

**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): August 5, 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	27612
(Address of principal executive offices)		(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 Q2 2020 Results

Second Quarter Total Company Net Revenue Increased 23% versus Prior Year to \$36.6 Million

Second Quarter BELBUCA® Net Sales Increased 34% versus Prior Year to \$32.3 Million

BELBUCA and Symproic® Each Reach All Time High TRx Volume and Market Share

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

RALEIGH, N.C., August 5, 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 second quarter ended June 30, 2020, as well as the following operational and performance highlights.

Key Business Highlights

- Total Company net revenue for the second quarter increased by 23% versus the prior year period to \$36.6 million. This growth was driven by BELBUCA net sales of \$32.3 million, an increase of 34% versus the prior year period, and Symproic net sales of \$3.4 million, an increase of 7% compared to the second quarter of 2019.
- Total BELBUCA prescriptions reached an all-time high of 104,687 during the second quarter, representing year-over-year prescription volume growth of 31%.
- Total Symproic prescriptions were more than 17,200 in the second quarter, representing growth of 11% versus the prior year.
- Appointed Jeffrey A. Bailey as interim Chief Executive Officer (CEO).
- Successfully adapted commercial model in response to evolving COVID-19 market conditions, which included a reduction in patient visits to physicians. This was demonstrated by robust brand performance year over year, while also tightly managing expenses to drive positive net income.

“Our business has proven to be extremely resilient during the second quarter as seen with the all-time high TRx volume and market shares achieved for both BELBUCA and Symproic,” stated Jeff Bailey, interim CEO of BDSI. “BDSI is in the best financial position it has ever been from a cash and profitability perspective, and fundamentally the demand for BELBUCA and Symproic is strong, positioning the company well to continue supporting our commercial team with new and enhanced tools adapted for the current environment.”

Second Quarter 2020 Financial Results

Total Company Net Revenue for the second quarter of 2020 was \$36.6 million, an increase of 23% compared to \$29.7 million in the second quarter of 2019, and a decrease of 4% compared to \$38.3 million in the first quarter of 2020.

BELBUCA Net Sales for the second quarter of 2020 were \$32.3 million, an increase of 34% compared to \$24.1 million in the second quarter of 2019, and a decrease of 3% compared to \$33.5 million in the first quarter of 2020.

Symproic Net Sales for the second quarter were \$3.4 million, an increase of 7% compared to \$3.2 million in the second quarter of 2019, and a decrease of 18% compared to \$4.2 million in the first quarter of 2020.

BUNAVAIL Net Sales for the second quarter were \$0.7 million, compared to \$0.8 million in the second quarter of 2019. In March of this year, the Company announced the planned discontinuation of marketing of BUNAVAIL and ceased shipping product on June 15, 2020.



Total Operating Expenses for the second quarter of 2020 were \$28.2 million, compared to \$26.7 million in the first quarter of 2020 and \$22.0 million in the second quarter of 2019. Second quarter costs declined \$3.6 million compared to the first quarter of 2020, excluding the \$5.1 million of non-recurring costs related to the CEO transition.

GAAP Net Income for the second quarter of 2020 was \$1.2 million, or \$0.01 per share, compared to GAAP net income of \$5.0 million, or \$0.05 per share, for the first quarter of 2020 and GAAP net loss of \$11.1 million, or (\$0.13) per share, in the second quarter of 2019.

EBITDA for the second quarter of 2020 was \$5.1 million, or 14% of net sales, compared to \$7.8 million in the first quarter of 2020 and \$4.8 million in the second quarter of 2019.

Non-GAAP Net Income for the second quarter of 2020 was \$9.6 million and reflects GAAP net income excluding stock-based compensation, non-cash amortization of intangible assets, non-recurring financial impact of the BUNAVAIL discontinuation and the non-recurring financial impact of the CEO transition.

Cash Position: As of June 30, 2020, cash and cash equivalents were approximately \$91.0 million, compared to \$63.9 million at December 31, 2019, reflecting the generation of \$5.0 million of positive operating cash flow and \$2.5 million in proceeds from the exercise of options, together with \$19.6 million of net proceeds from increasing our existing credit facility.

"A very important objective through this COVID-19 pandemic has been on the health and safety of our employees and the communities we serve," stated Jeff Bailey. "Lastly, I'd like to thank the entire BDSI team for their commitment and continued focus on meeting patient needs."

Conference Call & Webcast Details

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

Date:	Wednesday, August 5, 2020
Time:	8:30 AM Eastern Time
Domestic:	866-248-8441
International:	720-452-9102
Conference ID:	9339657
Webcast:	http://public.viavid.com/index.php?id=141000

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 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.

