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 3, 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 August 3, 2023, we issued a press release to report our financial results for the quarter ended June 30, 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

Exhibit No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated August 3, 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: August 3, 2023

By: /s/ Brian T. Crum

Brian T. Crum

Senior Vice President and General Counsel

Exhibit 99.1

LEXICON PHARMACEUTICALS REPORTS SECOND QUARTER 2023 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

INPEFA™ (sotagliflozin) receives FDA approval for the treatment of heart failure

INPEFA granted broad label across full range of left ventricular ejection fraction, including HFpEF and HFrEF, and for patients with or without diabetes

LX9211 moving into late-stage development for the treatment of diabetic peripheral neuropathic pain

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, August 3, 2023 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended June 30, 2023 and provided an update on key corporate milestones.

"This was a an important and productive quarter for Lexicon with achievement of a transformational milestone for the company and important advancements in our business," said Lonnel Coats, Lexicon's chief executive officer. "First, we received FDA approval for INPEFA (sotagliflozin) for the treatment of heart failure and, as a result of the significant investments made prior to approval and the extraordinary efforts of our team, we were able to commercially launch INPEFA in the U.S. within 30 days of FDA approval. As we noted at the time, the approval of INPEFA, along with the breadth of its label, is a major milestone in Lexicon's path to fulfilling its mission of pioneering medicines that transform patients' lives."

"Next, as we announced just a few weeks ago, we are moving LX9211 into late-stage development in diabetic peripheral neuropathic pain (DPNP) with a program that has been designed to optimize opportunities for success, time, and efficiency in satisfying regulatory requirements for approval."

Second Quarter Highlights

INPEFA™ (sotagliflozin)

- On May 26, Lexicon announced that the U.S. Food and Drug Administration (FDA) approved INPEFA (sotagliflozin), a once-daily oral tablet to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with:
    - heart failure or
    - type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors.

  The broad label encompasses heart failure patients across the full range of left ventricular ejection fraction (LVEF), including preserved ejection fraction and reduced ejection fraction, and patients with or without diabetes.

- On May 10, Lexicon announced that results of a new investigator-initiated economic analysis, based on results from the SOLOIST-WHF Phase 3 outcomes study of INPEFA, were presented on May 9 at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) annual meeting in Boston, Massachusetts. The analysis was led by the MedStar Health Research Institute in Washington, D.C. and was conducted from a U.S. healthcare sector perspective, in accordance with Consolidated Health Economic Evaluation Reporting Standards. The analysis was based on nine-month median follow-up data from the 1,222 patients enrolled in the Phase 3 SOLOIST-WHF trial and designed to extrapolate costs, life expectancy, and quality-adjusted life expectancy to estimate INPEFA's cost-effectiveness. The researchers determined that INPEFA is a clinically and economically attractive

medication and is cost-effective at commonly accepted willingness-to-pay thresholds in patients with diabetes and worsening heart failure.

- On June 25, Rahul Aggarwal, M.D., from Brigham & Women's Hospital, Harvard Medical School, Boston, MA, presented *The Efficacy of Sotagliflozin on Heart-Failure Related Outcomes is Independent of Baseline A1C* as an oral presentation at the American Diabetes Association Presidents' Select Abstract Session.

LX9211

- On June 23, Rodica Pop-Busui, M.D., Ph.D., from the Division of Metabolism, Endocrinology and Diabetes, Department of Internal Medicine, University of Michigan, Ann Arbor, MI presented *LX9211, an Orally-Administered, Non-opioid, AAK1 Inhibitor for Painful Diabetic Peripheral Neuropathy: Results from a Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study* as an oral presentation at the American Diabetes Association's 83rd Scientific Sessions.

- Also on June 23, Lexicon announced plans to advance its investigational drug LX9211 into late-stage development in a clinical program directed towards an application for regulatory approval in DPNP. The first late-stage study will be a Phase 2b dose optimization study, with start-up scheduled in the third quarter of 2023 and the initiation of dosing expected in the fourth quarter. The Phase 2b study includes an extension to run in parallel with planned next-stage Phase 3 studies.

