Phase 1 study. In addition, we successfully monetized ONSOLIS, which we expect to re-enter the market mid-2017, with our licensing agreement with Collegium Pharmaceutical. Finally, we remain in a strong financial position, as our cash runway extends into the third quarter of 2017. We are extremely optimistic on all business fronts as we move into the second half of the year."

FINANCIAL HIGHLIGHTS

Second Quarter Ended June 30, 2016 Financial Results Overview

- Net revenue for the second quarter ended June 2016, was $5.0 million, comprised primarily of $2.1 million of BUNAVAIL revenue and $2.5 million of contract revenue related to the license agreement with Collegium, compared to $1.7 million in the second quarter of 2015.
- Total operating expenses for the second quarter ended June 30, 2016, were $16.5 million, compared to $17.8 million in the second quarter of 2015.
- Net loss for the second quarter ended June 30, 2016, was $16.5 million, or ($0.31) per diluted share, compared to a net loss of $19.2 million, or ($0.37) per diluted share, in the same period of 2015.

Six Months Ended June 30, 2016 Financial Results Overview

- Total revenue for the six months ended June 30, 2016, was $8.0 million, compared to $14.8 million in the same period of 2015.
- Total operating expenses for the six months ended June 30, 2016, were $34.9 million, compared to $37.5 million in the same period of 2015.
- Net loss for the six months ended June 30, 2016, was $35.2 million, or ($0.66) per diluted share, compared to a net loss of $27.4 million, or ($0.53) per diluted share, in the same period of 2015.
- BDSI had cash and cash equivalents of approximately $57.5 million at June 30, 2016. This compares to cash and cash equivalents of approximately $69.4 million at March 31, 2016.

CORPORATE UPDATE AND RECENT ACCOMPLISHMENTS

BUNAVAIL (buprenorphine and naloxone) buccal film (CIII)

- BUNAVAIL prescription sales in the second quarter were relatively unchanged from the first quarter, while overall unit (film) sales increased 2%. Exclusive of Tennessee Medicaid, prescriptions for BUNAVAIL grew by 9% nationally, demonstrating continued underlying growth and adoption of BUNAVAIL.
- Through the second quarter of 2016, nearly 3,300 physicians have prescribed BUNAVAIL since launch, with 364 new prescribers added during the second quarter.
- Consolidation and transition from a contract sales organization to an internal sales force was completed during the second quarter. These changes are expected to reduce commercial expenses by approximately $20 million through the end of 2017.
- Two important managed care contracts were secured providing preferred access to BUNAVAIL in plans where access to BUNAVAIL has been limited.
    - As announced in July, access to BUNAVAIL will be improved substantially in an important managed care plan from its current non-formulary position to a preferred formulary position, while the current market leader is made non-preferred. The other branded buprenorphine/naloxone product will share preferred status with BUNAVAIL. The contract goes into effect on January 1, 2017.
    - Additionally, and not previously announced, BUNAVAIL has been added to an additional commercial plan. BUNAVAIL replaced Zubsolv and will share preferred status with Suboxone film. The contract went into effect on July 1, 2016.
    - BUNAVAIL is now in a much improved position to access these additional prescriptions.
- Data presented at the International Conference on Opioids demonstrating that in Tennessee, prescriptions of Suboxone decreased from a weekly consistent peak of more than 1,600 to less than 100 within one month of the switch, while BUNAVAIL prescriptions increased from a low of 19 to approximately 600. This approximate 63 percent reduction in overall prescriptions in the plan remained throughout the measurement period analyzed, which could result in a savings of approximately $14 million to the state budget.
- Following the final ruling by the Department of Health and Human Services, effective August 8, 2016, the limit on the number of *patients* an individual physician can treat with buprenorphine for opioid dependence has increased from 100 to 275.

BELBUCA (buprenorphine) buccal film (CIII)

- BELBUCA prescriptions continue to grow, totaling more than 1,300 during the week ending July 29. The number of repeat prescriptions also continues to grow.
- Endo reports increasing investments in new promotional efforts for BELBUCA.
- Endo filed BELBUCA regulatory submission in Canada.

ONSOLIS (fentanyl buccal soluble film) - Management of Breakthrough Pain in Opioid Tolerant Patients with Cancer

- Signed a licensing agreement under which BDSI granted the exclusive rights to develop and commercialize ONSOLIS in the U.S. to Collegium Pharmaceutical. Collegium is responsible for the future manufacturing, distribution, marketing and sales of ONSOLIS in the U.S.
- BDSI received a $2.5 million upfront non-refundable payment, and will receive another $4 million upon the first commercial sale of ONSOLIS in the U.S., which is anticipated to take place by mid-2017. Meda shares in a significant portion of the proceeds from milestones and royalties from ONSOLIS.
- BDSI is also eligible to receive up to $17 million in potential payments based on achievement of performance and sales milestones and upper-teen royalties based on various annual U.S. net sales thresholds.

Clonidine Topical Gel – Painful Diabetic Neuropathy

- Multi-center, randomized, double-blind, placebo-controlled Phase 2b study of Clonidine Topical Gel has reached its randomization goal.
- As a result, it is expected that topline study results will be available by the end of 2016, well ahead of schedule.

