



BioDelivery Sciences Reports Strong Q3 2020 Results

November 5, 2020

Total Company Net Revenue Increased 30% versus Prior Year Reaching a Record \$39.4 Million

Conference Call and Webcast Scheduled for 8:30 AM EST Today

RALEIGH, N.C., Nov. 05, 2020 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, today reported strong financial results for the third quarter ended September 30, 2020, as well as the following operational and performance highlights.

Key Business Highlights

- Total Company net revenue for the third quarter increased by 30% versus the prior year period to \$39.4 million. This growth was driven by BELBUCA® net sales of \$34.8 million, an increase of 31% versus the prior year period, and Symproic® net sales of \$3.5 million, an increase of 59% compared to the third quarter of 2019.
- BELBUCA reached all-time high prescription volume and market share, with total BELBUCA prescriptions of more than 114,500 during the third quarter, representing year-over-year prescription volume growth of 25%.
- Symproic reached all-time high prescription volume and market share, with total Symproic prescriptions of more than 18,100 in the third quarter, representing growth of 12% versus the prior year.
- Achieved significant growth to \$9.4 million of GAAP Net Income and an attractive 34% EBITDA Margin in the third quarter.
- Jeff Bailey appointed as Chief Executive Officer (CEO) after serving as interim CEO since May 2020.
- Announced that its Board of Directors authorized the repurchase of up to \$25.0 million of the Company's shares of common stock. The Company plans to utilize existing cash on hand to fund the share repurchase program.

"Our commercial execution during the third quarter has been extremely impactful as evidenced by strong prescription trends for both BELBUCA and Symproic, which have continued in October," stated Jeff Bailey, CEO of BDSI. "I am proud to permanently join the talented BDSI team and very confident in our ability to execute on our vision to deliver innovative products to patients while maximizing shareholder value."

Third Quarter 2020 Financial Results

Total Company Net Revenue for the third quarter of 2020 was a record \$39.4 million, an increase of 30% compared to \$30.3 million in the third quarter of 2019, and an increase of 8% compared to \$36.6 million in the second quarter of 2020.

BELBUCA Net Sales for the third quarter of 2020 were \$34.8 million, an increase of 31% compared to \$26.5 million in the third quarter of 2019, and an increase of 7% compared to \$32.3 million in the second quarter of 2020. While BELBUCA gross to net deductions increased in the third quarter as anticipated, primarily due to typical increases seen for Medicare coverage gap, along with increased Medicaid costs, those increases were favorably impacted by updates to our channel estimates reflected in the third quarter of 2020.

Symproic Net Sales for the third quarter were \$3.5 million, an increase of 59% compared to \$2.2 million in the third quarter of 2019, and an increase of 1% compared to \$3.4 million in the second quarter of 2020.

BUNAVAIL Net Revenue for the third quarter was \$0.6 million, reflecting the release of a portion of the returns reserves taken at the time discontinuation was announced. In March, the Company announced the discontinuation of marketing of BUNAVAIL.

Total Operating Expenses for the third quarter of 2020 were \$22.5 million, compared to \$23.4 million in the third quarter of 2019 and \$28.2 million in the second quarter of 2020.

GAAP Net Income for the third quarter of 2020 was \$9.4 million, or \$0.09 per share, compared to GAAP net income of \$0.4 million, or \$0.00 per share, in the third quarter of 2019 and GAAP net income of \$1.2 million, or \$0.01 per share, for the second quarter of 2020.

EBITDA for the third quarter of 2020 was \$13.4 million, or 34% of net sales, compared to \$3.5 million or 11.6% of net sales in the third quarter of 2019 and \$5.1 million or 13.9% of net sales in the second quarter of 2020.

Non-GAAP Net Income for the third quarter of 2020 was \$12.7 million and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets. This reflects an increase of \$9.2 million as compared to non-GAAP net income of \$3.5 million in the third quarter of 2019, excluding the same items, and an increase of \$3.1 million compared to non-GAAP net income of \$9.6 million in the second quarter of 2020, excluding stock-based compensation, non-cash amortization of intangible assets, the non-recurring financial impact of the BUNAVAIL discontinuation and the one-time expenses related to the CEO transition incurred in the second quarter.

