BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
May 17, 2016

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): May 17, 2016 (May 11, 2016)

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.)**
4131 ParkLake Ave., Suite #225		**27612**

Raleigh, NC
(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 May 11, 2016, BioDelivery Sciences International, Inc. (the Company), the Company s wholly-owned subsidiary Arius Pharmaceuticals, Inc. (Arius), and Collegium Pharmaceutical, Inc. (Collegium) executed a definitive License and Development Agreement (the License Agreement) under which the Company and Arius have granted the exclusive rights to develop and commercialize ONSOLIS® (fentanyl buccal soluble film) in the U.S. to Collegium.

Under terms of the License Agreement, Collegium will be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS in the U.S. The Company is obligated to use commercially reasonable efforts to continue the transfer of manufacturing to its anticipated manufacturer for ONSOLIS and to submit a corresponding Prior Approval Supplement (the Supplement) to the U.S. Food and Drug Administration with respect to the current New Drug Application for ONSOLIS. Following approval of the Supplement, the New Drug Application and manufacturing responsibility for ONSOLIS (including the manufacturing relationship with the Company s manufacturer, subject to the Company entering into an appropriate agreement with such manufacturer that is acceptable and assignable to Collegium) will be transferred to Collegium.

Financial terms of the License Agreement include:

- $2.5 million upfront non-refundable payment, payable to the Company within 30 days of execution of the License Agreement;
- Reimbursement to the Company for a pre-determined amount of the remaining expenses associated with the ongoing transfer of manufacturing of ONSOLIS;
- $4 million to the Company upon first commercial sale of ONSOLIS in the U.S;
- Up to $17 million in potential payments to the Company based on achievement of performance and sales milestones; and
- Upper-teen percent royalties payable by Collegium to the Company based on various annual U.S. net sales thresholds, subject to customary adjustments and the royalty sharing arrangements described below.

The License Agreement also contains customary termination provisions that include a right by either party to terminate upon the other party s uncured material breach, insolvency, or bankruptcy as well as in the event a certain commercial milestone is not met.

ONSOLIS was originally licensed to and launched in the U.S. by Meda AB (Meda). As previously announced, in January 2015, the Company and Arius entered into an assignment and revenue sharing agreement (the ARS Agreement) with Meda under which Meda transferred the marketing authorizations for ONSOLIS for the United States back to the Company. Under the ARS Agreement, financial terms were established that enable Meda to share in the proceeds of any new North American partnership for ONSOLIS that may be executed by the Company and/or Arius, and the execution of the License Agreement between the Company, Arius, and Collegium required the execution of a definitive termination agreement between the Company, Arius, and Meda embodying those royalty-sharing terms, returning ONSOLIS-related assets and rights in the U.S., Canada, and Mexico to the Company, and including certain other provisions. In addition, the Company s royalty obligations to CDC IV, LLC (CDC) and its assignees will remain in effect. CDC provided funding for the development of ONSOLIS in the past.

Item 7.01 Regulation FD Disclosure.

On May 11, 2016, the Company issued a press release announcing the execution of the License Agreement, which press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated May 11, 2016, regarding the Company s agreement with Collegium.

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, 2016

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio
Name: Ernest R. De Paolantonio
Title: Chief Financial Officer, Treasurer and Secretary