



BioDelivery Sciences Reports Fourth Quarter and Full-Year 2017 Financial Results and Provides Corporate Update

March 15, 2018

Full-year 2017 net revenue of \$62.0 million vs. \$15.5 million in 2016

BELBUCA® fourth quarter 2017 net revenue of \$9.4 million vs. \$6.4 million in third quarter; an increase of 47%

BELBUCA prescription growth of 84% in 2017 over 2016

Preferred coverage for BELBUCA secured with Humana, the second largest Medicare insurer in the country, effective March 1

BELBUCA launched in Canada in January by commercial partner Purdue (Canada)

Conference Call Today at 4:30 PM Eastern Time

RALEIGH, N.C., March 15, 2018 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ:BDSI) today reported financial results for the fourth quarter and year ended December 31, 2017 and provided an update on recent business highlights.

"We achieved strong revenue growth in both the fourth quarter and full-year 2017, driven by continued BELBUCA prescription growth," said Scott M. Plesha, President of BioDelivery Sciences. "For full-year 2017, we recorded BELBUCA prescription growth of 84% over 2016. The momentum we experienced with BELBUCA in 2017 has extended into 2018, as we reached an all-time high in monthly prescriptions of over 8,600 prescriptions in January and are on track for strong results in February following the highest 4-week total in prescriptions we have seen to date. We believe that BDSI is well-positioned to continue our growth trend with BELBUCA, as we have increased the size of our sales force, undertaken new marketing initiatives and achieved significant progress with new and improved managed care contracts."

"Additionally, we are particularly pleased with the addition of both commercial and Medicare preferred coverage of BELBUCA by Humana, effective the first of this month, particularly given that Humana is the second largest Medicare insurer in the country based on lives under management," continued Mr. Plesha. "This, along with new and improved coverage secured earlier this quarter with two other major payers, point to growing interest in, and improved access to, Schedule III options like BELBUCA."

Fourth Quarter 2017 Financial Highlights

Net revenue for the fourth quarter ended December 31, 2017, was \$12.5 million, compared to \$11.3 million in the third quarter of 2017, an increase of 11%, and \$3.9 million in the fourth quarter of 2016, an increase of 220%.

Total net revenue for BELBUCA (buprenorphine) buccal film and BUNAVAIL® (buprenorphine and naloxone) buccal film in the fourth quarter was \$9.4 million and \$1.7 million, respectively, versus \$6.4 million and \$1.7 million, in the third quarter of 2017. This compares to royalty revenue on BELBUCA from BDSI's former commercial partner, Endo, of \$1.3 million, and BUNAVAIL revenue of \$2.0 million in the fourth quarter of 2016.

Total operating expenses for the fourth quarter ended December 31, 2017, were \$21.6 million, compared to \$16.9 million and \$16.8 million in the third quarter of 2017 and fourth quarter of 2016, respectively. Increased operating expenses in the fourth quarter were due to a one-time charge associated with joining the opioid consortium, which is a collaborative effort among manufacturers of long-acting opioids to jointly fulfill FDA post-marketing study requirements. While BDSI will contribute to the costs associated with certain studies going forward, BDSI was required to provide funding in arrears for work completed prior to joining to the group. Participation in the opioid consortium allows the expenses associated with most of the post-approval study requirements to be shared among the participating companies instead of being conducted individually.

Net loss for the fourth quarter ended December 31, 2017, was \$16.2 million, or (\$0.29) per diluted share, compared to a net loss of \$12.0 million, or (\$0.21) per diluted share, in the third quarter. This compares to a net loss of \$15.9 million, or (\$0.29) per diluted share, in the same period of 2016.

At December 31, 2017, BDSI had cash and cash equivalents of approximately \$21.2 million. This compares to cash and cash equivalents of approximately \$19.7 million at September 30, 2017. In the fourth quarter, BDSI met the financial criteria to access a \$15 million tranche in its loan agreement with CRG.

Full-Year 2017 Financial Highlights

Net revenue for the year ended December 31, 2017, was \$62.0 million, compared to \$15.5 million for 2016. Total net sales of BELBUCA and BUNAVAIL for the 12-months ended December 31, 2017 and 2016, were \$27.0 million and \$7.9 million, respectively. Also recognized in net revenue for the 12-months ended December 31, 2017, was \$20 million of deferred revenue for BELBUCA upon termination of BDSI's commercialization license with Endo.

