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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 14, 2019**

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**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

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**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)

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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.

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**Item 8.01. Other Information.**

On March 14, 2019, BioDelivery Sciences International, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2018 and providing an update on the Company’s business operations, recent accomplishments, financial and company highlights and anticipated milestones for year 2019. A copy of the press release is attached as Exhibit 99.1 hereto.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

Exhibit

No.

Description

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99.1 [Press release, dated March 14, 2019 announcing the Company’s financial results for the year ended December 31, 2018.](#)

**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 revenue and BELBUCA prescription, and the implementation and success of our BELBUCA 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. All other trademarks and tradenames are owned by their respective owners.

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**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.

March 14, 2019

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mary Theresa Coelho

Name: Mary Theresa Coelho

Title: Chief Financial Officer and Treasurer



**BioDelivery Sciences Reports Strong 2018 Results and 2019 Expectations**

*BELBUCA® prescription growth further accelerated to an all-time high during the fourth quarter*

*Company increases Belbuca 2019 net sales expectations to \$80-\$85 million*

*Operating cash flow to become positive in 2019*

*Long-term potential for BELBUCA net sales believed to be \$250—\$300 million*

*Conference Call and Webcast scheduled for 4:30 pm ET today*

**Raleigh, North Carolina – March 14, 2018** — BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic pain, today reported financial results for the fourth quarter and full-year ending December 31, 2018, as well as the following operational and performance highlights:

**Key Business Highlights**

- BELBUCA prescription growth exceeded expectations during the fourth quarter 2018, with an increase of 126% year-over-year and a 27% increase over the prior quarter, resulting in the largest quarterly increase and an all-time quarterly high of more than 56,000 prescriptions.
- BELBUCA fourth quarter 2018 net revenue grew by 28.3% over prior quarter to \$15.9 million and to \$46 million for the full year, an increase of 70.5% versus prior year.
- 25 million lives with preferred access to BELBUCA were added during the fourth quarter, bringing the 2018 year-end total to more than 100 million lives.
- Added more than 1,100 new prescribers in the fourth quarter achieving a total of 5,358 unique prescribers during the period – both all-time highs for BELBUCA.
- Completed expansion of the sales, medical, and market access teams during the fourth quarter to further improve access and accelerate growth for BELBUCA.
- Further strengthened the executive leadership team with the appointment of Terry Coelho as Chief Financial Officer in January 2019.

“I am very pleased by the results achieved during the fourth quarter and for the entire year,” stated Herm Cukier, Chief Executive Officer of BDSI. “We succeeded in transforming the company into a rapidly growing commercial enterprise with sustained momentum as we enter 2019. The continued acceleration of BELBUCA scripts, along with increased preferred coverage and the expanded sales and medical teams, position us well to further deliver on our growth strategy in the year ahead.”



The Company expects full-year 2019 BELBUCA net revenue to be in the range of \$80-\$85 million and total Company net revenue to be in the range of \$85-\$90 million. The long-term net sales potential for BELBUCA is now seen to be in the range of \$250—\$300 million.

#### **Fourth Quarter 2018 Financial Results**

**Total Net Revenue.** Total net revenue for the fourth quarter ended December 31, 2018, was \$18.0 million, an increase of 27.4% compared to \$14.2 million in the third quarter of 2018, and an increase of 44.1% compared to \$12.5 million in the fourth quarter of 2017.

**BELBUCA Net Revenue.** BELBUCA net revenue in the fourth quarter ended December 31, 2018, was \$15.9 million, an increase of 28.3% compared to \$12.4 million in the third quarter 2018, and an increase of 68.3% compared to \$9.4 million in the fourth quarter 2017. The total net revenue growth was driven primarily by BELBUCA which comprised 88% of total net revenue in the quarter.

**Total Operating Expenses.** Total operating expenses for the fourth quarter ended December 31, 2018, were \$18.5 million, compared to \$14.2 million in the third quarter of 2018, and \$21.6 million in the fourth quarter of 2017. Total operating expenses in the quarter reflect the expansion of our commercial and medical teams.

