

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

December 18, 2017

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): December 18, 2017

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

27612

(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))

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 December 18, 2017, BioDelivery Sciences International, Inc. (the Company) issued a press release announcing that the U.S. Patent and Trademark Office has issued a Notice of Allowance of the Company's patent application for U.S. Patent Application Serial No. 13/724,959 (the Patent) that once formally granted, will be listed in the U.S. Food and Drug Administration publication Approved Drug Products with Therapeutic Equivalence Evaluations (known as the Orange Book) and will extend the exclusivity of BELBUCA[®] (buprenorphine) buccal film from July 2027 to December 2032. The Patent covers the method of using BioErodible MucoAdhesive (BEMA) for the treatment of chronic pain. The press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated December 18, 2017, announcing the issuance of a Notice of Allowance of the patent application for the Patent.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, the press release included herein, 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, 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, any implied benefits of the patent 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 events or otherwise, except as required by applicable law.

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.

December 18, 2017

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer, Secretary and Treasurer