

**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: March 10, 2021

**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation)	<b>001-31361</b> (Commission File Number)	<b>35-2089858</b> (IRS Employer Identification No.)
<b>4131 ParkLake Ave., Suite 225</b>		
<b>Raleigh NC</b> (Address of principal executive offices)		<b>27612</b> (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 Q4 and Record Full-Year 2020 Results**

*Total Company Net Revenue Increased 40% versus Prior Year to Reach an All-Time High of \$156.5 Million*

*Record Level Profitability with Net Income of \$25.7 Million, Full-Year EBITDA Margin of 26% and Operating Cash Generation of \$25 Million*

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

**RALEIGH, N.C., March 10, 2021** - 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 fourth quarter and full-year ended December 31, 2020, as well as the following operational and performance highlights.

### **Key Business Highlights**

- Total Company full-year net revenue of \$156.5 million delivered growth of 40% versus 2019 mainly driven by BELBUCA® (buprenorphine buccal film) CIII net sales of \$136.1 million, an increase of 40% compared to 2019, and Symproic® (naldemedine) net sales of \$14.7 million in 2020, an increase of 83% over 2019.
- Total Company net revenue for the fourth quarter increased by 33% versus the prior year period to \$42.2 million. This growth was driven by BELBUCA net sales of \$35.6 million, an increase of 26% versus the prior year period, and Symproic net sales of \$3.7 million, an increase of 35% compared to the fourth quarter of 2019.
- BELBUCA reached all-time high prescription volume and market share, with total BELBUCA prescriptions of close to 119,000 during the fourth quarter, representing year-over-year prescription volume growth of 21%.
- Symproic reached all-time high prescription volume and market share, with total Symproic prescriptions of close to 19,000 in the fourth quarter, representing growth of 10% versus the prior year.
- Achieved significant profitability delivering \$10.2 million of GAAP Net Income and an attractive 34% EBITDA margin in the fourth quarter of 2020, as well as full year GAAP net income of \$25.7 million, or \$0.26 per share, and a 26% EBITDA margin.
- The Company initiated share repurchases late in the fourth quarter under the previously announced share buyback program, completing purchases of 48,000 shares in the fourth quarter, and approximately 660,000 additional share purchases in the first quarter through March 8th, for approximately \$2.9 million in total.
- Terry Coelho promoted to Executive Vice President and Chief Financial Officer.

"The impressive momentum and growth of our innovative products has persisted through the fourth quarter and full year 2020. Our high performing commercial team has been responding effectively to the



evolving market conditions during the pandemic, and focused execution during the fourth quarter drove strong prescription trends for both BELBUCA and Symproic,” stated Jeff Bailey, CEO of BDSI. “Our brands continued to capture market share in 2020 and the Company is poised for continued success as the selling environment improves in 2021.”

#### ***Fourth Quarter 2020 Financial Results***

**Total Company Net Revenue** for the fourth quarter of 2020 was a record \$42.2 million, an increase of 33% compared to \$31.6 million in the fourth quarter of 2019, and an increase of 7% compared to \$39.4 million in the third quarter of 2020.

**BELBUCA Net Sales** for the fourth quarter of 2020 were \$35.6 million, an increase of 26% compared to \$28.3 million in the fourth quarter of 2019, and an increase of 2% compared to \$34.8 million in the third quarter of 2020. BELBUCA gross to net deductions increased in the fourth quarter as anticipated, primarily due to typical increases seen for Medicare coverage gap.

**Symproic Net Sales** for the fourth quarter were \$3.7 million, an increase of 35% compared to \$2.7 million in the fourth quarter of 2019, and an increase of 6% compared to \$3.5 million in the third quarter of 2020.

**BUNAVAIL Net Revenue** for the fourth quarter was \$2.4 million, reflecting the release of a portion of the sales returns reserves taken at the time discontinuation was announced. In June 2020, the Company discontinued marketing of BUNAVAIL.

**Total Operating Expenses** for the fourth quarter of 2020 were \$21.4 million, compared to \$23.8 million in the fourth quarter of 2019 and \$22.5 million in the third quarter of 2020.

**GAAP Net Income** for the fourth quarter of 2020 was \$10.2 million, or \$0.10 per share, compared to GAAP net loss of \$0.7 million, or \$0.01 per share, in the fourth quarter of 2019 and GAAP net income of \$9.4 million, or \$0.09 per share, in the third quarter of 2020.

