

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

February 09, 2009

**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 9, 2009 (February 5, 2009)**

**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))

**Item 8.01. Other Information.**

On February 5, 2009, BioDelivery Sciences International, Inc. (the Company) issued a press release regarding the initial results of a Phase 1 study assessing the tolerability, safety, and pharmacokinetics of the Company's Bioral Amphotericin B product candidate. 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 February 5, 2009, relating to the initial results of a Phase 1 study regarding Bioral Amphotericin B. This Current Report on Form 8-K and the exhibits hereto 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, could, would, should, believes, expects, anticipates, estimates, 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: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and the Company's need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA's or other regulatory review and/or approval and commercial launch of the Company's formulations and products and regulatory filings related to the same, 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).

**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 9, 2009

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer