

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

February 28, 2012

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): February 28, 2012

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.)

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801 Corporate Center Drive, Suite #210

Raleigh, NC

(Address of principal executive offices)

Registrant's telephone number, including area code: 919-582-9050

27607

(Zip Code)

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 February 28, 2012, BioDelivery Sciences International, Inc. (the Company) issued a press release announcing that the Company reached an agreement with the U.S. Food and Drug Administration (FDA) on the development program for the Company's Buprenorphine/Naloxone product candidate (BNX). 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 February 28, 2012, announcing an agreement with the FDA regarding the development program for BNX in a NDA for the treatment of opioid dependence.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, the press release referred to herein, and the 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, 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 future clinical trials of BEMA Buprenorphine/Naloxone and the FDA's review of such product as well as such product's ability to compete with currently approved products for the same indication) 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.

February 28, 2012

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer