



BioDelivery Sciences Reports Strong Second Quarter 2019 Results and Raises Net Sales Expectations

August 8, 2019

*BELBUCA® Net Sales Increased 147% versus Prior Year to All-Time High of \$24.1 Million
Raises Full-Year BELBUCA Net Sales Expectations to \$90 - \$93 Million
Raises Full-Year Total Company Net Sales Expectations to \$101 - \$105 Million
Raises Long-Term Combined Net Sales Expectations for BELBUCA and Symproic® to \$425 - \$500 Million*

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

RALEIGH, N.C., Aug. 08, 2019 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions, today reported strong financial results for the second quarter ended June 30, 2019, as well as the following operational and performance highlights:

Key Business Highlights

- Total company net revenue increased by 144% versus the prior year period to a new all-time high of \$29.7 million. This growth was driven by BELBUCA® (buprenorphine buccal film), CIII sales of \$24.1 million, an increase of 147% versus the prior year period, and the addition of Symproic® (naldemedine) tablets 0.2 mg to the commercial portfolio.
- Total BELBUCA prescriptions of more than 80,000 for the quarter was the highest ever for any three-month period. In addition, prescription growth for BELBUCA reached an all-time year-over-year record increase of 44,560 prescriptions, representing a 125% increase year-over-year and a 23% increase versus the prior quarter.
- Achieved a new all-time high of 6,579 unique BELBUCA prescribers during the quarter.
- Delivered highest ever number of quarterly prescriptions for Symproic achieving greater than 14% quarter-over-quarter growth and 40% growth versus prior year.
- Significantly strengthened financial position through debt refinancing, dramatically lowering cost of capital and extending maturity.

"The second quarter was highlighted by dramatic accomplishments across our entire organization and has positioned us to further build upon our commercial success," stated Herm Cukier, Chief Executive Officer of BDSI. "We have significant momentum with our core products and have strengthened the company's financial position. Our excellent performance in the second quarter is the fifth consecutive quarter of sustained and rapid growth. I believe our future is very promising, and as we raise our full-year BELBUCA and total company net sales expectations for the second time this year, we have great confidence in our growth trajectory into 2020 and beyond."

The company again increased its expectations for full-year 2019 BELBUCA net sales to \$90 - \$93 million, from the previous level of \$83 - \$88 million. The company also raised its total 2019 net sales expectations to \$101 - \$105 million, from the previous level of \$92 - \$100 million. Total net revenue expectations include \$7 - \$9 million of forecasted Symproic net sales, which is in line with the company's previous expectation.

With the strong performance achieved over the last five consecutive quarters, coupled with a solid balance sheet supporting the execution of the commercial growth plan, the company is raising its long-term combined net sales expectations for BELBUCA and Symproic to \$425 - \$500 million.

Second Quarter 2019 Financial Results

Total Net Revenue. Total net revenue for the second quarter ended June 30, 2019, was \$29.7 million, an increase of 50%, compared to \$19.8 million in the first quarter of 2019, and an increase of 144%, compared to \$12.2 million in the second quarter of 2018.

Total Net Product Sales. Total net product sales in the second quarter were \$28.1 million, an increase of 42%, compared to \$19.8 million in the first quarter of 2019 and an increase of 161% compared to \$10.8 million in the second quarter of 2018. This includes net product sales of Symproic of \$3.2 million in the initial quarter of commercialization following the acquisition of the product.

BELBUCA Net Sales. BELBUCA net sales in the second quarter were \$24.1 million, an increase of 29%, compared to \$18.7 million in the first quarter of 2019 and an increase of 147%, compared to \$9.7 million in the second quarter of 2018.

Total Operating Expenses. Total operating expenses in the quarter ended June 30, 2019, were \$22.0 million, compared to \$17.0 million in the first quarter of 2019 and \$14.9 million in the second quarter of 2018.

GAAP Net Loss. GAAP net loss for the quarter was \$11.1 million, or (\$0.13) per share, compared to the loss of \$3.8 million, or (\$0.05) per share, for the first quarter of 2019 and a GAAP net loss of \$9.8 million, or (\$0.16) per share, in the second quarter of 2018. The increase in net loss is driven by

the one-time debt refinancing costs of \$11.9 million.

EBITDA. EBITDA in the second quarter of 2019 was \$4.8 million or 16.1% of total net revenue, compared to \$0.1 million in the first quarter of 2019 and (\$5.6) million in the second quarter of 2018.

Non-GAAP Net Income. Non-GAAP net income for the quarter was \$4.4 million and reflects GAAP net loss excluding the non-recurring costs of the debt refinancing, stock-based compensation and non-cash amortization of intangible assets and warrant discounts.

Cash Position. BDSI had cash and cash equivalents of approximately \$57.2 million as of June 30, 2019. Based on current guidance, the company anticipates having positive operating cash flow by the fourth quarter of 2019.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, August 8, 2019, at 4:30 p.m. ET to present second quarter 2019 results and to provide a business update. Dial-in details are as follows:

Date: Thursday, August 8, 2019
Time: 4:30 PM EDT
Domestic: 800-347-6311
International: 720-543-0197
Passcode: 868 4665
Webcast: <http://public.viaid.com/index.php?id=135544>

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions. BDSI has built a portfolio of products that includes utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology 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, opioid dependence, and opioid-induced constipation.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This press release 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 those detailed in the BDSI's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the continued growth in BELBUCA net revenues and total net revenues in 2019 and the implementation and success of our Symproic strategic plan) may differ materially 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) including those set forth in our 2019 annual report on Form 10-K filed with the US Securities and Exchange Commission and subsequent filings. 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.

