

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

October 31, 2014

**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): October 31, 2014 (October 27, 2014)**

**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 October 27, 2014, BioDelivery Sciences International, Inc. (the Company) entered into a definitive Development and Exclusive License Option Agreement (the Development Agreement) with Evonik Corporation, an Alabama corporation (Evonik), to develop and commercialize an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence (the Product). Under the Development Agreement, the Company also has the right to pursue development of the Product for pain management.

Under the Development Agreement, Evonik has also granted to the Company two exclusive options to acquire exclusive worldwide licenses, with rights of sublicense, to certain patents and other intellectual property rights of Evonik to develop and commercialize certain products containing buprenorphine. If such options are exercised, such licenses would be memorialized in the License Agreement (as defined below).

Pursuant to the Development Agreement, Evonik is responsible for using commercially reasonable efforts to develop a formulation for the Product in accordance with a work plan mutually agreed upon by the parties (the Project). Should the Project proceed past the Product formulation stage, Evonik also has the right to manufacture clinical and commercial supplies of Product, such manufacturing arrangement to be negotiated by the Parties in good faith in a formal License and Supply Agreement(s) (the License Agreement), with such License Agreement covering Evonik's intellectual property rights to be entered into between the parties if certain conditions are met and terms are mutually agreed upon.

Upon execution of the Development Agreement and the delivery by Evonik to the Company of certain data and results achieved by Evonik from prior work performed by Evonik relating to the Product, the Company is obligated to pay to Evonik an initial, non-refundable, non-creditable, one-time payment as well as development service fees for work to be completed, together totaling up to \$2.16 million in accordance with an estimated budget set out in the Development Agreement (the Estimated Budget) for the mutually agreed Project. Evonik shall not bill the Company for amounts greater than the Estimated Budget unless change orders are executed by both parties.

Should Evonik and Company enter into the License Agreement following the attainment of a Phase I ready formulation for one or both of the opioid dependence or pain management indications, Company would pay Evonik certain non-refundable, non-creditable one-time payments in conjunction with certain future regulatory filings and approvals and royalties on net sales of Product.

The Development Agreement contains customary termination provisions, and the Company may additionally terminate the Development Agreement at any time after the completion of certain enumerated tasks as provided in the Development Agreement, for any reason or no reason, by providing written notice of termination to Evonik. Upon termination of the Development Agreement, Evonik will be paid any amounts owed to Evonik in accordance with the Estimated Budget for work that has been performed under the Development Agreement through the effective date of termination, including any reasonable, documented, non-cancelable third party costs and any reasonable, documented wind-down costs reasonably incurred by Evonik in connection with the Project. Should Company terminate for reasons other than for a material, uncured breach by Evonik or Evonik's bankruptcy, Evonik shall have the right to use any and all data and intellectual property generated under the Project for any purpose.

The Development Agreement contains customary provisions for confidentiality and mutual non-competition. The Development Agreement also contains other customary provisions regarding the activities of the parties in relation to the Product.

The Development Agreement is attached to this Current Report as Exhibit 10.1. All descriptions of the Development 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 Development Agreement described in Item 1.01 of this Current Report, the Company issued a press release on October 28, 2014. 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 Development and Exclusive License and Option Agreement, dated October 27, 2014, by and between the Company and Evonik Corporation.

99.1 Press release regarding Evonik Development Agreement, dated October 28, 2014.

**\* 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 results of the Company's collaboration with Evonik and the timing for the development of the product 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.

October 31, 2014

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer and Secretary