
**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): May 6, 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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On May 6, 2019, BioDelivery Sciences International, Inc. (the “Company”) announced its financial results for the first quarter ended March 31, 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 May 6, 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 BELBUCA net revenue and total net revenue in 2019 and the implementation and success of our Symproic strategic plan) may differ significantly from those set forth 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.

May 6, 2019

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mary Theresa Coelho

Name: Mary Theresa Coelho

Title: Chief Financial Officer and Treasurer



BioDelivery Sciences Reports Strong First Quarter 2019 Results and Raises BELBUCA® Full-Year Expectations

BELBUCA® Net Sales Increased by 134% versus Prior Year to All-time High of \$18.7 million

Symproic® Acquisition and Commercial Integration Successfully Completed

Company Raises Full-Year BELBUCA Net Sales Expectations to \$83 - \$88 Million

Confirms Full-Year Net Sales Expectations of \$92 - \$100 Million Including Symproic

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

Raleigh, North Carolina – May 6, 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 first quarter ended March 31, 2019, as well as the following operational and performance highlights:

Key Business Highlights:

- BELBUCA® (buprenorphine buccal film) CIII prescription growth experienced an all-time year-over-year record increase of 141% as well as a 16% increase versus prior quarter. The 65,230 prescriptions during the quarter also represents a record level for any three-month period.
- Total company revenue increased by 75% versus prior year to an all-time high of \$19.8 million. Growth versus prior year was driven by strength of BELBUCA performance, partially offset by decline in Bunavail sales and timing of ex-US royalties.
- Achieved record quarter over quarter growth in unique prescribers during the first quarter, reaching an all-time high of nearly 6,000.
- Acquired rights to commercialize Symproic® (naldemedine) tablets 0.2 mg in the U.S. on April 4, with BDSI's sales force fully trained and actively promoting Symproic as of May 2.
- Successfully raised \$50 million of gross proceeds in an underwritten public equity offering in April.

“We had an outstanding start to the year as demonstrated by the continued strong growth momentum of BELBUCA and the recent acquisition of Symproic,” stated Herm Cukier, Chief Executive Officer of BDSI. “The ability to seamlessly acquire and integrate a new product into our portfolio while achieving record-setting sales performance is a testament to the strong operational capabilities of our organization and gives me utmost confidence in our ability to sustain growth momentum for rest of year.”



The company has increased its expectations for full-year 2019 BELBUCA net sales to \$83 - \$88 million from previous level of \$80 - \$85 million. The company also reiterated its total 2019 net sales expectations of \$92 - \$100 million, including Symproic 2019 net sales expectations of \$7 - \$9 million, and the expectation to have positive cash flow from operations by year end.

First Quarter 2019 Financial Results

Total Net Revenue. Total net revenue for the first quarter ended March 31, 2019, was \$19.8 million, an increase of 10% compared to \$18.0 million in the fourth quarter of 2018, and an increase of 75% compared to \$11.3 million in the first quarter of 2018.

BELBUCA Net Sales. BELBUCA net sales in the first quarter ended March 31, 2019, was \$18.7 million, an increase of 18% compared to \$15.9 million in the fourth quarter 2018, and an increase of 134% compared to \$8.0 million in the first quarter 2018.

Total Operating Expenses. Total operating expenses for the first quarter ended March 31, 2019, were \$17.0 million, compared to \$18.5 million in the fourth quarter of 2018, and \$16.0 million in the first quarter of 2018.

Net Loss. Net loss for the first quarter ended March 31, 2019 was \$3.8 million, or (\$0.05) per share, compared to a loss of \$7.0 million, or (\$0.10) per share in the fourth quarter of 2018 and a loss of \$10.7 million or (\$0.18) per diluted share in the first quarter of 2018.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, May 6, 2019, at 4:30 p.m. ET to present first quarter 2019 results and to provide a business update. Dial-in details are as follows:

Conference Call Dial-In & Webcast Information:

Date:	Monday, May 6, 2019
Time:	4:30 PM Eastern Time
Domestic:	877-407-0789
International:	201-689-8562
Passcode:	13690336
Webcast:	http://public.viavid.com/index.php?id=134355



ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology and other drug delivery technologies 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. For more information, please visit us at www.bdsi.com or follow us on [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI) or Twitter [@BioDeliverySI](https://twitter.com/BDSI).

