



Lexicon Pharmaceuticals Reports Third Quarter 2023 Financial Results and Provides Business Update

November 8, 2023

Commercial launch of INPEFA® (sotagliflozin) as a differentiated, new treatment option for heart failure patients shows meaningful progress in Q3 with increasing demand across the cardiology community

Significant formulary inclusions effective in Q4 opening the opportunity for further commercial acceleration into 2024 and beyond

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

Conference Call and Webcast at 8:00 am Eastern Time

The Woodlands, Texas, November 8, 2023 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXR), today reported financial results for the three months ended September 30th, 2023 and provided an update on key corporate milestones.

"We achieved important milestones this quarter in commercially launching INPEFA (sotagliflozin) in the U.S. for the treatment of heart failure while simultaneously advancing LX9211 into late-stage development for diabetic peripheral neuropathic pain," said Lonnel Coats, Lexicon's chief executive officer. "We saw increasing prescription demand and clinical utilization for INPEFA throughout the third quarter notwithstanding limited access, and are now beginning to see important formulary wins, with some of the more notable becoming effective on November 1st. With additional formulary wins expected, coupled with increasing uptake from a broadening base of priority physicians, we are confident the momentum behind INPEFA will continue to accelerate as we enter 2024."

"We remain focused on showcasing the growing breadth of INPEFAs clinical evidence and strengthening value proposition at major medical meetings, further demonstrating its differentiated profile for heart failure patients."

"We are also continuing to present data regarding LX9211, for which we have commenced late-stage development in diabetic peripheral neuropathic pain, with patient enrollment expected to begin this quarter in a Phase 2b clinical trial. We remain excited about the clinical profile of LX9211 and believe it could become the first new, non-opioid drug for neuropathic pain in over two decades – an area where new treatment options are urgently needed. Our continued progress with the launch of INPEFA coupled with the advancement of LX9211 into late-stage development are both major milestones in Lexicon's path to fulfilling its mission of pioneering medicines that transform patients' lives."

Third Quarter Highlights

INPEFA® (sotagliflozin)

Launch Progress

- On June 26, Lexicon commenced the U.S. commercial launch of INPEFA (sotagliflozin) for the treatment of heart failure, with product made available in pharmacies and sales representatives deployed across the U.S.
- On October 9, Lexicon announced that Express Scripts, the pharmacy benefits management (PBM) business of The Cigna Group's Evernorth, determined that it would place INPEFA on its Premier Access and Premier Performance national formularies for Medicare patients on November 1, 2023. On November 1, Lexicon announced that Express Scripts had also determined that it would place INPEFA on its Basic and High Performance formularies for commercially insured patients on that date. These placements provide access to INPEFA for Express Scripts Medicare and commercial patients in plans that utilize these formularies and who meet the parameters of INPEFAs FDA-approved indication.

Publications and Data

- On August 8, Lexicon announced that a *post hoc* analysis of data from the SOLOIST-WHF Phase 3 outcomes study of sotagliflozin was published by the *Journal of the American College of Cardiology (JACC): Heart Failure*. The main endpoint of the analysis was first occurrence of cardiovascular death or heart failure-related event (hospitalizations or urgent care visits for heart failure) within 30 and 90 days after hospital discharge (not randomization) in the subgroup of patients who began study treatment on or before discharge. Treatment with sotagliflozin resulted in significant relative risk reductions of approximately 50% for readmission for non-fatal heart failure events and for the composite of cardiovascular death and readmission for heart failure at 30- or 90-days following hospital discharge versus placebo.
- On August 26, two analyses of clinical study results relating to sotagliflozin and Lexicon-supported data were presented during the European Society of Cardiology (ESC) Congress 2023 in Amsterdam, the Netherlands. Bertram Pitt, M.D., FACC, professor of medicine emeritus at the University of Michigan, School of Medicine, Ann Arbor, MI conducted an oral presentation entitled *Mediators of the benefit of sotagliflozin in patients with worsening heart failure in SOLOIST-WHF*. In addition, Marc Bonaca, M.D., M.P.H., University of Colorado Anschutz Medical Campus, Aurora, CO presented a moderated ePoster entitled *Temporal shift in heart failure diagnoses among hospitalized patients within a large US integrated health system*.
- On October 4, Craig Granowitz, M.D., Ph.D., Lexicon's senior vice president and chief medical officer, conducted an oral presentation entitled *Temporal shift in heart failure medications prescribed to hospitalized patients with and without diabetes in a large US integrated health system* at the 59th Annual Meeting of European Association for the Study of Diabetes (EASD) in Hamburg, Germany and online.
- On October 8, Michael J. Davies, Ph.D., Lexicon's executive director of clinical development, presented a new analysis of clinical trial data for sotagliflozin entitled *Sotagliflozin Reduces the Risk of Cardiovascular Events in Patients With Left Ventricular Hypertrophy Without Hypertension: A Post Hoc Analysis From SCORED* was presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting in Cleveland, Ohio.

