

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

March 04, 2019

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): March 1, 2019

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))

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 March 1, 2019, BDSI filed a complaint for patent infringement in Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, Defendants), asserting that the Defendants infringe 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 January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it has filed with the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA), containing a Paragraph IV Patent Certification, for a generic version of Belbuca® (buprenorphine) Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg. Because BDSI initiated a patent infringement suit to defend the patents identified in the Notice Letter within 45 days after receipt, 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. Chemo Research S.L.'s Notice Letter also does not provide any information on the timing or approval status of its ANDA.

BDSI believes that it will be able to prevail in this lawsuit. 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, one of the patents in suit, and ultimately settled, acknowledging the validity of this patent.

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 4, 2019

**BIODELIVERY SCIENCES INTERNATIONAL,
INC.**

By: /s/ Herm Cukier

Name: Herm Cukier

Title: Chief Executive Officer