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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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 91,009	\$ 63,888
Accounts receivable, net	48,126	38,790
Inventory, net	17,774	11,312
Prepaid expenses and other current assets	2,099	3,769
Total current assets	159,008	117,759
Property and equipment, net	1,508	2,075
Goodwill	2,715	2,715
License and distribution rights, net	56,842	60,309
Other intangible assets, net	—	47
Total assets	<u>\$ 220,073</u>	<u>\$ 182,905</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 56,646	\$ 53,993
Total current liabilities	56,646	53,993
Notes payable, net	78,274	58,568
Other long-term liabilities	383	580
Total liabilities	135,303	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 June 30, 2020 and December 31, 2019, respectively; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 and 618 shares outstanding at June 30, 2020 and December 31, 2019, respectively.	—	2
Common Stock, \$0.001 par value; 175,000,000 shares authorized at June 30, 2020 and December 31, 2019, respectively; 100,916,511 and 96,189,074 shares issued; 100,901,020 and 96,173,583 shares outstanding at June 30, 2020 and December 31, 2019, respectively.	99	96
Additional paid-in capital	445,180	436,306
Treasury stock, at cost, 15,491 shares, as of June 30, 2020 and December 31, 2019.	(47)	(47)
Accumulated deficit	(360,462)	(366,593)
Total stockholders' equity	84,770	69,764
Total liabilities and stockholders' equity	<u>\$ 220,073</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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product sales	\$ 36,445	\$ 28,056	\$ 74,161	\$ 47,815
Product royalty revenues	137	1,461	700	1,471
Contract revenues	—	160	—	160
Total Revenues:	36,582	29,677	74,861	49,446
Cost of sales	5,435	4,923	10,995	8,975
Expenses:				
Selling, general and administrative	28,211	21,955	54,948	38,944
Total Expenses:	28,211	21,955	54,948	38,944
Income/(loss) from operations	2,936	2,799	8,918	1,527
Interest expense, net	(1,693)	(13,937)	(2,987)	(16,498)
Other income, net	8	8	8	8
Income/(loss) before income taxes	\$ 1,251	\$ (11,130)	\$ 5,939	\$ (14,963)
Income tax recovery/(provision)	(86)	—	192	—
Net income/(loss) attributable to common stockholders	\$ 1,165	\$ (11,130)	\$ 6,131	\$ (14,963)
Basic				
Weighted average common stock shares outstanding	100,136,893	83,821,811	98,541,877	77,571,003
Basic earnings/(loss) per share	\$ 0.01	\$ (0.13)	\$ 0.06	\$ (0.19)
Diluted				
Weighted average common stock shares outstanding	108,111,201	83,821,811	107,062,161	77,571,003
Diluted earnings/(loss) per share	\$ 0.01	\$ (0.13)	\$ 0.06	\$ (0.19)



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

	Six months ended June 30	
	2020	2019
Operating activities:		
Net income/(loss)	\$ 6,131	\$ (14,963)
Adjustments to reconcile net income/(loss) to net cash flows from operating activities		
Depreciation and amortization	446	168
Accretion of debt discount and loan costs	142	11,374
Amortization of intangible assets	3,515	3,187
Provision for inventory obsolescence	72	149
Stock-based compensation expense	6,306	2,711
Changes in assets and liabilities:		
Accounts receivable	(9,336)	(11,252)
Inventories	(6,534)	(4,716)
Prepaid expenses and other assets	1,670	(110)
Accounts payable and accrued liabilities	2,617	9,078
Taxes payable	(40)	—
Net cash flows provided by/(used in) operating activities	<u>4,989</u>	<u>(4,374)</u>
Investing activities:		
Product acquisitions	—	(20,674)
Acquisitions of equipment	—	(79)
Net cash flows used in investing activities	<u>—</u>	<u>(20,753)</u>
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	2,569	1,070
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	<u>22,132</u>	<u>38,520</u>
Net change in cash and cash equivalents	<u>27,121</u>	<u>13,393</u>
Cash and cash equivalents at beginning of period	63,888	43,822
Cash and cash equivalents at end of period	<u>\$ 91,009</u>	<u>\$ 57,215</u>



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

	Three Months Ended June 30,		Three Months Ended March 31,		Six Months Ended June 30,	
	2020	2019	2020	2020	2019	
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)						
GAAP net income/(loss)	\$ 1,165	\$ (11,130)	\$ 4,966	\$ 6,131	\$ (14,963)	
Add back/(subtract):						
Income tax recovery/(provision)	86	—	(278)	(192)	—	
Net interest expense	1,685	13,929	1,294	2,979	16,490	
Depreciation and amortization	2,159	1,981	1,802	3,960	3,356	
EBITDA	\$ 5,095	\$ 4,780	\$ 7,784	\$ 12,878	\$ 4,883	
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)						
GAAP net income/(loss)	\$ 1,165	\$ (11,130)	\$ 4,966	\$ 6,131	\$ (14,963)	
Non-GAAP adjustments:						
Stock-based compensation expense	1,364	1,569	1,520	6,305	2,712	
Amortization of intangible assets	1,734	1,898	1,781	93	3,187	
Amortization of warrant discount	—	179	—	—	448	
Non-recurring financial impact of debt refinance	—	11,866	—	—	11,866	
Non-recurring financial impact of CEO transition	5,078	—	—	5,078	—	
Non-recurring financial impact of BUNAVAIL discontinuation	295	—	—	295	—	
Non-GAAP net income/(loss)	\$ 9,636	\$ 4,382	\$ 8,267	\$ 17,902	\$ 3,250	