BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
January 06, 2009

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) January 6, 2009 (January 2, 2009)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-31361**	**35-2089858**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: 919-582-9050

n/a

(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))

Item 1.01 Entry into a Material Definitive Agreement.

On January 2, 2009, BioDelivery Sciences International, Inc. (the Company), and Arius Pharmaceuticals, Inc., a wholly-owned subsidiary of the Company (Arius), entered into amendments to the following previously executed material agreements between the Company, Arius and Meda AB (Meda) which relate to the commercialization of the Company s lead product candidate, ONSOLIS™ (formerly known as BEMA™ Fentanyl):

1. License and Development Agreement, dated August 2, 2006 (the EU Agreement with the amendment entered into being referred to as the EU Amendment), which relates to the commercialization of ONSOLIS in the European Union; and

2. License and Development Agreement, dated September 5, 2007 (the NA Agreement with the amendment entered into being referred to as the NA Amendment), which relates to the commercialization of ONSOLIS in the United States, Canada and Mexico.

None of the financial terms (such as sales royalties to be received by the Company) contained in either the EU Agreement or the NA Agreements as previously entered into have been amended.

European Union Amendment

Pursuant to the EU Amendment, the Company will receive US $3,000,000 in consideration of the following changes made to the EU Agreement:

Meda has been granted worldwide commercialization rights to ONSOLIS, with the exception of Taiwan and the Republic of Korea (the rights to which shall be retained by the Company). The sales royalties to be received by Company will be the same for all territories as that agreed to for Europe. As such, the definition of Territory in the EU Agreement has been amended to mean all countries of the world other than the United States, Canada, Mexico, Taiwan and the Republic of Korea and the definition of Licensed Patent Rights has been amended to include patents owned by the Company and that have been issued in Australia and that are pending in Japan.

In addition, various terms of the EU Agreement have been modified to reflect the rights and obligations of both the Company and Meda in recognition of the expansion of the scope of the EU Agreement. The Company and Meda have also modified several terms of the related BEMA Fentanyl Supply Agreement between the parties, dated September 5, 2007, to reflect the changes in the territorial scope of the expanded territory definition of the EU Agreement.

North American Amendment

Pursuant to the NA Amendment, the Company will receive US $3,000,000 as an advance against the anticipated aggregate US $30,000,000 BEMA Fentanyl approval milestone provided for in the NA Agreement. Under the original NA Agreement, the Company is to receive an aggregate milestone payment of US $30,000,000 associated with the approval and commercial launch of

ONSOLIS, as follows: US $15,000,000 upon approval by the U.S. Food and Drug Administration (FDA), and an additional US $15,000,000 upon the completion of quantities of ONSOLIS sufficient for launch stocks. Both milestones are anticipated to be paid to the Company upon FDA approval which is anticipated in the second quarter of 2009.

As a result of the foregoing, the definition of the US Approval Milestone in the NA Agreement has been amended and replaced with the following definition: US Approval Milestone means (i) US$11,900,000 if FDA approval of an NDA filed with respect to the Fentanyl Product occurs on or before June 30, 2009, (ii) US$11,800,000 if FDA approval of an NDA filed with respect to the Fentanyl Product occurs after June 30, 2009 and on or before December 1, 2009, or (iii) US$15,000,000 if FDA Approval of an NDA filed with respect to the Fentanyl Product occurs after December 1, 2009. .

Also, pursuant to the NA Amendment, certain adjustments to Meda s commercial plan in North America under the NA Agreement have been amended to reflect the continuing dialogue between the Company and Meda and their monitoring of the opioid market in preparation for the commercial launch of ONSOLIS.

CDC/Arius Two Consents

In order to facilitate the completion of the EU Amendment and the NA Amendment with Meda, certain consents and agreements were required from CDC IV, LLC (CDC) and Arius Two, Inc., a wholly owned subsidiary of the Company (Arius Two). Effective January 2, 2009, the Company obtained the consents necessary from CDC and Arius Two to enter into the EU Amendment and NA Amendment.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

*10.1	Letter Amendment, effective January 2, 2009, between the Company, Arius and Meda relating to European commercialization rights for ONSOLIS.
*10.2	Amendment to License and Development Agreement, effective January 2, 2009, between the Company, Arius and Meda relating to the North American commercialization rights for ONSOLIS.
10.3	Consent Agreement, dated January 2, 2009, between the Company, Arius and CDC.
10.4	Amendment Consent (EU), dated January 2, 2009, between Arius and Arius Two.
10.5	Amendment Consent (NA), dated January 2, 2009, between Arius and Arius Two.
99.1	Press Release, dated January 5, 2009, regarding the EU Amendment and the NA Amendment.

*** 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.**

Cautionary Note on Forward-Looking Statements

This Current Report on Form 8-K and the exhibits hereto and the statements of representatives and partners of BioDelivery Sciences International, Inc. (the Company) related thereto contain or may contain, among other things, certain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company s plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , expects , anticipates , esti 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, including those detailed in the Company s filings with the Securities and Exchange Commission. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and the Company s need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s or other regulatory review and/or approval and commercial launch of the Company s formulations and products and regulatory filings related to the same, may differ significantly 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.

January 6, 2009

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty
Name: James A. McNulty
Title: Secretary, Treasurer and Chief Financial Officer