
**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 8, 2018

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.

Item 8.01. Other Information.

On November 8, 2018, BioDelivery Sciences International, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 30, 2018 and providing an update on the Company’s business operations, recent accomplishments, financial and company highlights, and anticipated milestones. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

<u>No.</u>	<u>Description</u>
99.1	Press release, dated November 8, 2018, announcing the Company’s September 30, 2018 financial results.

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.

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 8, 2018

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer, Secretary and Treasurer



BioDelivery Sciences Reports Strong Third Quarter 2018 Financial Results

- *BELBUCA® continued on an accelerated growth trajectory, with revenue increasing 92% YOY and 27% versus prior quarter*
- *BELBUCA total prescriptions experienced its largest quarter over quarter increase since launch*

Conference Call And Webcast Scheduled For 4:30 PM ET Today

Raleigh, North Carolina – Nov. 08, 2018 — BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing commercial stage specialty pharmaceutical company dedicated to patients living with chronic pain, today reported record financial results for the third quarter ending September 30, 2018, as well as the following operational and performance highlights:

Third Quarter Operational Highlights Include

- Achieved strong BELBUCA® revenue performance with sales increasing to \$12.4 million, up 92% YOY and 27% versus prior quarter
- Sustained robust BELBUCA prescription growth achieving a new high of 44,180 TRxs, up 95% versus prior year and 25% versus prior quarter. The quarterly increase of 8,690 scripts versus prior quarter was the highest for the product since launch
- Secured expanded market access for Belbuca to an additional 25 million lives, bringing the total population with preferred coverage to more than 75 million covered lives
- Successfully began implementing its four point Belbuca strategic plan for sustained growth, including expanding the sales organization by more than 30% and starting to build the new medical team
- Strengthened the executive leadership team with appointment of James Vollins as Company General Counsel, Chief Compliance Officer and Corporate Secretary

“I am very pleased by the results achieved during the third quarter across the organization,” stated Herm Cukier, CEO of BDSI. “Our continued focus on commercial execution enabled us to achieve very robust growth for BELBUCA and created a sizeable foundation to further build shareholder value for the long term. We also started implementing our previously announced four point BELBUCA strategic plan during the quarter, and were thrilled to strengthen our leadership team with the hiring of our new General Counsel. These elements of growth momentum and continued progress put us in a strong position to finish the year strong and build for future success.”

With the performance achieved through the first three quarters, and a strong balance sheet supporting the execution of the BELBUCA growth plan, the company is expecting total year 2018 financial performance for BELBUCA and total Company net revenue to be in the upper end of previous guidance.



Third Quarter 2018 Financial Results

Total Net Revenue. Total net revenue for the third quarter ended September 30, 2018, was \$14.2 million, an increase of 16% compared to \$12.2 million in the second quarter of 2018, and an increase of 26% compared to \$11.3 million in the third quarter of 2017.

BELBUCA® Net Revenue. BELBUCA net revenue in the third quarter ended September 30, 2018, was \$12.4 million, an increase of 27% compared to second quarter 2018 revenue of \$9.7 million, and an increase of 92% compared to third quarter 2017 revenue of \$6.4 million.

Total Operating Expenses. Total operating expenses for the third quarter ended September 30, 2018, were \$14.2 million, compared to second quarter 2018 expenses of \$14.9 million, and third quarter 2017 expenses of \$16.9 million.

Non-GAAP Net Loss for the third quarter of 2018 was \$6.4 million or (\$0.10) per share, compared to second quarter 2018 net loss of \$9.8 million, or (\$0.16) per diluted share, and a third quarter 2017 net loss of \$12.0 million, or (\$0.21) per diluted share.

GAAP Net Loss for the third quarter ended September 30, 2018 was \$18.9 million, or (\$0.29) per basic and diluted share, including a one-time non-cash charge of \$12.5 million for the beneficial conversion feature of the Series B Preferred Stock.

