

**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): November 12, 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)

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))

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).

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 November 12, 2019, BioDelivery Sciences International, Inc. (the “Company”) announced its financial results for the third quarter ended September 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.

- (i) Exhibits

Exhibit No.	Description
99.1	<u>Press release issued by the Company on November 12, 2019, furnished herewith.</u>

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.

November 12, 2019

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: _____ /s/ Mary Theresa Coelho
Name: Mary Theresa Coelho
Title: Chief Financial Officer and Treasurer

BioDelivery Sciences Reports Strong Third Quarter Results, Raises Full Year 2019 and Provides 2020 Net Sales Expectations

BELBUCA® Net Sales Increased by 115% versus Prior Year to All-time High of \$26.5 Million

Raises Full Year 2019 Total Company Net Sales Expectations to \$105 - \$110 Million

Provides Full Year 2020 BELBUCA Net Sales Expectations of \$150 - \$160 Million and

Total Company Net Sales Expectations of \$165 - \$175 Million

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

RALEIGH, N.C., November 12, 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 third quarter ended September 30, 2019, as well as the following operational and performance highlights.

Key Business Highlights:

- Total Company net revenue increased by 114% versus the prior year period to a new all-time high of \$30.3 million. This growth was driven by BELBUCA® (buprenorphine buccal film), CIII sales of \$26.5 million, an increase of 115% versus the prior year period, and the addition of Symproic® (naldemedine) tablets 0.2mg to the commercial portfolio.
 - Total BELBUCA prescriptions of more than 89,600 for the quarter were the highest ever for any three-month period. In addition, BELBUCA achieved record year over year prescription volume growth of more than 45,000 during the quarter.
 - Total Symproic prescriptions reached an all-time high of 15,686, representing more than 39% growth versus the prior year period.
 - Achieved record number of unique prescribers during the quarter for both BELBUCA and Symproic.
 - Significantly improved insurance coverage for BELBUCA by adding an additional 14 million covered lives within commercial and health exchange plans with preferred status as of January 1, 2020. This brings the total commercial coverage for BELBUCA to more than 90% of covered lives, with approximately 55% being in preferred status.
 - Achieved substantial increase in insurance coverage for Symproic by adding more than 14 million commercial covered lives having preferred or preferred exclusive coverage by January 1, 2020, bringing the total commercial coverage for Symproic to more than 40% in preferred or preferred exclusive status.
 - Strong presence at the PAINWeek® 2019 National Conference on Pain for Frontline Practitioners, including the presentation of five scientific posters about BELBUCA and Symproic.
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“The third quarter was, once again, highlighted by very strong performance and achievements across the entire organization,” stated Herm Cukier, CEO of BDSI. “We continue to see significant growth momentum for BELBUCA and positive indicators of growth emerging for Symproic. The success achieved in the third quarter marks the sixth straight quarter of sustained rapid growth and fuels our confidence to raise total net sales expectations for full year 2019 and provide expectations for 2020. Given the increased utilization by physicians, significantly expanded access across payers, and tailwinds from federal health policy initiatives, I believe BELBUCA and Symproic are positioned for sustained growth.”

The Company raised expectations for full year 2019 total net sales to \$105 - \$110 million from the previous level of \$101 - \$105 million, and reiterated the expectation to be operationally cash flow positive during the fourth quarter. In addition, BDSI provided full year 2020 BELBUCA net sales expectations of \$150 – \$160 million and total Company net sales expectations of \$165 – \$175 million.

Third Quarter 2019 Financial Results

Total Net Revenue. Total net revenue for the third quarter ended September 30, 2019 was \$30.3 million, an increase of 114% compared to \$14.2 million in the third quarter of 2018, and an increase of 2% compared to \$29.7 million in the second quarter of 2019.

BELBUCA Net Sales in the third quarter were \$26.5 million, an increase of 115% compared to \$12.4 million in the third quarter of 2018, and an increase of 10% compared to \$24.1 million in the second quarter of 2019.

Symproic Net Sales in the third quarter were \$2.2 million, \$1.0 million below the second quarter net sales which had benefited from an agreed fee as part of a distribution agreement with Shionogi. The third quarter was the first full quarter of commercialization following acquisition of the product and reflects a standard gross to net revenue deductions approach.

Bunavail® Net Sales in the third quarter were \$0.9 million, a reduction of \$0.5 million compared to the third quarter of 2018 and an increase of \$0.1 million compared to the second quarter of 2019.

Product Royalty Revenue in the third quarter was \$0.7 million, an increase of \$0.3 million compared to the third quarter of 2018 and a reduction of \$0.9 million compared to the second quarter of 2019.

Total Operating Expenses. Total operating expenses in the quarter ended September 30, 2019 were \$23.4 million, compared to \$22.0 million in the second quarter of 2019 and \$14.2 million in the third quarter of 2018. The growth compared to the second quarter of 2019 reflects ongoing investments in marketing, sales and medical affairs.

GAAP Net Income. GAAP net income for the quarter was \$0.4 million, compared to GAAP net loss of \$11.1 million for the second quarter of 2019 and GAAP net loss of \$6.4 million in the third quarter of 2018.

EBITDA in the third quarter of 2019 was \$3.5 million or 11.6% of net sales, compared to \$4.8 million in the second quarter of 2019 and (\$2.3) million in the third quarter of 2018.

Non-GAAP Net Income. Non-GAAP net income for the quarter was \$3.5 million and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets.

Cash Position. As of September 30, 2019, cash and cash equivalents were approximately \$55.9 million, compared to cash and cash equivalents of \$43.8 million as of December 31, 2018.

