



BioDelivery Sciences Reports Strong Second Quarter 2018 Financial Results

August 9, 2018

BELBUCA® Continues Its Accelerated Record Prescription Growth of 80% YOY and 31% Versus the Prior Quarter

Company Provides Overview of New Plan to Capitalize on Long Term Net Revenue Potential of \$200 Million For Belbuca

BDSI Conference Call and Webcast Scheduled for 4:30 PM ET Today

RALEIGH, N.C., Aug. 09, 2018 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a leading specialty pharmaceutical company focused on patients living with chronic pain, today reported financial results for the second quarter ending June 30, 2018, as well as the following operational and performance highlights:

- Achieved accelerated BELBUCA® performance with scripts growing by 80% YOY and 31% versus prior quarter.
- Expanded Company leadership, including on-boarding of new Chief Executive Officer, hiring of new Chief Medical Officer, reconstituting the Board and selected a new Chairman.
- Strengthened balance sheet by completing a \$50 million capital raise.

"The second quarter was highlighted by strong prescription growth, organization development, and execution across the Company that has resulted in significant progress toward our 2018 goals," said Herm Cukier, Chief Executive Officer of BDSI. "Based on the current prescription momentum and further growth potential, we believe the opportunity for BELBUCA longer term may well be more than \$200 million per year. This has been a successful first half of the year, and I am confident in our ability to continue to execute effectively going forward."

The Company also announced that management has established a growth plan for BELBUCA which is expected to capitalize on the long-term potential of the product. The plan includes further expansion of the sales team, building out the market access and medical affairs teams, and creating a consumer social media plan. More information will be provided at an upcoming analyst meeting to be held later this year.

For BUNAVAIL®, the company continues to believe it is an important treatment option for opioid dependent patients given its unique dosing and delivery technology. While challenges remain, we will continue efforts to improve access to the drug for all patients and with healthcare providers on their awareness and utilization.

Given the strong company performance during the first half of the year and effective execution, total year 2018 financial expectation for Belbuca is expected to be in the range of \$41 - \$43 million net revenue. Total Company net revenue is expected to be in the range of \$50 - \$52 million.

Summary of Second Quarter 2018 Financial Results

Total net revenue. Total net revenue for the second quarter ended June 30, 2018, was \$12.2 million, compared to \$11.3 million in the first quarter of 2018, an increase of 8%, and \$8.7 million in the second quarter of 2017, an increase of 39%.

Total product net revenue. Total product net revenue for BELBUCA® (buprenorphine) buccal film and BUNAVAIL® (buprenorphine and naloxone) buccal film in the second quarter ended June 30, 2018, was \$9.7 million and \$1.1 million, respectively, versus \$8.0 million and \$1.8 million, respectively, in the first quarter of 2018, and \$6.6 million and \$1.3 million, respectively, in the second quarter of 2017.

Total operating expenses. Total operating expenses for the second quarter ended June 30, 2018, were \$14.9 million, compared to \$16.0 million in the first quarter of 2018, and \$17.6 million in the second quarter of 2017.

Net loss. Net loss for the second quarter ended June 30, 2018, was \$9.8 million, or (\$0.16) per diluted share, compared to a net loss of \$10.7 million, or (\$0.18) per diluted share, in the first quarter of 2018; and a net loss of \$14.9 million, or (\$0.27) per diluted share, in the second quarter of 2017.

Cash position. At June 30, 2018, BDSI had cash and cash equivalents of approximately \$55.7 million. This compares to cash and cash equivalents of approximately \$21.2 million at December 31, 2017.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and audio webcast today, August 9, 2018 at 4:30 p.m. ET to present second quarter 2018 results and provide a business update. Dial-in details are as follows:

Thursday, August 9 @ 4:30pm Eastern Time

Domestic: 800-458-4121
International: 323-794-2093
Passcode: 2839790
Webcast: <http://public.viavid.com/index.php?id=130332>

Replays available through August 23, 2018:

Domestic: 844-512-2921
International: 412-317-6671
Conference ID: 2839790

About BioDelivery Sciences International, Inc.

