

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

September 19, 2012

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): September 19, 2012 (September 13, 2012)

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.)

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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 September 13, 2012, BioDelivery Sciences International, Inc. (the Company) and its wholly-owned subsidiary Arius Pharmaceuticals, Inc. (Arius) executed a Manufacturing, Supply, and License Agreement (the Agreement), effective April 26, 2012, with LTS LOHMANN Therapie-Systeme AG (LTS), under which LTS will manufacture and supply to the Company its BREAKYL product for distribution outside of the United States and Canada. The Company is required to supply BREAKYL product to Meda AB (Meda), KUNWHA Pharmaceutical Co., Ltd. (Kunwha), and TTY Biopharm Co., Ltd. (TTY) pursuant to the Company's obligations under certain license and supply agreements under which Meda, Kunwha, and TTY develop and commercialize the BREAKYL product. BREAKYL is the tradename for the Company's ONSOLIS product in the E.U.

In addition to the Agreement's manufacturing and supply obligations, which contain certain exclusivity provisions for the benefit of LTS, under the Agreement, LTS has granted the Company a low single-digit royalty-bearing, nonexclusive license to certain patent and other intellectual property rights related to the BREAKYL.

Furthermore, the Agreement provides for certain amendments that certain Process Development Agreement, dated December 15, 2006, between the Company and LTS (the PDA) to that effect that: (i) all past, present, and future royalty or similar payment obligations and related obligations of the Company and its affiliates under the PDA are waived and terminated and (ii) the only royalty or similar payments due to LTS with respect to the Company's, its affiliates' or licensees' manufacture, use, sales, export, or import of BREAKYL are those set forth in the Agreement.

The foregoing description of the terms of the Agreement is qualified in its entirety by reference to the terms and provisions of the Agreement filed as Exhibit 10.1 to this Current Report, which terms and provisions are incorporated by reference in this Item 1.01.

Item 9.01. Financial Statements and Exhibits.

Set forth below is a list of Exhibits included as part of this Current Report.

*10.1 Manufacturing, Supply and License Agreement, executed September 13, 2012 and effective as of April 26, 2012, by and among the Company, Arius, and LTS.

*** 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, the exhibit hereto 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, should, believes, expects, anticipates, estimates, in 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, those relating to LTS or the Company's performance under the Agreement) 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.

September 19, 2012

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and CFO