

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

August 28, 2008

**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) August 28, 2008

**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)

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))

**Items 7.01 and 8.01. Regulation FD Disclosure and Other Information.**

On August 28, 2008, BioDelivery Sciences International, Inc. (the Company) issued a press release regarding the Company's receipt of a complete response letter from the U.S. Food and Drug Administration regarding the Company's New Drug Application for its BEMA Fentanyl product. The press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release, dated August 28, 2008, relating to the Company's receipt of a complete response letter from the U.S. Food and Drug Administration regarding the Company's New Drug Application for its BEMA Fentanyl product

This Current Report on Form 8-K and the exhibits hereto may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions and other statements identified by words such as may, could, would, should, believes, expects, p 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. Actual results may differ 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).

**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.

August 28, 2008

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer