

**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: December 20, 2021

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 Ave., Suite 225 Raleigh, NC. (Address of principal executive offices)		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 December 20, 2021, BioDelivery Sciences International, Inc. (the “Company”) issued a press release to announce that the United States District Court for the District of Delaware (the “Court”) issued an opinion in favor of the Company in the Company’s previously disclosed patent litigation against Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Inc. and Alvogen Group, Inc. (together, “Alvogen”). A copy of the press release is furnished as Exhibit 99.1 to this report on Form 8-K.

The information set forth under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or 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.

Item 8.02 Other Events.

On December 20, 2021, the Court issued an opinion in favor of the Company in the Company’s previously disclosed patent litigation against Alvogen. The Court’s opinion upheld the validity of claims in the Company’s patent 8,147, 866 (the “’866 Patent”), which expires in 2027, and patent 9,901,539, which expires in 2032. Alvogen conceded infringement of these claims. Accordingly, BDSI expects to maintain market exclusivity of BELBUCA against Alvogen until 2032. The Company had previously settled a lawsuit over the ‘866 Patent with Teva Pharmaceuticals USA (“Teva”) that granted Teva the right to begin selling its generic product on January 23, 2027, or earlier under certain circumstances. The Court’s opinion also stated that some claims of the ‘866 Patent and patent 9,655,843, a third Company patent which expires in 2027, are invalid.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on December 20, 2021, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document contained in Exhibit 104)

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.

December 21, 2021

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: _____ /s/ James Vollins
Name: James Vollins
Title: General Counsel



BioDelivery Sciences Prevails in BELBUCA® ANDA Litigation Maintaining Patent Exclusivity Against Alvogen Until 2032

RALEIGH, N.C., December 20, 2021 - BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, today announced that the U.S. District Court of Delaware has issued an opinion in favor of BDSI in the company's patent litigation against Alvogen Group, Inc. and its affiliates, who filed an Abbreviated New Drug Application (ANDA) for BDSI's BELBUCA® product on May 23, 2018. The opinion by the trial judge upholds the validity of claims in BDSI's patents 8,147,866 (the '866 patent), which expires in 2027, and 9,901,539 (the '539 patent), which expires in 2032. Alvogen conceded infringement of these claims. Accordingly, BDSI expects market exclusivity of BELBUCA against Alvogen until 2032.

"We are pleased with the Court's decision and look forward to continuously supplying BELBUCA to chronic pain patients," stated Jeff Bailey, CEO of BDSI. "We would like to thank our shareholders for their support during the lengthy litigation period. With the removal of this legal overhang, we will continue to focus on business development and creating additional shareholder value."

Dechert LLP was the lead counsel representing BDSI.

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions. BDSI has built a portfolio of differentiated pain and neurology products and leverages its experienced sales and marketing organization to educate prescribers on their unique features. BDSI's products address serious and debilitating conditions, including chronic pain, acute migraine and opioid-induced constipation.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This press release and any statements of employees, representatives, and partners of BioDelivery Sciences International, Inc. ("BDSI") 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 BDSI'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 expressions. These statements are based upon the current beliefs and expectations of BDSI's management and are subject to significant risks and uncertainties, including those detailed in BDSI's filings with the Securities and Exchange Commission. Actual results including, without limitation, the expectations for: continued patent exclusivity through 2027 and 2032 as well as our continued focus on business development, may differ materially from those set forth or implied 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 BDSI's control) including the risk that the current COVID-19 pandemic impacts on our supply chain, commercial partners, patients and their physicians and the healthcare facilities in which they work, and our personnel are greater than we anticipate, as well as those set forth in our 2020 annual report on Form 10-K filed with the US Securities and Exchange Commission



and subsequent filings. BDSI 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.

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