

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

October 15, 2015

**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): October 15, 2015**

**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 Avenue, Suite #225**

**Raleigh, NC**

**27612**

**(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 8.01. Other Information.**

On October 15, 2015, BioDelivery Sciences International, Inc. (the Company) issued a press release announcing the U.S. Food and Drug Administration (FDA) has approved the Company's Supplemental New Drug Application (sNDA) for a manufacturing specification change for BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII), allowing for the immediate release of certain batches of BUNAVAIL inventory to wholesalers. A copy of such press release is attached as Exhibit 99.1 hereto.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release, dated October 15, 2015, announcing FDA approval of manufacturing specification change for BUNAVAIL.

**Cautionary Note Regarding Forward-Looking Statements**

This press release, the presentations described herein, and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the Company) related thereto (including, without limitation, at the presentations described herein) 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, p 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 duration of the BUNAVAIL supply constraints described herein or the impact of such constraints on the Company, its business and results of operations) 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 presentations 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.

October 15, 2015

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Title: Chief Financial Officer, Secretary and Treasurer