

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

February 16, 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 16, 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 16, 2012, BioDelivery Sciences International, Inc. (the Company) issued a press release announcing that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance regarding the Company's patent application (No. 13/184306) and, once the patent is granted, will extend the exclusivity of the BioErodible MucoAdhesive (BEMA) drug delivery technology for its BEMA Buprenorphine and BEMA Buprenorphine/Naloxone products from 2020 to 2027. As a result, pursuant to the licensing and development agreement with Endo Pharmaceuticals, the Company is entitled to a milestone payment in the amount of \$15 million upon the final granting of this patent and an additional milestone payment of \$20 million at the time of approval of a New Drug Application (NDA) for BEMA Buprenorphine for the treatment of chronic pain. 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 16, 2012, announcing the issuance of a Notice of Allowance by the U.S. Patent and Trademark Office regarding the BioDelivery Sciences International, Inc.'s BioErodible MucoAdhesive (BEMA) drug delivery technology and related milestone payments.

Cautionary Note Regarding Forward-Looking Statements

This press release 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 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 (i) relating to the Company's commercial partnership with Endo Pharmaceuticals (including the milestone payment due upon issuance of the patent described herein), (ii) of regulatory review of BEMA Buprenorphine and the payment of related milestone payments to the Company or (iii) sales results for BEMA Buprenorphine and resulting potential royalty payments to the Company) 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 16, 2012

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer