

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

December 13, 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): December 13, 2016 (December 7, 2016)

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

Raleigh, NC

**(Address of principal executive
offices)**

27612

(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 December 7, 2016, BioDelivery Sciences International, Inc. (BDSI), Arius Pharmaceuticals Inc. and Arius Pharmaceuticals Two Inc., each of which is a wholly-owned subsidiary of BDSI (which, together with the BDSI will be referred to herein as the Company) entered into an agreement (the Termination Agreement) with Endo Pharmaceuticals, Inc. (Endo) terminating Endo s licensing of rights for BELBUCA[®] (buprenorphine) buccal film. The closing of the Termination Agreement, and the formal termination of the BELBUCA license to Endo and closing of the transactions further described below to be undertaken in connection therewith (the Closing), is expected to occur on January 6, 2017.

Upon Closing, the Company will purchase from Endo the following assets (the Assets): (i) current BELBUCA product inventory and work-in-progress, (ii) material manufacturing contracts related to BELBUCA, (iii) BELBUCA-related domain names and trademarks (including the BELBUCA trademark), (iv) BELBUCA-related manufacturing equipment, and (v) all pre-approval regulatory submissions, including any Investigational New Drug Applications and New Drug Applications, regulatory approvals and post-approval regulatory submissions concerning BELBUCA. The purchase price for the Assets (the Asset Purchase Price) will be equal to the sum of (i) the aggregate book value of the portion of the transferred product inventory forecasted to be used or sold by BDSI, (ii) the aggregate book value of work-in-progress inventory, and (iii) the assumption of any assumed liabilities. Upon Closing, BDSI will accept transfer of the Assets and assume and agree to discharge when due all applicable liabilities assumed by BDSI, which consist of post-Closing obligations for liabilities and payments associated with the Assets, the assumed contracts related to the Assets and applicable taxes (with the obligation for pre-Closing and other certain liabilities resulting from the acts or omissions of Endo being retained by Endo).

The Asset Purchase Price, together with all other payments (including a non-compete covenant payment) due to Endo under the Termination Agreement, is of such an amount that will not materially impact the Company s future cash flows and will be paid to Endo in four quarterly installments on the last calendar day of each quarter in 2017. Furthermore, the Company will not be responsible for future royalties or milestone payments to Endo, and Endo will not be obligated to any future milestone payments to the Company. The Termination Agreement contains customary representations and warranties and mutual releases and indemnification.

At the Closing, the Company and Endo will enter into a Transition Services Agreement (the terms and form of which have been substantially agreed to) which governs the post-Closing rights and responsibilities of the Company and Endo in connection with the license termination and the transfer of the Assets to BDSI. Under this agreement, the Company and Endo agreed to the handling of transition matters such as managing customer contracts, BELBUCA price reporting, payments, returns and rebates, and customer and managed care relations. In connection therewith, Endo has agreed to provide to the Company an agreed upon number of work hours to be provided by Endo personnel during the transition for certain of these transition services and other assistance with respect to the transition of BELBUCA to the Company.

The descriptions of the agreements set forth above do not purport to be complete and are qualified in their entirety by reference to the complete text of such agreements, which BDSI intends to file as exhibits to the Company s Annual Report on 10-K for the year ended December 31, 2016.

Item 8.01. Other Information.

On December 8, 2016, BDSI issued a press release announcing that the execution of the Termination 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 December 8, 2016, announcing the Company's execution of the Termination Agreement.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, the press release included herein, the conference call referenced in such press release, 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 otherwise. 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 results of the Company's reacquisition of, and commercialization efforts for BELBUCA as described herein) 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.

December 13, 2016

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer, Treasurer and Secretary