Total operating expenses for the year ended December 31, 2017, were \$71.9 million, compared to \$68.2 million for the year ended December 31, 2016.

Net income for the year ended December 31, 2017, was \$5.3 million, or \$0.09 per diluted share, compared to a net loss of \$67.1 million, or (\$1.25) per diluted share, for the year ended December 31, 2016. The increase in net income was principally attributable to BELBUCA net profitability, favorable valuation of the reacquisition of BELBUCA and recognition of deferred revenue associated with the commercialization license termination with Endo.

RECENT COMPANY HIGHLIGHTS

Commercial

- Achieved solid BELBUCA growth in the fourth quarter, with total prescription sales increasing 10% over the prior quarter. BELBUCA total prescriptions reached their highest monthly total to date in January 2018 with over 8,600 prescriptions, and BELBUCA results are expected to be strong in February and into March, as the rolling 4-week prescription total is the highest recorded to date.
- BELBUCA sales metrics demonstrated meaningful first year improvement since termination of the Endo commercial license and commencement of BDSI's own commercialization efforts with BELBUCA, with prescriptions in 2017 up 84% over 2016.
- Recently signed a commercial and Medicare agreement with Humana adding BELBUCA as a preferred agent that became effective on March 1, 2018. Humana is the second largest provider in terms of Medicare lives under management, with more than 7.7 million currently participating in Humana Part D benefits. BDSI also secured new coverage early in the first quarter of 2018 with a number of significant additional plans, including ProCareRx, which moved BELBUCA from non-formulary, not covered, to a preferred agent, and improved coverage through other plans, such as United Healthcare, which removed step-through requirements to access BELBUCA.
- Recently increased number of sales representatives from 65 to 85 adding over 3,500 new healthcare practitioner targets and multiple new geographies not previously covered by BDSI's sales force.
- Effective January 30, 2018, BELBUCA is commercially available in Canada via BDSI's exclusive agreement with Purdue (Canada). BDSI has received upfront and milestone payments under this agreement and is eligible for additional milestones and royalties on net sales.
- BUNAVAIL contract with TennCare renewed for 2 years at a more favorable discount rate to BDSI.

Corporate

- Appointed Scott M. Plesha, formerly BDSI's Senior Vice President of Sales and Marketing, to the role of President, effective January 2, 2018.
- Entered into non-exclusive licenses with Teva that will not allow them to begin selling generic versions of BELBUCA in the U.S. until January 23, 2027, and BUNAVAIL until July 23, 2018, or potentially earlier under certain conditions. These settlements provide additional certainty with respect to BDSI's patent portfolio, while averting future costs associated with litigation.
- BDSI reacquired ONSOLIS[®] (fentanyl buccal soluble film) from Collegium Pharmaceutical, Inc. and is currently assessing options for commercializing the product, including the use of BDSI's own sales force or potentially out-licensing the product.

Conference Call & Webcast

Thursday, March 15th @ 4:30pm Eastern Time

Domestic: 866-548-4713
International: 323-794-2093
Passcode: 6437809
Webcast: <http://public.viavid.com/index.php?id=128377>

Replays available through March 29:

Domestic: 844-512-2921
International: 412-317-6671
Conference ID: 6437809

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](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 conference call and webcast 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 those detailed in the BDSI's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results of the Company's commercialization programs for BELBUCA, BUNAVAIL and ONSOLIS as described herein) 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 CONSOLIDATED BALANCE SHEETS (U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	December 31,	
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,195	\$ 32,019
Accounts receivable, net	8,852	2,967
Inventory	6,091	3,368
Prepaid expenses and other current assets	3,610	4,136
	39,748	42,490
Property and equipment, net	3,778	4,230
Goodwill	2,715	2,715
BELBUCA® license and distribution rights intangible asset, net	40,500	-
Other intangible assets, net	1,360	2,285
Total assets	\$ 88,101	\$ 51,720
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 26,149	\$ 17,572
Deferred revenue, current	-	1,716
Total current liabilities	26,149	19,288
Notes payable, less current maturities, net	47,660	29,272

