



BioDelivery Sciences Reports Second Quarter 2017 Financial Results and Provides Corporate Update

August 9, 2017

Conference Call Today at 4:30 PM Eastern Time

BELBUCA second quarter net revenue of \$6.6 million; 44% increase over first quarter

BELBUCA second quarter gross profit of \$5.3 million; 43% increase over first quarter

BELBUCA gross profit of 80% in second quarter and year-to-date

BELBUCA approved for marketing in Canada and licensed to Purdue (Canada) with early 2018 launch anticipated

Two additional Orange Book listed patents granted strengthening patent protection for BELBUCA, BUNAVAIL and ONSOLIS

RALEIGH, N.C., Aug. 9, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) today reported financial results for the three and six months ended June 30, 2017, and provided an update on recent business highlights and upcoming milestones.

"The U.S. currently faces a very serious crisis with regard to prescription opioid abuse, addiction and overdose. Our two buprenorphine-containing products provide important options to address the needs of those with chronic pain and opioid dependence, and we believe this is becoming increasingly recognized by healthcare providers, and that these dynamics are likely aiding our commercial performance with BELBUCA[®]," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "Our strong start with our focused commercial effort behind BELBUCA continued in the second quarter, with solid 44% growth in BELBUCA net sales to \$6.6 million compared to net sales of \$4.6 million in the first quarter. This is accentuated by sales from May onward that exceeded the previous sales peak reached by our former commercial partner Endo in December 2016. The increasing number of both prescriptions and number of BELBUCA prescribers provide us with the confidence that our commercial strategy is working, and we anticipate continued growth. We also believe that the addition of government payers, such as Medicare Part D, which represents nearly 40% of the total prescriptions for long-acting opioids, provides further opportunity for growth as we look ahead to 2018."

Dr. Sirgo continued, "We also achieved important progress with our BELBUCA licensing efforts outside the U.S. Our second quarter marketing approval for BELBUCA by Health Canada was followed shortly thereafter by our licensing agreement with Purdue (Canada) for the licensing, distribution, marketing, and sale of BELBUCA in Canada. We anticipate the launch will take place early next year. Beyond this agreement, we are focused on advancing toward additional commercial transactions for ex-U.S. rights to BELBUCA this year, which will further support sustained future growth and our expansion strategy for this important product."

"Our cash on hand, in combination with expected BELBUCA and BUNAVAIL[®] revenue, provide us the capital runway to support our current operating plan into the second half of 2018. In addition, this runway does not include our ability to access up to an additional \$30 million from our current CRG loan, the availability of which is dependent upon BDSI achieving certain funding conditions."

Second Quarter 2017 Financial Highlights

Net revenue for the second quarter ended June 30, 2017, was approximately \$8.7 million compared to \$29.5 million in the first quarter of 2017, and \$5.0 million in the second quarter of last year. First quarter 2017 revenue included \$20.0 million of non-cash deferred revenue recognized as part of the reacquisition of BELBUCA and termination of the Endo license in January 2017. This deferred revenue was part of the \$50 million NDA approval milestone payment received by BDSI from Endo.

Total net revenue of BELBUCA and BUNAVAIL in the second quarter were \$6.6 million and \$1.3 million, respectively, versus \$4.6 million and \$3.2 million in the first quarter of 2017. BUNAVAIL sales of \$3.2 million in the first quarter included \$1.7 million in sales shipped to wholesalers prior to January 1, 2017, and recognized during the first quarter as we adopted the sell-in method, which records sales based on product sold to wholesalers, versus the previously utilized sell-through method.

Total operating expenses for the second quarter ended June 30, 2017, were \$17.6 million, compared to \$16.5 million in the second quarter of 2016, with the increase due to increased general and administrative costs due to the amortization of \$1.1 million of the \$45.0 million intangible from the favorable valuation of the BELBUCA reacquisition.

Net loss for the second quarter ended June 30, 2017, was \$14.9 million, or (\$0.27) per basic and diluted share, compared to a net loss of \$16.5 million, or (\$0.31) per basic and diluted share, in the same period of 2016. The decrease in net loss was attributable principally to net sales from the reacquisition of BELBUCA in January 2017.

BDSI had cash and cash equivalents of approximately \$27.5 million at June 30, 2017. This compares to cash and cash equivalents of approximately \$35.2 million at March 31, 2017.

Six Months Ended June 30, 2017 Financial Highlights

Net revenue for the six months ended June 30, 2017, was approximately \$38.2 million, compared to \$8.0 million in the same period of 2016. Total net

sales of BELBUCA and BUNAVAIL in the first six months of 2017 were \$11.1 million and \$4.6 million, respectively. This compares to BUNAVAIL total net revenue of \$4.2 million in the six months ended June 30, 2016. Also recognized in net revenue for the six months ended June 30, 2017, was \$20 million of deferred revenue for BELBUCA upon termination of the license with Endo.

Total operating expenses for the six months ended June 30, 2017, were \$33.5 million, compared to \$34.9 million in the same period of 2016. The reduction in operating expenses was primarily attributable to a decrease in research and development spending, offset somewhat by the amortization of \$2.2 million of the \$45.0 million intangible from the favorable valuation of the BELBUCA reacquisition.

Net income for the six months ended June 30, 2017, was \$33.4 million, or \$0.61 per basic and \$0.60 per diluted share, compared to a net loss of \$35.2 million, or (\$0.66) per basic and diluted share, in the same period of 2016. The increase in net income was attributable principally to BELBUCA net sales, favorable valuation of the licensing and distribution agreement for BELBUCA and recognition of deferred revenue associated with the license termination and reacquisition of BELBUCA.

Recent Company Milestones

Commercial

- BELBUCA (buprenorphine) buccal film (CIII) generated net revenue of \$6.6 million in the second quarter of 2017, an increase of 44% over the first quarter of 2017. The June annualized net revenue run rate for BELBUCA exceeds \$33 million.
- Signed an exclusive agreement with Purdue Pharma (Canada) for the licensing, distribution, marketing, and sale of BELBUCA in Canada. BDSI is eligible to receive upfront and potential milestones of up to CAD \$4.5 million, as well as royalties on net sales. BDSI expects Purdue to launch BELBUCA in Canada in early 2018.

Regulatory

- Approval for BELBUCA received from Health Canada in June.
- Received approval from the U.S. Food and Drug Administration (FDA) for a Supplemental New Drug Application (sNDA) expanding the indication for BUNAVAIL (buprenorphine and naloxone) buccal film (CIII) to include induction of buprenorphine treatment for opioid dependence. Induction is the first step to assist a patient in discontinuing or markedly reducing their use of opioids.

Managed Care

- BELBUCA prescriptions increased 19% from the first to second quarter of 2017 within United Healthcare commercial book of business. This follows implementation of a contract on January 1, 2017, providing preferred access to BELBUCA over Butrans.
- Additional significant managed care contract secured and announced in the second quarter with a January 1, 2018, effective date.

Intellectual Property

- Two new Orange Book listed patents further extend and strengthen patent protection on BELBUCA, BUNAVAIL and ONSOLIS® (fentanyl buccal soluble film) (CII).
- Patent issued extending patent protection on ONSOLIS from January 2020 to July 2027; issued patent is associated with a \$3 million milestone payment to BDSI from Collegium Pharmaceutical, payment of which is due upon FDA approval of the supplemental application supporting the new manufacturer for ONSOLIS.

Key Anticipated Milestones

- Continued prescription and revenue growth of BELBUCA
- Opportunity for additional managed care contracts, particularly Medicare for BELBUCA
- BELBUCA launch in Canada in early 2018 by Purdue (Canada)
- Opportunity to execute additional commercial transaction for ex-U.S. rights to BELBUCA
- Planned regulatory submission later this year to qualify the new manufacturer for ONSOLIS, facilitating a potential return of the product to market in the first half of 2018

Conference Call & Webcast

<u>Wednesday, August 9 at 4:30 PM Eastern Time</u>	
Domestic:	888-539-3696
International:	719-325-4772

Passcode:	2753949
Webcast:	http://public.viavid.com/index.php?id=125148
Replays available through August 23rd:	
Domestic:	844-512-2921
International:	412-317-6671
Conference ID:	2753949

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 marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain 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) and **BELBUCA[®]** (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. **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 and for full prescribing and safety information on BUNAVAIL, please visit www.bunavail.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, 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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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	June 30,	December 31,
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,508	\$ 32,019
Accounts receivable	7,753	3,569
Inventory	6,564	3,368
Prepaid expenses and other current assets	2,657	4,136
Total current assets	44,482	43,092
Property and equipment, net	4,437	4,230
Goodwill	2,715	2,715
BELBUCA license and distribution rights intangible	42,750	-
Other intangible assets, net	1,800	2,285
Total assets	\$ 96,184	\$ 52,322
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 30,613	\$ 18,174
Deferred revenue, current	-	1,716
Total current liabilities	30,613	19,890
Notes payable, current maturities, net	35,251	29,272
Deferred revenue, long term	-	20,000
Other long-term liabilities	4,050	825
Total liabilities	69,914	69,987
Commitments and contingencies (Notes 11 and 15)		

