

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
May 22, 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) May 22, 2006 (May 16, 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)

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)

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- “ 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 1.01. Entry into a Material Definitive Agreement.

On May 16, 2006, BioDelivery Sciences International, Inc. (the Company) consummated a transaction with CDC IV, LLC (CDC) pursuant to which \$7 million in funds previously committed by CDC in July 2005 to fund the clinical development of the Company's BEMA™ Fentanyl product have been converted into shares of common stock, par value \$.001, of the Company (Common Stock) at \$3.50 per share.

As a result of this transaction, CDC was issued 2 million shares of Common Stock in return for accelerating the funding of the \$4.2 million balance of \$7 million of aggregate commitment under the Company's July 2005 agreements with CDC and for eliminating the \$7 million milestone payable to CDC upon the approval by the FDA of BEMA™ Fentanyl. As of the closing of this transaction, the Company has a cash position of approximately \$7.4 million and stockholders' equity of approximately \$7.88 million.

The 2 million shares of Common Stock granted to CDC in the transaction are equivalent to a price of \$3.50 per share based on the total \$7 million funded. In addition, CDC was issued a warrant (the Warrant) to purchase an additional 904,000 shares of Common Stock at \$3.00 per share. Until such time as the shares of Common Stock underlying the Warrant are registered with the Securities and Exchange Commission, CDC shall have the right to exercise the Warrant on a cashless basis. In addition, until the date that is ninety (90) days subsequent to regulatory approval of BEMA™ Fentanyl, the exercise price of the Warrant will be reduced to a price equal to the per share price of issuances of securities by the Company at less than the Warrant exercise price.

The Company has agreed to register the shares of Common Stock issued to CDC in this transaction plus the shares of Common Stock underlying the Warrant with the Securities and Exchange Commission. The shares of Common Stock and Warrant were sold and issued to CDC pursuant to Section 4(2) of the Securities Act of 1933, as amended, in a transaction not involving any public offering.

On July 15, 2005, the Company entered into a clinical development and license agreement with CDC pursuant to which CDC was to provide up to \$7 million in funding for the clinical development of BEMA Fentanyl. Following an up front payment of \$2 million made in February 2006, the Company was receiving equal monthly payments in accordance with the expected timeline for the BEMA Fentanyl Phase III development program. Under the prior agreement, the Company was to repay the \$7 million to CDC within 60 days of approval by the Food and Drug Administration (FDA) of BEMA Fentanyl. As such, the funding was accounted for on the Company's balance sheet as a refundable deposit. Under the amended CDC transaction, the full \$7 million commitment is immediately converted into shares of Common Stock and the Company received an immediate cash infusion of \$4.2 million, the balance of the CDC committed funds. As under the original arrangement, CDC will receive royalties based on net sales of BEMA Fentanyl.

Pursuant to the CDC development agreement, and concurrently with the timing of CDC's initial \$2.0 million payment to the Company in February 2006, the Company entered into a security agreement granting CDC a security interest in assets related to BEMA Fentanyl. Such security agreement remains in place, and, as in the original agreement, the security interest granted to CDC will terminate on FDA approval of BEMA Fentanyl. However, the clinical development and license agreement and security agreement were amended in the present transaction to eliminate the obligation of the Company to reimburse CDC \$7 million prior to the release of CDC's security interest in BEMA Fentanyl.

Item 3.02. Unregistered Sales of Equity Securities.

See Item 1.01 of this Current Report.

Item 9.01. Financial Statements and Exhibits.

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

- 10.1 Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC IV, LLC.
- 10.2 Warrant, dated May 16, 2006, made by the Company in favor of CDC.
- 10.3 Amendment No. 2, dated as of May 16, 2006, to that certain Clinical Development and License Agreement, dated as of July 14, 2005, between the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC.
- 10.4 Amendment No. 1, dated as of May 16, 2006, to that certain Security Agreement, dated as of February 15, 2006, between the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC.
- 10.5 Amended and Restated Registration Rights Agreement, dated as of May 16, 2006, by and between the Company and CDC IV, LLC.

99.1 Press Release, dated May 17, 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.

May 22, 2006

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and CFO