

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
August 09, 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 9, 2006 (August 2, 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.

(a) On August 2, 2006, Arius Two, Inc. (Arius Two), a newly formed, a wholly-owned subsidiary of BioDelivery Sciences International, Inc. (BDSI), entered into an Intellectual Property Assignment Agreement and related agreements with QLT USA, Inc. (QLT) pursuant to which Arius Two purchased intellectual property rights owned by QLT related to its BEMA technology for territories located outside of the United States. BDSI, through its subsidiary Arius Pharmaceuticals, Inc. (Arius), previously licensed exclusive rights to the BEMA technology for such territories. Arius Two paid \$3,000,000 for the acquired intellectual property rights, consisting of \$1 million in cash and a promissory note, secured by the purchased assets, for \$2 million. Payments under such note are due as follows: (i) \$1 million due March 31, 2007 and (ii) \$1 million within 10 business days of initial non-U.S. approval of any BEMA product. In addition to the purchased BEMA intellectual property rights, QLT granted to BDSI the option, for a period of 12 months, to purchase the intellectual property rights owned by QLT related to its BEMA technology for the United States territory. If such option is exercised, the purchase price for the United States territory would be \$7,000,000, which would be paid over time.

(b) On August 2, 2006, BDSI and Arius (collectively with BDSI, the Company) and Meda AB, a Swedish corporation (Meda), entered into a License and Development Agreement (the License Agreement) pursuant to which the Company granted Meda an exclusive license to develop and sell the Company s BEMAFentanyl product (BEMA Fentanyl , as further described below) in Europe in exchange for an upfront payment of \$2,500,000, milestone payments, and a double digit royalty on sales. Milestone payments, totaling \$7,500,000, shall be received by the Company upon the achievement of certain milestones. As part of this transaction, Meda and the Company have also entered into a BEMA Fentanyl Supply Agreement pursuant to which Meda shall acquire, and the Company shall supply (directly or indirectly through third party contractors), all of Meda s requirements of BEMAFentanyl product.

In connection with the above referenced transactions, certain consents and agreements were required of CDC IV, LLC (CDC) and Laurus Master Fund, Ltd. (Laurus). The Company is a party to several existing agreements with CDC pursuant to which CDC has funded the development of the Company s BEMAFentanyl product and is also a party to two separate \$2.5 million secured convertible promissory notes and related agreements, as amended, with Laurus entered into in, respectively, February 2005 and May 2005. Each of CDC and Laurus entered into agreements with the Company as of August 2, 2006 wherein they granted the required consents to the structure and payment schedule of the non-U.S. BEMA purchase transaction between Arius Two and QLT. In addition, CDC granted the required consent to the structure and payment schedule of the License Agreement with Meda.

Item 9.01. Financial Statements and Exhibits.

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

- *10.1. Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT and Arius Two.
- *10.2. Secured Promissory Note dated August 2, 2006, by Arius Two in favor of QLT.
- 10.3. Security Agreement, dated August 2, 2006, between Arius Two and QLT.
- 10.4. Patent and Trademark Security Agreement, dated August 2, 2006, between Arius Two and QLT.
- 10.5. Guaranty, dated August 2, 2006, by BDSI in favor of QLT.
- 10.6. Assignment of Patents and Trademarks, dated August 2, 2006, by QLT in favor of Arius Two, Inc.
- 10.7. BEMA Acquisition Consent, Amendment, and Waiver, dated August 2, 2006, by and between Arius, Arius Two and CDC IV, LLC.

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- 10.8 Letter agreement, dated August 2, 2006 between BDSI, Arius, Arius Two, and CDC IV, LLC.
 - 10.9 Consent and Waiver Agreement, dated August 2, 2006, by and among Laurus Master Fund, BDSI, Arius and Arius Two.
 - *10.10 Second Amendment Agreement, dated August 2, 2006, between QLT and Arius.
 - *10.11. BEMA License Agreement, dated August 2, 2006, between Arius Two and Arius.
 - *10.12. First Amendment Agreement, dated August 2, 2006, between Arius Two and Arius.
 - *10.13. License and Development Agreement, dated August 2, 2006, by and between BDSI, Arius and Meda.
 - *10.14 BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between BDSI, Arius and Meda.
 - *10.15 Sublicensing Consent, dated August 2, 2006, between Arius and Arius Two.
 - *10.16 Sublicensing Consent and Amendment, dated August 2, 2006, by BDSI, Arius and CDC IV, LLC.
 - 10.17 Letter agreement, dated August 2, 2006, between Meda, Arius, Arius Two, and BDSI.
 - 99.1 Press Release, dated August 3, 2006, relating to agreement with QLT.
 - 99.2 Press Release, dated August 3, 2006, relating to agreement with Meda.
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* **Confidential treatment is requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.**

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.

August 9, 2006

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and CEO