LX9211

- In June, Lexicon announced the planned advancement of AAK1-inhibitor LX9211 into late-stage development in diabetic peripheral neuropathic pain. During Q3, our teams have continued the preparations for the Phase 2b dose optimization study, with the first patient expected to be enrolled in early December 2023.
- On September 7, Lexicon announced a series of presentations relating to LX9211 occurring throughout the third and fourth quarters. Data were or will be shared in four oral presentations and one poster presentation at various global congresses, including *NeuPSIG 2023 International Congress on Neuropathic Pain*, held September 7-9 in Lisbon, Portugal; *33rd Annual Meeting of the Diabetic Neuropathy Study Group (NeuroDiab)*, held September 28-October 1 in Thessaloniki, Greece; *59th Annual Meeting of the European Association for the Study of Diabetes (EASD)*, held October 2-6 in Hamburg, Germany and online; *17th Annual Pain Therapeutics Summit (Arrowhead Conference)*, held October 19-20 in San Diego, California; and *2nd World Brain Disorders and Neuroscience Summit (BDNS)*, being held November 9-11 in Singapore and online.

Third Quarter 2023 Financial Highlights

Revenues: Revenues for the third quarter of 2023 were \$0.2 million, primarily from the recent commercial launch of INPEFA. INPEFA net product revenues from launch (late June) through September 30, 2023 total \$0.4 million.

Research and Development (R&D) Expenses: Research and development expenses for the third quarter of 2023 increased to \$17.6 million from \$10.6 million for the corresponding period in 2022, primarily due to higher manufacturing costs and higher external research and 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 third quarter of 2023 increased to \$32.2 million from \$12.6 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.

Net Loss: Net loss for the third quarter of 2023 was \$50.5 million, or \$0.21 per share, as compared to a net loss of \$23.4 million, or \$0.13 per share, in the corresponding period in 2022. For the third quarters of 2023 and 2022, net loss included non-cash, stock-based compensation expense of \$3.9 million and \$2.6 million, respectively.

Cash and Investments: As of September 30, 2023, Lexicon had \$218.4 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 8:00 am ET / 7:00 am 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 2598226. 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 \geq 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 m²) and in patients with heart failure with eGFR < 60 mL/min/1.73 m². 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/1.73m² 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 m² or on dialysis. After starting therapy in the studies, patients were discontinued if eGFR fell below 15 mL/min/1.73 m² or were initiated on chronic dialysis.
- **Hepatic Impairment:** INPEFA is not recommended in patients with moderate or severe hepatic impairment.

[Click here for full Prescribing Information.](#)

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.lexipharma.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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenues:				
Net product revenue	\$ 148	\$ -	\$ 438	\$ -
Royalties and other revenue	14	39	64	111
Total revenues	162	39	502	111
Operating expenses:				
Cost of Sales	7	-	15	-
Research and development, including stock-based compensation of \$1,337, \$939, \$3,842 and \$3,069, respectively.....	17,558	10,557	44,125	38,839
Selling, general and administrative, including stock-based compensation of \$2,561, \$1,709, \$7,286, and \$5,183, respectively.....	32,228	12,577	81,375	31,754
Total operating expenses	49,793	23,134	125,515	70,593
Loss from operations	(49,631)	(23,095)	(125,013)	(70,482)
Interest expense	(3,899)	(864)	(7,680)	(1,677)
Interest and other income, net.....	3,005	572	5,330	709
Net loss.....	<u>\$ (50,525)</u>	<u>\$ (23,387)</u>	<u>\$ (127,363)</u>	<u>\$ (71,450)</u>

Net loss per common share, basic and diluted

	\$ (0.21)	\$ (0.13)	\$ (0.60)	\$ (0.45)
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Shares used in computing net loss per

common share, basic and diluted.....	244,925	174,904	213,112	157,984
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Consolidated Balance Sheet Data

(In thousands)

	As of September 30, 2023	As of December 31, 2022
Cash and investments.....	\$ 218,427	\$ 138,357
Property and equipment, net.....	2,134	2,071
Goodwill.....	44,543	44,543
Total assets.....	276,479	194,299
Long-term debt, net of issuance costs.....	99,265	48,579
Accumulated deficit.....	(1,717,083)	(1,589,720)
Total stockholders' equity.....	139,510	117,124