

BioDelivery Sciences Reports Strong 2018 Results and 2019 Expectations

BELBUCA® prescription growth further accelerated to an all-time high during the fourth quarter

Company increases Belbuca 2019 net sales expectations to \$80-\$85 million

Operating cash flow to become positive in 2019

Long-term potential for BELBUCA net sales believed to be \$250—\$300 million

Conference Call and Webcast scheduled for 4:30 pm ET today

Raleigh, North Carolina – March 14, 2019 — BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic pain, today reported financial results for the fourth quarter and full-year ending December 31, 2018, as well as the following operational and performance highlights:

Key Business Highlights

- BELBUCA prescription growth exceeded expectations during the fourth quarter 2018, with an increase of 126% year-over-year and a 27% increase over the prior quarter, resulting in the largest quarterly increase and an all-time quarterly high of more than 56,000 prescriptions.
- BELBUCA fourth quarter 2018 net revenue grew by 28.3% over prior quarter to \$15.9 million and to \$46 million for the full year, an increase of 70.5% versus prior year.
- 25 million lives with preferred access to BELBUCA were added during the fourth quarter, bringing the 2018 year-end total to more than 100 million lives.
- Added more than 1,100 new prescribers in the fourth quarter achieving a total of 5,358 unique prescribers during the period – both all-time highs for BELBUCA.
- Completed expansion of the sales, medical, and market access teams during the fourth quarter to further improve access and accelerate growth for BELBUCA.
- Further strengthened the executive leadership team with the appointment of Terry Coelho as Chief Financial Officer in January 2019.

“I am very pleased by the results achieved during the fourth quarter and for the entire year,” stated Herm Cukier, Chief Executive Officer of BDSI. “We succeeded in transforming the company into a rapidly growing commercial enterprise with sustained momentum as we enter 2019. The continued acceleration of BELBUCA scripts, along with increased preferred coverage and the expanded sales and medical teams, position us well to further deliver on our growth strategy in the year ahead.”

The Company expects full-year 2019 BELBUCA net revenue to be in the range of \$80-\$85 million and total Company net revenue to be in the range of \$85-\$90 million. The long-term net sales potential for BELBUCA is now seen to be in the range of \$250—\$300 million.

Fourth Quarter 2018 Financial Results

Total Net Revenue. Total net revenue for the fourth quarter ended December 31, 2018, was \$18.0 million, an increase of 27.4% compared to \$14.2 million in the third quarter of 2018, and an increase of 44.1% compared to \$12.5 million in the fourth quarter of 2017.

BELBUCA Net Revenue. BELBUCA net revenue in the fourth quarter ended December 31, 2018, was \$15.9 million, an increase of 28.3% compared to \$12.4 million in the third quarter 2018, and an increase of 68.3% compared to \$9.4 million in the fourth quarter 2017. The total net revenue growth was driven primarily by BELBUCA which comprised 88% of total net revenue in the quarter.

Total Operating Expenses. Total operating expenses for the fourth quarter ended December 31, 2018, were \$18.5 million, compared to \$14.2 million in the third quarter of 2018, and \$21.6 million in the fourth quarter of 2017. Total operating expenses in the quarter reflect the expansion of our commercial and medical teams.

Net Loss. Net loss for the fourth quarter ended December 31, 2018, was \$7.0 million, or (\$0.10) per share, compared to a loss of \$18.9 million, or (\$0.29) per share in the third quarter of 2018.

Year-End 2018 Financial Results

Total Net Revenue. Total net revenue for the full-year 2018 was \$55.6 million, a decrease of 10.2% compared to \$62.0 million for the year ended December 31, 2017. Total net revenue for 2017 included \$20 million in contract revenues recorded in January 2017 resulting from the termination of the licensing agreement with Endo and the return of BELBUCA rights to BDSI. Total net 2018 revenue growth was 32.5% excluding the aforementioned \$20 million in contract revenues.

BELBUCA Net Revenue. BELBUCA net revenue for the year ended December 31, 2018, was \$46.0 million, an increase of 70.5% compared to \$27.0 million for the year ended December 31, 2017. The long-term potential for BELBUCA net revenue is expected to be over \$250 million.

Total Operating Expenses. Total operating expenses for the year ended December 31, 2018, were \$63.5 million, compared to \$71.9 million for the year ended December 31, 2017. The year-over-year reduction was primarily due to 2017 costs associated with joining the opioid consortium, along with remaining R&D expenses.

Net Loss. Net loss for the year ended December 31, 2018, was \$46.4 million, or (\$0.73) per diluted share, compared to net income of \$5.3 million, or \$0.09 per diluted share for the year ended December 31, 2017. The full-year 2018 net loss included a one-time non-cash charge of \$12.5 million for the beneficial conversion feature of the Series B Preferred Stock.