Cash Position: As of September 30, 2020, cash and cash equivalents were approximately \$100.2 million, compared to \$63.9 million at December 31, 2019, reflecting the generation of positive operating cash flow of \$9.0 million and \$14.0 million in the three and nine month periods, respectively, through September 30th. The total cash flow generation year to date of \$36.3 million includes the operating cash generation of \$14.0 million, \$2.8 million in proceeds from the exercise of options, and \$19.6 million of net proceeds from increasing our existing credit facility.

"The continuing market performance of both BELBUCA and Symproic, together with our strong profitability and balance sheet, and most importantly the commitment of our team to serving patients, position BDSI well to continue to drive long-term shareholder value," stated Jeff Bailey.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, November 5, 2020, at 8:30 a.m. ET to present third quarter 2020 results and to provide a business update. Dial-in details are as follows:

Date: Thursday, November 5, 2020
Time: 8:30 AM Eastern Time
Domestic: 877-407-0789
International: 201-689-8562
Conference ID: 13710272
Webcast: <http://public.viavid.com/index.php?id=141502>

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 address serious and debilitating conditions, including chronic pain 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 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 BDSI's management and are subject to significant risks and uncertainties, including those detailed in BDSI's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the continued growth in BELBUCA and Symproic net sales and total company net revenue in 2020) 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 BDSI's control) including the risk that the current coronavirus pandemic impacts on our supply chain, commercial partners, patients and their physicians and the healthcare facilities in which they work, and our personnel are greater than we anticipate, as well as 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.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the United States, or GAAP, including non-GAAP net income and EBITDA. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income adjusts for one-time and non-cash charges by excluding the following from GAAP net income: stock-based compensation expense, amortization of intangible assets, amortization of certain warrant discount costs in second quarter 2019, and the financial impact of certain one-time items that are non-recurring, including the financial impact of the debt refinancing in the second quarter 2019, the discontinuation of marketing of BUNAVAIL, and costs associated with the CEO transition.

EBITDA excludes net interest, including both interest expenses and interest income, provision for (benefit from) income taxes, depreciation and amortization.

The Company's management and board of directors utilize these non-GAAP financial measures to evaluate the Company's performance. The Company provides these non-GAAP measures of the Company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the Company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income and EBITDA are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income and EBITDA should not be considered measures of our liquidity.

A reconciliation of certain GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

© 2020 BioDelivery Sciences International, Inc. All rights reserved.

Contact:

Bob Yedid

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 100,177	\$ 63,888
Accounts receivable, net	43,830	38,790
Inventory, net	18,887	11,312
Prepaid expenses and other current assets	5,754	3,769
Total current assets	168,648	117,759
Property and equipment, net	1,485	2,075
Goodwill	2,715	2,715
License and distribution rights, net	55,109	60,309
Other intangible assets, net	—	47
Total assets	\$ 227,957	\$ 182,905
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 53,409	\$ 53,993
Total current liabilities	53,409	53,993
Notes payable, net	78,363	58,568
Other long-term liabilities	300	580
Total liabilities	132,072	113,141
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series A Non-Voting Convertible Preferred Stock, \$0.001 par value, 0 and 2,093,155 shares outstanding at September 30, 2020 and December 31, 2019, respectively; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 and 618 shares outstanding at September 30, 2020 and December 31, 2019, respectively.	—	2
Common Stock, \$0.001 par value; 235,000,000 and 175,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 101,126,452 and 96,189,074 shares issued; 101,110,961 and 96,173,583 shares outstanding at September 30, 2020 and December 31, 2019, respectively.	100	96
Additional paid-in capital	446,910	436,306
Treasury stock, at cost, 15,491 shares as of September 30, 2020 and December 31, 2019.	(47)	(47)
Accumulated deficit	(351,078)	(366,593)
Total stockholders' equity	95,885	69,764
Total liabilities and stockholders' equity	\$ 227,957	\$ 182,905

