

**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): March 12, 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 Fourth Quarter and Full-Year 2019 Results**

*Full-Year Total Company Net Sales Increased 100% versus Prior Year to \$111.4 Million*

*Full-Year BELBUCA® Net Sales Increased 112% versus Prior Year to \$97.5 Million*

*Fourth Quarter Total Company Net Sales Increased 75% versus Prior Year to \$31.6 Million*

*Fourth Quarter BELBUCA® Net Sales Increased 78% versus Prior Year to \$28.3 Million*

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

**RALEIGH, N.C., March 12, 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 fourth quarter and full-year ended December 31, 2019, as well as the following operational and performance highlights.

### **Key Business Highlights**

- Total Company full-year net sales of \$111.4 million delivered growth of 100% versus 2018 and was driven by BELBUCA® (buprenorphine buccal film), CIII net sales of \$97.5 million, an increase of 112% compared to 2018, and the addition of Symproic® (naldemedine) tablets 0.2mg to the commercial portfolio, which delivered \$8.1 million net sales in 2019.
- Total Company net revenue for the fourth quarter increased by 75% versus the prior year period to a new all-time high of \$31.6 million. This growth was driven by BELBUCA sales of \$28.3 million, an increase of 78% versus the prior year period, and the addition of Symproic to the commercial portfolio.
- Total BELBUCA prescriptions of more than 96,000 for the fourth quarter were the highest ever for any three-month period, representing year-over-year prescription volume growth of more than 70% in the quarter.
- Total Symproic prescriptions reached an all-time high of 16,555 in the fourth quarter, representing more than 36% growth versus the prior year period.
- Achieved record number of unique prescribers during the quarter for both BELBUCA and Symproic.
- In addition, as previously released, the Company recently presented the positive results from the BELBUCA Phase I respiratory drive study at the American Academy of Pain Medicine's (AAPM) 36<sup>th</sup> Annual Meeting.

"I am very pleased by the continued strong execution during the fourth quarter, culminating in a very successful and transformative year for the Company in 2019," stated Herm Cukier, CEO of BDSI. "The continued growth of BELBUCA and Symproic, in addition to the commercial and scientific plans we have developed, position us for long-term sustained success. We continue to monitor the COVID-19 pandemic for any potential impact which may arise in this rapidly evolving situation, and remain focused on bringing important clinical value to patients."

## Fourth Quarter 2019 Financial Results

**Total Company Net Revenue** for the fourth quarter of 2019 was \$31.6 million, an increase of 75% compared to \$18.0 million in the fourth quarter of 2018, and an increase of 4% compared to \$30.3 million in the third quarter of 2019.

**BELBUCA Net Sales** for the fourth quarter of 2019 were \$28.3 million, an increase of 78% compared to \$15.9 million in the fourth quarter of 2018, and an increase of 7% compared to \$26.5 million in the third quarter of 2019.

**Symproic Net Sales** for the fourth quarter were \$2.7 million, an increase of 25% compared to \$2.2 million in the third quarter of 2019.

**BUNAVAIL Net Sales** for the fourth quarter were (\$0.5) million, a reduction of 141.7% compared to \$1.2 million in the fourth quarter of 2018. Net sales for the fourth quarter of 2019 reflect \$2.3 million of one-time additional revenue related reserves in connection with the March 2020 announcement of the discontinuation of marketing of BUNAVAIL.

**Product Royalty Revenue** for the fourth quarter was \$1.2 million, an increase of \$0.2 million compared to \$1.0 million in the fourth quarter of 2018 and an increase of \$0.5 million compared to the third quarter of 2019.

**Total Operating Expenses** for the fourth quarter of 2019 were \$23.8 million, compared to \$23.4 million in the third quarter of 2019 and \$18.5 million in the fourth quarter of 2018.

**GAAP Net Loss** for the fourth quarter of 2019 was \$0.7 million compared to GAAP net income of \$0.4 million for the third quarter of 2019 and GAAP net loss of \$7.0 million in the fourth quarter of 2018.

**EBITDA** in the fourth quarter of 2019 was \$4.1 million, or 13.0% of net sales, compared to \$3.5 million in the third quarter of 2019 and (\$3.0) million in the fourth quarter of 2018.

**Non-GAAP Net Income** for the quarter was \$6.4 million and reflects GAAP net income excluding stock-based compensation, non-cash amortization of intangible assets, and the non-recurring financial impact of \$3.8 million related to the discontinuation of marketing of BUNAVAIL.

## Full-Year 2019 Financial Results

**Total Net Revenue** for full-year 2019 was \$111.4 million, an increase of 100% compared to \$55.6 million for full-year 2018.

**BELBUCA Net Sales** for full-year 2019 were \$97.5 million, an increase of 112% compared to \$46.0 million for full-year 2018.

