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 9, 2021

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))

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 8.01 Other Events

On September 9, 2021, BioDelivery Sciences International, Inc. (the "**Company**"), completed the acquisition of certain patents, trademarks, regulatory approvals and other rights related to ELYXYB™ (*celecoxib oral solution*) (the "**Product**") and its commercialization in the United States and Canada (the "**Territory**") from Dr. Reddy's Laboratories Limited, a company incorporated under the laws of India ("**DRL**").

This transaction was completed in accordance with the terms of an asset purchase agreement entered into by the Company and DRL on August 3, 2021 (the "**Asset Purchase Agreement**").

Pursuant to the Asset Purchase Agreement, the Company paid DRL a $6 million up-front payment at the closing. In addition, the Company will pay DRL $9 million on August 3, 2022, and up to an additional $9 million upon achievement of certain regulatory milestones and quarterly earn-out payments on potential sales of the Product in the Territory that range from high single digits to the low double digits (subject to reduction in certain circumstances) of net sales based on volume of sales. DRL will also be entitled to one-time payments upon the achievement of six escalating sales milestones, which range from $4 million to be paid upon the achievement of $50 million in net sales in a calendar year to $100 million to be paid upon the achievement of $1 billion in net sales in a calendar year, up to a total of $262 million.

The description of the Asset Purchase Agreement and the transactions contemplated thereby contained herein does not purport to be complete and is qualified in its entirety by reference to the complete text of the Asset Purchase Agreement, a copy of which was filed with the Securities and Exchange Commission as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 4, 2021 (File No. 001-31361) and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated September 9, 2021
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.

September 9, 2021

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mary Theresa Coelho

Name: Mary Theresa Coelho

Title: Executive Vice President, Chief Financial Officer and Treasurer

BioDelivery Sciences International Completes Acquisition of ELYXYB™ for Acute Migraine Treatment in the U.S. and Canada

Expands Portfolio and Establishes Growth Platform in Neurology

The First and Only FDA-Approved, Ready-to-Use Oral Solution for the Acute Treatment of Migraine with or without Aura in Adults

Commercial Launch Planned for Q1 2022

Investor Day on October 14, 2021

RALEIGH, N.C., September 9, 2021 -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with chronic conditions, announced today that it has completed the acquisition of U.S. and Canadian rights to ELYXYB™ (celecoxib oral solution) from Dr. Reddy's Laboratories Limited.

ELYXYB is the first and only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults. BDSI intends to launch ELYXYB in the first quarter of 2022. Additionally, BDSI plans to conduct an ELYXYB pediatric study, which will have the potential to address the significant unmet needs of pediatric and adolescent patients suffering from migraine attacks.

Migraine is a debilitating condition for almost 40 million people in the U.S. Many acute migraine sufferers are searching for treatments that provide relief quickly and conveniently.

"The availability of ELYXYB represents a significant therapeutic development for the acute treatment of migraine," stated Richard Lipton, MD, Edwin S. Lowe Chair in Neurology at Albert Einstein College of Medicine, Director of the Montefiore Headache Center, and one of the clinical investigators for the ELYXYB studies. "With rapid onset of action delivered in a unique, ready-to-use oral solution, ELYXYB provides a convenient, quick relief treatment option to help patients return to functioning in their everyday lives."

ELYXYB is an oral solution of celecoxib, formulated using a self-micro emulsifying drug delivery system that improves solubility and bioavailability of the drug leading to better absorption[1]. This allows for the administration of a lower dose of drug to achieve therapeutic effect relative to a conventional oral solid dosage form. For adult patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. ELYXYB's unit-dose oral solution makes it convenient for patients to take it immediately upon emergence of acute migraine attacks.