Buprenorphine 30 Day Injection – Pain & Opioid Dependence

- Pre-clinical data demonstrates the ability of BDSI's buprenorphine injection formulation to provide therapeutic plasma levels of buprenorphine out to one month.
- Two pre-clinical studies are in process. Completion and analysis of these two studies will determine the timing of the Investigational New Drug (IND) submission. The submission timing is not anticipated to have an impact on the overall development timeline as activities to support the Phase 1 clinical study, are progressing. The study is expected to begin in the fourth quarter of this year.

Key Anticipated 2016-2017 Milestones

- Last patient completes Clonidine Topical Gel Phase 2b study, with data expected by end of year.
- IND filing of Buprenorphine 30 Day Injection for the treatment of opioid dependence and initiation of a single dose pharmacokinetic study are anticipated in the fourth quarter of 2016.
- Implementation of recently awarded BUNAVAIL managed care contracts effective January 1, 2017.

Conference Call & Webcast

Tuesday, August 9 @ 8:00 am Eastern Time	
Domestic:	888-427-9419
International:	719-325-2361
Passcode:	3069498
Webcast:	***http://public.viavid.com/index.php?id=120421***
Replays available through August 23rd:	
Domestic:	877-870-5176
International:	858-384-5517
Conference ID:	3069498

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 opioid dependence, chronic pain, breakthrough cancer pain and painful diabetic neuropathy. 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 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

CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,464	$ 83,560
Accounts receivable, net	2,408	2,488

Inventory	4,426	2,558
Prepaid expenses and other current assets	3,612	3,933
Total current assets	67,910	92,539
Property and equipment, net	4,299	4,262
Goodwill	2,715	2,715
Other intangible assets, net	2,771	3,256
Total assets	$ 77,695	$ 102,772
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 19,059	$ 19,501
Notes payable, current maturities, net	7,533	6,707
Deferred revenue, current	1,965	1,875
Derivative liability	114	—
Total current liabilities	28,671	28,083
Notes payable, less current maturities, net	21,540	22,168
Deferred revenue, long-term	20,000	20,000
Other long-term liabilities	825	825
Total liabilities	71,036	71,076
Commitments and contingencies (Notes 7 and 12)	—	—
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 June 30, 2016 and December 31, 2015	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 53,610,470 and 52,730,799 shares issued; 53,594,979 and 52,715,308 shares outstanding at June 30, 2016 and December 31, 2015, respectively	54	53
Additional paid-in capital	285,072	274,891
Treasury stock, at cost, 15,491 shares	(47)	(47)

Accumulated deficit	(278,422)	(243,203)
Total stockholders' equity	6,659	31,696
Total liabilities and stockholders' equity	$ 77,695	$ 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 June 30,		**Six Months Ended June 30,**	
	2016	**2015**	**2016**	**2015**
Revenues:				
Product sales	$ 2,110	$ 833	$ 4,212	$ 1,510
Product royalty revenues	394	469	1,328	663
Research and development reimbursements	—	80	4	855
Contract revenues	2,500	351	2,500	11,759
Total Revenues:	5,004	1,733	8,044	14,787
Cost of sales	4,094	2,621	6,644	3,745
Expenses:				
Research and development	4,008	4,506	9,385	11,054
Selling, general and administrative	12,496	13,287	25,551	26,468
Total Expenses:	16,504	17,793	34,936	37,522
Loss from operations	(15,594)	(18,681)	(33,536)	(26,480)
Interest expense, net	(914)	(527)	(1,691)	(947)
Derivative gain	22	—	22	—

Other (expense) income, net	—	(3)	(14)	23
Net loss	$ (16,486)	$ (19,211)	$ (35,219)	$ (27,404)
Basic and diluted loss per share:	$ (0.31)	$ (0.37)	$ (0.66)	$ (0.53)
Weighted average common stock shares outstanding:	53,594,979	52,401,747	53,412,813	52,156,657

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

	Six months ended June 30,	
	2016	**2015**
Operating activities:		
Net loss	$ (35,219)	$ (27,404)
Depreciation	212	167
Accretion of debt discount	198	278
Amortization of intangible assets	485	485
Derivative liability	114	—
Stock-based compensation expense	7,457	7,658
Changes in assets and liabilities:		
Accounts receivable	80	1,614
Inventories	(1,868)	295
Prepaid expenses and other assets	321	133
Accounts payable and accrued expenses	(441)	(2,210)
Deferred revenue	90	(366)
Net cash flows from operating activities	(28,571)	(19,350)

Investing activities:		
Purchase of equipment	(249)	(583)
Net cash flows from investing activities	(249)	(583)
Financing activities:		
Proceeds from issuance of common stock	2,459	—
Equity financing costs	40	(40)
Proceeds from exercise of stock options	225	303
Proceeds from exercise of common stock warrants	—	1
Payment on note payable	—	(3,335)
Proceeds from notes payable	—	20,667
Payment of deferred financing fees	—	(486)
Return of short swing profits	—	6
Net cash flows from financing activities	2,724	17,116
Net change in cash and cash equivalents	(26,096)	(2,817)
Cash and cash equivalents at beginning of year	83,560	70,472
Cash and cash equivalents at end of year	**$ 57,464**	**$ 67,655**
Cash paid for interest	$ 1,358	$ 491

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SOURCE BioDelivery Sciences International, Inc.

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