Form 8-K September 12, 2007

# **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) September 12, 2007 (September 11, 2007)

# **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))

#### Item 1.01. Entry into a Material Definitive Agreement.

On September 11, 2007, BioDelivery Sciences International, Inc. (the Company), entered into a \$1 million unsecured promissory note (the Note) with Meda AB (Meda). The Note was co-signed by the Company s wholly-owned subsidiary, Arius Pharmaceuticals, Inc. (Arius).

Repayment of the \$1 million received by the Company from Meda shall be due on Meda s payment of the \$30 million upfront license payment (the \$30 Million Payment ) to the Company under the Company s License and Development Agreement with Meda dated September 5, 2007 (the License Agreement ). The Company expects to receive the \$30 Million Payment from Meda (less the \$1 million evidenced by the Note) upon the conclusion of the Hart Scott Rodino Act (HSR Act ) review period required for the transaction contemplated by the License Agreement, for which the Company and Meda have requested early termination.

Pursuant to the License Agreement, the Company and Arius have agreed to grant to Meda an exclusive commercial license to manufacture, market, sell, and, following regulatory approval, continue development of the Company s BEMA Fentanyl product in the United States, Mexico and Canada.

#### Pursuant to the Note:

- (i) no interest shall accrue unless an Event of Default (as defined below) occurs, in which case interest shall accrue at the rate provided for in Section 4.06(d) of the License Agreement, and
- (ii) the unpaid principal sum under the Note shall be due and payable as follows: (A) if the HSR Date (as defined below) occurs prior to termination of the License Agreement by either party pursuant to Section 1A.03 thereof, payment shall be made by crediting Meda with the unpaid principal amount against the \$30 Million Payment; and (B) if either party terminates the License Agreement pursuant to Section 1A.03 thereof, payment shall be due and payable by BDSI on the tenth (10<sup>th</sup>) business day following such termination. The term HSR Date means the date that the applicable waiting period, including any extensions thereof, under the HSR Act shall have expired or the applicable parties shall have received early termination thereof.

Upon the occurrence of any one or more of the following events (each, an Event of Default ), Meda at its option may declare all amounts due under the Note: (a) the failure to make any payment of principal due pursuant to the terms of the Note; or (b) the material breach by BDSI of any of its obligations under Section 1A of the License Agreement and the failure to cure such breach within ten business days after written notice from Meda; or (c) upon or after the cessation of operations of BDSI or the bankruptcy, insolvency, dissolution or winding up of BDSI.

#### Item 2.03 Creation of a Direct Financial Obligation

As more fully described in Item 1.01, which information is incorporated in this Item 2.03 by reference, the Company has entered into a \$1 million unsecured note in favor of 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 Note, dated September 11, 2007, by the Company in favor of Meda.

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.

September 12, 2007

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty Name: James A. McNulty

Title: Secretary, Treasurer and CFO