BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K/A
May 17, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K/A

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): May 17, 2011 (May 12, 2011)

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))

EXPLANATORY NOTE

BioDelivery Sciences International, Inc. (the **Company**) is filing this Current Report on Form 8-K/A to amend the Company s Current Report on Form 8-K initially filed with the Securities and Exchange Commission on May 13, 2011 (the **Original Report**) to amend its disclosure in Item 1.01 to clarify what the Company s royalties are with respect to the CDLA (as defined below) and the Company s ONSOLIS® product. After adjusting for the amended royalty to CDC/Athyrium (as defined below) described herein, the Company continues to retain from its existing commercial partners a double-digit royalty on net sales of ONSOLIS® at all thresholds after satisfaction of its royalty obligations to CDC/Athyrium. The Original Report was not correct on this point, so the Company is voluntarily amending the Original Report to make this clarification.

Item 1.01. Entry into a Material Definitive Agreement

On May 12, 2011, the Company and its wholly owned subsidiaries, Arius Pharmaceuticals, Inc. (**Arius**) and Arius Two, Inc. (**Arius Two**), entered into an Amendment to Clinical Development and License Agreement (the **CDLA Amendment**) by and among CDC V, LLC (**CDC**), NB Athyrium LLC (**Athyrium**), the Company, Arius and Arius Two.

The CDLA Amendment amends certain terms of that certain Clinical Development and License Agreement, dated as of July 14, 2005 and as amended (the **CDLA**), under which CDC s predecessors provided funding for the clinical development of the Company s ONSOLIS® product. Athyrium is a party to the CDLA Amendment as CDC has previously, in addition to providing certain other rights to Athyrium, assigned certain of CDC s rights to receive royalties from the Company under the CDLA to Athyrium. Arius and Arius Two are parties to the CDLA as they legally hold certain intellectual property rights to ONSOLIS®.

As previously disclosed in the Company s Annual Report on Form 10-K for the fiscal year ending December 31, 2010, the Company has recently been in discussions with CDC and Athyrium relating to the interpretation of a provision of the CDLA calling for upward adjustments to the royalty owed to CDC based on the pricing of competitive products to ONSOLIS®. The CDLA Amendment was entered into in order to memorialize the agreements of the parties with respect to such interpretation, as well as certain other matters. Under the terms of the CDLA Amendment:

1. The royalty to be paid by the Company to CDC/Athyrium on net sales of ONSOLIS® (taking into account various adjustments in the original CDLA), and all other products utilizing the Company s BEMA® delivery technology that incorporate fentanyl (other than a Combo-Fentanyl Product referenced below), has been fixed (with no possibility of future upward adjustments) at (i) a low double digit royalty on net sales under a certain threshold and (ii) a mid-single digit royalty on net sales above such threshold, which in each case represents an increase of approximately 2% of net sales over the rate at which the Company had previously been paying royalties to CDC/Athyrium based on the upward royalty rate adjustments provided for in the CDLA prior to the execution of the CDLA Amendment. Even after adjusting for the amended royalty to CDC/Athyrium, the Company continues to retain from its existing commercial partners a double-digit royalty on net sales of ONSOLIS® at all thresholds after satisfaction of its royalty obligations to CDC/Athyrium.

2. The royalty to be paid by the Company to CDC/Athyrium on net sales of a combination BEMA® product that includes fentanyl together with a particular additional active ingredient (a **Combo-Fentanyl Product**) has been set at: (i) a mid-single digit royalty on net sales under a certain threshold and (ii) a low-single digit royalty on net sales above such threshold, unless such Combo-Fentanyl Product is regulatorily approved for an indication for which ONSOLIS® is approved (or a substantially similar indication), in which case royalties shall be paid at the same level as for ONSOLIS® until later of (i) the earlier of (a) loss of patent rights covering ONSOLIS® or (b) July 1, 2018 or (ii) the first day of the calendar quarter following the calendar quarter during which generic transmucosal formulations of fentanyl have more prescriptions filled than ONSOLIS® (which determination shall be made on country-by-country basis). The Company is not presently developing a Combo-Fentanyl Product.

3. The Company s reporting requirements to CDC and CDC s involvement generally in the development of any Combo-Fentanyl Product has been materially reduced and the parties have confirmed CDC s ownership of all clinical data generated by or on behalf of the Company related to any fentanyl-based BEMA® product.

4. The existing royalty term for all fentanyl-based BEMA® products has been clarified to run country-by-country and product-by product basis.

5. The Company shall immediately pay to CDC all overdue royalties, as calculated based on royalty reports issued to CDC to date (sales periods through December 31, 2010), at the agreed upon, updated royalty rates. This payment is equal to $284,585.

A copy of the CDLA Amendment is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference. The description of the material terms of the CDLA Amendment contained in this Current Report on Form 8-K is qualified in its entirety by reference to Exhibit 10.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

10.1 Amendment to Clinical Development and License Agreement, dated May 12, 2011, by and among CDC V, LLC, NB Athyrium LLC, the Company, Arius and Arius Two * +

* Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

\+ Previously filed as Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 13, 2011.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K of the Company, the exhibits hereto, and public statements of representatives of the Company related thereto, 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, many of which are beyond the Company s control. 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, estimates, 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 may differ significantly from those set forth in the forward-looking statements. 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.

May 17, 2011

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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