

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
July 18, 2017

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): July 18, 2017 (July 12, 2017)

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.)

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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement

On July 12, 2017, BioDelivery Sciences International, Inc. (BDSI), its wholly-owned subsidiary Arius Pharmaceuticals, Inc. (collectively with BDSI, the Company), and Purdue Pharma, an Ontario limited partnership (Purdue), entered into a License Agreement (the License Agreement) under which the Company granted to Purdue the exclusive rights to commercialize BELBUCA® (buprenorphine hydrochloride buccal film) in Canada. BELBUCA is BDSI s approved treatment for the management of pain severe enough to require daily, continuous, long-term treatment and that is opioid-responsive and for which alternative options are inadequate.

Also on July 12, 2017, the Company and Purdue also entered into a Supply Agreement (the Supply Agreement) under which the Company agreed to supply (directly or indirectly through third party contractors) to Purdue, and Purdue agreed to acquire exclusively from the Company, all of Purdue s needs of BELBUCA in connection with Purdue s activities under the License Agreement, subject to certain exceptions.

Under the terms of the License Agreement, Purdue is responsible for the distribution, marketing and sale of BELBUCA in Canada. In connection therewith, the Company and Purdue each have agreed to use their best efforts to cause a transfer to Purdue of the current marketing authorization in Canada for BELBUCA, including the previously issued Notice of Compliance for BELBUCA in Canada and BELBUCA s Canadian drug identification numbers.

Financial terms of the License Agreement include: (i) total upfront and other cash milestone payments (relating to marketing authorization transfer and certain other marketing- and sales-related milestones) of up to an aggregate of CAD\$4.5 million, including approximately CAD\$1.5 million which is expected to be paid to the Company during 2017; (ii) a low double digit percent royalty payable quarterly by Purdue to the Company based on Canadian net sales of BELBUCA, which royalty rate is subject to adjustment in certain negotiated circumstances; (iii) an annual royalty fee commencing a period of time after the commercial launch of BELBUCA in Canada, which fee is creditable against royalties payable by Purdue and subject to reduction in certain negotiated circumstances; and (iv) reimbursement by Purdue of certain fees and expenses incurred by the Company for obtaining and transferring to Purdue the marketing authorization for BELBUCA in Canada, a portion of which will be credited against royalties payable by Purdue.

The License Agreement grants to Purdue certain rights of first negotiation and rights of first refusal for Canadian rights to certain buprenorphine-based products that the Company may seek to out license or itself develop or commercialize in the future, and the parties have agreed to certain restrictions on their ability to commercialize certain competing products in Canada. The License Agreement also contains customary confidentiality, indemnification and other provisions.

The License Agreement continues until the later of (a) the first date on which there is not a valid claim of the licensed patents covering BELBUCA in Canada as set forth in the License Agreement or (b) a negotiated date in the calendar year immediately following the first complete calendar year following the a particular anniversary of the Launch in which a predetermined amount of net sales of BELBUCA in Canada is not met. The License Agreement contains certain negotiated as well as customary early termination provisions including, among others, termination rights related to unexpected regulatory costs, a right by either party to terminate the License Agreement upon the other party s uncured material breach of the License Agreement or Supply Agreement, insolvency, or bankruptcy, and a right by the Company to terminate in the event first commercial sale in Canada does not occur within a certain period of marketing authorization transfer or license fees are not paid. Purdue may also terminate the License Agreement if Purdue determines, in its sole discretion, that BELBUCA is not economically viable for Purdue in Canada or in the event BDSI is acquired by a company commercializing certain limited types of competing products in Canada.

The description of the License Agreement and Supply Agreement above is qualified in its entirety by reference to the full agreements, which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017.

Item 8.01. Other Information.

On July 12, 2017, BDSI and Purdue issued a press release announcing the execution of the License Agreement. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated July 12, 2017, announcing the License Agreement between the Company and Purdue.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, the press release included herein, and any statements of representatives and partners of BioDelivery Sciences International, Inc. (the Company) related thereto 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, potential or 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 (including, without limitation, the operational and financial results of the Company's commercialization agreement for BELBUCA in Canada described herein and in the attached press release) 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.

July 18, 2017

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer, Treasurer and Secretary