
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 3, 2021

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)

8800 Technology Forest Place
The Woodlands, Texas 77381
(Former address if changed since last report)

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	LXX	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 3, 2021, we issued a press release to report our financial results for the quarter ended September 30, 2021. 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 3, 2021
EX-104	— Cover Page Interactive Data File (embedded within the Inline XBRL document)

**LEXICON PHARMACEUTICALS REPORTS THIRD QUARTER 2021
FINANCIAL RESULTS AND PROVIDES CLINICAL UPDATE**

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, November 3, 2021 - [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXX), today reported financial results for the three months ended September 30, 2021 and provided an update on key milestones.

“We are on track for submission around year-end of our new drug application for sotagliflozin for the treatment of heart failure in patients with type 2 diabetes,” said Lonnel Coats, Lexicon’s chief executive officer. “Momentum continues to build for the adoption of SGLT inhibitors into the first-line heart failure treatment regimen, as most recently evidenced by the new clinical practice guidelines issued in late August by the European Society of Cardiology (ESC). We believe that sotagliflozin’s unique mechanism of action as a dual SGLT1 and SGLT2 inhibitor offers differentiating advantages in this emerging market, with a particular opportunity in heart failure with preserved ejection fraction (HFpEF), and that a primary point of engagement will be with specialists treating patients who have been recently hospitalized for worsening heart failure, which was the cornerstone of our SOLOIST study. We are building our launch readiness team in preparation for potentially bringing sotagliflozin to patients suffering from heart failure and living with type 2 diabetes next year.”

Third Quarter Highlights

Sotagliflozin

- ESC issued new treatment guidelines adding SGLT inhibitors to the standard of care for the prevention and treatment of heart failure. Sotagliflozin was specifically recommended for the primary prevention of heart failure in type 2 diabetes patients with risk factors for its development and the treatment of heart failure in patients with type 2 diabetes, and was also noted in the guidelines in the context of worsening heart failure.
- Additional analyses of sotagliflozin data from the SOLOIST and SCORED Phase 3 clinical studies were presented at the ESC Congress 2021 highlighting the benefits seen in reduced heart failure hospitalizations, myocardial infarction and stroke.

LX9211

- Patient enrollment continued in two ongoing Phase 2 clinical studies of LX9211 for the treatment of diabetic peripheral neuropathic pain and the treatment of post-herpetic neuralgia. Results from these clinical studies are currently expected in the first half of 2022.

Corporate

- Craig B. Granowitz, M.D., Ph.D. joined Lexicon as senior vice president and chief medical officer, with a deep and successful history in cardiovascular medicine. Dr. Granowitz will lead the build-out of Lexicon’s medical affairs organization as the company prepares for the potential launch of sotagliflozin for the treatment of heart failure in patients with type 2 diabetes.

Third Quarter 2021 Financial Highlights

Revenues: Revenues for the three months ended September 30, 2021 were negligible as compared to \$6.6 million for the corresponding period in 2020, primarily due to the absence of product revenues as a result of Lexicon’s sale of its XERMELO® product and related assets to TerSera Therapeutics LLC during the third quarter of 2020.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended September 30, 2021 decreased to \$15.7 million from \$40.1 million for the corresponding period in 2020, primarily due to decreases in external clinical development costs related to sotagliflozin resulting from the completion of clinical studies.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the three months ended September 30, 2021 decreased to \$7.3 million from \$12.0 million for the corresponding period in 2020, primarily due to lower salaries and benefits costs as a result of reductions in personnel in September 2020 and lower marketing expenses, all primarily associated with the sale of XERMELLO and related assets during the third quarter of 2020.

Net Loss: Net loss for the three months ended September 30, 2021 was \$23.1 million, or \$0.16 per share, as compared to net income of \$82.6 million, or \$0.71 per diluted share, in the corresponding period in 2020. The three months ended September 30, 2020 included a gain of \$132.8 million from the sale of XERMELLO and related assets to TerSera. For the three months ended September 30, 2021 and 2020, net income included non-cash, stock-based compensation expense of \$2.7 million and \$1.9 million, respectively.

Cash and Investments: As of September 30, 2021, Lexicon had \$120.9 million in cash and investments, as compared to \$152.3 million as of December 31, 2020.

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 888-645-5785 (U.S./Canada) or 970-300-1531 (international). The conference ID for all callers is 8564549. 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 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 m² 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 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 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, 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, 2020, 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,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Revenues:				
Net product revenue	\$ -	\$ 6,542	\$ -	23,404
Collaborative agreements	-	-	-	33
Royalties and other revenue	23	92	284	359
Total revenues	23	6,634	284	23,796
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	-	633	-	1929
Research and development, including stock-based compensation of \$1,138, \$1,029, \$3,608 and \$5,154, respectively	15,682	40,147	38,548	152,629
Selling, general and administrative, including stock-based compensation of \$1,574, \$875, \$4,741, and \$5,440, respectively	7,303	11,997	23,496	40,798
Impairment loss on buildings	-	-	-	1,600
Total operating expenses	22,985	52,777	62,044	196,956
Other operating income:				
Gain on sale of XERMELO	-	132,818	-	132,818
Income (loss) from operations	(22,962)	86,675	(61,760)	(40,342)
Loss on debt extinguishments, net	-	(255)	-	(255)
Interest expense	(171)	(4,118)	(507)	(14,374)
Interest and other income, net	11	301	120	1,892
Net income (loss)	\$ (23,122)	\$ 82,603	\$ (62,147)	\$ (53,079)
Net income (loss) per common share, basic	\$ (0.16)	\$ 0.77	\$ (0.43)	\$ (0.50)
Net income (loss) per common share, diluted	\$ (0.16)	\$ 0.71	\$ (0.43)	\$ (0.50)
Shares used in computing net income (loss) per common share, basic.....	145,820	107,309	144,558	106,974
Shares used in computing net income (loss) per common share, diluted.....	145,820	117,552	144,558	106,974

Consolidated Balance Sheet Data

(In thousands)

	As of Sept. 30, 2021	As of December 31, 2020
	(Unaudited)	
Cash and investments.....	\$ 120,918	\$ 152,275
Property and equipment, net.....	1,311	295
Goodwill.....	44,543	44,543
Total assets.....	172,330	203,788
Current debt.....	11,693	11,646
Accumulated deficit.....	(1,462,165)	(1,400,018)
Total stockholders' equity.....	136,603	156,371

For Inquiries:

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