

**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 8, 2019

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 Capital 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).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On August 8, 2019, BioDelivery Sciences International, Inc. (the “Company”) announced its financial results for the second quarter ended June 30, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company on August 8, 2019, furnished herewith.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, the press release included herein (and the conference call referred to in such press release), and any statements of representatives and partners of the Company 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 the Company’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 the Company’s management and are subject to significant risks and uncertainties, including those detailed in the Company’s filings with the Securities and Exchange Commission. Actual results (including, without limitation, the continued growth in long-term combined BELBUCA and Symproic net sales and BELBUCA and total company net sales in 2019 and the implementation and success of our Symproic strategic plan) 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 the Company’s control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

ONSOLIS®, BUNAVAIL® and BELBUCA® are registered trademarks of the Company. BUNAVAIL and BELBUCA logos are trademarks owned by the Company. The Company has an exclusive license to use and display the Symproic registered trademark in order to commercialize Symproic in the United States. All other trademarks and tradenames are owned by their respective owners.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

August 8, 2019

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mary Theresa Coelho

Name: Mary Theresa Coelho

Title: Chief Financial Officer and Treasurer

BioDelivery Sciences Reports Strong Second Quarter 2019 Results and Raises Net Sales Expectations

BELBUCA® Net Sales Increased 147% versus Prior Year to All-Time High of \$24.1 Million

Raises Full-Year BELBUCA Net Sales Expectations to \$90 – \$93 Million

Raises Full-Year Total Company Net Sales Expectations to \$101 – \$105 Million

Raises Long-Term Combined Net Sales Expectations for BELBUCA and Symproic® to \$425 – \$500 Million

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

RALEIGH, N.C., August 8, 2019 - BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions, today reported strong financial results for the second quarter ended June 30, 2019, as well as the following operational and performance highlights:

Key Business Highlights

- Total company net revenue increased by 144% versus the prior year period to a new all-time high of \$29.7 million. This growth was driven by BELBUCA® (buprenorphine buccal film), CIII sales of \$24.1 million, an increase of 147% versus the prior year period, and the addition of Symproic® (naldemedine) tablets 0.2 mg to the commercial portfolio.
- Total BELBUCA prescriptions of more than 80,000 for the quarter was the highest ever for any three-month period. In addition, prescription growth for BELBUCA reached an all-time year-over-year record increase of 44,560 prescriptions, representing a 125% increase year-over-year and a 23% increase versus the prior quarter.
- Achieved a new all-time high of 6,579 unique BELBUCA prescribers during the quarter.
- Delivered highest ever number of quarterly prescriptions for Symproic achieving greater than 14% quarter-over-quarter growth and 40% growth versus prior year.
- Significantly strengthened financial position through debt refinancing, dramatically lowering cost of capital and extending maturity.

“The second quarter was highlighted by dramatic accomplishments across our entire organization and has positioned us to further build upon our commercial success,” stated Herm Cukier, Chief Executive Officer of BDSI. “We have significant momentum with our core products and have strengthened the company’s financial position. Our excellent performance in the second quarter is the fifth consecutive quarter of sustained and rapid growth. I believe our future is very promising, and as we raise our full-year BELBUCA and total company net sales expectations for the second time this year, we have great confidence in our growth trajectory into 2020 and beyond.”

The company again increased its expectations for full-year 2019 BELBUCA net sales to \$90 – \$93 million, from the previous level of \$83 – \$88 million. The company also raised its total 2019 net sales expectations to \$101 – \$105 million, from the previous level of \$92 – \$100 million. Total net revenue expectations include \$7 – \$9 million of forecasted Symproic net sales, which is in line with the company’s previous expectation.

With the strong performance achieved over the last five consecutive quarters, coupled with a solid balance sheet supporting the execution of the commercial growth plan, the company is raising its long-term combined net sales expectations for BELBUCA and Symproic to \$425 – \$500 million.

Second Quarter 2019 Financial Results

Total Net Revenue. Total net revenue for the second quarter ended June 30, 2019, was \$29.7 million, an increase of 50%, compared to \$19.8 million in the first quarter of 2019, and an increase of 144%, compared to \$12.2 million in the second quarter of 2018.