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 2018 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.

© 2019 BioDelivery Sciences International, Inc. All rights reserved.

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	\$ 41,329	\$ 43,822
Accounts receivable, net.	16,008	13,627
Inventory, net	7,259	5,406
Prepaid expenses and other current assets	2,970	3,188
Total current assets	67,566	66,043
Property and equipment, net	3,952	3,072
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	34,875	36,000
Other intangible assets, net	539	703
Total assets	<u>\$ 109,647</u>	<u>\$ 108,533</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 23,484	\$ 21,539
Total current liabilities	23,484	21,539
Notes payable, net	52,286	51,652
Other long-term liabilities	6,355	5,600
Total liabilities	82,125	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 March 31, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 2,400 and 3,100 shares outstanding at March 31, 2019 and December 31, 2018, respectively.	2	2
Common Stock, \$.001 par value; 125,000,000 shares authorized at March 31, 2019 and December 31, 2018, respectively; 75,333,254 and 75,793,725 shares issued; 75,317,763 and 70,778,234 shares outstanding at March 31, 2019 and December 31, 2018, respectively.	74	71
Additional paid-in capital	382,614	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(355,121)	(351,288)
Total stockholders' equity	27,522	29,742
Total liabilities and stockholders' equity	<u>\$ 109,647</u>	<u>\$ 108,533</u>

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

	Three Months Ending March 31,	
	2019	2018
Revenues:		
Product sales	19,759	9,838
Product royalty revenues	2	440
Contract revenue	8	1,003
Total Revenues	19,769	11,281
Cost of sales	4,052	3,415
Expenses:		
Research and development:	—	2,484
Selling, general and administrative	16,989	13,505
Total expenses	16,989	15,989
Loss from operations	(1,272)	(8,123)
Interest expense, net	(2,561)	(2,505)
Other expense, net	—	(7)
Loss before income taxes	\$ (3,833)	\$ (10,635)
Income tax expense	—	(74)
Net loss attributable to common stockholders	\$ (3,833)	\$ (10,709)
Basic and diluted:		
Weighted average common stock shares outstanding	71,344,831	58,062,997
Basic and diluted loss per share	\$ (0.05)	\$ (0.18)

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

	Three Months Ending March 31,	
	2019	2018
Operating activities:		
Net loss	\$ (3,833)	\$ (10,709)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation	85	230
Accretion of debt discount and loan costs	634	625
Amortization of Intangible Assets	1,289	1,289
Provision (benefit) for inventory obsolescence	149	(66)
Stock based compensation expense	1,141	2,921
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(2,381)	864
Inventories	(2,002)	716
Prepaid expenses and other assets	218	782
Accounts payable and accrued expenses	1,814	(3,413)
Deferred revenue	—	—
Net cash flows from operating activities	<u>(2,886)</u>	<u>(6,761)</u>
Investing activities:		
BELBUCA Acquisitions	—	(1,951)
Purchase of equipment	—	(73)
Disposal of property and equipment	(79)	—
Net cash flows from investing activities	<u>(79)</u>	<u>(2,024)</u>
Financing activities:		
Proceeds from exercise of stock options	472	130
Payment of deferred financing fees	—	(450)
Net cash flows from (used in) by financing activities	<u>472</u>	<u>(320)</u>
Net change in cash and cash equivalents	(2,493)	(9,105)
Cash and cash equivalents at beginning of year	43,822	21,195
Cash and cash equivalents at end of year	<u>\$ 41,329</u>	<u>\$ 12,090</u>
Cash paid for interest	\$ 1,931	\$ 1,880