Cash Position. At September 30, 2018, BDSI had cash and cash equivalents of approximately \$49.5 million.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and audio webcast today, November 8, 2018 at 4:30 p.m. ET to present third quarter 2018 results and provide a business update. Dial-in details are as follows:

Domestic: 800-479-1004
International: 323-794-2599
Passcode: 9394131
Webcast: <http://public.viavid.com/index.php?id=131852>

Replays available through November 22, 2018

Domestic: 844-512-2921
International: 412-317-6671
Conference ID: 9394131

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 breakthrough cancer pain, chronic pain and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: www.bdsi.com

Facebook: [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI)

Twitter: [@BioDeliverySI](https://twitter.com/BioDeliverySI)

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and BELBUCA® (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. For full prescribing information and important safety information on BDSI products please visit www.bdsi.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit www.BELBUCA.com and for full prescribing and safety information on BUNAVAIL, please visit www.bunavail.com.

Cautionary Note on Forward-Looking Statements

This press release, the presentation described herein, 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 revenue and Belbuca prescription, and the implementation and success of our Belbuca strategic plan) may differ significantly 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). 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>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 49,482	\$ 21,195
Accounts receivable	12,568	8,852
Inventory	5,434	6,091
Prepaid expenses and other current assets	4,155	3,610
Total current assets	71,639	39,748
Property and equipment, net	3,170	3,778
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	37,125	40,500
Other intangible assets, net	867	1,360
Total assets	<u>\$ 115,516</u>	<u>\$ 88,101</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 23,919	\$ 26,149
Total current liabilities	23,919	26,149
Notes payable, net	50,516	47,660
Other long-term liabilities	5,511	5,415
Total liabilities	79,946	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 September 30, 2018 and December 31, 2017, respectively; Series B Non-Voting Convertible Preferred Stock, \$.001 par value, 3,100 and 0 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	2	2
Common Stock, \$.001 par value; 125,000,000 and 75,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 70,598,687 and 55,904,072 shares issued; 70,583,196 and 55,888,581 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	71	56
Additional paid-in capital	379,824	313,922
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(344,280)	(305,056)
Total stockholders' equity	35,570	8,877
Total liabilities and stockholders' equity	<u>\$ 115,516</u>	<u>\$ 88,101</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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales	\$ 13,763	\$ 8,118	\$ 34,367	\$ 23,798
Product royalty revenues	370	1,409	2,197	3,682
Research and development reimbursements	—	532	—	799
Contract revenue	23	1,194	1,047	21,194
Total Revenues:	<u>14,156</u>	<u>11,253</u>	<u>37,611</u>	<u>49,473</u>
Cost of sales	<u>3,779</u>	<u>4,445</u>	<u>11,760</u>	<u>14,261</u>
Expenses:				
Research and development:	699	1,986	4,038	6,246
Sales, general and administrative	13,489	14,867	41,013	44,094
Total Expenses:	<u>14,188</u>	<u>16,853</u>	<u>45,051</u>	<u>50,340</u>
Loss from operations	(3,811)	(10,045)	(19,200)	(15,128)
Interest expense	(2,567)	(1,893)	(7,598)	(6,657)
Other expense, net	(2)	(13)	(8)	(28)
Bargain purchase gain	—	—	—	27,336
(Loss) income before income taxes	<u>\$ (6,380)</u>	<u>\$ (11,951)</u>	<u>\$ (26,806)</u>	<u>\$ 5,523</u>
Income tax benefit	—	—	(53)	15,972
Net (loss) income	<u>\$ (6,380)</u>	<u>\$ (11,951)</u>	<u>\$ (26,859)</u>	<u>\$ 21,495</u>
Beneficial conversion feature of convertible preferred stock	(12,500)	—	(12,500)	—
Net (loss) income attributable to common stockholders	<u>\$ (18,880)</u>	<u>\$ (11,951)</u>	<u>\$ (39,359)</u>	<u>\$ 21,495</u>
Basic:				
Basic (loss) income per share:	<u>\$ (0.29)</u>	<u>\$ (0.21)</u>	<u>\$ (0.65)</u>	<u>\$ 0.39</u>
Weighted average common stock shares outstanding:	<u>64,900,007</u>	<u>55,604,708</u>	<u>60,599,456</u>	<u>55,170,569</u>
Diluted:				
Diluted (loss) income per share:	<u>\$ (0.29)</u>	<u>\$ (0.21)</u>	<u>\$ (0.65)</u>	<u>\$ 0.38</u>
Weighted average common stock shares outstanding:	<u>64,900,007</u>	<u>55,604,708</u>	<u>60,599,456</u>	<u>56,204,358</u>

