BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
February 12, 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): February 8, 2016

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.)**

4131 ParkLake Ave., 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 Events

On February 8, 2016, BioDelivery Sciences International, Inc. (the Company) received a purported notice relating to a paragraph IV certification from Actavis Laboratories UT, Inc. (Actavis) seeking to find invalid three Orange Book listed patents of the Company (the Patents) relating specifically to the Company s BUNAVAIL® buccal film for the maintenance treatment of opioid dependence. The paragraph IV certification relates to an Abbreviated New Drug Application (the ANDA) filed by Actavis with the U.S Food and Drug Administration (FDA) for a generic formulation of BUNAVAIL. The Patents subject to Acatvis certification (which relate to the Company s BEMA® film delivery technology) are U.S. Patent Nos. 7,579,019 (the 019 Patent), 8,147,866 and 8,703,177.

The Company believes that Actavis claims of invalidity of the Patents are wholly without merit and, as it has done in the past, the Company intends to vigorously defend its intellectual property. The Company is highly confident that the Patents are valid, as evidenced in part by the fact that the 019 Patent has already been the subject of an unrelated *inter partes* review (IPR) before the U.S. Patent and Trademark Office (the USPTO) under which the Company prevailed and all claims of the 019 Patent survived. Although there is a pending request for rehearing of the final IPR decision regarding the 019 Patent pending at the USPTO, the Company believes the USPTO s decision will be upheld.

The Company believes that the taking of this type of action by generic drug manufacturers such as Actavis has become common business practice in the pharmaceutical industry. Actavis has already filed paragraph IV certifications against patents relating to products competitive to BUNAVAIL over the past several years, most notably Suboxone by Indivior and Zubsolv by Orexo.

Under the Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the Hatch-Waxman Amendments), after receipt of a valid paragraph IV notice, the Company may, and in this case plans to, bring a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the certification notice. If such a suit is commenced within this 45 day period, the Company is entitled to receive a 30 month stay on FDA s ability to give final approval to any proposed products that reference BUNAVAIL. In the present case, the 30 month stay is expected to preempt any final approval by FDA on Actavis ANDA until at least August of 2018. In addition, given the FDA approval of BUNAVAIL, the Company is entitled to three years of market exclusivity for BUNAVAIL ending in June 2017. Given this timeframe, Actavis action is not unexpected.

In addition, the Company notes that it has additional pending intellectual property which, if issued, would be capable of extending the patent life of all three of the Company s BEMA-related products, including BUNAVAIL, and potentially be listed in the Orange Book.

The information contained herein is intended to be considered in the context of more complete information included in the Company s filings with the U.S. Securities and Exchange Commission (SEC) and other public announcements that the Company has made and may make from time to time by press release, conference call or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, conference calls or through other public disclosures. For more information on the risks associated with the Company s efforts to secure and maintain intellectual property protection, please see the Risk Factors section of the Company s Annual Report on Form 10-K filed for the fiscal year ending December 31, 2014 and in the Company s other SEC reports.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K and any statements of representatives and partners of 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 similar expressio 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 Actavis paragraph IV certification and the Company s defense of its intellectual property as described in this 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.

February 12, 2016

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer