

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

December 02, 2013

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 2, 2013

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.)

801 Corporate Center Drive, Suite #210

Raleigh, NC
(Address of principal executive offices)

27607
(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 December 2, 2013, BioDelivery Sciences International, Inc. (the Company) announced that it engaged in a positive pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding the clinical development program for the Company's Clonidine Topical Gel product, which will allow the program to proceed to Phase 3 clinical studies in the first quarter of 2014. A copy of such press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated December 2, 2013, announcing the Company's pre-NDA meeting with the FDA regarding the Company's Clonidine Topical Gel product.

BDSI® and BEMA® are registered trademarks of BioDelivery Sciences International, Inc. The BioDelivery Sciences logo and BUNAVAIL are trademarks owned by BioDelivery Sciences International, Inc. ONSOLIS® is a registered trademark of Meda Pharmaceuticals, Inc. BREAKYL is a trademark owned by Meda Pharma GmbH & Co. KG. PAINKYL™ is a trademark owned by TTY Biopharm. All other trademarks and tradenames are owned by their respective owners.

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 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, 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 timing for and results of the clinical trials and proposed NDA submissions for, and FDA review of, the Company's products in development, as well as the outcomes of the Company's commercial plans) 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 2, 2013

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer and Secretary