

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
August 24, 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) August 24, 2006

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

0-28931
(Commission File Number)

35-2089858
(IRS Employer

of incorporation)

Identification No.)

2501 Aerial Center Parkway, Suite 205

Morrisville, North Carolina
(Address of principal executive offices)

27560
(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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Items 7.01 and 8.01. Regulation FD Disclosure and Other Events

On August 24, 2006, BioDelivery Sciences International, Inc. (BDSI) issued the following statement:

BioDelivery Sciences International, Inc. would like to respond to the assertions made by CDC IV, LLC (CDC) and Elliott Associates, L.P., a New York City-based hedge fund (Elliott), in CDC IV's Schedule 13D filing (the Schedule 13D) filed with the Securities and Exchange Commission on August 22, 2006.

We believe that the reason CDC filed its Schedule 13D is because CDC offered us a financing proposal with certain terms that, in their view, triggered a filing requirement. The basic terms they offered were as follows: in exchange for funds to be provided by CDC (to be used solely to fund our Phase III BEMA Fentanyl product and for no other purpose):

(i) CDC would receive: (A) a significantly increased royalty over their current royalty participation on potential future sales of BEMA Fentanyl, (B) a payment equal to 100% of the entire proposed new money invested upon regulatory approval of BEMA Fentanyl anywhere in the world, (C) minimum guaranteed royalties starting in the second year after regulatory approval (and for each year thereafter) equal to 90% of the amount of the proposed new money invested, and (D) additional warrants to purchase shares of our common stock, and

(ii) as a condition to funding, our management would be replaced and CDC would receive a seat on BDSI's board of directors.

We found CDC's proposal unattractive and also surprising in that, just three months ago, they elected to acquire 2 million shares of our common stock at a 40% premium to the then current market price of \$2.50 per share.

We also find the assertions about our management and directors in the letter attached to the Schedule 13D disturbing because, among other things, when CDC acquired their BDSI shares in May 2006, they publicly expressed their favorable view of both BEMATM Fentanyl and BDSI's entire business plan and model. Equally inconsistent with their present actions, just last month, CDC voluntarily consented in writing to our BEMATM Fentanyl European licensing agreement with Meda AB and our BEMATM asset purchase and option with QLT USA, Inc.

We believe that underlying CDC's motivations is their particular interest in our BEMATM Fentanyl product and CDC's contractual rights under the July 2005 Development Agreement to receive royalties on potential future sales of BEMATM Fentanyl. While the Schedule 13D assertions are crafted as the concerns of a stockholder, we believe that CDC and Elliott's actions are actually a means to pressure management into giving them, for their personal benefit, an even greater economic interest in this particular corporate asset.

While, in fact, we already spend more than a majority of our resources on BEMATM Fentanyl and have stated publicly and reaffirm our belief that it is our lead product, we also believe in the potential of other BEMATM-based products, such as our Phase I pain product BEMATM LA, as well as our Bioral[®] formulations in development. We are not prepared to abandon these opportunities as CDC would prefer. In short, all BDSI stockholders should question CDC's interests and motivations when they propose that we spend all of our resources on the one asset that they have a particular and significant economic interest in.

Taking all of the foregoing and other considerations as a whole, our Board of Directors, exercising its business judgment, found the terms of the CDC financing proposal unacceptable and rejected it.

The management team and Board of Directors of BDSI are united in rejecting CDC and Elliott's assertions and in continuing to further BDSI's stated business plans. We are also committed to working to resolve this matter.

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).

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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 24, 2006

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo

Name: Mark A. Sirgo

Title: President and Chief Executive Officer