**Symproic Net Sales** for full-year 2019 were \$8.1 million, reflecting three quarters of sales during 2019.

**BUNAVAIL Net Sales** for full-year 2019 were \$2.3 million, a reduction of 57.4% compared to \$5.4 million for full-year 2018.

**Product Royalty Revenue** for full-year 2019 was \$3.5 million, compared to \$4.2 million for full-year 2018.

**Total Operating Expenses** for full-year 2019 were \$86.1 million, compared to \$63.5 million for full-year 2018.

**GAAP Net Loss** for full-year 2019 was \$15.3 million compared to GAAP net loss of \$33.9 million for full-year 2018.



**EBITDA** for full-year of 2019 was \$12.5 million, or 11.2% of net sales compared to (\$17.5) million, or (31.4)% of net sales for full-year 2018.

**Non-GAAP Net Income** for full-year 2019 was \$13.2 million and reflects GAAP net income excluding stock-based compensation, non-cash amortization of intangible assets and certain warrant discount costs, one-time expenses related to our debt refinancing in May 2019, and the non-recurring financial impact related to the discontinuation of the marketing of BUNAVAIL.

**Cash Position:** As of December 31, 2019, cash and cash equivalents were approximately \$63.9 million, compared to cash and cash equivalents of \$43.8 million as of December 31, 2018, and \$55.9 million in the third quarter of 2019, reflecting positive cash flow of \$8.0 million in the fourth quarter of 2019, and \$20.1 million for full-year 2019.

### Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, March 12, 2020, at 4:30 p.m. ET to present fourth quarter 2019 results and to provide a business update. Dial-in details are as follows:

Date:	Thursday, March 12, 2020
Time:	4:30 PM EST
Domestic:	877-407-0789
International:	201-689-8562
Conference ID:	13699178
Webcast:	<a href="http://public.viavid.com/index.php?id=138131">http://public.viavid.com/index.php?id=138131</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, 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 our debt refinancing in May 2019 and 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**  
**CONSOLIDATED BALANCE SHEETS**  
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	December 31,	
	2019	2018
<b>ASSETS</b>		
Current assets:		
Cash	\$ 63,888	\$ 43,822
Accounts receivable, net	38,790	13,627
Inventory, net	11,312	5,406
Prepaid expenses and other current assets	3,769	3,188
<b>Total current assets</b>	<b>117,759</b>	<b>66,043</b>
Property and equipment, net	2,075	3,072
Goodwill	2,715	2,715
License and distribution rights, net	60,309	36,000
Other intangible assets, net	47	703
<b>Total assets</b>	<b>\$ 182,905</b>	<b>\$ 108,533</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 53,993	\$ 21,539
<b>Total current liabilities</b>	<b>53,993</b>	<b>21,539</b>
Notes payable, net	58,568	51,652
Other long-term liabilities	580	5,600
<b>Total liabilities</b>	<b>113,141</b>	<b>78,791</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, 2,093,155 shares outstanding at both December 31, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 618 and 3,100 shares outstanding at December 31, 2019 and December 31, 2018 respectively.	2	2
Common Stock, \$0.001 par value; 175,000,000 and 125,000,000 shares authorized at December 31, 2019 and December 31, 2018 respectively; 96,189,074 and 70,793,725 shares issued; 96,173,583 and 70,778,234 shares outstanding at December 31, 2019 and December 31, 2018, respectively.	96	71
Additional paid-in capital	436,306	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(366,593)	(351,288)
<b>Total stockholders' equity</b>	<b>69,764</b>	<b>29,742</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 182,905</b>	<b>\$ 108,533</b>



**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,		
	2019	2018	2017
<b>Revenues:</b>			
Product sales	\$ 107,888	\$ 51,410	\$ 34,922
Product royalty revenues	3,341	3,389	5,070
Research and development reimbursements	—	—	799
Contract revenue	160	841	21,194
Total revenues	111,389	55,640	61,985
Cost of sales	21,590	15,783	19,496
<b>Expenses:</b>			
Research and development	—	4,903	13,040
Selling, general and administrative	86,063	58,602	58,869
Total expenses	86,063	63,505	71,909
Income (loss) from operations	3,736	(23,648)	(29,420)
Interest expense	(19,040)	(10,192)	(8,577)
Bargain purchase gain	—	—	27,336
Other income (expense), net	4	(14)	(26)
Loss before income taxes	(15,300)	(33,854)	(10,687)
Income tax (expense) benefit	(5)	(13)	15,972
Net (loss) income	(15,305)	(33,867)	5,285
Beneficial conversion feature of convertible preferred stock	—	(12,500)	—
Net (loss) income attributable to common stockholders	\$ (15,305)	\$ (46,367)	\$ 5,285
<b>Basic:</b>			
Weighted average common stock shares outstanding	83,213,704	63,165,063	55,355,802
Basic (loss) earnings per share	\$ (0.180)	\$ (0.730)	\$ 0.10
<b>Diluted:</b>			
Diluted weighted average common stock shares outstanding	83,213,704	63,165,063	56,402,479
Diluted (loss) earnings per share	\$ (0.180)	\$ (0.730)	\$ 0.09



