

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2020

BioDelivery Sciences International, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction
of incorporation)

001-31361
(Commission
File Number)

35-2089858
(IRS Employer
Identification No.)

4131 ParkLake Ave., Suite #225
Raleigh, NC
(Address of principal executive offices)

27,612
(Zip Code)

Registrant's telephone number, including area code: 919-582-9050

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))



BioDelivery Sciences Reports Strong Q1 2020 Results

First Quarter Total Company Net Sales Increased 94% versus Prior Year to \$38.3 Million

First Quarter BELBUCA® Net Sales Increased 79% versus Prior Year to \$33.5 Million

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

RALEIGH, N.C., May 7, 2020 - 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 first quarter ended March 31, 2020, as well as the following operational and performance highlights.

Key Business Highlights

- Total Company net revenue for the first quarter increased by 94% versus the prior year period to a record level of \$38.3 million. This growth was driven by BELBUCA sales of \$33.5 million, an increase of 79% versus the prior year period, and Symproic® sales of \$4.2 million.
- Total BELBUCA prescriptions reached an all-time high of 99,400 during the first quarter, representing year-over-year prescription volume growth of more than 52%.
- Total Symproic prescriptions were more than 16,100 in the first quarter, representing growth of 19% versus the prior year period.
- Achieved record number of unique prescribers during the quarter for both BELBUCA and Symproic.
- Continued to expand BELBUCA Medicare patient access with the addition of more than two million covered lives, the vast majority of which have preferred access to BELBUCA, through a national PBM.
- Expanded BELBUCA commercial coverage within two important regional plans representing nearly 900,000 lives that can receive BELBUCA without being required to first fail two CII long-acting opioids.
- Strong financial position driven by performance and positive cash flow of \$6.7 million in the quarter.

"I am very pleased by the success and momentum we achieved during the first quarter," stated Herm Cukier, CEO of BDSI. "Both BELBUCA and Symproic prescriptions were experiencing considerable growth before the start of the COVID-19 pandemic, helping deliver strong first quarter results. I am also very proud of how the organization rapidly transitioned our efforts to virtual connectivity with our prescribers, ensured continuity of supply, and continued to provide valuable service to patients. While these are unprecedented and uncertain times, I remain very confident in the clinical value of our products and the long-term prospects for the company."

First Quarter 2020 Financial Results

Total Company Net Revenue for the first quarter of 2020 was \$38.3 million, an increase of 94% compared to \$19.8 million in the first quarter of 2019, and an increase of 21% compared to \$31.6 million in the fourth quarter of 2019.

BELBUCA Net Sales for the first quarter of 2020 were \$33.5 million, an increase of 79% compared to \$18.7 million in the first quarter of 2019, and an increase of 18% compared to \$28.3 million in the fourth quarter of 2019.



Symproic Net Sales for the first quarter were \$4.2 million, an increase of 54% compared to \$2.7 million in the fourth quarter of 2019.

BUNAVAIL Net Sales for the first quarter were \$0.1 million compared to \$1.1 million in the first quarter of 2019. In March of this year, the Company announced the planned discontinuation of marketing of BUNAVAIL in 2020.

Total Operating Expenses for the first quarter of 2020 were \$26.7 million, compared to \$23.8 million in the fourth quarter of 2019 and \$17.0 million in the first quarter of 2019.

GAAP Net Income for the first quarter of 2020 was \$5.0 million, or \$0.05 per share, compared to GAAP net loss of \$0.7 million, or (\$0.01) per share, for the fourth quarter of 2019 and GAAP net loss of \$3.8 million, or (\$0.05) per share, in the first quarter of 2019.

EBITDA in the first quarter of 2020 was \$7.8 million, or 20% of net sales, compared to \$4.1 million in the fourth quarter of 2019 and \$0.1 million in the first quarter of 2019.

Non-GAAP Net Income for the quarter was \$8.3 million and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets.

Cash Position: As of March 31, 2020, cash and cash equivalents were approximately \$70.6 million, compared to \$63.9 million in the fourth quarter of 2019, reflecting positive cash flow of \$6.7 million in the first quarter of 2020.

2020 Net Sales Guidance:

Given the uncertainty surrounding the COVID-19 pandemic, the Company is withdrawing its 2020 BELBUCA and Total Company net sales guidance, previously introduced in November 2019.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, May 7, 2020, at 4:30 p.m. ET to present first quarter 2020 results and to provide a business update. Dial-in details are as follows:

Date:	Thursday, May 7, 2020
Time:	4:30 PM Eastern Time
Domestic:	800-289-0571
International:	720-543-0206
Conference ID:	6176462
Webcast:	http://public.viavid.com/index.php?id=139300

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, 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 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 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, and the financial impact of certain one-time items that are non-recurring, including the impact of the discontinuation of marketing of BUNAVAIL.

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



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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)

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 70,613	\$ 63,888
Accounts receivable, net	45,114	38,790
Inventory, net	15,003	11,312
Prepaid expenses and other current assets	2,600	3,769
Total current assets	133,330	117,759
Property and equipment, net	1,995	2,075
Goodwill	2,715	2,715
License and distribution rights, net	58,576	60,309
Other intangible assets, net	—	47
Total assets	<u>\$ 196,616</u>	<u>\$ 182,905</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 60,931	\$ 53,993
Total current liabilities	60,931	53,993
Notes payable, net	58,634	58,568
Other long-term liabilities	463	580
Total liabilities	120,028	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 March 31, 2020 and December 31, 2019, respectively; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 and 618 shares outstanding at March 31, 2020 and December 31, 2019, respectively.	—	2
Common Stock, \$0.001 par value; 175,000,000 shares authorized at March 31, 2020 and December 31, 2019, respectively; 99,821,408 and 96,189,074 shares issued; 99,805,917 and 96,173,583 shares outstanding at March 31, 2020 and December 31, 2019, respectively.	99	96
Additional paid-in capital	438,163	436,306
Treasury stock, at cost, 15,491 shares, as of March 31, 2020 and December 31, 2019.	(47)	(47)
Accumulated deficit	(361,627)	(366,593)
Total stockholders' equity	76,588	69,764
Total liabilities and stockholders' equity	<u>\$ 196,616</u>	<u>\$ 182,905</u>



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		
	March 31, 2020	Dec. 31, 2019	March 31, 2019
Revenues:			
Product sales	\$ 37,715	\$ 30,450	\$ 19,759
Product royalty revenues	563	1,187	2
Contract revenues	—	—	8
Total Revenues:	38,278	31,637	19,769
Cost of sales	5,560	7,264	4,052
Expenses:			
Selling, general and administrative	26,736	23,759	16,989
Total Expenses:	26,736	23,759	16,989
Income (loss) from operations	5,982	614	(1,272)
Interest expense	(1,293)	(1,308)	(2,561)
Other expense, net	(1)	(1)	—
Income (loss) before income taxes	\$ 4,688	\$ (695)	\$ (3,833)
Income tax benefit	278	(1)	—
Net income (loss) attributable to common stockholders	\$ 4,966	\$ (696)	\$ (3,833)
Basic			
Weighted average common stock shares outstanding	97,118,267	92,118,497	71,344,831
Basic earnings (loss) per share	\$ 0.05	\$ (0.01)	\$ (0.05)
Diluted			
Weighted average common stock shares outstanding	106,965,762	92,118,497	71,344,831
Diluted earnings (loss) per share	\$ 0.05	\$ (0.01)	\$ (0.05)



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

	Three months ended		
	March 31, 2020	Dec. 31, 2019	March 31, 2019
Operating activities:			
Net income (loss)	\$ 4,966	\$ (696)	\$ (3,833)
Adjustments to reconcile net loss to net cash flows from operating activities			
Depreciation	21	1,592	85
Accretion of debt discount and loan costs	65	67	634
Amortization of intangible assets	1,781	1,896	1,289
Provision for inventory obsolescence	405	140	149
Stock-based compensation expense	1,520	1,438	1,141
Changes in assets and liabilities:			
Accounts receivable	(6,324)	(5,368)	(2,381)
Inventories	(4,096)	(685)	(2,002)
Prepaid expenses and other assets	1,169	1,106	218
Accounts payable and accrued liabilities	6,920	17,432	1,814
Taxes payable	(40)	—	—
Net cash flows provided by (used in) operating activities	6,387	16,922	(2,886)
Investing activities:			
Product Acquisitions	—	(10,011)	—
Disposal of property and equipment	—	—	(79)
Net cash flows used in investing activities	—	(10,011)	(79)
Financing activities:			
Proceeds from exercise of stock options	338	1,127	472
Debt issuance costs	—	(13)	—
Net cash flows provided by financing activities	338	1,114	472
Net change in cash and cash equivalents	6,725	8,025	(2,493)
Cash and cash equivalents at beginning of period	63,888	55,863	43,822
Cash and cash equivalents at end of period	\$ 70,613	\$ 63,888	\$ 41,329



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

Reconciliations of non-GAAP metrics to most directly comparable U.S. GAAP financial measures:

The following tables reconcile net income/(loss) earnings and computations (in thousands) under GAAP to a Non-GAAP basis.

	Three months ended		
	March 31, 2020	Dec. 31, 2019	March 31, 2019
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)			
GAAP net income/(loss)	\$ 4,966	\$ (696)	\$ (3,833)
Add back:			
Provision for income taxes	(278)	1	—
Net interest expense	1,294	1,308	2,561
Depreciation and amortization	1,802	3,491	1,375
EBITDA	\$ 7,784	\$ 4,104	\$ 103
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)			
GAAP net income/(loss)	4,966	(696)	(3,833)
Non-GAAP adjustments:			
Stock-based compensation expense	1,520	1,438	1,142
Amortization of intangible assets	1,781	1,899	1,289
Amortization of warrant discount	—	—	269
Non-recurring financial impact – BUNAVAIL discontinuation	—	3,750	—
Non-GAAP net income/(loss)	\$ 8,267	\$ 6,391	\$ (1,133)