Second Quarter 2023 Financial Highlights

Research and Development (R&D) Expenses: Research and development expenses for the second quarter of 2023 increased to $14.5 million from $13.4 million for the corresponding period in 2022, primarily due to higher manufacturing costs in preparation to market INPEFA for heart failure and higher clinical external research development expenses related to the LX9211 program, partially offset by lower professional and consulting fees.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the second quarter of 2023 increased to $30.0 million from $10.7 million for the corresponding period in 2022, primarily due to increases in salaries and benefits, professional and consulting costs and marketing costs relating to preparations for the commercial launch of INPEFA in heart failure.

Net Loss: Net loss for the second quarter of 2023 was $44.9 million, or $0.22 per share, as compared to a net loss of $24.6 million, or $0.16 per share, in the corresponding period in 2022. For the second quarters of 2023 and 2022, net loss included non-cash, stock-based compensation expense of $3.8 million and $2.8 million, respectively.

Cash and Investments: As of June 30, 2023, Lexicon had $256.7 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 3524352. 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 INPEFA™ (sotagliflozin)

Discovered using Lexicon's unique approach to gene science, INPEFA™ (sotagliflozin) is an oral inhibitor of two proteins responsible for glucose regulation known as sodium-glucose cotransporter types 2 and 1 (SGLT2 and SGLT1). SGLT2 is responsible for glucose and sodium reabsorption by the kidney and SGLT1 is responsible for glucose and sodium absorption in the gastrointestinal tract. Sotagliflozin has been studied in multiple patient populations encompassing heart failure, diabetes, and chronic kidney disease in clinical studies involving approximately 20,000 patients.

INDICATION

INPEFA is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with:

- heart failure or
- type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

IMPORTANT SAFETY INFORMATION

Dosing: Assess renal function and volume status and, if necessary, correct volume depletion prior to initiation of INPEFA. INPEFA dosing for patients with decompensated heart failure may begin when patients are hemodynamically stable, including when hospitalized or immediately upon discharge.

Contraindications: INPEFA is contraindicated in patients with hypersensitivity to INPEFA or any of its components.

Ketoacidosis: INPEFA increases the risk of ketoacidosis in patients with type 1 diabetes mellitus (T1DM). Type 2 diabetes Mellitus (T2DM) and pancreatic disorders are also risk factors. The risk of ketoacidosis may be greater with higher doses. There have been postmarketing reports of fatal events of ketoacidosis in patients with type 2 diabetes using sodium glucose transporter 2 (SGLT2) inhibitors. Before initiating INPEFA, assess risk factors for ketoacidosis. Consider ketone monitoring in patients with T1DM and consider ketone monitoring in others at risk for ketoacidosis and educate patients on the signs/symptoms of ketoacidosis. Patients receiving INPEFA may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. INPEFA is not indicated for glycemic control. Assess patients who present with signs and symptoms of metabolic acidosis or ketoacidosis, regardless of blood glucose level. If suspected, discontinue INPEFA, evaluate, and treat promptly. Monitor patients for resolution of ketoacidosis before restarting INPEFA.

Volume Depletion: INPEFA can cause intravascular volume depletion which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. There have been post-marketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients with type 2 diabetes mellitus receiving SGLT2 inhibitors. Patients with impaired renal function (eGFR < 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating INPEFA in patients with one or more of these characteristics, assess volume status and renal function, and monitor for signs and symptoms of hypotension during therapy.

Urosepsis and Pyelonephritis: Treatment with SGLT2 inhibitors, including INPEFA, increases the risk for urinary tract infections. Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been reported. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INPEFA may increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used with INPEFA.

Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Reports of Fournier's Gangrene, a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in post-marketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors. Assess patients who present with pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue INPEFA, closely monitor patient signs and symptoms, and provide appropriate alternative therapy for heart failure.

Genital Mycotic Infections: INPEFA increases the risk of genital mycotic infections. Monitor and treat as appropriate.

Urinary Glucose Test and 1,5-anhydroglucitol (1,5-AG) Assay: these are not reliable for patients taking SGLT2 inhibitors. Use alternative testing methods to monitor glucose levels.

Common Adverse Reactions: the most commonly reported adverse reactions (incidence ≥ 5%) were urinary tract infection, volume depletion, diarrhea, and hypoglycemia.

Drug Interactions:

- **Digoxin:** Monitor patients appropriately as there is an increase in the exposure of digoxin when coadministered with INPEFA 400 mg.
- **Uridine 5'-diphospho-glucuronosyltransferase (UGT) Inducer:** The coadministration of rifampicin, an inducer of UGTs, with sotagliflozin resulted in a decrease in the exposure of sotagliflozin.
- **Lithium:** Concomitant use of an SGLT2 inhibitor with lithium may decrease serum lithium concentrations. Monitor serum lithium concentration more frequently during INPEFA initiation and with dosage changes.

