

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): August 2, 2022

**Lexicon Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**000-30111**  
(Commission File Number)

**76-0474169**  
(I.R.S. Employer  
Identification Number)

**2445 Technology Forest Blvd., 11th Floor**  
**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:
<b>Title of each class</b>				<b>Trading Symbol(s)</b>				<b>Name of each exchange on which registered</b>
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 2.02 Results of Operation and Financial Condition

On August 2, 2022, we issued a press release to report our financial results for the quarter ended June 30, 2022. A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1.

The information in this Form 8-K and the Exhibit attached to this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

## Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	— <a href="#">Press Release of Lexicon Pharmaceuticals, Inc. dated August 2, 2022</a>
EX-104	— Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**LEXICON PHARMACEUTICALS REPORTS SECOND QUARTER 2022  
FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE**

***Sotagliflozin New Drug Application for Heart Failure Accepted for Review by FDA,  
with PDUFA Action Date Anticipated in May 2023***

***LX9211 Phase 2 Clinical Proof-of-Concept Achieved in Painful Diabetic Neuropathy,  
Promising Novel Mechanism of Action in Neuropathic Pain***

***Conference Call and Webcast at 5:00 pm Eastern Time***

**The Woodlands, Texas, August 2, 2022** - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXX), today reported financial results for the three months ended June 30, 2022 and provided an update on key milestones.

“We received acceptance last week of our New Drug Application (NDA) for sotagliflozin for the treatment of heart failure with a standard review assigned by the FDA and a PDUFA action date anticipated in May 2023,” said Lonnel Coats, Lexicon’s chief executive officer. “As we mentioned in the announcement of the acceptance, we are seeking a broad heart failure label in the NDA, informed by our regulatory discussions, that encompasses heart failure patients with and without diabetes. We believe that the results of SOLOIST-WHF in patients admitted for recent worsening heart failure will be an important element distinguishing our proposed label.”

“In another major accomplishment this quarter, we announced positive top-line results from our Phase 2 RELIEF-DPN-1 study of LX9211 in painful diabetic neuropathy at the end of June, achieving proof-of-concept for LX9211 with its novel mechanism of action in a historically difficult to treat indication,” Mr. Coats continued. “We expect to report top-line results in the fourth quarter of this year from a second proof-of-concept study of LX9211 in post-herpetic neuralgia. We believe that our recent achievements for both sotagliflozin and LX9211 have the potential to be transformative for our organization, our stakeholders, and most importantly, patients.”

**Second Quarter Highlights**

**Sotagliflozin**

- A poster was presented at the 6<sup>th</sup> Annual HEART IN DIABETES Conference evaluating the effect of sotagliflozin on major adverse cardiovascular events (MACE: cardiovascular [CV] death, non-fatal myocardial infarction [MI] and non-fatal stroke) across the sotagliflozin clinical program of over 20,000 patients with type 1 or type 2 diabetes. The results showed that treatment with sotagliflozin was associated with a statistically significant and clinically meaningful reduction in MACE in patients with T1D and T2D.
- A new analysis of data from the SCORED Phase 3 clinical trial of sotagliflozin was presented at the 82nd Scientific Sessions of the American Diabetes Association. The analysis showed that treatment with sotagliflozin significantly reduced HbA1c overall and across prespecified subgroups, including those with stage 4 chronic kidney disease with a severe decrease in glomerular filtration rate (eGFR <30mL/min/1.73m<sup>2</sup>), possibly reflecting the dual SGLT-1/2 mechanism of action of sotagliflozin.

**LX9211**

- Positive top-line results for the Phase 2 proof-of-concept study of LX9211 for the treatment of painful diabetic neuropathy (RELIEF-DPN-1) were achieved at the end of the second quarter of 2022. Full results from the complete RELIEF-DPN-1 study are expected to be presented at a medical meeting in the fourth quarter of 2022.

- Patient enrollment continued in the Phase 2 proof-of-concept study of LX9211 for the treatment of post-herpetic neuralgia (RELIEF-PHN-1), from which top-line results are expected in the fourth quarter of 2022.

