

**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: May 6, 2021

**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)		27612 (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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001	BDSI	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).





## BioDelivery Sciences Reports First Quarter 2021 Results

*Total Company Net Revenue of \$41 Million, an Increase of 7% versus Prior Year  
Net Income of \$5.2 Million, EBITDA Margin of 22% and Operating Cash Generation of \$11 Million*

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

**RALEIGH, N.C., May 6, 2021** - BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a 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, 2021, including the following operational and performance highlights.

### Key Business Highlights

- Total Company net revenue for the first quarter increased by 7% versus the prior year period to \$41.0 million. This growth was driven by BELBUCA® net sales of \$36.4 million, which increased 9%, and Symproic® net sales of \$4.4 million, which increased 5%.
- BELBUCA continued to deliver an all-time high quarterly market share, despite pandemic challenges and the impact of winter storm Uri. Total BELBUCA prescriptions were approximately 113,000 during the first quarter, representing year-over-year prescription volume growth of 9%.
- Total Symproic prescriptions were approximately 17,000 in the first quarter, consistent with prescriptions for the prior year period.
- Continued to achieve strong profitability, delivering \$5.2 million of GAAP Net Income and an attractive 22% EBITDA margin in the first quarter of 2021.
- The Company repurchased 1.6 million shares in the quarter under its share buyback program, at an average price of \$3.87 per share.

“We again delivered solid top and bottom-line growth in a challenging quarter against the backdrop of the pandemic and weather-related disruptions, resulting in 22% EBITDA margin and \$11 million operating cash flow generation,” stated Jeff Bailey, CEO of BDSI. “Our performance highlights the strength of our commercial team and the persistent market demand for our highly differentiated products. We expect continued success as the selling environment improves throughout the year, including increases of in-office patient visits and more face-to-face interactions with health care providers by our sales representatives.”

### First Quarter 2021 Financial Results

**Total Company Net Revenue** for the first quarter of 2021 was \$41.0 million, an increase of 7% compared to \$38.3 million in the first quarter of 2020. Total product net revenue, including sales of BELBUCA and Symproic, grew 8% year over year. Severe winter weather conditions, especially in the South-Central region where the Company has strong market presence, affected patients' access to their physicians and pharmacies. Additionally, the severe weather delayed shipments of the Company's products to pharmacy distribution centers of the major wholesalers.



**BELBUCA Net Sales** for the first quarter of 2021 were \$36.4 million, an increase of 9% compared to \$33.5 million in the first quarter of 2020. As we typically experience each year, BELBUCA gross to net deductions were lower in the first quarter, largely due to the Medicare coverage gap impact.

**Symproic Net Sales** for the first quarter were \$4.4 million, an increase of 5% compared to \$4.2 million in the first quarter of 2020. Symproic net sales benefited from reduced gross to net deductions in the first quarter due to the typical decreases seen for Medicare coverage gap, as well as updates to our gross to net deductions related to channel estimates.

**Total Operating Expenses** for the first quarter of 2021 were \$27.8 million, compared to \$26.7 million in the first quarter of 2020. The increase in spending as compared to fourth quarter of 2020 was driven by increased investments in sales and marketing and \$3.0 million higher legal spend in the quarter, primarily due to costs associated with the Paragraph IV patent litigation.

**GAAP Net Income** for the first quarter of 2021 was \$5.2 million, or \$0.05 per share, compared to GAAP net income of \$5.0 million, or \$0.05 per share, in the first quarter of 2020.

**EBITDA** for the first quarter of 2021 was \$9.2 million, or 22% of net sales, compared to \$7.8 million or 20% of net sales, in the first quarter of 2020.

**Non-GAAP Net Income** for the first quarter of 2021 was \$8.5 million and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets as compared to non-GAAP net income of \$8.3 million in the first quarter of 2020, excluding the same items

**Cash Position:** As of March 31, 2021, cash and cash equivalents were approximately \$116.4 million, compared to \$111.6 million as of December 31, 2020. The total cash flow generation over the quarter of \$4.9 million includes continued strong operating cash generation of \$11.1 million, partially offset by \$6.1 million used to repurchase shares in the quarter.

#### ***Financial Guidance***

The Company reiterates its 2021 financial guidance, with full year 2021 total Company net sales of \$170 - \$180 million, including full year 2021 BELBUCA net sales of \$155 - \$165 million. Total operating expenses are expected to be in the range of \$115 - \$120 million, as the Company continues to invest to support the growth of its brands, and EBITDA is expected to be in the range of \$40 - \$50 million in 2021. The Company expects to continue delivering positive operating cash flow throughout 2021.

“Our confidence in the continued growth of our brands and the profitability of our business remains unchanged. This is demonstrated by our continuing investments behind our portfolio, together with the share repurchase program which is underway. We remain on track to drive long-term shareholder value, and are actively considering potential business development opportunities,” stated Jeff Bailey.

#### **Conference Call & Webcast Details**

BioDelivery Sciences will host a conference call and webcast today, May 6, 2021, at 8:30 a.m. ET to present first quarter 2021 results and to provide a business update. Dial-in details are as follows:



Date:	Thursday, May 6, 2021
Time:	8:30 AM Eastern Time
Domestic:	877-407-0789
International:	201-689-8562
Conference ID:	13718097
Webcast:	<a href="http://public.viavid.com/index.php?id=144116">http://public.viavid.com/index.php?id=144116</a>

#### **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 expectations for total company net sales, BELBUCA net sales, operating expenses, EBITDA and operating cash flows in 2021) 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 2020 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 and non-cash amortization of intangible assets.