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities:		
Net (loss) income	\$ (26,859)	\$ 21,495
Depreciation	685	465
Accretion of debt discount and loan costs	2,953	1,941
Amortization of intangible assets	3,868	4,103
Impairment loss on equipment	78	—
Provision for inventory obsolescence	396	—
Stock-based compensation expense	4,896	10,223
Deferred income taxes	—	(15,972)
Bargain purchase gain	—	(27,336)
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(3,581)	(7,222)
Inventories	261	2,314
Prepaid expenses and other assets	(545)	1,826
Accounts payable and accrued expenses	(427)	8,998
Deferred Revenue	—	(21,716)
Net cash flows from operating activities	(18,275)	(20,881)
Investing activities:		
BELBUCA acquisition	(1,951)	(3,902)
Purchase of equipment	(155)	(5)
Net cash flows from investing activities	(2,106)	(3,907)
Financing activities:		
Proceeds from issuance of Series B preferred stock	50,000	—
Equity financing costs	(1,410)	—
Proceeds from notes payable	—	45,000
Proceeds from exercise of stock options	528	313
Payment of notes payable	—	(30,000)
Payment of deferred financing fees	(450)	(2,798)
Net cash flows from financing activities	48,668	12,515
Net change in cash and cash equivalents	28,287	(12,273)
Cash and cash equivalents at beginning of year	21,195	32,019
Cash and cash equivalents at end of year	\$ 49,482	\$ 19,746
Cash paid for interest	\$ 4,645	\$ 3,816

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Basic:				
Net (loss) income under GAAP	\$ (18,880)	\$ (11,951)	\$ (39,359)	\$ 21,495
Adjustment to beneficial conversion feature of convertible preferred stock	12,500	—	12,500	—
Net (loss) income attributable to common stockholders' Non-GAAP	(6,380)	(11,951)	(26,859)	21,495
Weighted average common stock shares outstanding:	<u>64,900,007</u>	<u>55,604,708</u>	<u>60,599,456</u>	<u>55,170,569</u>
Basic (loss) income per common share	<u>\$ (0.10)</u>	<u>\$ (0.21)</u>	<u>\$ (0.44)</u>	<u>\$ 0.39</u>
Diluted:				
Net (loss) income under GAAP	\$ (18,880)	\$ (11,951)	\$ (39,359)	\$ 21,495
Adjustment to beneficial conversion feature of convertible preferred stock	12,500	—	12,500	—
Net (loss) income attributable to common stockholders' Non-GAAP	(6,380)	(11,951)	(26,859)	21,495
Weighted average common stock shares outstanding:	<u>64,900,007</u>	<u>55,604,708</u>	<u>60,599,456</u>	<u>55,170,569</u>
Effect of dilutive options and warrants	<u>—</u>	<u>—</u>	<u>—</u>	<u>1,033,789</u>
Diluted weighted average common shares outstanding	<u>64,900,007</u>	<u>55,604,708</u>	<u>60,599,456</u>	<u>56,204,358</u>
Diluted (loss) income per common share	<u>\$ (0.10)</u>	<u>\$ (0.21)</u>	<u>\$ (0.44)</u>	<u>\$ 0.38</u>

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Diluted EPS under GAAP	\$ (0.29)	\$ (0.21)	\$ (0.65)	\$ 0.38
Diluted EPS adjustment to beneficial conversion feature of convertible preferred stock	0.19	—	0.21	—
Diluted EPS Non-GAAP	\$ (0.10)	\$ (0.21)	\$ (0.44)	\$ 0.38