© 2019 BioDelivery Sciences International, Inc. All rights reserved.

Contact:

Mary Coleman
Vice President, Investor Relations and Corporate Communications
BioDelivery Sciences International, Inc.
mcoleman@bdsi.com

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS) (Unaudited)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,215	\$ 43,822
Accounts receivable, net.	24,879	13,627
Inventory, net	9,974	5,406
Prepaid expenses and other current assets	3,298	3,188
Total current assets	95,366	66,043
Property and equipment, net	3,853	3,072
Goodwill	2,715	2,715
License and distribution rights, net	63,778	36,000

Other intangible assets, net	375	703
Total assets	\$ 166,087	\$ 108,533

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable and accrued liabilities	\$ 40,762	\$ 21,539
Total current liabilities	40,762	21,539

Notes payable, net	58,448	51,652
Other long-term liabilities	727	5,600
Total liabilities	99,937	78,791

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, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 1,716 and 3,100 shares outstanding at June 30, 2019 and December 31, 2018, respectively.	2	2
Common Stock, \$.001 par value; 125,000,000 shares authorized at June 30, 2019 and December 31, 2018, respectively; 89,535,024 and 75,793,725 shares issued; 89,519,533 and 70,778,234 shares outstanding at June 30, 2019 and December 31, 2018, respectively.	88	71
Additional paid-in capital	432,358	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(366,251)	(351,288)
Total stockholders' equity	66,150	29,742

Total liabilities and stockholders' equity	\$ 166,087	\$ 108,533
--	-------------------	-------------------

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,	
	2019	2018	2019	2018
Revenues:				
Product sales	\$ 28,056	\$ 10,766	\$ 47,815	\$ 20,604
Product royalty revenues	1,461	1,386	1,471	1,826
Contract revenue	160	23	160	1,026
Total Revenues:	29,677	12,175	49,446	23,456
Cost of sales	4,923	4,566	8,975	7,981
Expenses:				
Research and development:	-	854	-	3,338
Sales, general and administrative	21,955	14,021	38,944	27,526
Total Expenses:	21,955	14,875	38,944	30,864
Income (loss) from operations	2,799	(7,266)	1,527	(15,389)
Interest expense	(13,937)	(2,525)	(16,498)	(5,030)
Other (expense) income, net	8	1	8	(6)
Loss before income taxes	\$ (11,130)	\$ (9,790)	\$ (14,963)	\$ (20,425)
Income tax benefit (expense)	-	20	-	(54)
Net loss attributable to common stockholders	\$ (11,130)	\$ (9,770)	\$ (14,963)	\$ (20,479)
Basic and diluted				
Weighted average common stock shares outstanding:	83,821,811	59,400,317	77,571,003	58,735,351
Basic and diluted loss per share:	\$ (0.13)	\$ (0.16)	\$ (0.19)	\$ (0.35)

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

	Six Months Ended June 30,	
	2018	2018
Operating activities:		
Net loss	\$ (14,963) \$ (20,479)
Depreciation and amortization	168	456
Impairment loss on equipment	-	78
Accretion of debt discount and loan costs	11,374	1,782
Amortization of intangible assets	3,187	2,578
Provision for inventory obsolescence	149	412
Stock-based compensation expense	2,711	4,004
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(11,252) (423)
Inventories	(4,716) (489)
Prepaid expenses and other assets	(110) 1,454
Accounts payable and accrued expenses	9,078	(1,118)
Net cash flows from operating activities	(4,374) (11,745)
Investing activities:		
Product acquisitions	(20,674) (1,951)
Acquisitions of equipment	(79) (122)
Net cash flows from investing activities	(20,753) (2,073)
Financing activities:		
Proceeds from issuance of common stock	48,000	-
Proceeds from issuance of Series B preferred stock	-	50,000
Equity financing costs	(410) (1,509)
Proceeds from notes payable	60,000	-
Proceeds from exercise of stock options	1,070	306
Payment of notes payable	(67,346) -
Loss on refinancing of former debt	(2,794) -
Payment of deferred financing fees	-	(450)
Net cash flows from financing activities	38,520	48,347
Net change in cash and cash equivalents	13,393	34,529
Cash and cash equivalents at beginning of year	43,822	21,195
Cash and cash equivalents at end of year	\$ 57,215	\$ 55,724

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
RECONCILIATION OF NON-GAAP METRICS
(U.S. DOLLARS, IN THOUSANDS)
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	2019	2018	2019	2018
GAAP net income/(loss)	\$ (11,130) \$ (9,770) \$ (14,963) \$ (20,479
Add back:				
Provision for income taxes	-	(20)	53
Net interest expense	13,929	2,525	16,490	5,037
Depreciation and amortization	1,981	1,679	3,356	3,199
EBITDA	\$ 4,780	\$ (5,586) \$ 4,883	\$ (12,190
Reconciliation of GAAP net income/(loss) to non-GAAP net income/(loss)				
GAAP net income/(loss)	\$ (11,130) \$ (9,770) \$ (14,963) \$ (20,479

Non-GAAP adjustments:				
Stock-based compensation expense	1,569	1,084	2,712	4,005
Amortization of intangible assets	1,898	1,289	3,187	2,578
Amortization of warrant discount	179	269	448	538
Non-recurring financial impact of debt refinance	11,866	-	11,866	-
Non-GAAP net income/(loss)	\$ 4,382	\$ (7,128)	\$ 3,250	\$ (13,358)



Source: BioDelivery Sciences International, Inc.