**EBITDA** for the fourth quarter of 2020 was \$14.3 million, or 34% of net sales, compared to \$4.1 million or 13% of net sales, in the fourth quarter of 2019.

**Non-GAAP Net Income** for the fourth quarter of 2020 was \$13.7 million and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets. This reflects an increase of \$7.3 million as compared to non-GAAP net income of \$6.4 million in the fourth quarter of 2019, excluding the same items plus the non-recurring financial impact of discontinuation of the marketing of BUNAVAIL.

#### ***Full-Year 2020 Financial Results***

**Total Net Revenue** for full-year 2020 was \$156.5 million, an increase of 40% compared to \$111.4 million for full-year 2019.

**BELBUCA Net Sales** for full-year 2020 were \$136.1 million, an increase of 40% compared to \$97.5 million for full-year 2019.



**Symproic Net Sales** for full-year 2020 were \$14.7 million, an increase of 83% compared to 2019. The Company acquired Symproic in April 2019 and generated net sales of \$8.1 million during the period from April to December 2019.

**BUNAVAIL Net Revenue** for full-year 2020 was \$3.7 million, compared to \$2.3 million for full-year 2019, and includes the release of certain sales returns reserves of \$2.4 million following the discontinuation of marketing in June 2020.

**Product Royalty Revenue** for full-year 2020 was \$1.9 million, compared to \$3.5 million for full-year 2019.

**Total Operating Expenses** for full-year 2020 were \$98.8 million, compared to \$86.1 million for full-year 2019.

**GAAP Net Income** for full-year 2020 was \$25.7 million, or \$0.26 per share, an increase of \$41.0 million compared to GAAP net loss of \$15.3 million, or \$(0.18) per share, for full-year 2019.

**EBITDA** for full-year 2020 was \$40.5 million, or 26% of net sales, an increase of \$28.0 million compared to \$12.5 million, or 11% of net sales for full-year 2019.

**Non-GAAP Net Income** for full-year 2020 was \$44.2 million and reflects GAAP net income excluding stock-based compensation, non-cash amortization of intangible assets, one-time expenses related to the CEO transition were incurred in 2020, and the non-recurring financial impact related to the discontinuation of the marketing of BUNAVAIL.

**Cash Position:** As of December 31, 2020, cash and cash equivalents were approximately \$111.6 million, compared to \$63.9 million as of December 31, 2019. The total cash flow generation over 2020 of \$47.7 million includes operating cash generation of \$25 million, \$3.4 million in proceeds from the exercise of options, and net proceeds of \$19.6 million from the draw down in May 2020 of \$20 million from our existing debt facility, partially offset by \$0.2 million used to repurchase shares in the quarter.

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

The Company expects full year 2021 total net sales of \$170 - \$180 million, including full year 2021 BELBUCA net sales of \$155 - \$165 million. These estimates incorporate the expected impact in Q1 2021 from the winter storms in the South-Central region, which affected some of the Company's most productive territories. 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 being operating cash flow positive throughout 2021.

"I'm proud of how the BDSI team really pulled together, and also thrived, during 2020 in what was a challenging year for the industry due to the pandemic. I would like to recognize the efforts and contributions of all BDSI employees. I have great confidence that, with the strength of this team, high-growth brands, and a strong balance sheet, BDSI will continue to drive long-term shareholder value," stated Jeff Bailey.



### Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, March 10, 2021, at 8:30 a.m. ET to present fourth quarter and full-year 2020 results and to provide a business update. Dial-in details are as follows:

Date:	Wednesday, March 10, 2021
Time:	8:30 AM Eastern Time
Domestic:	877-407-0789
International:	201-689-8562
Conference ID:	13715530
Webcast:	<a href="http://public.viavid.com/index.php?id=143193">http://public.viavid.com/index.php?id=143193</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 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, non-cash 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 financial impact of the debt refinancing in 2019, the discontinuation of marketing of BUNAVAIL, and costs associated with the CEO transition in 2020.

