

**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): July 7, 2021

**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**  
**Raleigh, NC.**  
(Address of principal executive offices)

**001-31361**  
(Commission  
File Number)

**35-2089858**  
(IRS Employer  
Identification No.)

**27612**  
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001	BDSI	The Nasdaq Global Select Market

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 7.01 Regulation FD Disclosure.**

On September 7, 2018, BioDelivery Sciences International, Inc. (the “Company”) 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 the Company’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 in December of 2032. This complaint follows receipt by the Company on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) for a generic version of BELBUCA® Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg).

A three day bench trial against Alvogen was conducted commencing on March 1, 2021. At the conclusion of trial, the U.S. District Court for the District of Delaware (the “Court”) ordered the parties to submit post-trial briefs. Post-trial briefing was completed on May 26, 2021. The Company subsequently moved the Court to strike (i.e., remove from the Court’s consideration) three patent invalidity defenses raised for the first time in Alvogen’s post-trial briefs and two documents improperly cited in Alvogen’s post-trial briefs. On June 28, 2021, the Court granted the Company’s motion to strike in its entirety. In addition, on June 28, 2021, the Court enjoined Alvogen from launching its generic product until the Court issues its final decision on the merits. The Company remains confident in the validity of its Orange Book patents listed for BELBUCA.

*The information set forth under Item 7.01 is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.*

**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.

July 7, 2021

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: \_\_\_\_\_ /s/ Mary Theresa Coelho  
Name: Mary Theresa Coelho  
Title: Executive Vice President, Chief Financial Officer and Treasurer