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

	Year Ended December 31,		
	2019	2018	2017
<b>Operating activities:</b>			
Net (loss) income	\$ (15,305)	\$ (33,867)	\$ 5,285
Adjustments to reconcile net (loss) income to net cash flows provided by (used in) operating activities			
Depreciation	1,846	740	693
Accretion of debt discount and loan costs	11,508	4,138	2,392
Amortization of intangible assets	6,981	5,157	5,425
Provision for (recovery from) inventory obsolescence	197	(56)	243
Impairment loss on equipment	—	78	—
Stock-based compensation expense	5,416	5,941	14,801
Deferred income taxes	—	40	(15,972)
Bargain purchase gain	—	—	(27,336)
Changes in assets and liabilities, net of effect of acquisition:			
Accounts receivable	(25,163)	(4,640)	(5,884)
Inventories	(6,102)	741	2,448
Prepaid expenses and other assets	(581)	422	526
Accounts payable and accrued expenses	32,275	(2,807)	6,644
Deferred revenue	—	—	(21,716)
Net cash flows provided by (used in) operating activities	11,072	(24,113)	(32,451)
<b>Investing activities:</b>			
Product acquisitions	(30,685)	(1,951)	(5,853)
Acquisitions of equipment	(79)	(112)	(11)
Net cash flows used in investing activities	(30,764)	(2,063)	(5,864)
<b>Financing activities:</b>			
Proceeds from exercise of stock options	2,321	670	439
Proceeds from issuance of common stock, less underwriters discount	48,000	—	—
Proceeds from issuance of Series B preferred stock	—	50,000	—
Payment on note payable	(67,346)	—	(30,000)
Proceeds from notes payable	59,987	—	60,000
Equity finance costs	(410)	(1,417)	—
Payment of deferred financing fees	—	(450)	(2,948)
Loss on refinancing of former debt	(2,794)	—	—
Net cash flows provided by financing activities	39,758	48,803	27,491
Net change in cash and cash equivalents	20,066	22,627	(10,824)
Cash and cash equivalents at beginning of year	43,822	21,195	32,019
<b>Cash and cash equivalents at end of year</b>	<b>\$ 63,888</b>	<b>\$ 43,822</b>	<b>\$ 21,195</b>

**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.

	Year Ended December 31,		
	2019	2018	2017
<b>Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)</b>			
GAAP net income/(loss)	\$ (15,305)	\$ (33,867)	\$ 5,285
Add back:			
Provision for income taxes	5	14	(15,972)
Net interest expense	19,036	10,206	(18,733)
Depreciation and amortization	8,748	6,188	6,119
<b>EBITDA</b>	<b>\$ 12,484</b>	<b>\$ (17,459)</b>	<b>\$ (23,301)</b>
<b>Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)</b>			
GAAP net income/(loss)	(15,305)	(33,867)	5,285
Non-GAAP adjustments:			
Stock-based compensation expense	5,416	5,941	14,800
Amortization of intangible assets	6,981	5,157	5,425
Amortization of warrant discount	448	1,076	832
Non-recurring financial impact of debt refinance	11,866	—	—
Non-recurring financial impact of BUNAVAIL discontinuation	3,750	0	0
Non-recurring financial impact of bargain purchase gain	0	0	(27,336)
<b>Non-GAAP net income/(loss)</b>	<b>\$ 13,156</b>	<b>\$ (21,693)</b>	<b>\$ (994)</b>

	Quarter Ended December 31,	
	2019	2018
<b>Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)</b>		
GAAP net income/(loss)	\$ (696)	\$ (7,008)
Add back:		
Provision for income taxes	1	(40)
Net interest expense	1,308	2,600
Depreciation and amortization	3,491	1,470
<b>EBITDA</b>	<b>\$ 4,104</b>	<b>\$ (2,978)</b>
<b>Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)</b>		
GAAP net income/(loss)	(696)	(7,008)
Non-GAAP adjustments:		
Stock-based compensation expense	1,438	1,045
Amortization of intangible assets	1,899	1,289
Amortization of warrant discount	—	269
Non-recurring financial impact of BUNAVAIL discontinuation	3,750	—
<b>Non-GAAP net income/(loss)</b>	<b>\$ 6,391</b>	<b>\$ (21,693)</b>