Cash Position. At December 31, 2018, BDSI had cash and cash equivalents of approximately \$43.8 million. Based on current guidance, the company anticipates turning operating cash flow positive in 2019.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, March 14, 2019, at 4:30 p.m. ET to present fourth quarter and full-year 2018 results and to provide a business update. Dial-in details are as follows:

Conference Call Dial-In & Webcast Information:

Date: Thursday, March 14, 2019
Time: 4:30 PM Eastern Time
Domestic: 877-407-0789
International: 201-689-8562
Passcode: 13687656

Webcast: <http://public.viaavid.com/index.php?id=133294>

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic pain. 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. For more information, please visit us at www.bdsi.com or follow us on Facebook.com/BioDeliverySI or Twitter BDSI @BioDeliverySI.

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) 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 2017 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.

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	\$ 43,822	\$ 21,195
Accounts receivable, net.	13,627	8,852
Inventory, net	5,406	6,091
Prepaid expenses and other current assets	3,188	3,610
Total current assets	66,043	39,748
Property and equipment, net	3,072	3,778
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	36,000	40,500
Other intangible assets, net	703	1,360
Total assets	\$ 108,533	\$ 88,101
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 21,539	\$ 26,149
Total current liabilities	21,539	26,149
Notes payable, net	51,652	47,660
Other long-term liabilities	5,600	5,415
Total liabilities	78,791	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 December 31, 2018 and December 31, 2017, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 3,100 and 0 shares outstanding at December 31, 2018 and December 31, 2017, respectively	2	2
Common Stock, \$.001 par value; 125,000,000 and 75,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 70,793,725 and 55,904,072 shares issued; 70,778,234 and 55,888,581 shares outstanding at September 30, 2018 and December 31, 2017, respectively	71	56
Additional paid-in capital	381,004	313,922
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(351,288)	(305,056)
Total stockholders' equity	29,742	8,877
Total liabilities and stockholders' equity	\$ 108,533	\$ 88,101

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales	\$ 51,410	\$ 34,922	\$ 8,266
Product royalty revenues	3,389	5,070	3,646
Research and development reimbursements	—	799	1,134
Contract revenue	841	21,194	2,500
Total Revenues:	55,640	61,985	15,546
Cost of sales	15,783	19,496	11,258
Expenses:			
Research and development:	4,903	13,040	18,878
Sales, general and administrative	58,602	58,869	49,345
Total Expenses:	63,505	71,909	68,223
Loss from operations	(23,648)	(29,420)	(63,935)
Interest expense	(10,192)	(8,577)	(3,267)
Other expense, net	(14)	(26)	64
Bargain purchase gain	—	27,336	—
Loss before income taxes	\$ (33,854)	\$ (10,687)	\$ (67,138)
Income tax benefit	(13)	15,972	—
Net (loss) income	\$ (33,867)	\$ 5,285	\$ (67,138)
Beneficial conversion feature of convertible preferred stock	(12,500)	—	—
Net (loss) income attributable to common stockholders	\$ (46,367)	\$ 5,285	\$ (67,138)
Basic:			
Basic (loss) income per share:	\$ (0.73)	\$ 0.10	\$ (1.25)
Weighted average common stock shares outstanding:	63,165,063	55,355,802	53,679,134
Diluted:			
Diluted (loss) income per share:	\$ (0.73)	\$ 0.09	\$ (1.25)
Weighted average common stock shares outstanding:	63,165,063	56,402,479	53,679,134

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

	Year Ended December 31,		
	2018	2017	2016
Operating activities:			
Net (loss) income	\$ (33,867)	\$ 5,285	\$ (67,138)
Depreciation	740	693	437
Accretion of debt discount and loan costs	4,138	2,392	397
Amortization of intangible assets	5,157	5,425	971
Impairment loss on equipment	(56)	243	—
Provision for inventory obsolescence	78	—	—
Stock-based compensation expense	5,941	14,801	14,931
Deferred income taxes	40	(15,972)	—
Bargain purchase gain	—	(27,336)	—
Changes in assets and liabilities, net of effect of acquisition:			
Accounts receivable	(4,640)	(5,884)	(862)
Inventories	741	2,448	(810)
Prepaid expenses and other assets	422	526	(203)
Accounts payable and accrued expenses	(2,807)	6,644	(1,546)
Deferred revenue	—	(21,716)	(159)
Net cash flows from operating activities	(24,113)	(32,451)	(53,982)
Investing activities:			
BELBUCA acquisition	(1,951)	(5,853)	—
Purchase of equipment	(112)	(11)	(405)
Net cash flows from investing activities	(2,063)	(5,864)	(405)
Financing activities:			
Proceeds from sales of securities, net of costs incurred	—	—	40
Proceeds from exercise of stock options	670	439	297
Issuance of common stock	—	—	2,460
Issuance of warrants	—	—	49
Proceeds from issuance of Series B preferred stock	50,000	—	—
Payment on note payable	—	(30,000)	—
Proceeds from notes payable	—	60,000	—
Equity finance costs	(1,417)	—	—
Payment of deferred financing fees	(450)	(2,948)	—
Net cash flows from financing activities	48,803	27,491	2,846
Net change in cash and cash equivalents	22,627	(10,824)	(51,541)
Cash and cash equivalents at beginning of year	21,195	32,019	83,560
Cash and cash equivalents at end of year	\$ 43,822	\$ 21,195	\$ 32,019
Cash paid for interest	\$ 6,053	\$ 5,285	\$ 2,870