## **Second Quarter 2022 Financial Highlights**

**Research and Development (R&D) Expenses:** Research and development expenses for the second quarter of 2022 increased to \$13.4 million from \$10.3 million for the corresponding period in 2021, primarily due to increases in salaries and benefits and higher professional and consulting costs related to the resubmission of our NDA for sotagliflozin.

**Selling, General and Administrative (SG&A) Expenses:** Selling, general and administrative expenses for the second quarter of 2022 increased to \$10.7 million from \$7.9 million for the corresponding period in 2021, primarily due to increases in salaries and benefits, professional and consulting costs and marketing costs relating to preparations for the commercial launch of sotagliflozin.

**Net Loss:** Net loss for the second quarter of 2022 was \$24.6 million, or \$0.16 per share, as compared to a net loss of \$18.1 million, or \$0.13 per share, in the corresponding period in 2021. For the second quarters of 2022 and 2021, net loss included non-cash, stock-based compensation expense of \$2.8 million for both quarters.

**Cash and Investments:** As of June 30, 2022, Lexicon had \$62.0 million in cash and investments, as compared to \$86.7 million as of December 31, 2021. This amount does not include \$82.2 million in approximate net proceeds received from the company's July 27, 2022 public offering and concurrent private placement of its common stock.

## **Conference Call and Webcast Information**

Lexicon management will hold a live conference call and webcast today at 5:00 pm ET / 4:00 pm CT to review its financial and operating results and to provide a general business update. The dial-in number for the conference call is 888-886-7786 and the conference ID for all callers is 78319165. The live webcast and replay may be accessed by visiting Lexicon's website at [www.lexpharma.com/events](http://www.lexpharma.com/events). An archived version of the webcast will be available on the website for 14 days.

## **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 heart failure, neuropathic pain, diabetes and metabolism and other indications. For additional information, please visit [www.lexpharma.com](http://www.lexpharma.com).

## **Safe Harbor Statement**

*This press release contains "forward-looking statements," including statements relating to 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 sotagliflozin, LX9211 and its other potential 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 sotagliflozin, LX9211 and its other potential drug candidates on its anticipated timelines, successfully commercialize any products for which it obtains regulatory approval, 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, 2021, 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.*

**Lexicon Pharmaceuticals, Inc.**  
**Selected Financial Data**

**Consolidated Statements of Operations Data**

*(In thousands, except per share data)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenues:				
Royalties and other revenue	\$ 35	\$ 234	\$ 72	\$ 261
Operating expenses:				
Research and development, including stock-based compensation of \$1,098, \$1,184, \$2,130 and \$2,470, respectively	13,356	10,257	28,282	22,866
Selling, general and administrative, including stock-based compensation of \$1,734, \$1,602, \$3,474 and \$3,167, respectively	10,686	7,936	19,177	16,193
Total operating expenses	24,042	18,193	47,459	39,059
Loss from operations	(24,007)	(17,959)	(47,387)	(38,798)
Interest expense	(703)	(169)	(813)	(336)
Interest and other income, net	123	61	137	109
Net Loss	<u>\$ (24,587)</u>	<u>\$ (18,067)</u>	<u>\$ (48,063)</u>	<u>\$ (39,025)</u>
Net loss per common share, basic and diluted	\$ (0.16)	\$ (0.13)	\$ (0.32)	\$ (0.27)
Shares used in computing net loss per common share, basic and diluted	149,616	144,451	149,384	143,917

**Consolidated Balance Sheet Data**

*(In thousands)*

	As of June 30, 2022	As of December 31, 2021
Cash and investments	\$61,968	\$86,743
Property and equipment, net	1,035	1,176
Goodwill	44,543	44,543
Total assets	112,325	136,909
Long-term debt, net of issuance costs	23,631	-
Accumulated deficit	(1,535,839)	(1,487,776)
Total stockholders' equity	70,830	113,595

**For Inquiries:**

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