Total Net Product Sales. Total net product sales in the second quarter were \$28.1 million, an increase of 42%, compared to \$19.8 million in the first quarter of 2019 and an increase of 161% compared to \$10.8 million in the second quarter of 2018. This includes net product sales of Symproic of \$3.2 million in the initial quarter of commercialization following the acquisition of the product.

BELBUCA Net Sales. BELBUCA net sales in the second quarter were \$24.1 million, an increase of 29%, compared to \$18.7 million in the first quarter of 2019 and an increase of 147%, compared to \$9.7 million in the second quarter of 2018.

Total Operating Expenses. Total operating expenses in the quarter ended June 30, 2019, were \$22.0 million, compared to \$17.0 million in the first quarter of 2019 and \$14.9 million in the second quarter of 2018.

GAAP Net Loss. GAAP net loss for the quarter was \$11.1 million, or (\$0.13) per share, compared to the loss of \$3.8 million, or (\$0.05) per share, for the first quarter of 2019 and a GAAP net loss of \$9.8 million, or (\$0.16) per share, in the second quarter of 2018. The increase in net loss is driven by the one-time debt refinancing costs of \$11.9 million.

EBITDA. EBITDA in the second quarter of 2019 was \$4.8 million or 16.1% of total net revenue, compared to \$0.1 million in the first quarter of 2019 and (\$5.6) million in the second quarter of 2018.

Non-GAAP Net Income. Non-GAAP net income for the quarter was \$4.4 million and reflects GAAP net loss excluding the non-recurring costs of the debt refinancing, stock-based compensation and non-cash amortization of intangible assets and warrant discounts.

Cash Position. BDSI had cash and cash equivalents of approximately \$57.2 million as of June 30, 2019. Based on current guidance, the company anticipates having positive operating cash flow by the fourth quarter of 2019.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, August 8, 2019, at 4:30 p.m. ET to present second quarter 2019 results and to provide a business update. Dial-in details are as follows:

Date:	Thursday, August 8, 2019
Time:	4:30 PM EDT
Domestic:	800-347-6311
International:	720-543-0197
Passcode:	868 4665
Webcast:	http://public.viaavid.com/index.php?id=135544

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 and those in development address serious and debilitating conditions such as chronic pain, breakthrough cancer 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 the 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 the BDSI's management and are subject to significant risks and uncertainties, including those detailed in the BDSI's filings with the Securities and Exchange Commission. Actual results (including, without

limitation, the continued growth in BELBUCA net revenues and total net revenues in 2019 and the implementation and success of our Symproic strategic plan) 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 the BDSI's control) including 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.

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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)

	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,215	\$ 43,822
Accounts receivable, net.	24,879	13,627
Inventory, net	9,974	5,406
Prepaid expenses and other current assets	3,298	3,188
Total current assets	<u>95,366</u>	<u>66,043</u>
Property and equipment, net	3,853	3,072
Goodwill	2,715	2,715
License and distribution rights, net	63,778	36,000
Other intangible assets, net	375	703
Total assets	<u>\$ 166,087</u>	<u>\$ 108,533</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 40,762	\$ 21,539
Total current liabilities	40,762	21,539
Notes payable, net	58,448	51,652
Other long-term liabilities	727	5,600
Total liabilities	<u>99,937</u>	<u>78,791</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series A Non-Voting Convertible Preferred Stock, \$.001 par value, 2,093,155 shares outstanding at both June 30, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 1,716 and 3,100 shares outstanding at June 30, 2019 and December 31, 2018, respectively.	2	2
Common Stock, \$.001 par value; 125,000,000 shares authorized at June 30, 2019 and December 31, 2018, respectively; 89,535,024 and 75,793,725 shares issued; 89,519,533 and 70,778,234 shares outstanding at June 30, 2019 and December 31, 2018, respectively.	88	71
Additional paid-in capital	432,358	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	<u>(366,251)</u>	<u>(351,288)</u>
Total stockholders' equity	<u>66,150</u>	<u>29,742</u>
Total liabilities and stockholders' equity	<u>\$ 166,087</u>	<u>\$ 108,533</u>

