
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): November 9, 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:
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 November 9, 2022, we issued a press release to report our financial results for the quarter ended September 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated November 9, 2022
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: November 9, 2022

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

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

NDA for Sotagliflozin Remains on Track for May 2023 PDUFA Date Following Mid-Cycle Review Meeting

Final Data from Successful RELIEF-DPN-1 Study of LX9211 in Painful Diabetic Neuropathy to Be Presented at 16th Annual Pain Therapeutics Summit Next Week

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, November 9, 2022 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended September 30, 2022 and provided an update on key corporate milestones.

“Our mid-cycle review meeting with the FDA was held this week for our NDA for sotagliflozin for the treatment of heart failure, which remains on track for its PDUFA action date in May 2023,” said Lonnel Coats, Lexicon’s chief executive officer. “This past weekend, important data for sotagliflozin were presented at two major medical conferences, notably including an oral presentation at the American Heart Association Scientific Sessions 2022 on reduced cardiovascular mortality and hospital readmissions for heart failure at 30- and 90-days post discharge in patients hospitalized for worsening heart failure in the SOLOIST-WHF trial.”

“This coming Monday, final data from our successful RELIEF-DPN-1 study of LX9211 in painful diabetic neuropathy will be presented at the 16th Annual Pain Therapeutics Summit in Washington, D.C., which we will follow with a conference call discussing the results and their importance in an area of significant unmet need,” Mr. Coats continued. “Finally, we completed enrollment earlier this quarter in our RELIEF-PHN-1 study of LX9211 in post-herpetic neuralgia, from which we expect to report top-line data before year-end.”

Third Quarter Highlights

Sotagliflozin

- The U.S. Food and Drug Administration (FDA) accepted for review and filed Lexicon’s New Drug Application (NDA) for sotagliflozin for the treatment of heart failure. The FDA assigned a standard review for the NDA filing with a Prescription Drug User Fee Act (PDUFA) target action date in May 2023.
- Two posters were presented at the 70th annual European Society of Cardiology Congress, highlighting protein expression analyses comparing sotagliflozin, a dual SGLT1 and SGLT2 inhibitor, with a selective SGLT2 inhibitor in cell-based models relative to inflammation and thrombosis.
 - The first poster, “*Sotagliflozin, a Dual SGLT1/2 Inhibitor, Reduced Expression of Neutrophil Degranulation Proteins During Endothelial Dysfunction Compared with a Selective SGLT2 Inhibitor,*” concluded that the favorable effects of sotagliflozin on mechanisms of inflammation have implications for ischemic disease, including myocardial infarction and stroke.
 - The second poster, “*Sotagliflozin, a Dual SGLT1/2 Inhibitor, Reduced Expression of Platelet Activators During Endothelial Dysfunction Compared to Empagliflozin,*” concluded that the effects of dual SGLT1 and SGLT2 inhibition on platelet activity may have implications for reduced atherothrombotic risk.
- A manuscript entitled “*Metabolic, Intestinal, and Cardiovascular Effects of Sotagliflozin Compared with Empagliflozin in Patients with Type 2 Diabetes: A Randomized, Double-Blind Study*” was published in the September issue of the journal *Diabetes Care*. Results from the study showed significant differences between the agents with respect to certain incremental incretin levels following meals, particularly at breakfast. Sotagliflozin significantly reduced postprandial glucose, insulin, and glucose-dependent insulinotropic polypeptide (GIP) and significantly increased glucagon-

like peptide 1 (GLP-1), in each case relative to empagliflozin and consistent with sotagliflozin's inhibition of intestinal SGLT-1. The favorable changes in these measures were noted in the manuscript as having potential implications for cardiovascular disease.

LX9211

- A poster was presented and an oral presentation was given at the PAINWeek 2022 National Conference on Pain Management. The poster and presentation, each titled "*LX9211, a Novel Therapeutic Approach to Treatment of Neuropathic Pain,*" described the mechanism of action of LX9211's novel target, adaptor-associated protein kinase 1 (AAK1), as well as results from multiple preclinical models of neuropathic pain after treatment with LX9211.
- A poster was presented at the IASP World Congress on Pain, titled "*Efficacy, Safety, and Pharmacokinetics of LX9211 in the Treatment of Diabetic Peripheral Neuropathic Pain (RELIEF-DPN-1),*" outlining the study design, baseline patient characteristics, and positive results of the primary endpoint of the study.

Public Offering and Concurrent Private Placement

- Lexicon completed a public offering and concurrent private placement of common stock, with net proceeds to the company of \$94.3 million.

Third Quarter 2022 Financial Highlights

Research and Development (R&D) Expenses: Research and development expenses for the third quarter of 2022 decreased to \$10.6 million from \$15.7 million for the corresponding period in 2021, primarily due to lower clinical external research expenses and professional and consulting costs.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the third quarter of 2022 increased to \$12.6 million from \$7.3 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 third quarter of 2022 was \$23.4 million, or \$0.13 per share, as compared to a net loss of \$23.1 million, or \$0.16 per share, in the corresponding period in 2021. For the third quarters of 2022 and 2021, net loss included non-cash, stock-based compensation expense of \$2.6 million and \$2.7 million, respectively.

Cash and Investments: As of September 30, 2022, Lexicon had \$136.2 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenues:				
Royalties and other revenue	\$ 39	\$ 23	\$ 111	\$ 284
Operating expenses:				
Research and development, including stock-based compensation of \$939, \$1,138, \$3,069 and \$3,608, respectively	10,557	15,682	38,839	38,548
Selling, general and administrative, including stock-based compensation of \$1,709, \$1,574, \$5,183 and \$4,741, respectively	12,577	7,303	31,754	23,496
Total operating expenses	<u>23,134</u>	<u>22,985</u>	<u>70,593</u>	<u>62,044</u>
Loss from operations	(23,095)	(22,962)	(70,482)	(61,760)
Interest expense	(864)	(171)	(1,677)	(507)
Interest and other income, net	572	11	709	120
Net Loss	<u>\$ (23,387)</u>	<u>\$ (23,122)</u>	<u>\$ (71,450)</u>	<u>\$ (62,147)</u>
Net loss per common share, basic and diluted	\$ (0.13)	\$ (0.16)	\$ (0.45)	\$ (0.43)
Shares used in computing net loss per common share, basic and diluted	174,904	145,820	157,984	144,558

Consolidated Balance Sheet Data

(In thousands)

	As of September 30, 2022	As of December 31, 2021
Cash and investments	\$136,203	\$86,743
Property and equipment, net	932	1,176
Goodwill	44,543	44,543
Total assets	191,685	136,909
Long-term debt, net of issuance costs	23,784	-
Accumulated deficit	(1,559,226)	(1,487,776)
Total stockholders' equity	144,018	113,595

For Inquiries:

Mike Kelly
Lexicon Pharmaceuticals, Inc.
mkelly@lexpharma.com