Conference Call & Webcast Details

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

Date: Tuesday, November 12, 2019
Time: 4:30 PM EST
Domestic: 877-407-0789
International: 201-689-8562
Passcode: 13696283
Webcast: <http://public.viavid.com/index.php?id=136899>

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 long-term combined BELBUCA and Symproic net sales and BELBUCA net sales and total company net revenue in 2019 and 2020 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 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.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principals 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 from GAAP results: stock-based compensation expense, amortization of intangible assets, amortization of certain warrant discount costs and the financial impact of our debt refinancing which closed in May 2019, as it is non-recurring.

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
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)
(Unaudited)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,863	\$ 43,822
Accounts receivable, net	33,422	13,627
Inventory, net	10,766	5,406
Prepaid expenses and other current assets	4,874	3,188
Total current assets	104,925	66,043
Property and equipment, net	3,713	3,072
Goodwill	2,715	2,715
License and distribution rights, net	62,044	36,000
Other intangible assets, net	211	703
Total assets	\$ 173,608	\$ 108,533
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 46,545	\$ 21,539
Total current liabilities	46,545	21,539
Notes payable, net	58,515	51,652
Other long-term liabilities	654	5,600
Total liabilities	105,714	78,791
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 September 30, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 1,698 and 3,100 shares outstanding at September 30, 2019 and December 31, 2018, respectively.	2	2
Common Stock, \$.001 par value; 175,000,000 shares authorized at September 30, 2019 and 125,000,000 shares authorized at December 31, 2018, respectively; 89,796,774 and 70,793,725 shares issued; 89,781,283 and 70,778,234 shares outstanding at September 30, 2019 and December 31, 2018, respectively.	90	71
Additional paid-in capital	433,746	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(365,897)	(351,288)
Total stockholders' equity	67,894	29,742
Total liabilities and stockholders' equity	\$ 173,608	\$ 108,533

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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales	\$ 29,623	\$ 13,763	\$ 77,438	\$ 34,367
Product royalty revenues	683	370	2,154	2,197
Contract revenues	—	23	160	1,047
Total Revenues:	30,306	14,156	79,752	37,611
Cost of sales	5,350	3,779	14,325	11,760
Expenses:				
Research and development	—	699	—	4,038
Selling, general and administrative	23,360	13,489	62,304	41,013
Total Expenses:	23,360	14,188	62,304	45,051
Income (loss) from operations	1,596	(3,811)	3,123	(19,200)
Interest expense	(1,234)	(2,567)	(17,732)	(7,598)
Other (expense) income, net	(3)	(2)	5	(8)
Income (loss) before income taxes	\$ 359	\$ (6,380)	\$ (14,604)	\$ (26,806)
Income tax expense	(5)	—	(5)	(53)
Net income (loss)	\$ 354	\$ (6,380)	\$ (14,609)	\$ (26,859)
Beneficial conversion feature of convertible preferred stock	—	(12,500)	—	(12,500)
Net income (loss) attributable to common stockholders	\$ 354	\$ (18,880)	\$ (14,609)	\$ (39,359)
Basic				
Weighted average common stock shares outstanding	89,649,922	64,900,007	81,612,112	60,599,456
Basic earnings (loss) per share	\$ —	\$ (0.29)	\$ (0.18)	\$ (0.65)
Diluted				
Weighted average common stock shares outstanding	105,138,894	64,900,007	81,612,112	60,599,456
Diluted earnings (loss) per share	\$ —	\$ (0.29)	\$ (0.18)	\$ (0.65)

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

	Nine months ended September 30,	
	2019	2018
Operating activities:		
Net loss	\$ (14,609)	\$ (26,859)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation and amortization	253	685
Impairment loss on equipment	—	78
Accretion of debt discount and loan costs	11,441	2,953
Amortization of intangible assets	5,084	3,868
Provision for inventory obsolescence	57	396
Stock-based compensation expense	3,978	4,896
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(19,795)	(3,581)
Inventories	(5,416)	261
Prepaid expenses and other assets	(1,686)	(545)
Accounts payable and accrued liabilities	14,844	(427)
Net cash flows used in operating activities	(5,849)	(18,275)
Investing activities:		
Product acquisitions	(20,674)	(1,951)
Acquisitions of equipment	(79)	(155)
Net cash flows used in investing activities	(20,753)	(2,106)
Financing activities:		
Proceeds from issuance of common stock	48,000	—
Proceeds from issuance of Series B preferred stock	—	50,000
Equity issuance costs	(410)	(1,410)
Proceeds from notes payable	60,000	—
Proceeds from exercise of stock options	1,193	528
Payment on note payable	(67,346)	—
Loss on refinancing of former debt	(2,794)	—
Payment of deferred financing fees	—	(450)
Net cash flows provided by financing activities	38,643	48,668
Net change in cash and cash equivalents	12,041	28,287
Cash and cash equivalents at beginning of period	43,822	21,195
Cash and cash equivalents at end of period	\$ 55,863	\$ 49,482



BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

RECONCILIATION OF NON-GAAP METRICS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	2019	2018	2019	2018
GAAP net income/(loss)	\$ 354	\$ (6,380)	\$ (14,609)	\$ (26,859)
Add back:				
Provision for income taxes	4	—	4	53
Net interest expense	1,237	2,569	17,727	7,606
Depreciation and amortization	1,904	1,519	5,259	4,718
EBITDA	\$ 3,499	\$ (2,292)	\$ 8,381	\$ (14,482)
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)				
GAAP net income/(loss)	354	(6,380)	(14,609)	(26,859)
Non-GAAP adjustments:				
Stock-based compensation expense	1,267	892	3,978	4,896
Amortization of intangible assets	1,898	1,289	5,084	3,868
Amortization of warrant discount	—	269	448	807
Non-recurring financial impact of debt refinance	—	—	11,866	—
Non-GAAP net income/(loss)	\$ 3,519	\$ (3,930)	\$ 6,767	\$ (17,288)