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): March 2, 2023

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)**

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

Exhibit No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated March 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: March 2, 2023

By: /s/ Brian T. Crum

Brian T. Crum

Senior Vice President and General Counsel

Exhibit 99.1

LEXICON PHARMACEUTICALS REPORTS FOURTH QUARTER 2022 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

NDA for Sotagliflozin on Track for May 2023 PDUFA date following Late-Cycle Review Meeting

LX9211 Demonstrates Consistent Results in Full Data from RELIEF-DPN-1 in Diabetic Peripheral Neuropathic Pain and Top-Line Data from RELIEF-PHN-1 in Post-Herpetic Neuralgia

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, March 2, 2023 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months and full-year ended December 31, 2022 and provided an update on key corporate milestones.

"We are on track for the PDUFA action date in May of this year for our NDA for sotagliflozin for the treatment of heart failure, as confirmed during this week's FDA late-cycle review meeting," said Lonnel Coats, Lexicon's chief executive officer. "We believe the uniqueness of our data from the SOLOIST-WHF trial provides a point of clinical differentiation and provides a strong opportunity to launch into a growing market with recently adopted medical treatment guidelines recommending the use of SGLT inhibitors as a key pillar of heart failure treatment."

"We continue to advance the science across our portfolio with the upcoming presentation of sotagliflozin-related analyses 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, including a featured presentation on the time to clinical benefit of sotagliflozin in people with worsening heart failure. In parallel, we are equally excited about the clinical progress of our AAK1-inhibitor, LX9211. We plan to advance LX9211 into late-stage development in neuropathic pain, supported by data from Phase 2 proof-of-concept studies in painful diabetic neuropathy (PDN) and postherpetic neuralgia (PHN), both completed in 2022."

Fourth Quarter Highlights

Sotagliflozin

- On November 6, a new analysis of results from the SOLOIST-WHF Phase 3 outcomes study of sotagliflozin was presented at the American Heart Association Scientific Sessions 2022 in Chicago, Illinois. The oral presentation was titled "*The effect of the dual SGLT1 and 2 inhibitor sotagliflozin on cardiovascular mortality and hospital readmission rates for heart failure at 30- and 90-days post discharge in patients with type 2 diabetes hospitalized for worsening heart failure in the SOLOIST-WHF trial*" and showed that treatment with sotagliflozin resulted in a significant relative risk reduction versus placebo of approximately 50% for readmission for non-fatal heart failure events and for the composite of cardiovascular death and readmission for heart failure at both 30 and 90 days following hospital discharge.

- A poster was presented at the American Society of Nephrology Kidney Week 2022 annual scientific meeting in Orlando, Florida on November 5. The poster was titled *"Effect of sotagliflozin on albuminuria in patients with type 2 diabetes and chronic kidney disease"* and described the results of a post hoc analysis of clinical data from the SCORED trial that showed sotagliflozin significantly reduced urine albumin-to-creatinine ratio (UACR) and had favorable effects on albuminuria progression and regression from a higher UACR category.

LX9211

- An oral presentation, titled "*A Phase 2 Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of LX9211 in the Treatment of Diabetic Peripheral Neuropathic Pain (RELIEF-DPN-1),*" was given at the 16th Annual Pain Therapeutics Summit in Washington, D.C. on November 14. The presentation of full data from the entire 11-week evaluation period of the study, which included a 5-week placebo run-off period following the initial 6-week treatment period, showed consistent and statistically significant treatment-period benefits in measures of particular importance in diabetic peripheral neuropathic pain for both dose arms compared to placebo, such as reductions in burning pain ($p<0.001$ and $p=0.017$, respectively) and interference of pain on sleep ($p=0.005$ and $p=0.002$, respectively).

- On December 21, we announced topline results of our RELIEF-PHN-1 Phase 2 proof-of-concept study of LX9211 in postherpetic neuralgia. LX9211 achieved a reduction in average daily pain score (ADPS) of 2.42 points from baseline at week 6 compared to a reduction of 1.62 points in the placebo arm, with a placebo adjusted difference of 0.80 points ($p=0.12$). Although these results did not reach statistical significance on the primary endpoint of the study, overall study results demonstrated clear evidence of effect. Separation of LX9211 from placebo on ADPS was seen at week 1 and maintained consistently thereafter, with an average placebo-adjusted reduction over the 6-week dosing period of 0.80 points ($p=0.03$).

Fourth Quarter 2022 Financial Highlights

Unless otherwise stated, all comparisons are for the fourth quarter and full year of 2022 compared to the fourth quarter and full year of 2021.

Research and Development (R&D) Expenses: Research and development expenses for the fourth quarter of 2022 decreased to $14.0 million from $16.5 million for the corresponding period in 2021, and for the full-year decreased to $52.8 million from $55.0 million in 2021, primarily due to lower professional and consulting fees in 2022 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 fourth quarter of 2022 increased to $16.3 million from $8.8 million for the corresponding period in 2021, and for the full-year increased to $48.1 million from $32.3 million 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 in heart failure.

Net Loss: Net loss for the fourth quarter of 2022 was $30.5 million, or $0.16 per share, as compared to a net loss of $25.6 million, or $0.17 per share, in the corresponding period in 2021. For the fourth quarters of 2022 and 2021, net loss included non-cash, stock-based compensation expense of $3.3 million and $2.2 million, respectively. Net loss for the full-year 2022 was $101.9 million, or $0.62 per share, as compared to a net loss of $87.8 million, or $0.60 per share in 2021. For the full years of 2022 and 2021, net loss included non-cash, stock-based compensation expense of $11.5 million and $10.6 million, respectively.

Cash and Investments: As of December 31, 2022, Lexicon had $138.4 million in cash and investments, as compared to $86.7 million as of December 31, 2021.

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 70766912. 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, 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 December 31,**		**Years Ended December 31,**	
	2022	**2021**	**2022**	**2021**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Royalties and other revenue	$ 28	$ 14	$ 139	$ 298
Operating expenses:				
Research and development, including stock-based compensation of $1,184, $676, $4,253 and $4,284, respectively	13,977	16,498	52,816	55,046
Selling, general and administrative, including stock-based compensation of $2,084, $1,552, $7,267 and $6,293, respectively	16,329	8,846	48,083	32,342
Total operating expenses	30,306	25,344	100,899	87,388
Loss from operations	(30,278)	(25,330)	(100,760)	(87,090)
Interest expense	(1,103)	(295)	(2,780)	(802)
Interest and other income, net	887	14	1,596	134
Net Loss	$ (30,494)	$ (25,611)	$ (101,944)	$ (87,758)
Net loss per common share, basic and diluted	$ (0.16)	$ (0.17)	$ (0.62)	$ (0.60)
Shares used in computing net loss per common share, basic and diluted	188,726	148,897	165,733	145,652

Consolidated Balance Sheet Data *(In thousands)*	**As of December 31, 2022**	**As of December 31, 2021**
Cash and investments	$ 138,357	$ 86,743
Property and equipment, net	2,071	1,176
Goodwill	44,543	44,543
Total assets	194,299	136,909
Long-term debt, net of issuance costs	48,579	-
Accumulated deficit	(1,589,720)	(1,487,776)
Total stockholders' equity	117,124	113,595

For Investor Inquiries:

Carrie Siragusa
Lexicon Pharmaceuticals, Inc.
csiragusa@lexpharma.com

For Media Inquiries:

Alina Kolomeyer
Lexicon Pharmaceuticals, Inc.
akolomeyer@lexpharma.com