BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
September 14, 2018

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 14, 2018 (September 7, 2018)

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		**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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Information.

On September 7, 2018, BDSI filed a complaint for patent infringement in Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group, Incorporated (collectively, Alvogen), asserting that Alvogen infringes BDSI s Orange Book listed patents for Belbuca®, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539 expiring December of 2032. This complaint follows a receipt by BDSI on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen has filed with the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Belbuca® (buprenorphine) Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because BDSI initiated a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Alvogen s notice letter also does not provide any information on the timing or approval status of its ANDA.

In its Paragraph IV Certification, Alvogen does not contest infringement of at least several independent claims of each of the 866, 843, and 539 patents. Rather, Alvogen advances only invalidly arguments for these independent claims. BDSI believes that it will be able to prevail on its claims of infringement of these patents, particularly as Alvogen does not contest infringement to certain claims of each patent. Additionally, as it has done in the past, BDSI intends to vigorously defend its intellectual property against assertions of invalidity. Each of the three patents carry a presumption of validity, which can only be overcome by clear and convincing evidence. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (Teva) had previously sought to litigate the validity of the 866 patent and ultimately settled, acknowledging the validity of this patent. Under the settlement agreement, Teva cannot make generic versions of Belbuca® until January 23, 2027, or earlier under certain circumstances. BDSI also continues to prosecute additional patent applications that would cover Belbuca®.

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 14, 2018

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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