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 chronic pain, breakthrough cancer 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](https://www.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. For full prescribing information and important safety information on BDSI products 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, the presentation described herein, and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. ("BDSI") 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 BDSI'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 BDSI's management and are subject to significant risks and uncertainties, including the risk that our growth plan for BELBUCA is not successful in the time frame we currently expect or at all and those detailed in the BDSI's filings with the Securities and Exchange Commission. Actual results, including, our 2018 full year financial expectations, may differ significantly from those set forth or implied 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 BDSI's control). BDSI 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,

	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,724	\$ 21,195
Accounts receivable	9,410	8,852
Inventory	6,168	6,091
Prepaid expenses and other current assets	2,156	3,610
Total current assets	73,458	39,748
Property and equipment, net	3,366	3,778
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	38,250	40,500
Other intangible assets, net	1,032	1,360
Total assets	\$ 118,821	\$ 88,101

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	\$ 23,228	\$ 26,149
Total current liabilities	23,228	26,149
Notes payable, net	49,394	47,660
Other long-term liabilities	5,462	5,415
Total liabilities	78,084	79,224
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series A Non-Voting Convertible Preferred Stock, \$.001 par value, 2,093,155 shares outstanding at both June 30, 2018 and December 31, 2017, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 5,000 and 0 shares outstanding at June 30, 2018 and December 31, 2017, respectively;	2	2
Common Stock, \$.001 par value; 75,000,000 shares authorized; 59,459,446 and 55,904,072 shares issued; 59,443,955 and 55,888,581 shares outstanding at June 30, 2018 and December 31, 2017, respectively.	59	56
Additional paid-in capital	366,123	313,922
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(325,400)	(305,056)
Total stockholders' equity	40,737	8,877
Total liabilities and stockholders' equity	\$ 118,821	\$ 88,101

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,	
	2018	2017	2018	2017
Revenues:				
Product sales	\$ 10,766	\$ 7,886	\$ 20,604	\$ 15,680
Product royalty revenues	1,386	613	1,826	2,273
Research and development reimbursements	-	245	-	267
Contract revenue	23	-	1,026	20,000
Total Revenues:	12,175	8,744	23,456	38,220
Cost of sales	4,566	4,171	7,981	9,816

Expenses:				
Research and development:	854	1,590	3,338	4,260
Sales, general and administrative	14,021	15,970	27,526	29,227
Total Expenses:	14,875	17,560	30,864	33,487
Loss from operations	(7,266)) (12,987)) (15,389)) (5,083)
Interest expense	(2,525)) (1,878)) (5,030)) (4,764)
Other expense, net	1) (14)) (6)) (15)
Bargain purchase gain	-	-	-	27,336
(Loss) income before income taxes	\$ (9,790)) \$ (14,879)) \$ (20,425)) \$ 17,474
Income tax benefit	20	-	(54)) 15,972
Net (loss) income attributable to common stockholders	\$ (9,770)) \$ (14,879)) \$ (20,479)) \$ 33,446
Basic:				
Basic (loss) income per share:	\$ (0.16)) \$ (0.27)) \$ (0.35)) \$ 0.61
Weighted average common stock shares outstanding:	59,400,317	55,388,774	58,735,351	54,949,901
Diluted:				
Diluted (loss) income per share:	\$ (0.16)) \$ (0.27)) \$ (0.35)) \$ 0.60
Weighted average common stock shares outstanding:	59,400,317	55,388,774	58,735,351	55,836,769

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. DOLLARS, IN THOUSANDS)
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Operating activities:		
Net (loss) income	\$ (20,479)) \$ 33,446
Depreciation and amortization	456	226
Impairment loss on equipment	78	-
Accretion of debt discount and loan costs	1,782	1,491
Amortization of intangible assets	2,578	2,735
Provision for inventory obsolescence	412	21
Stock-based compensation expense	4,004	6,000
Deferred income taxes	-	(15,972)
Bargain purchase gain	-	(27,336)
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(423)) (4,183)
Inventories	(489)) 2,660
Prepaid expenses and other assets	1,454	1,034
Accounts payable and accrued liabilities	(1,118)) 4,904
Deferred Revenue	-	(21,716)
Net cash flows from operating activities	(11,745)) (16,690)
Investing activities:		
BELBUCA acquisition	(1,951)) -
Purchase of equipment	(122)) (2)
Net cash flows from investing activities	(2,073)) (2)
Financing activities:		
Proceeds from issuance of Series B preferred stock	50,000	-
Equity financing costs	(1,509)) -
Proceeds from notes payable	-	45,000
Proceeds from exercise of stock options	306	-
Payment of notes payable	-	(30,000)
Payment of deferred financing fees	(450)) (2,798)

Net cash flows from financing activities	48,347	12,202	
Net change in cash and cash equivalents	34,529	(4,490)
Cash and cash equivalents at beginning of year	21,195	32,019	
Cash and cash equivalents at end of year	\$ 55,724	\$ 27,529	
Cash paid for interest	\$ 3,249	\$ 2,373	

 [Primary Logo](#)

Source: BioDelivery Sciences International, Inc.