**Net Loss.** Net loss for the fourth quarter ended December 31, 2018, was \$7.0 million, or (\$0.10) per share, compared to a loss of \$18.9 million, or (\$0.29) per share in the third quarter of 2018.

#### **Year-End 2018 Financial Results**

**Total Net Revenue.** Total net revenue for the full-year 2018 was \$55.6 million, a decrease of 10.2% compared to \$62.0 million for the year ended December 31, 2017. Total net revenue for 2017 included \$20 million in contract revenues recorded in January 2017 resulting from the termination of the licensing agreement with Endo and the return of BELBUCA rights to BDSI. Total net 2018 revenue growth was 32.5% excluding the aforementioned \$20 million in contract revenues.

**BELBUCA Net Revenue.** BELBUCA net revenue for the year ended December 31, 2018, was \$46.0 million, an increase of 70.5% compared to \$27.0 million for the year ended December 31, 2017. The long-term potential for BELBUCA net revenue is expected to be over \$250 million.

**Total Operating Expenses.** Total operating expenses for the year ended December 31, 2018, were \$63.5 million, compared to \$71.9 million for the year ended December 31, 2017. The year-over-year reduction was primarily due to 2017 costs associated with joining the opioid consortium, along with remaining R&D expenses.

**Net Loss.** Net loss for the year ended December 31, 2018, was \$46.4 million, or (\$0.73) per diluted share, compared to net income of \$5.3 million, or \$0.09 per diluted share for the year ended December 31, 2017. The full-year 2018 net loss included a one-time non-cash charge of \$12.5 million for the beneficial conversion feature of the Series B Preferred Stock.



**Cash Position.** At December 31, 2018, BDSI had cash and cash equivalents of approximately \$43.8 million. Based on current guidance, the company anticipates turning operating cash flow positive in 2019.

#### **Conference Call & Webcast Details**

BioDelivery Sciences will host a conference call and webcast today, March 14, 2019, at 4:30 p.m. ET to present fourth quarter and full-year 2018 results and to provide a business update. Dial-in details are as follows:

#### **Conference Call Dial-In & Webcast Information:**

Date: Thursday, March 14, 2019  
Time: 4:30 PM Eastern Time  
Domestic: 877-407-0789  
International: 201-689-8562  
Passcode: 13687656

Webcast: <http://public.viaavid.com/index.php?id=133294>

#### **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 pain. 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, and opioid dependence. For more information, please visit us at [www.bdsi.com](http://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) 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 2017 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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**Contacts**

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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, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash	\$ 43,822	\$ 21,195
Accounts receivable, net.	13,627	8,852
Inventory, net	5,406	6,091
Prepaid expenses and other current assets	3,188	3,610
Total current assets	66,043	39,748
Property and equipment, net	3,072	3,778
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	36,000	40,500
Other intangible assets, net	703	1,360
Total assets	<u>\$ 108,533</u>	<u>\$ 88,101</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 21,539	\$ 26,149
Total current liabilities	21,539	26,149
Notes payable, net	51,652	47,660
Other long-term liabilities	5,600	5,415
Total liabilities	78,791	79,224
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 December 31, 2018 and December 31, 2017, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 3,100 and 0 shares outstanding at December 31, 2018 and December 31, 2017, respectively	2	2
Common Stock, \$.001 par value; 125,000,000 and 75,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 70,793,725 and 55,904,072 shares issued; 70,778,234 and 55,888,581 shares outstanding at September 30, 2018 and December 31, 2017, respectively	71	56
Additional paid-in capital	381,004	313,922
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(351,288)	(305,056)
Total stockholders' equity	29,742	8,877
Total liabilities and stockholders' equity	<u>\$ 108,533</u>	<u>\$ 88,101</u>