Deferred revenue, long term	-	20,000
Other long-term liabilities	5,415	825
Total liabilities	79,224	69,385
Commitments and contingencies		
Stockholders' equity (deficit):		
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 December 31, 2017 and 2016, respectively.	2	2
Common Stock, \$.001 par value; 75,000,000 shares authorized; 55,904,072 and 54,133,511 shares issued; 55,888,581 and 54,118,020 shares outstanding at December 31, 2017 and 2016, respectively	56	54
Additional paid-in capital	313,922	292,667
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(305,056)	(310,341)
Total stockholders' equity (deficit)	8,877	(17,665)
Total liabilities and stockholders' equity (deficit)	\$ 88,101	\$ 51,720

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,		4th Quarter 2017	4th Quarter 2016
	2017	2016		
Revenues:				
Product Sales	34,922	8,266	11,123	2,046
Product Royalties	5,070	3,646	1,387	1,253
Sponsored research revenue	799	1,134	-	633
Contract revenue	21,194	2,500	-	
Total Revenues	61,985	15,546	12,510	3,932
Cost of sales	19,496	11,258	5,235	2,301
Expenses:				
Research and development:	13,040	18,878	6,793	5,092
Sales, general and administrative	58,869	49,345	14,774	11,740
Total expenses	71,909	68,223	21,567	16,832
Loss from operations	(29,420)	(63,935)	(14,292)	(15,200)
Interest expense, net	(8,577)	(3,267)	(1,920)	(740)
Bargain purchase gain	27,336	-		
Other (expense) income, net	(26)	64	1	1
Loss before income taxes	\$ (10,687)	\$ (67,138)	\$ (16,211)	\$ (15,941)
Income tax benefit	15,972	-		
Net income (loss) attributable to common stockholders	\$ 5,285	\$ (67,138)	\$ (16,211)	\$ (15,941)
Basic:				
Weighted average common stock shares outstanding	55,355,802	53,679,134	55,880,152	54,118,202
Basic earnings (loss) per share	\$ 0.10	\$ (1.25)	\$ (0.29)	\$ (0.29)
Diluted:				

Diluted weighted average common stock shares outstanding	56,402,479	53,679,134	55,880,152	54,118,202
	\$ 0.09	\$ (1.25)	\$ (0.29)	\$ (0.29)

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

	Year Ended December 31,	
	2017	2016
Operating activities:		
Net income (loss)	\$ 5,285	\$ (67,138)
Adjustments to reconcile net (loss) income to net cash flows from operating activities		
Depreciation	693	437
Accretion of discount	2,392	397
Amortization of Intangible Assets	5,425	971
Provision for inventory obsolescence	243	-
Stock based compensation	14,801	14,931
Deferred income taxes	(15,972)	-
Bargain purchase gain	(27,336)	-
Changes in assets and liabilities:		
Accounts receivable	(5,884)	(862)
Inventories	2,448	(810)
Prepaid expenses and other assets	526	(203)
Accounts payable and accrued expenses	6,644	(1,546)
Deferred Revenue	(21,716)	(159)
Net cash flows from operating activities	(32,451)	(53,982)
Investing activities:		
Acquisitions	(5,853)	-
Purchase of equipment	(11)	(405)
Net cash flows from investing activities	(5,864)	(405)
Financing activities:		
Proceeds from sales of securities	-	40
Proceeds from exercise of stock options	439	297
Proceeds from exercise of common stock warrants	-	-
Issuance of warrants	-	49
Issuance of common stock	-	2,460
Payment on note payable	(30,000)	-
Proceeds from notes payable	60,000	-
Return on short swing profits	-	-
Payment of deferred financing fees	(2,948)	-
Net cash flows from financing activities	27,491	2,846
Net change in cash and cash equivalents	(10,824)	(51,541)
Cash and cash equivalents at beginning of year	32,019	83,560
Cash and cash equivalents at end of year	\$ 21,195	\$ 32,019
Cash paid for interest	\$ 5,285	\$ 2,870

 [Primary Logo](#)