Stockholders' equity:

Preferred Stock, \$.001 par value; 5,000,000 shares authorized; 2,093,155 and 2,093,155 shares of Series A Non-Voting Convertible Preferred Stock outstanding at both June 30, 2017 and December 31, 2016 and 2015, respectively.	2	2
Common Stock, \$.001 par value; 75,000,000 shares authorized; 55,491,463 and 54,133,511 shares issued; 55,475,972 and 54,118,020 shares outstanding at June 30, 2017 and December 31, 2016, respectively.	55	54
Additional paid-in capital	303,155	292,667
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(276,895)	(310,341)
Total stockholders' equity (deficit)	26,270	(17,665)
Total liabilities and stockholders' equity	\$ 96,184	\$ 52,322

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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,	
	2017	2016	2017	2016
Revenues:				
Product sales	\$ 7,886	\$ 2,110	\$ 15,680	\$ 4,212
Product royalty revenues	613	394	2,273	1,328
Research and development reimbursements	245	-	267	4
Contract revenue	-	2,500	20,000	2,500
Total Revenues:	8,744	5,004	38,220	8,044
Cost of sales	4,171	4,094	9,816	6,644
Expenses:				
Research and development:	1,590	4,008	4,260	9,385

Sales, general and administrative	15,970	12,496	29,227	25,551
Total Expenses:	17,560	16,504	33,487	34,936
Loss from operations	(12,987)	(15,594)	(5,083)	(33,536)
Interest expense	(1,878)	(914)	(4,764)	(1,691)
Derivative gain	-	22	-	22
Other expense, net	(14)	-	(15)	(14)
Bargain purchase gain	-	-	27,336	-
(Loss) income before income taxes	\$ (14,879)	\$ (16,486)	\$ 17,474	\$ (35,219)
Income tax benefit	-	\$ -	15,972	\$ -
Net (loss) income attributable to common stockholders	\$ (14,879)	\$ (16,486)	\$ 33,446	\$ (35,219)

Basic:

Basic (loss) income per share:	\$ (0.27)	\$ (0.31)	\$ 0.61	\$ (0.66)
Weighted average common stock shares outstanding:	55,388,774	53,594,979	54,949,901	53,412,813

Diluted:

Diluted (loss) income per share:	\$ (0.27)	\$ (0.31)	\$ 0.60	\$ (0.66)
Weighted average common stock shares outstanding:	55,388,774	53,594,979	55,836,769	53,412,813

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

Six Months Ended June 30,

	2017	2016
Operating activities:		
Net income (loss)	\$ 33,446	\$ (35,219)
Depreciation	226	212

Accretion of debt discount and loan costs	1,491	198
Amortization of Intangible Assets	2,735	485
Derivative liability	-	114
Stock-based compensation expense	6,000	7,457
Deferred income taxes	(15,972)	-
Bargain purchase gain	(27,336)	-
Changes in assets and liabilities:		
Accounts receivable	(4,183)	80
Inventories, net of effect of acquisition	2,660	(1,868)
Prepaid expenses and other assets	1,034	321
Accounts payable and accrued expenses, net of effect of acquisition	4,904	(441)
Deferred Revenue	(21,716)	90
Net cash flows from operating activities	(16,711)	(28,571)
Investing activities:		
Purchase of equipment	(2)	(249)
Net cash flows from investing activities	(2)	(249)
Financing activities:		
Proceeds from notes payable	45,000	-
Payment of notes payable	(30,000)	-
Payment of deferred financing fees	(2,798)	-
Equity financing costs	-	40
Proceeds from exercise of stock options	-	225
Proceeds from issuance of common stock	-	2,459
Net cash flows from financing activities	12,202	2,724
Net change in cash and cash equivalents	(4,511)	(26,096)
Cash and cash equivalents at beginning of year	32,019	83,560
Cash and cash equivalents at end of year	\$ 27,508	\$ 57,464
Cash paid for interest	\$ 2,373	\$ 1,358

SOURCE BioDelivery Sciences International, Inc.

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