**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,		
	2018	2017	2016
<b>Revenues:</b>			
Product sales	\$ 51,410	\$ 34,922	\$ 8,266
Product royalty revenues	3,389	5,070	3,646
Research and development reimbursements	—	799	1,134
Contract revenue	841	21,194	2,500
Total Revenues:	<u>55,640</u>	<u>61,985</u>	<u>15,546</u>
Cost of sales	<u>15,783</u>	<u>19,496</u>	<u>11,258</u>
<b>Expenses:</b>			
Research and development:	4,903	13,040	18,878
Sales, general and administrative	58,602	58,869	49,345
Total Expenses:	<u>63,505</u>	<u>71,909</u>	<u>68,223</u>
Loss from operations	(23,648)	(29,420)	(63,935)
Interest expense	(10,192)	(8,577)	(3,267)
Other expense, net	(14)	(26)	64
Bargain purchase gain	—	27,336	—
Loss before income taxes	<u>\$ (33,854)</u>	<u>\$ (10,687)</u>	<u>\$ (67,138)</u>
Income tax benefit	(13)	15,972	—
Net (loss) income	<u>\$ (33,867)</u>	<u>\$ 5,285</u>	<u>\$ (67,138)</u>
Beneficial conversion feature of convertible preferred stock	(12,500)	—	—
Net (loss) income attributable to common stockholders	<u>\$ (46,367)</u>	<u>\$ 5,285</u>	<u>\$ (67,138)</u>
<b>Basic:</b>			
Basic (loss) income per share:	<u>\$ (0.73)</u>	<u>\$ 0.10</u>	<u>\$ (1.25)</u>
Weighted average common stock shares outstanding:	<u>63,165,063</u>	<u>55,355,802</u>	<u>53,679,134</u>
<b>Diluted:</b>			
Diluted (loss) income per share:	<u>\$ (0.73)</u>	<u>\$ 0.09</u>	<u>\$ (1.25)</u>
Weighted average common stock shares outstanding:	<u>63,165,063</u>	<u>56,402,479</u>	<u>53,679,134</u>

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

	Year Ended December 31,		
	2018	2017	2016
<b>Operating activities:</b>			
Net (loss) income	\$ (33,867)	\$ 5,285	\$ (67,138)
Depreciation	740	693	437
Accretion of debt discount and loan costs	4,138	2,392	397
Amortization of intangible assets	5,157	5,425	971
Impairment loss on equipment	(56)	243	—
Provision for inventory obsolescence	78	—	—
Stock-based compensation expense	5,941	14,801	14,931
Deferred income taxes	40	(15,972)	—
Bargain purchase gain	—	(27,336)	—
<b>Changes in assets and liabilities, net of effect of acquisition:</b>			
Accounts receivable	(4,640)	(5,884)	(862)
Inventories	741	2,448	(810)
Prepaid expenses and other assets	422	526	(203)
Accounts payable and accrued expenses	(2,807)	6,644	(1,546)
Deferred revenue	—	(21,716)	(159)
Net cash flows from operating activities	<u>(24,113)</u>	<u>(32,451)</u>	<u>(53,982)</u>
<b>Investing activities:</b>			
BELBUCA acquisition	(1,951)	(5,853)	—
Purchase of equipment	(112)	(11)	(405)
Net cash flows from investing activities	<u>(2,063)</u>	<u>(5,864)</u>	<u>(405)</u>
<b>Financing activities:</b>			
Proceeds from sales of securities, net of costs incurred	—	—	40
Proceeds from exercise of stock options	670	439	297
Issuance of common stock	—	—	2,460
Issuance of warrants	—	—	49
Proceeds from issuance of Series B preferred stock	50,000	—	—
Payment on note payable	—	(30,000)	—
Proceeds from notes payable	—	60,000	—
Equity finance costs	(1,417)	—	—
Payment of deferred financing fees	(450)	(2,948)	—
Net cash flows from financing activities	<u>48,803</u>	<u>27,491</u>	<u>2,846</u>
Net change in cash and cash equivalents	22,627	(10,824)	(51,541)
Cash and cash equivalents at beginning of year	21,195	32,019	83,560
<b>Cash and cash equivalents at end of year</b>	<b><u>\$ 43,822</u></b>	<b><u>\$ 21,195</u></b>	<b><u>\$ 32,019</u></b>
Cash paid for interest	<u>\$ 6,053</u>	<u>\$ 5,285</u>	<u>\$ 2,870</u>