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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### **Contact:**

Bob Yedid  
LifeSci Advisors  
646-597-6989  
[Bob@LifeSciAdvisors.com](mailto:Bob@LifeSciAdvisors.com)



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

	December 31, 2020	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 111,584	\$ 63,888
Accounts receivable, net	48,150	38,790
Inventory, net	17,443	11,312
Prepaid expenses and other current assets	5,208	3,769
<b>Total current assets</b>	<b>182,385</b>	<b>117,759</b>
Property and equipment, net	1,418	2,075
Goodwill	2,715	2,715
License and distribution rights, net	53,376	60,309
Other intangible assets, net	—	47
<b>Total assets</b>	<b>\$ 239,894</b>	<b>\$ 182,905</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 52,995	\$ 53,993
<b>Total current liabilities</b>	<b>52,995</b>	<b>53,993</b>
Notes payable, net	78,452	58,568
Other long-term liabilities	213	580
<b>Total liabilities</b>	<b>131,660</b>	<b>113,141</b>
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; 2,714,300 shares issued; Series A Non-Voting Convertible Preferred Stock, \$0.001 par value, 0 and 2,093,155 shares outstanding at December 31, 2020 and December 31, 2019, respectively; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 and 618 shares outstanding at December 31, 2020 and December 31, 2019 respectively.	—	2
Common Stock, \$0.001 par value; 235,000,000 and 175,000,000 shares authorized at December 31, 2020 and December 31, 2019 respectively; 101,417,441 and 96,189,074 shares issued; 101,354,447 and 96,173,583 shares outstanding at December 31, 2020 and December 31, 2019, respectively.	104	96
Additional paid-in capital	449,264	436,306
Treasury stock, at cost, 62,994 and 15,491 shares as of December 31, 2020 and December 31, 2019, respectively	(252)	(47)
Accumulated deficit	(340,882)	(366,593)
<b>Total stockholders' equity</b>	<b>108,234</b>	<b>69,764</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 239,894</b>	<b>\$ 182,905</b>





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

	Quarter Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
<b>Revenues:</b>				
Product sales	\$ 41,628	\$ 30,450	\$ 154,574	\$ 107,888
Product royalty revenues	539	1,187	1,897	3,341
Contract revenues	—	—	—	160
<b>Total Revenues:</b>	<b>42,167</b>	<b>31,637</b>	<b>156,471</b>	<b>111,389</b>
Cost of sales	8,294	7,265	24,665	21,590
<b>Expenses:</b>				
Selling, general and administrative	21,418	23,759	98,827	86,063
<b>Total Expenses:</b>	<b>21,418</b>	<b>23,759</b>	<b>98,827</b>	<b>86,063</b>
<b>Income from operations</b>	<b>12,455</b>	<b>613</b>	<b>32,979</b>	<b>3,736</b>
Interest expense, net	(2,028)	(1,308)	(7,013)	(19,040)
Other (expense)/income, net	3	(1)	(3)	4
Income/(loss) before income taxes	10,430	(696)	25,963	(15,300)
Income tax benefit	(233)	—	(252)	(5)
Net income/(loss)	10,197	(696)	25,711	(15,305)
<b>Net income/(loss) attributable to common stockholders</b>	<b>\$ 10,197</b>	<b>\$ (696)</b>	<b>\$ 25,711</b>	<b>\$ (15,305)</b>
<b>Basic</b>				
Weighted average common stock shares outstanding	101,178,994	92,118,497	99,830,520	83,213,704
Basic earnings/(loss) per share	\$ 0.10	\$ (0.01)	\$ 0.26	\$ (0.18)
<b>Diluted</b>				
Weighted average common stock shares outstanding	105,648,727	92,118,497	105,062,522	83,213,704
Diluted earnings/(loss) per share	\$ 0.10	\$ (0.01)	\$ 0.24	\$ (0.18)



