

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
March 02, 2006

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) March 2, 2006 (March 1, 2006)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

0-28931
(Commission File Number)

35-2089858
(IRS Employer

Identification No.)

2501 Aerial Center Parkway, Suite 205

Morrisville, North Carolina
(Address of principal executive offices)

07103
(Zip Code)

Registrant's telephone number, including area code: (919) 653-5160

Not Applicable

(Former name or former address, if changed since last report)

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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))
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Item 7.01. Regulation FD Disclosure.

On March 1, 2006, BioDelivery Sciences International, Inc. (the Company) issued a press release announcing that the Company had received a non-approvable letter from the Food and Drug Administration regarding the Company's Emezin® product. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

Set forth below is a list of Exhibits included as part of this Current Report.

99.1 Press Release, dated March 1, 2006

This Current Report on Form 8-K 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, 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. 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.

March 2, 2006

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo, Pharm.D.
Title: President & CEO