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.

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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, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 116,436	\$ 111,584
Accounts receivable, net	48,294	48,150
Inventory, net	16,968	17,443
Prepaid expenses and other current assets	4,449	5,208
Total current assets	186,147	182,385
Property and equipment, net	1,626	1,418
Goodwill	2,715	2,715
License and distribution rights, net	51,642	53,376
<b>Total assets</b>	<b>\$ 242,130</b>	<b>\$ 239,894</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 54,584	\$ 52,995
Total current liabilities	54,584	52,995
Notes payable, net	78,538	78,452
Other long-term liabilities	154	213
Total liabilities	133,276	131,660
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 shares outstanding at March 31, 2021 and December 31, 2020, respectively.	—	—
Common Stock, \$0.001 par value; 235,000,000 shares authorized at March 31, 2021 and December 31, 2020, respectively; 101,702,234 and 101,417,441 shares issued; 100,061,096 and 101,354,447 shares outstanding at March 31, 2021 and December 31, 2020, respectively.	104	104
Additional paid-in capital	450,794	449,264
Treasury stock, at cost, 1,641,138 and 62,994 shares as of March 31, 2021 and December 31, 2020, respectively	(6,399)	(252)
Accumulated deficit	(335,645)	(340,882)
Total stockholders' equity	108,854	108,234
<b>Total liabilities and stockholders' equity</b>	<b>\$ 242,130</b>	<b>\$ 239,894</b>

**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,	
	2021	2020
<b>Revenues:</b>		
Product sales, net	\$ 40,804	\$ 37,715
Product royalty revenues	216	563
<b>Total Revenues:</b>	<b>41,020</b>	<b>38,278</b>
<b>Cost of sales</b>	<b>5,821</b>	<b>5,560</b>
<b>Expenses:</b>		
Selling, general and administrative	27,761	26,736
<b>Total Expenses:</b>	<b>27,761</b>	<b>26,736</b>
<b>Income from operations</b>	<b>7,438</b>	<b>5,982</b>
Interest expense, net	(1,979)	(1,293)
Other expense, net	—	(1)
Income before income taxes	\$ 5,459	\$ 4,688
Income tax provision	(222)	278
<b>Net income attributable to common stockholders</b>	<b>\$ 5,237</b>	<b>\$ 4,966</b>
<b>Basic</b>		
Weighted average common stock shares outstanding	100,988,245	97,118,267
Basic earnings per share	\$ 0.05	\$ 0.05
<b>Diluted</b>		
Weighted average common stock shares outstanding	105,396,793	106,965,762
<b>Diluted earnings per share</b>	<b>\$ 0.05</b>	<b>\$ 0.05</b>

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

	Three months ended March 31,	
	2021	2020
Operating activities:		
<b>Net income</b>	<b>\$ 5,237</b>	<b>\$ 4,966</b>
Adjustments to reconcile net income to net cash flows from operating activities		
Depreciation	19	21
Accretion of debt discount and loan costs	86	65
Amortization of intangible assets	1,735	1,781
Provision for inventory obsolescence	369	405
Stock-based compensation expense	1,490	1,520
Changes in assets and liabilities:		
Accounts receivable	(144)	(6,324)
Inventories	106	(4,096)
Prepaid expenses and other assets	602	1,169
Accounts payable and accrued liabilities	1,597	6,920
Taxes payable	—	(40)
<b>Net cash flows provided by operating activities</b>	<b>11,097</b>	<b>6,387</b>
Investing activities:		
Purchase of equipment	(296)	—
<b>Net cash flows used in investing activities</b>	<b>(296)</b>	<b>—</b>
Financing activities:		
Proceeds from exercise of stock options	198	338
Payment on share repurchase	(6,147)	—
Net cash flows (used in) provided by financing activities	(5,949)	338
<b>Net change in cash and cash equivalents</b>	<b>4,852</b>	<b>6,725</b>
Cash and cash equivalents at beginning of period	111,584	63,888
<b>Cash and cash equivalents at end of year</b>	<b>\$ 116,436</b>	<b>\$ 70,613</b>

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

<b>Reconciliation of GAAP net income to EBITDA (non-GAAP)</b>	<b>Three Months Ended,</b>		
	<b>March 31, 2021</b>	<b>December 31, 2020</b>	<b>March 31, 2020</b>
<b>GAAP net income</b>	<b>\$ 5,237</b>	<b>\$ 10,197</b>	<b>4,966</b>
Add back/(subtract):			
Income tax provision	222	233	(278)
Net interest expense	1,979	2,022	1,294
Depreciation and amortization	1,753	1,806	1,802
<b>EBITDA</b>	<b>\$ 9,191</b>	<b>\$ 14,258</b>	<b>\$ 7,784</b>
<b>Reconciliation of GAAP net income to Non-GAAP net income</b>			
<b>GAAP net income</b>	<b>5,237</b>	<b>10,197</b>	<b>4,966</b>
Non-GAAP adjustments:			
Stock-based compensation expense	1,490	1,750	1,520
Amortization of intangible assets	1,735	1,733	1,781
<b>Non-GAAP net income</b>	<b>\$ 8,462</b>	<b>\$ 13,680</b>	<b>\$ 8,267</b>