

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
July 21, 2005

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) July 21, 2005 (July 15, 2005)

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)

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)
 - .. 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 July 15, 2005, BioDelivery Sciences International, Inc. (the Company) entered into a clinical development and license agreement with Clinical Development Capital LLC (CDC) pursuant to which CDC will provide, beginning in February 2006 and subject to certain conditions, up to \$7 million in funding (including a \$2 million upfront payment and subsequent monthly payments over a year) for the clinical development of the Company's BEMA Fentanyl product. All funds made available to the Company under the transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and, therefore, such funds will be accounted for by the Company as a refundable deposit. No assurances can be given that CDC's funding commitment will fully fund all clinical development costs for BEMA Fentanyl.

Under the agreement, which is effective as of July 14, 2005, CDC is entitled to receive:

as referenced above, a milestone fee equal to the lesser of \$7 million or the actual amount provided by CDC for development of BEMA Fentanyl;

royalties based on net sales of BEMA Fentanyl (including minimum royalties); and

a portion of any licensing revenue received by the Company prior to FDA approval of BEMA Fentanyl, which amount, if any, will be deducted from the milestone fee described above.

In addition, the Company granted CDC a warrant exercisable for up to 500,000 shares of the Company's common stock at an exercise price of \$3.50 per share.

Upon execution of the CDC agreement, all data, information, and intellectual property rights concerning BEMA Fentanyl were exclusively licensed by the Company to CDC, subject to CDC's return grant of an exclusive license for the Company to utilize all such information and rights. Further, CDC shall own all data generated in the course of the product development supported by its funds, provided that the Company shall have an exclusive license to use such data for purposes of its development and commercialization of BEMA Fentanyl.

CDC's obligation to provide funding for the clinical development of BEMA Fentanyl is conditioned upon, among certain other conditions, the Company's:

demonstration of certain technical criteria with respect to BEMA Fentanyl,

initiation of the Phase III clinical trial to be supported by CDC by a certain date, and

establishment of a contractual relationship providing for the supply of BEMA Fentanyl.

CDC shall provide development funding to the Company in the form of a \$2.0 million upfront payment, to be made upon satisfaction of the aforementioned conditions, and monthly payments, for a period of twelve months, beginning February 10, 2006. The total of the upfront payment and monthly payments shall not exceed, in the aggregate, the lesser of: (i) \$7,000,000

or (ii) the costs incurred in conducting the clinical development of BEMA Fentanyl, and such monthly amounts are subject to downward adjustment depending on the achievement by the Company of patient enrollment targets.

Royalties under the CDC agreement are subject to upward adjustments: (i) for delays in obtaining regulatory approval for BEMA Fentanyl, (ii) for the market entry of certain defined competing products in the United States prior to the first commercial sale of BEMA Fentanyl, or (iii) if the average selling price of BEMA Fentanyl is less than that of certain defined competing products. In the event that the Company does not diligently pursue the development and regulatory approval of BEMA Fentanyl or if the Company encounters certain specified negative circumstances regarding the development of BEMA Fentanyl, CDC has the right to pursue development and commercialization of BEMA Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of the Company's BEMA Fentanyl assets to CDC, provided that, under certain conditions, the Company may, despite such negative circumstances, retain the Company's rights to BEMA Fentanyl and continue pursuing its development and/or commercialization itself subject to the reimbursement of all funding provided by CDC and payment of all royalties due, pro rated based on the amount of funding provided by CDC, under the development agreement.

The warrant issued to CDC is exercisable at \$3.50 per share and contains certain antidilution provisions with respect to certain issuances of stock (or issuance of securities convertible into stock) at a price per share less than the exercise price stated in the warrant during the six months following its issuance. Also, the number of shares for which the warrant may be exercised is subject to adjustment based on the amount of funding provided by CDC, provided the warrant shall not, in any event, be exercisable for less than 100,000 shares of the Company's common stock. Finally, such warrant expires after the earlier of: (i) 5:00 p.m. Eastern Time on the second anniversary of the approval by the FDA of the first NDA relating to BEMA Fentanyl, (ii) the closing of the Company's sale of all or substantially all of its assets or the acquisition of the Company by another entity by means of merger or other transaction as a result of which stockholders of the Company immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of the Company.

Pursuant to the CDC development agreement, the Company also agreed that, concurrently with the timing of CDC's initial \$2.0 million payment to the Company, the Company shall enter into a security agreement granting CDC a security interest in assets related to BEMA Fentanyl, which interest terminates upon the payment by the Company to CDC of the milestone payment (due within sixty (60) days of FDA approval of BEMA Fentanyl) equal to the lesser of \$7 million or the actual amount provided by CDC for development of BEMA Fentanyl.

Item 9.01. Financial Statements and Exhibits.

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

- 4.1 Common Stock Purchase Warrant, dated as of July 14, 2005, by the Company in favor of Clinical Development Capital LLC.

- 10.1 Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2).

- 10.2 Form of Security Agreement to be entered into by and among the Company, Arius Pharmaceuticals, Inc and Clinical Development Capital LLC.

- 10.3 Registration Rights Agreement, dated as of July 14, 2005, by and between the Company and Clinical Development Capital LLC.

- 99.1 Press Release, dated July 18, 2005, relating to the CDC transaction.

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 (which include statements regarding CDC and the Company's transaction with CDC) 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.

July 21, 2005

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo

Name: Mark A. Sirgo

Title: President and Chief Operating Officer