BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
April 01, 2013

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): April 1, 2013 (March 26, 2013)

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))

Item 1.01. Entry into a Material Definitive Agreement.

Item 3.02 Unregistered Sales of Equity Securities.

On March 26, 2013, BioDelivery Sciences International, Inc. (the Company) entered into a definitive Exclusive License Agreement (the License Agreement) with Arcion Therapeutics, Inc., a Delaware corporation (Arcion), pursuant to which Arcion agreed to grant to the Company an exclusive commercial world-wide license, with rights of sublicense, under certain patent and other intellectual property rights of Arcion to develop, manufacture, market, and sell gel products containing clonidine (or a derivative thereof), alone or in combination with other active ingredients, for topical administration for the treatment of painful diabetic neuropathy and other indications (Products).

Pursuant to the License Agreement, the Company is responsible for using commercially reasonable efforts to develop and commercialize Products, including the use of such efforts to conduct certain clinical trials within certain time frames.

Upon execution of the License Agreement, the Company is obligated to issue to Arcion 500,516 unregistered shares of the Company s common stock (having a fair market value of $2 million), which shares are subject to a nine month lock-up and certain limitations on sale thereafter. The issuance of such shares was exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) thereof. In addition, the Company is required to make the following payments to Arcion:

- $2.5 million upon filing and acceptance by FDA of an NDA with respect to a Product, payable, at the Company s option, in cash or unregistered shares of the Company s common stock (with such shares also being subject to a nine month lock-up and certain limitations on sale thereafter); and

- up to a potential $60 million in cash payments upon achieving certain pre-determined sales thresholds in the U.S., none of which occur prior to achieving at least $200 million in U.S. net sales.

In addition, the Company shall pay Arcion $35 million in cash on initial FDA approval of a Product, unless:

- the Company does not receive at least $70 million in FDA approval-related milestone payments from its US sublicensees (if any) with respect to Products, in which case the Company shall pay Arcion a pro rated amount between $17.5 million and $35 million based on the total amount of such milestone payments received by the Company and its affiliates from their sublicensees (if any); or

- the FDA requires or recommends the performance of a capsaicin challenge test as a precondition or precursor to the prescribing of the Product (as a condition of approval, a labeling requirement, or otherwise), in which case such milestone shall be reduced to $17.5 million, but the first and second sales threshold payments described above shall each be increased by $8 million.

All milestone payments due Arcion under the License Agreement are payable only once each.

In addition to the milestones set forth above, the Company will pay Arcion:

- a low single digit royalty on the Company s and its affiliates net sales of Products in the U.S.;

a low double digit percentage of all sales-based payments received by the Company and its affiliates with respect to sublicensees sales of Products in the U.S.;

a low single digit on all net sales of Products outside the U.S.; and

a low double digit percentage of all milestone payments received by the Company and its affiliates from their sublicensees that are triggered by the receipt of regulatory approval of the Product in certain jurisdictions outside of the U.S.,

with the aforementioned sales royalties subject to certain reductions, on a country-by-country and Product-by-Product basis, under certain agreed upon circumstances. In addition, in the event the amount due upon FDA approval of the Product in the U.S. is less than $35 million for any reason other than an FDA requirement or recommendation of a capsaicin challenge test, as described above, the Company shall pay Arcion a portion of any milestone payments received by the Company and its affiliates from their sublicensees on the basis of any events occurring in the U.S. following FDA approval but prior to (and including) first commercial sale of a Product in the U.S., and certain of the payments to Arcion referred to above shall also be subject to upward adjustment (with such upward adjustments payable in the form of cash or unregistered shares of the Company s common stock, as elected by the Company), until such time as the sum of all such additional payments and upward adjustments (including the value of any issuances of stock, if elected by the Company) and the initial amount paid on the initial FDA approval totals $35 million.

The License Agreement contains customary termination provisions, and the Company s payment obligations to Arcion under the License Agreement expire, on a country-by-country and Product-by-Product basis, on the latest to occur of (i) the first date on which there are no licensed patents covering a Product in a country, (ii) the expiration of any form of regulatory or data exclusivity in a country, or (iii) the tenth anniversary of the first commercial sale in a country.

The Company is obligated to use commercially reasonable efforts to commence a Phase 2 clinical trial within an agreed upon period after executing the License Agreement and complete a Phase 2 clinical trial within an agreed upon additional period of such execution, in addition to having certain obligations with respect to European regulatory authorities in the event of certain positive Phase 3 clinical trial data.

The License Agreement provides the Company with a right of first negotiation with respect to all intellectual property, know-how or other assets of Arcion concerning the Product in the event Arcion in the future elects to sell, transfer, dispose of or assign any such assets. If triggered and exercised, this right would enable the Company to purchase such assets and extinguish its financial and other obligations under, the License Agreement. The License Agreement also contains other customary provisions regarding the activities of the parties in relation to the Product.

The License Agreement is attached to this Current Report as Exhibit 10.1. All descriptions of the License 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 License Agreement described in Item 1.01 of this Current Report, the Company issued a press release on March 26, 2013. 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	Exclusive License Agreement, dated March 26, 2013, by and between the Company and Arcion Therapeutics, Inc.
99.1	Press release regarding Arcion License Agreement, dated March 26, 2013.

*** 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, shou believes, expects, anticipates, estimates, intends, plans, 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 timing for and results of the clinical trials and proposed NDA submissions for, and FDA review of, the clonidine 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.

April 1, 2013

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty
Name: James A. McNulty
Title: Secretary, Treasurer and CFO