BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
January 11, 2012

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 11, 2012 (January 5, 2012)

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

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))

Item 1.01. Entry into a Material Definitive Agreement.

On January 5, 2012, BioDelivery Sciences International, Inc. (the Company), Arius Pharmaceuticals, Inc. a wholly-owned subsidiary of the Company (Arius), and Arius Two, Inc., a wholly-owned subsidiary of the Company (Arius Two), entered into a definitive License and Development Agreement (the License Agreement) with Endo Pharmaceuticals Inc., a Delaware corporation (Endo), pursuant to which the Company, Arius and Arius Two agreed to grant to Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company s BEMA® Buprenorphine product (the Product) and to complete U.S. development of the Product for purposes of seeking FDA approval.

The License Agreement is attached to this Current Report as Exhibit 10.1. All descriptions of the License Agreement herein are qualified in their entirety to the text of Exhibit 10.1 hereto, which is incorporated herein by reference.

Pursuant to the License Agreement, the Company is responsible for the completion of all clinical trials regarding the Product necessary to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in order to obtain approval of the Product in the United States, pursuant to a development plan set forth in the License Agreement (as it may be amended pursuant to the License Agreement). The Company is responsible for all development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of the Product on a worldwide basis. In addition, Endo is responsible for all filings required to be in order to obtain regulatory approval of the Product.

Pursuant to the License Agreement, the Company will receive the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the License Agreement with respect to the Product):

- $30 million by January 19, 2012;
- up to an aggregate of $95 million in potential milestone payments based on pre-defined intellectual property, clinical development and regulatory events, including $15 million upon issuance of a certain patent covering the Product; and
- up to an aggregate of $55 million based on the achievement of certain potential sales milestones.

Such milestone payments are further subject to certain other conditions, adjustments and qualifications set forth in the License Agreement.

In addition to the milestone payments set forth above, the Company is also entitled to receive a tiered, mid- to upper-teen royalty on net sales of the Product in the United States and a mid- to high-single digit royalty on net sales of the Product outside the United States, which royalty payments are subject to certain restrictions and adjustment features.

The term of the License Agreement shall last, on a country-by-country basis, until the later of: (i) 10 years from the date of the first commercial sale of the Product in a particular country or (ii) the date on which the last valid claim of the Company s patents covering the Product in a particular country has expired or been invalidated. The License Agreement shall be subject to termination: (i) by Endo, at any time, upon a specific amount of prior written notice to the Company, (ii) by Endo and the Company upon their mutual written agreement, (iii) by either party upon a material default of breach of the License Agreement and such default or breach is not cured within a specified timeframe, (iv) the voluntary or involuntary bankruptcy of either party or (v) by the Company if Endo does not meet certain diligence obligations outside of the United States.

Item 1.02 Termination of a Material Definitive Agreement

In September 2007, the Company, through its wholly-owned subsidiary Arius Two, purchased all U.S. rights related to the BEMA drug delivery technology, including all patent rights and related intellectual property and other assets, from TOLMAR Therapeutics, Inc. (formerly known as QLT USA, Inc.) (Tolmar) for $7 million, consisting of $3 million in cash and a promissory note of $4 million, $2 million of which was paid in July 2009 following approval by the FDA of the Company s ONSOLIS® product in the United States, and $2 million of which would be due within 30 days of the end of the calendar quarter during which cumulative net sales of BEMA-based products reach $30 million. To secure the Company s obligation under the Tolmar note, the Company granted Tolmar a security interest in the U.S., Canadian, and Mexican BEMA assets, subject to a license of those assets from Tolmar that would be granted to the Company on terms substantially similar to those governing such assets under the original license between Tolmar and the Company s wholly-owned subsidiary Arius upon any exercise of rights under such security interest.

On January 5, 2012, the Company and Arius Two executed a letter agreement with Tolmar and its parent company, TOLMAR Holding, Inc., whereby the parties agreed that, if Arius Two paid Tolmar $1.05 million by February 28, 2012, Tolmar would accept such payment as satisfaction in full of the remaining $2 million outstanding under the Tolmar note and, upon receipt of such payment (i) the related security agreements, security interests, liens, guaranties and payment obligations with respect to such note and the assets securing its repayment would terminate, (ii) Tolmar would execute a corresponding release and (iii) neither the Company nor Arius Two will have any further payment obligations to Tolmar under the note or BEMA acquisition documents, except with respect to certain indemnification obligations of Arius Two. Arius Two paid the $1.05 million contemplated by the letter agreement on January 6, 2012, fully satisfying the outstanding balance of the note, and Tolmar subsequently executed its final release of the related security interests contemplated by the letter agreement.

The foregoing description of the letter agreement is not complete and is qualified in its entirety by reference to the full text of the letter agreement, a copy of which is filed herewith as Exhibit H to the License Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

In connection with the License Agreement described in Item 1.01 of this Current Report, the Company issued a press release on January 6, 2012. This press release is attached to this Current Report as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

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

*10.1 License and Development Agreement, dated January 5, 2012, by and among the Company, Arius, Arius Two and Endo.

99.1 Press Release, dated January 6, 2012.

*** 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 (including the Exhibits hereto) and any related statements of representatives and partners of the Company 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, will, could, would, should, believes, expects, anticipates, estimates, intends, plans, or similar expressions. These state 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, the results (i) stemming from the Company s commercial partnership with Endo, (ii) of regulatory review of BEMA Buprenorphine and related milestone payments to the Company or (iii) sales results for BEMA Buprenorphine and resulting royalty payments to the Company) 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). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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 11, 2012

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty
Name: James A. McNulty
Title: Secretary, Treasurer and CFO