

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

December 30, 2011

**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 30, 2011 (December 29, 2011)

**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 December 29, 2011, BioDelivery Sciences International, Inc. (the "Company") issued a press release announcing the Company's response to the announcement by the U.S. Food and Drug Administration that a class-wide Risk Evaluation Mitigation Strategy covering transmucosal fentanyl products has been approved. 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 29, 2011, announcing the Company's response to the FDA's approval of the class-wide Risk Evaluation Mitigation Strategy for transmucosal fentanyl products.

**Cautionary Note Regarding Forward-Looking Statements**

This press release 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. Such 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 impact of the TIRF on marketing efforts for, sales of and royalty revenue to BDSI relating to ONSOLIS) 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 30, 2011

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer