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): January 14, 2021

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)**	**(I.R.S. 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)

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

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))

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 January 14, 2021, we issued a press release providing a regulatory update on sotagliflozin in heart failure. 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 No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated January 14, 2021
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: January 14, 2021

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

Exhibit 99.1

LEXICON PHARMACEUTICALS PROVIDES REGULATORY UPDATE ON SOTAGLIFLOZIN IN HEART FAILURE

The Woodlands, Texas, January 14, 2021 – Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) announced today that it has received U.S. Food and Drug Administration (FDA) regulatory feedback that the results of its SOLOIST and SCORED Phase 3 clinical studies can support a new drug application (NDA) submission for an indication to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent visits for heart failure in adult patients with type 2 diabetes with either worsening heart failure or additional risk factors for heart failure.

The feedback was provided in response to a request made by Lexicon following the completion of the SOLOIST and SCORED studies relating to the potential submission of an NDA based on the results of such studies, taking into account their early close-out and other considerations. This regulatory feedback clears a key hurdle for partnership discussions around sotagliflozin in heart failure and enables a potential NDA filing in 2021.

Lonnel Coats, Lexicon's president and chief executive officer, will present at the 39th Annual J.P. Morgan Healthcare Conference today at 2:50 p.m. ET. A webcast of the event will be available in the "Events" section of the Lexicon website at www.lexpharma.com.

About the SOLOIST and SCORED Studies

SOLOIST was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 1,222 patients with type 2 diabetes who had recently been hospitalized for worsening heart failure. The primary endpoint was the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in patients treated with sotagliflozin compared with placebo.

SCORED was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 10,584 patients with type 2 diabetes, chronic kidney disease with eGFR of 25 to 60 ml per minute per 1.73 m^2 of body-surface area, and risks for cardiovascular disease. The primary endpoint was the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in patients treated with sotagliflozin compared with placebo.

Both SOLOIST and SCORED achieved their respective primary endpoints. Results from both studies were presented at the Late-Breaking Science Session of the American Heart Association (AHA) Scientific Sessions 2020 and simultaneously published in *The New England Journal of Medicine (NEJM)* in two separate articles titled: "Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure" and "Sotagliflozin in Patients with Diabetes and Chronic Kidney Disease."

About Sotagliflozin

Discovered using Lexicon's unique approach to gene science, sotagliflozin is an oral dual inhibitor of two proteins responsible for glucose regulation known as sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2). SGLT1 is responsible for glucose absorption in the gastrointestinal tract, and SGLT2 is responsible for glucose reabsorption by the kidney. Sotagliflozin is approved in the European Union (EU) for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes with a body mass index ≥ 27 kg/m^2, who could not achieve adequate glycemic control despite optimal insulin therapy, but has not yet been commercially launched.

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 clinical development of and regulatory filings for sotagliflozin, partnership discussions relating to sotagliflozin and the potential therapeutic and commercial potential of sotagliflozin, as well as Lexicon's financial position and long-term outlook on its business, including the clinical development of, regulatory filings for, and potential therapeutic and commercial potential of its other 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.

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