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

	Year Ended December 31,		
	2020	2019	2018
<b>Operating activities:</b>			
<b>Net income (loss)</b>	<b>\$ 25,711</b>	<b>\$ (15,305)</b>	<b>\$ (33,867)</b>
Adjustments to reconcile net income (loss) to net cash flows used in operating activities			
Depreciation	538	1,846	740
Accretion of debt discount and loan costs	320	11,508	4,138
Amortization of intangible assets	6,981	6,981	5,157
Provision for (recovery from) inventory obsolescence	1,870	197	(56)
Impairment loss on equipment	—	—	78
Stock-based compensation expense	9,595	5,416	5,941
Deferred income taxes	—	—	40
<b>Changes in assets and liabilities, net of effect of acquisition:</b>			
Accounts receivable	(9,360)	(25,163)	(4,640)
Inventories	(8,001)	(6,102)	741
Prepaid expenses and other assets	(1,439)	(581)	422
Accounts payable and accrued expenses	(1,234)	32,275	(2,807)
<b>Net cash flows used in operating activities</b>	<b>24,981</b>	<b>11,072</b>	<b>(24,113)</b>
<b>Investing activities:</b>			
Product acquisitions	—	(30,685)	(1,951)
Acquisitions of equipment	(13)	(79)	(112)
<b>Net cash flows used in investing activities</b>	<b>(13)</b>	<b>(30,764)</b>	<b>(2,063)</b>
<b>Financing activities:</b>			
Proceeds from exercise of stock options	3,369	2,321	670
Proceeds from issuance of common stock, less underwriters fee discount	—	48,000	—
Proceeds from issuance of Series B preferred stock	—	—	50,000
Payment on note payable	—	(67,346)	—
Proceeds from notes payable	20,000	59,987	—
Equity finance costs	—	(410)	(1,417)
Payment of deferred financing fees	(436)	—	(450)
Loss on refinancing of former debt	—	(2,794)	—
Payment on share repurchase	(205)	—	—
<b>Net cash flows from financing activities</b>	<b>22,728</b>	<b>39,758</b>	<b>48,803</b>
<b>Net change in cash and cash equivalents</b>	<b>47,696</b>	<b>20,066</b>	<b>22,627</b>
Cash and cash equivalents at beginning of year	63,888	43,822	21,195
<b>Cash and cash equivalents at end of year</b>	<b>\$ 111,584</b>	<b>\$ 63,888</b>	<b>\$ 43,822</b>



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

Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	Year Ended December 31,		
	2020	2019	2018
<b>GAAP net income/(loss)</b>	<b>\$ 25,711</b>	<b>\$ (15,305)</b>	<b>\$ (33,867)</b>
Add back/(subtract):			
Income tax provision	252	5	14
Net interest expense	7,013	19,036	10,206
Depreciation and amortization	7,521	8,748	6,188
<b>EBITDA</b>	<b>\$ 40,497</b>	<b>\$ 12,484</b>	<b>\$ (17,459)</b>
<b>Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)</b>			
<b>GAAP net income/(loss)</b>	<b>25,711</b>	<b>(15,305)</b>	<b>(33,867)</b>
Non-GAAP adjustments:			
Stock-based compensation expense	6,107	5,416	5,941
Amortization of intangible assets	6,982	6,981	5,157
Amortization of warrant discount	—	448	1,076
Non-recurring financial impact of debt refinance	—	11,866	—
Non-recurring financial impact of BUNAVAIL discontinuation	295	3,750	—
Non-recurring financial impact of CEO transition	5,145	—	—
<b>Non-GAAP net income/(loss)</b>	<b>\$ 44,240</b>	<b>\$ 13,156</b>	<b>\$ (21,693)</b>

Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	Quarter Ended,		
	December 31, 2020	September 30, 2020	December 31, 2019
<b>GAAP net income/(loss)</b>	<b>\$ 10,197</b>	<b>\$ 9,383</b>	<b>\$ (696)</b>
Add back:			
Provision for income taxes	233	211	1
Net interest expense	2,022	2,012	1,308
Depreciation and amortization	1,806	1,754	3,491
<b>EBITDA</b>	<b>\$ 14,258</b>	<b>\$ 13,360</b>	<b>\$ 4,104</b>
<b>Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)</b>			
<b>GAAP net income/(loss)</b>	<b>10,197</b>	<b>9,383</b>	<b>(696)</b>
Non-GAAP adjustments:			
Stock-based compensation expense	1,750	1,473	1,438
Amortization of intangible assets	1,733	1,734	1,899
Non-recurring financial impact of BUNAVAIL discontinuation	—	—	3,750
Non-recurring financial impact of CEO transition	—	67	—
<b>Non-GAAP net income</b>	<b>\$ 13,680</b>	<b>\$ 12,657</b>	<b>\$ 6,391</b>