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,	
	2019	2018	2019	2018
Revenues:				
Product sales	\$ 28,056	\$ 10,766	\$ 47,815	\$ 20,604
Product royalty revenues	1,461	1,386	1,471	1,826
Contract revenue	160	23	160	1,026
Total Revenues:	<u>29,677</u>	<u>12,175</u>	<u>49,446</u>	<u>23,456</u>
Cost of sales	<u>4,923</u>	<u>4,566</u>	<u>8,975</u>	<u>7,981</u>
Expenses:				
Research and development:	—	854	—	3,338
Sales, general and administrative	21,955	14,021	38,944	27,526
Total Expenses:	<u>21,955</u>	<u>14,875</u>	<u>38,944</u>	<u>30,864</u>
Income (loss) from operations	2,799	(7,266)	1,527	(15,389)
Interest expense	(13,937)	(2,525)	(16,498)	(5,030)
Other (expense) income, net	8	1	8	(6)
Loss before income taxes	<u>\$ (11,130)</u>	<u>\$ (9,790)</u>	<u>\$ (14,963)</u>	<u>\$ (20,425)</u>
Income tax benefit (expense)	—	20	—	(54)
Net loss attributable to common stockholders	<u>\$ (11,130)</u>	<u>\$ (9,770)</u>	<u>\$ (14,963)</u>	<u>\$ (20,479)</u>
Basic and diluted				
Weighted average common stock shares outstanding:	<u>83,821,811</u>	<u>59,400,317</u>	<u>77,571,003</u>	<u>58,735,351</u>
Basic and diluted loss per share:	<u>\$ (0.13)</u>	<u>\$ (0.16)</u>	<u>\$ (0.19)</u>	<u>\$ (0.35)</u>

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

	Six Months Ended June 30,	
	2018	2018
Operating activities:		
Net loss	\$ (14,963)	\$ (20,479)
Depreciation and amortization	168	456
Impairment loss on equipment	—	78
Accretion of debt discount and loan costs	11,374	1,782
Amortization of intangible assets	3,187	2,578
Provision for inventory obsolescence	149	412
Stock-based compensation expense	2,711	4,004
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(11,252)	(423)
Inventories	(4,716)	(489)
Prepaid expenses and other assets	(110)	1,454
Accounts payable and accrued expenses	9,078	(1,118)
Net cash flows from operating activities	<u>(4,374)</u>	<u>(11,745)</u>
Investing activities:		
Product acquisitions	(20,674)	(1,951)
Net disposals and purchase of equipment	(79)	(122)
Net cash flows from investing activities	<u>(20,753)</u>	<u>(2,073)</u>
Financing activities:		
Proceeds from issuance of common stock	48,000	—
Proceeds from issuance of Series B preferred stock	—	50,000
Equity financing costs	(410)	(1,509)
Proceeds from notes payable	60,000	—
Proceeds from exercise of stock options	1,070	306
Payment of notes payable	(67,346)	—
Loss on refinancing of former debt	(2,794)	—
Payment of deferred financing fees	—	(450)
Net cash flows from financing activities	<u>38,520</u>	<u>48,347</u>
Net change in cash and cash equivalents	13,393	34,529
Cash and cash equivalents at beginning of year	43,822	21,195
Cash and cash equivalents at end of year	<u>\$ 57,215</u>	<u>\$ 55,724</u>

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	2019	2018	2019	2018
GAAP net income/(loss)	\$ (11,130)	\$ (9,770)	\$ (14,963)	\$ (20,479)
Add back:				
Provision for income taxes	—	(20)	—	53
Net interest expense	13,929	2,525	16,490	5,037
Depreciation and amortization	1,981	1,679	3,356	3,199
EBITDA	\$ 4,780	\$ (5,586)	\$ 4,883	\$ (12,190)
Reconciliation of GAAP net income/(loss) to non-GAAP net income/(loss)				
GAAP net income/(loss)	\$ (11,130)	\$ (9,770)	\$ (14,963)	\$ (20,479)
Non-GAAP adjustments:				
Stock-based compensation expense	1,569	1,084	2,712	4,005
Amortization of intangible assets	1,898	1,289	3,187	2,578
Amortization of warrant discount	179	269	448	538
Non-recurring financial impact of debt refinance	11,866	—	11,866	—
Non-GAAP net income/(loss)	\$ 4,382	\$ (7,128)	\$ 3,250	\$ (13,358)