

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K/A

March 24, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A

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): March 24, 2017 (December 7, 2016)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

4131 ParkLake Ave., Suite #225

001-31361
(Commission

File Number)

35-2089858
(IRS Employer

Identification No.)

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))

EXPLANATORY NOTE

This Amendment No. 1 to Form 8-K (this Form 8-K/A) amends the Current Report on Form 8-K originally filed by BioDelivery Sciences International, Inc. (the Company) with the Securities and Exchange Commission on December 13, 2016 (the Original Report). The Original Report reported (pursuant to Items 1.01, 8.01 and 9.01 of Form 8-K), that on December 7, 2016, the Company and certain of its subsidiaries had entered into a termination agreement (the Termination Agreement) with Endo Pharmaceuticals, Inc. (Endo) terminating Endo's licensing of rights to the Company's product BELBUCA® (buprenorphine) buccal film (CIII) (BELBUCA). In connection with the Termination Agreement, the Company acquired certain assets (the Assets) from Endo and paid certain consideration. Reference is made to the Original Report for additional information relating to this transaction. In addition, on January 9, 2017, the Company filed a second Current Report on Form 8-K (the Second Report) to report (pursuant to Items 8.01 and 9.01 of Form 8-K) that the Company had consummated the transactions contemplated by the Termination Agreement.

Since the filing of the Original Report and the Second Report, the Company has determined that the acquisition of the Assets should be treated as the acquisition of a business for financial accounting purposes and therefore should also have been reported in the Second Report under Item 2.01 of Form 8-K. Therefore, and the Company hereby amends the Original Report and the Second Report accordingly.

In addition, the Company, following discussions between the Company and the staff of U.S. Securities and Exchange Commission (the SEC), plans to file, via an amendment to the Second Report, certain abbreviated audited financial statement and pro forma financial information related to the Assets under Items 9.01(a) and 9.01(b) of Form 8-K as required by the rules and regulations of the SEC, such audited statements and information to be filed when available.

The remainder of the Original Report and the Second Report (including the exhibits thereto) remain unchanged.

Item 2.01. Completion of Acquisition or Disposition of Assets.

On January 9, 2017, BioDelivery Sciences International, Inc. (the Company) consummated the transactions contemplated by that certain Termination Agreement, dated December 7, 2016 (the Termination Agreement), by and between the Company, its wholly-owned subsidiaries, Arius Pharmaceuticals Inc. and Arius Two Inc., and Endo Pharmaceuticals, Inc. (Endo). The Termination Agreement terminated Endo's licensing rights for the Company's product BELBUCA® (buprenorphine) buccal film (CIII) (BELBUCA).

At the closing of the transactions contemplated by the Termination Agreement (the Closing), the Company purchased 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) was 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 the Company, (ii) the aggregate book value of work-in-progress inventory, and (iii) the assumption of any assumed liabilities. Upon Closing, the Company accepted transfer of the Assets and assumed and agreed to discharge when due all applicable liabilities assumed by the Company, which consisted 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, 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 entered into a Transition Services Agreement which will govern the post-Closing rights and responsibilities of the Company and Endo in connection with the license termination and the transfer of the Assets to the Company. 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 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 Company has determined that the acquisition of the Assets should be treated as the acquisition of a business for financial accounting purposes. Therefore, the Company plans to file, via an amendment to this Report, certain abbreviated audited financial statement and pro forma financial information related to the Assets under Items 9.01(a) and 9.01(b) of Form 8-K as required by the rules and regulations of the U.S. Securities and Exchange Commission when such audited statements and information are available.

Item 9.01. Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

To be provided by amendment to the Second Report.

(b) Pro forma financial information.

To be provided by amendment to the Second Report.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K/A 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, 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 results of the Company's reacquisition of, and commercialization efforts for BELBUCA as described therein) 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.

March 24, 2017

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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