

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
October 26, 2015

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): October 26, 2015

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

4131 ParkLake Avenue, Suite #225

001-31361
(Commission

File Number)

35-2089858
(IRS Employer

Identification No.)

27612

Raleigh, NC
(Address of principal executive offices) **(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))

Item 8.01. Other Information.

On October 26, 2015, BioDelivery Sciences International, Inc. (the Company) and Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (Endo), issued a press release announcing the approval by the U.S. Food and Drug Administration (FDA) of BELBUCA (buprenorphine) buccal film for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

The FDA's approval of BELBUCA triggered a milestone payment to the Company from Endo of \$50 million pursuant to the 2012 worldwide license and development agreement between the Company and Endo for the development and commercialization of BELBUCA.

A joint press release from Endo and the Company announcing the FDA's approval is attached hereto as Exhibit 99.1 and a press release from the Company announcing the achievement of the milestone is attached hereto as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of the Company and Endo, dated October 26, 2015, announcing FDA approval of BELBUCA.

99.2 Press release of the Company, dated October 26, 2015, announcing the triggering of a \$50 million milestone payment from Endo to the Company.

Cautionary Note Regarding Forward-Looking Statements

This press release and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (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, 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 results of (i) the anticipated commercial launch of BELBUCA; (ii) the potential for additional milestone payments and royalties to the Company from Endo and (iii) the timing for the use of the Company's current cash resources as described herein) 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 presentations or otherwise, except as required by applicable law.

BDSI®, BEMA® and BUNAVAIL® are registered trademarks of BioDelivery Sciences International, Inc. The BioDelivery Sciences and BUNAVAIL logos are trademarks owned by BioDelivery Sciences International, Inc. BELBUCA is owned by Endo International plc or one of its affiliates. 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.

October 26, 2015

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer, Secretary and Treasurer