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 September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product sales	\$ 38,785	\$ 29,623	\$ 112,946	\$ 77,438
Product royalty revenues	658	683	1,358	2,154
Contract revenues	—	—	—	160
Total Revenues:	39,443	30,306	114,304	79,752
Cost of sales	5,376	5,350	16,371	14,325
Expenses:				
Selling, general and administrative	22,461	23,360	77,408	62,304
Total Expenses:	22,461	23,360	77,408	62,304
Income from operations	11,606	1,596	20,525	3,123
Interest expense, net	(2,010)	(1,234)	(4,997)	(17,732)
Other (expense)/income, net	(2)	(3)	6	5
Income/(loss) before income taxes	\$ 9,594	\$ 359	\$ 15,534	\$ (14,604)
Income tax provision	(211)	(5)	(19)	(5)
Net income/(loss) attributable to common stockholders	\$ 9,383	\$ 354	\$ 15,515	\$ (14,609)
Basic				
Weighted average common stock shares outstanding	101,031,317	89,649,922	99,377,748	81,612,112
Basic earnings/(loss) per share	\$ 0.09	\$ —	\$ 0.16	\$ (0.18)
Diluted				
Weighted average common stock shares outstanding	105,783,568	105,138,894	104,836,493	81,612,112
Diluted earnings/(loss) per share	\$ 0.09	\$ —	\$ 0.15	\$ (0.18)

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

	Nine months ended September 30, 2020	
	2020	2019
Operating activities:		
Net income/(loss)	\$ 15,515	\$ (14,609)
Adjustments to reconcile net income/(loss) to net cash flows from operating activities		
Depreciation and amortization	467	253
Accretion of debt discount and loan costs	231	11,441
Amortization of intangible assets	5,248	5,084
Provision for inventory obsolescence	(297)	57
Stock-based compensation expense	7,845	3,978
Changes in assets and liabilities:		
Accounts receivable	(5,040)	(19,795)
Inventories	(7,278)	(5,416)
Prepaid expenses and other assets	(1,985)	(1,686)
Accounts payable and accrued liabilities	(701)	14,844
Taxes payable	(40)	—
Net cash flows provided by/(used in) operating activities	13,965	(5,849)
Investing activities:		
Product acquisitions	—	(20,674)
Acquisitions of equipment	—	(79)
Net cash flows used in investing activities	—	(20,753)

Financing activities:			
Proceeds from issuance of common stock	—		48,000
Equity issuance costs	—		(410)
Proceeds from notes payable	20,000		60,000
Proceeds from exercise of stock options	2,761		1,193
Payment on note payable	—		(67,346)
Loss on refinancing of former debt	—		(2,794)
Payment on deferred financing fees	(437)		—
Net cash flows provided by financing activities	22,324		38,643
Net change in cash and cash equivalents	36,289		12,041
Cash and cash equivalents at beginning of period	63,888		43,822
Cash and cash equivalents at end of period	\$ 100,177		\$ 55,863

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)				
GAAP net income/(loss)	\$ 9,383	\$ 354	\$ 15,515	\$ (14,609)
Add back/(subtract):				
Income tax provision	211	4	19	4
Net interest expense	2,012	1,237	4,991	17,727
Depreciation and amortization	1,754	1,904	5,715	5,259
EBITDA	\$ 13,360	\$ 3,499	\$ 26,240	\$ 8,381
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)				
GAAP net income/(loss)	9,383	354	15,515	(14,609)
Non-GAAP adjustments:				
Stock-based compensation expense	1,473	1,267	4,424	3,978
Amortization of intangible assets	1,734	1,898	5,248	5,084
Amortization of warrant discount	—	—	—	448
Non-recurring financial impact of debt refinance	—	—	—	11,866
Non-recurring financial impact of CEO transition	67	—	5,078	—
Non-recurring financial impact of BUNAVAIL discontinuation	—	—	295	—
Non-GAAP net income/(loss)	\$ 12,657	\$ 3,519	\$ 30,560	\$ 6,767



Source: BioDelivery Sciences International