"ELYXYB's pivotal studies showed that the percentage of patients achieving Most Bothersome Symptom (MBS) freedom at two hours post-dose was significantly greater for those patients receiving ELYXYB versus those receiving placebo. Study 2 demonstrated that the percentage of patients reaching headache pain freedom two hours post-dose was significantly greater for those receiving ELYXYB versus those receiving placebo. The data also showed meaningful speed of onset with T_{max} achieved in approximately 60 minutes," said Thomas Smith, MD, Chief Medical Officer at BDSI, and a former thought leader in the migraine space. "BDSI looks forward to expanding our impact in Migraine and to deepening our commitment to our patients-first philosophy."

"The acquisition of ELYXYB represents a critical step to building our presence in Neurology which is an excellent strategic adjacency to our pain franchise," said Jeff Bailey, CEO of BDSI.

"We are confident that ELYXYB will contribute to BDSI's revenue growth and profitability over time, with patent protection until 2036. Our extensive commercial expertise, robust corporate infrastructure, and

strong financial position will allow us to successfully commercialize ELYXYB and continue to pursue additional value-enhancing business development opportunities," Bailey indicated.

BDSI will host an Investor Day on October 14, 2021, to discuss ELYXYB in further detail.

Please see Important Safety Information about ELYXYB below.

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 products that includes utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs. BDSI's marketed products address serious and debilitating conditions, including chronic pain 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 contribution of ELYXYB to the Company's revenue growth and shareholder value, the timing of commercial launch of ELYXYB, the Company's expansion into neurology, the growth of the migraine market and the significant unmet need in pediatric migraine patients 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 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.

ELYXYB INDICATION AND USAGE

ELYXYB is indicated in adults for the acute treatment of migraine with or without aura.

Limitations of Use: ELYXYB is not indicated for the preventive treatment of migraine.

ELYXYB IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use *[see Warnings and Precautions (5.1)]*.
ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications (4) and Warnings and Precautions (5.1)]*.

Gastrointestinal Bleeding, Ulceration, and Perforation

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events *[see Warnings and Precautions (5.2)]*.

ELYXYB is contraindicated in patients with:

- Known hypersensitivity to celecoxib, any components of the drug product, or sulfonamides (4)
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
- In the setting of CABG surgery (4)

To minimize the potential risk for an adverse cardiovascular (CV) event in NSAID-treated patients, use ELYXYB for the fewest number of days per month as needed, based on individual treatment goals. Physicians and patients should remain alert for the development of such events, throughout the entire treatment course, even in the absence of previous CV symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

Avoid the use of ELYXYB in patients with a recent myocardial infarction (MI) unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

NSAIDs, including ELYXYB, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with celecoxib. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occurred in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for one year. However, even short-term NSAID therapy is not without risk.

Avoid the use of ELYXYB in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ELYXYB is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Elevations of ALT or AST (less than three times ULN) may occur in up to 15% of patients treated with NSAIDs, including ELYXYB.

Long-term administration of NSAIDs, including celecoxib, the active ingredient in ELYXYB, has resulted in renal papillary necrosis and other renal injury.

No information is available from controlled clinical studies regarding the use of celecoxib in patients with severe renal impairment. The renal effects of celecoxib may hasten the progression of renal dysfunction in patients with preexisting renal disease.

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, nonsteroidal anti-inflammatory drugs or combination of these drugs for 10 or more days per month), including ELYXYB, may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

NSAIDs, including ELYXYB, may increase the risk of bleeding events. Co-morbid conditions such as coagulation disorders or concomitant use of warfarin, other anticoagulants, antiplatelet drugs (e.g., aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors (SNRIs) may increase this risk.

Most common adverse reaction (at least 3% and greater than placebo) is dysgeusia.

These are not all the side effects associated with ELYXYB.

Please see Patient Information, Instructions For Use, Medication Guide and Full Prescribing Information for ELYXYB

(https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212157s000lbl.pdf)

1 Arindam Pal, Srinivas Shenoy, Anirudh Gautam, Sagar Munjal, Jing Neu, Mathangi Gopalakrishnan & Joga Gobburru, Clinical Drug Investigation volume 37, pages 937–946(2017)

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