
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): May 2, 2023

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:

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 2.02 Results of Operation and Financial Condition

On May 2, 2023, we issued a press release to report our financial results for the quarter ended March 31, 2023. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated May 2, 2023
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: May 2, 2023

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

**LEXICON PHARMACEUTICALS REPORTS FIRST QUARTER 2023
FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE**

NDA for Sotagliflozin on Track for May 27th, 2023 PDUFA date

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, May 2, 2023 - [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXRX), today reported financial results for the three months ended March 31, 2023 and provided an update on key corporate milestones.

“Our NDA for sotagliflozin for the treatment of heart failure is on track for its May 27th PDUFA action date,” said Lonnel Coats, Lexicon’s chief executive officer. “With both recently adopted medical treatment guidelines recommending the use of SGLT inhibitors as a key pillar of heart failure treatment and the unique data from our SOLOIST-WHF trial, we believe we have a strong value proposition for clinical differentiation in the heart failure market. Should we receive regulatory approval, we are prepared to promptly launch in the United States in the first half of 2023.”

“As we have previously shared, we continue preparations to advance LX9211 into late-stage development in neuropathic pain, supported by data from Phase 2 proof-of-concept studies in diabetic peripheral neuropathic pain (DPN) and postherpetic neuralgia (PHN), both completed in 2022, and expect feedback from our interactions from the FDA in Q2.”

First Quarter Highlights

Sotagliflozin

- On March 4th, new analyses of results from our SOLOIST-WHF Phase 3 outcomes study of sotagliflozin were presented at the American College of Cardiology’s 72nd Annual Scientific Session Together With World Heart Federation’s World Congress of Cardiology in New Orleans, Louisiana. The “*Time to Clinical Benefit of Sotagliflozin in People with Worsening Heart Failure in SOLOIST-WHF*” post hoc analysis examined the timing of clinical benefit of sotagliflozin, defined as the first day post randomization when the hazard ratio (HR) for risk for the primary outcome of total number of cardiovascular deaths, hospitalizations for heart failure, and urgent visits for heart failure was statistically significant ($p < 0.05$) and remained significant throughout follow up. A subgroup analysis was also conducted in patients with left ventricular ejection fraction (LVEF) $< 50\%$ or $\geq 50\%$. The analysis showed a statistically significant reduction in the risk for the primary outcome on Day 27, or time to clinical benefit of 27 days, in patients with worsening heart failure (WHF) treated with sotagliflozin. Furthermore, these findings were generally consistent across the LVEF range.

First Quarter 2022 Financial Highlights

Research and Development (R&D) Expenses: Research and development expenses for the first quarter of 2023 decreased to \$12.1 million from \$14.9 million for the corresponding period in 2022, primarily due to lower external research development costs and professional and consulting fees in 2023 related to the preparations for the submission of our application for regulatory approval to market sotagliflozin for heart failure.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the first quarter of 2023 increased to \$19.1 million from \$8.5 million for the corresponding period in 2022, primarily

due to increases in headcount and in professional and consulting fees relating to preparations for the commercial launch of sotagliflozin in heart failure.

Net Loss: Net loss for the first quarter of 2023 was \$31.9 million, or \$0.17 per share, as compared to a net loss of \$23.5 million, or \$0.16 per share, in the corresponding period in 2022. For the first quarters of 2023 and 2022, net loss included non-cash, stock-based compensation expense of \$3.4 million and \$2.8 million, respectively.

Cash and Investments: As of March 31, 2023, Lexicon had \$105.9 million in cash and investments, as compared to \$138.4 million as of December 31, 2022.

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 888-317-6003 and the conference ID for all callers is 2576268. The live webcast and replay may be accessed by visiting Lexicon's website at 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.

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, 2022, 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 March 31,	
	2023	2022
	(Unaudited)	
Revenues:		
Royalties and other revenue	\$ 24	\$ 37
Operating expenses:		
Research and development, including stock-based compensation of \$1,203 and \$1,032, respectively	12,026	14,926
Selling, general and administrative, including stock-based compensation of \$2,212 and \$1,740, respectively	19,140	8,491
Total operating expenses	31,166	23,417
Loss from operations	(31,142)	(23,380)
Interest expense	(1,821)	(110)
Interest and other income, net	1029	14
Net Loss	\$ (31,934)	\$ (23,476)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.16)
Shares used in computing net loss per common share, basic and diluted	189,014	149,150

Consolidated Balance Sheet Data

(In thousands)

	As of March 31, 2023	As of December 31, 2022
Cash and investments	105,937	138,357
Property and equipment, net	2,207	2,071
Goodwill	44,543	44,543
Total assets	162,716	194,299
Long-term debt, net of issuance costs	48,845	48,579
Accumulated deficit	(1,621,654)	(1,589,720)
Total stockholders' equity	88,046	117,124

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