UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 11, 2020

Lexicon Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-30111**	**76-0474169**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification Number)**

8800 Technology Forest Place
The Woodlands, Texas 77381
(Address of principal executive offices and Zip Code)

(281) 863-3000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of 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	**LXRX**	**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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 December 11, 2020, we issued a press release announcing that we received Fast Track designation from the U.S. Food and Drug Administration for the development of LX9211 in diabetic peripheral neuropathic pain. The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and incorporated herein by this reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated December 11, 2020.
EX-104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Lexicon Pharmaceuticals, Inc.

Date: December 11, 2020

By: /s/ BRIAN T. CRUM
Brian T. Crum
Vice President and General Counsel

NEWS RELEASE

FOR IMMEDIATE RELEASE

LEXICON PHARMACEUTICALS RECEIVES FAST TRACK DESIGNATION FROM THE FDA FOR LX9211 FOR DIABETIC PERIPHERAL NEUROPATHIC PAIN

The Woodlands, Texas, December 11, 2020 – Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), announced today that it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the development of LX9211 in diabetic peripheral neuropathic pain.

"The FDA's Fast Track designation of LX9211 reflects the serious unmet medical need of people suffering from diabetic peripheral neuropathic pain," said Praveen Tyle, Ph.D., executive vice president of research and development. "We look forward to working closely with the FDA throughout the clinical development process to bring this potential new innovative treatment to patients as quickly as possible."

Lexicon is currently enrolling patients with diabetic peripheral neuropathic pain in a Phase 2 proof-of-concept study of LX9211 and is preparing to initiate a second Phase 2 clinical trial of LX9211 in post-herpetic neuralgia.

The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drugs that are being developed to treat serious conditions and fill unmet medical needs. The purpose of the designation is to expedite the timeline for bringing important new drugs to patients. Programs receiving Fast Track designation may benefit from early and frequent interactions with the FDA over the course of drug development. In addition, the Fast Track designation program provides eligibility for accelerated approval and priority review if relevant criteria are met and enables sponsors to submit individual sections of a New Drug Application (NDA) for review on a rolling-submission basis.

About LX9211

LX9211 is a potent, orally delivered, selective small molecule inhibitor of adapter-associated kinase 1 (AAK1). Lexicon identified AAK1 in its target discovery efforts as a promising approach for the treatment of neuropathic pain, and identified LX9211 and another development candidate in a neuroscience drug discovery alliance with Bristol-Myers Squibb from which Lexicon holds exclusive development and commercialization rights. Preclinical studies of LX9211 demonstrated central nervous system penetration and reduction in pain behavior in models of neuropathic pain without affecting opiate pathways.

About Lexicon Pharmaceuticals

Lexicon is a biopharmaceutical company with a mission of pioneering medicines that transform patients' lives. Through its Genome5000™ program, Lexicon scientists studied the role and function of nearly 5,000 genes and identified more than 100 protein targets with significant therapeutic potential in a range of diseases. Through the precise targeting of these proteins, Lexicon is pioneering the discovery and

development of innovative medicines to safely and effectively treat disease. Lexicon advanced one of these medicines to market and has a pipeline of promising drug candidates in discovery and clinical and preclinical development in neuropathic pain, heart failure, diabetes and metabolism and other indications. For additional information, please visit www.lexpharma.com.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements relating to Lexicon's financial position, long-term outlook on its business and the clinical development and therapeutic and commercial potential of its drug candidates. In addition, this press release also contains forward looking statements relating to Lexicon's growth and future operating results, discovery and development of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. All forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including Lexicon's ability to meet its capital requirements, successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of LX9211, sotagliflozin and its other potential drug candidates on its anticipated timelines, achieve its operational objectives, obtain patent protection for its discoveries and establish strategic alliances, as well as additional factors relating to manufacturing, intellectual property rights, and the therapeutic or commercial value of its drug candidates. Any of these risks, uncertainties and other factors may cause Lexicon's actual results to be materially different from any future results expressed or implied by such forward-looking statements. Information identifying such important factors is contained under "Risk Factors" in Lexicon's annual report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission. Lexicon undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

For Inquiries:

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