

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
January 28, 2015

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 28, 2015 (January 23, 2015)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-31361
(Commission

File Number)

35-2089858
(IRS Employer

Identification No.)

801 Corporate Center Drive, Suite #210

Raleigh, NC
(Address of principal executive offices)

27607
(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 23, 2015, BioDelivery Sciences International, Inc. (BDSI) entered into a definitive Assignment and Revenue Sharing Agreement (the Assignment Agreement) with Arius Pharmaceuticals, Inc., its wholly-owned subsidiary (together with BDSI, the Company) and Meda AB, a corporation organized under the laws of Sweden (Meda), relating to certain licensing rights for the Company s ONSOLIS (fentanyl buccal soluble film) product (the Product). On September 5, 2007, the Company entered into a License and Development Agreement with Meda (the Meda License) for the development and commercialization of the Product. Under the Meda License, Meda obtained marketing authorizations for the Product in the United States, and the right to seek marketing authorizations for the Product in Canada and Mexico. The Assignment Agreement provides that Meda will transfer the rights to such United States marketing authorizations and the right to seek such Canadian and Mexican marketing authorizations relating to the Product back to the Company.

The Product was approved by the U.S. Food and Drug Administration (FDA) and launched commercially in July of 2009. Under the Assignment Agreement, for a period of up to approximately one year, the Company shall have the right and shall use commercially reasonable efforts to work directly with the FDA to attempt to resolve certain previously disclosed issues relating to the Product in the United States and seek, and attempt to negotiate a definitive license agreement with, one or more new commercial partners for the Product in the subject countries (such an agreement, a Replacement License and such a partner, a Replacement Licensee).

Pursuant to the Assignment Agreement, prior to entering into any material discussions with a potential Replacement Licensee, the Company shall enter into a confidentiality agreement with such potential Replacement Licensee limiting the disclosure of certain of Meda s confidential information, provided that the Company may disclose any such confidential information to the potential Replacement Licensee to the extent that it relates to the negotiation of a Replacement License. Following the effective date of the Assignment Agreement, Meda s rights and obligations related to the development and commercialization the Product in the subject countries shall be suspended. Prior to the entry by the Company into a Replacement License, the Company and Meda shall negotiate in good faith a form of definitive termination agreement addressing in further detail the termination of the Meda License and its effects (the Termination Agreement).

Pursuant to the Assignment Agreement, any Termination Agreement is required to include provisions requiring the Company to share with Meda various percentages of revenue received by the Company under any Replacement License for the Product after, subject to certain limitations, first deducting from such revenue payments required to be made by the Company under that certain Clinical Development and License Agreement, dated July 14, 2005, as amended, between the Company, the Company s subsidiary Arius Two, Inc. and CDC V, LLC.

In the event that the Company has not identified a Replacement Licensee and entered into a Replacement License by a certain agreed upon date, Meda will have the right, but not the obligation, to demand that the marketing authorizations, and the rights to pursue marketing authorizations, for the Product in the subject countries revert back to Meda, with the full reinstatement of all of Meda s rights and obligations under the Meda License. Notwithstanding the foregoing, Meda s rights to terminate the Meda License remain unaffected by the Assignment Agreement. Subject to any such reversion of rights back to Meda or earlier termination, the Assignment Agreement shall terminate on the earlier of (i) the termination of the Meda License or (ii) 11:59 p.m. Eastern (U.S.) time on February 28, 2016 without Meda s exercising its right to cause reactivation or the Company s execution of a Replacement License with a Replacement Licensee.

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

Item 7.01 Regulation FD Disclosure

In connection with the Assignment Agreement described in Item 1.01 of this Current Report, the Company issued a press release on January 27, 2015. 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 Assignment and Revenue Sharing Agreement, dated January 23, 2015, by and between the Company and Meda.

99.1 Press release regarding the Meda Assignment Agreement, dated January 27, 2015.

*** 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 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, believes, expects, anticipates, estimates, intends, plans, or similar expressions. These statements are based upon 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 anticipated benefits of the Company's reacquisition of rights to ONSOLIS as described in this Current Report) 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 28, 2015

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer and Secretary