Use in Specific Populations:

- **Pregnancy and Lactation:** INPEFA is not recommended during the second and third trimesters of pregnancy, nor while breastfeeding.
- **Geriatric Use:** No INPEFA dosage change is recommended based on age. No overall differences in efficacy were detected between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Elderly patients may be at increased risk for volume depletion adverse reactions, including hypotension.
- **Renal Impairment:** INPEFA was evaluated in patients with chronic kidney disease (eGFR 25 to 60 mL/min/1.73 m^2) and in patients with heart failure with eGFR < 60 mL/min/1.73 m^2. The safety profile of INPEFA across eGFR subgroups in these studies was consistent with the known safety profile. There was an increase in volume-related adverse events (e.g., hypotension, dizziness) in patients with eGFR < 30 mL/min/1.73m^2 relative to the overall safety population. Efficacy and safety studies with INPEFA did not enroll patients with an eGFR less than 25 mL/min/1.73 m^2 or on dialysis. After starting therapy in the studies, patients were discontinued if eGFR fell below 15 mL/min/1.73 m^2 or were initiated on chronic dialysis.
- **Hepatic Impairment:** INPEFA is not recommended in patients with moderate or severe hepatic impairment.

For full prescribing information see https://www.lexpharma.com/inpefa-US-PI.pdf**.**

About Heart Failure

About 6.7 million Americans suffer from heart failure, a progressive, debilitating condition that is becoming more prevalent. Heart failure is the leading cause of hospitalizations for individuals aged 65 and older, triggering approximately 1.3 million hospitalizations a year.

About the SOLOIST-WHF Study

SOLOIST-WHF was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of INPEFA 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 INPEFA compared with placebo.

SOLOIST-WHF achieved its primary endpoint, with overall tolerability similar to placebo. Results 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 an article titled: “Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure.”

About the SCORED Study

SCORED was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of INPEFA versus placebo when added to standard of care in 10,584 patients with type 2 diabetes, chronic kidney disease with eGFR of 25 ml to 60 ml per minute per 1.73 m^2 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 INPEFA compared with placebo. Key secondary endpoints included total number of events of deaths from cardiovascular causes, non-fatal myocardial infarction, and non-fatal stroke.

SCORED achieved its primary endpoint, with overall tolerability similar to placebo. Results 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 an article titled: “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 has advanced multiple 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 commercialization of its approved products and the clinical development of, regulatory filings for, and potential therapeutic and commercial potential of its other drug candidates. In addition, this press release also contains forward looking statements relating to Lexicon’s growth and future operating results, discovery, development and commercialization 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 commercialize its approved products, successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of its other 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 approved products and other 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 June 30,**		**Six Months Ended June 30,**	
	2023	**2022**	**2023**	**2022**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Net product revenue	$ 291	$ —	$ 291	$ —
Royalties and other revenue	26	35	49	72
Total revenues	317	35	340	72
Operating expenses:				
Cost of Sales	8	—	8	—
Research and development, including stock-based compensation of $1,302, $1,098, $2,505 and $2,130, respectively	14,541	13,356	26,567	28,282
Selling, general and administrative, including stock-based compensation of $2,513, $1,734, $4,725, and $3,474, respectively	30,008	10,686	49,147	19,177
Total operating expenses	44,557	24,042	75,722	47,459
Loss from operations	(44,240)	(24,007)	(75,382)	(47,387)
Interest expense	(1,960)	(703)	(3,781)	(813)
Interest and other income, net	1,296	123	2,325	137
Net loss	$ (44,904)	$ (24,587)	$ (76,838)	$ (48,063)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.16)	$ (0.39)	$ (0.32)
Shares used in computing net loss per common share, basic and diluted	204,783	149,616	196,942	149,384

Consolidated Balance Sheet Data *(In thousands)*	**As of June 30, 2023**	**As of December 31, 2022**
Cash and investments	$256,739	$138,357
Property and equipment, net	2,202	2,071
Goodwill	44,543	44,543
Total assets	316,724	194,299
Long-term debt, net of issuance costs	98,772	48,579
Accumulated deficit	(1,666,558)	(1,589,720)
Total stockholders' equity	186,361	117,124

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