Lexicon Pharmaceuticals Reports Second Quarter 2024 Financial Results and Provides Business Update

August 2, 2024

INPEFA® (sotagliflozin) Net Sales of $1.6 Million in Q2 2024

Resubmitted NDA for ZYNQUISTA ™ (sotagliflozin) in Type 1 Diabetes, Launch Preparations Underway with PDUFA Goal Date of December 20, 2024

Commenced SONATA Phase 3 Study of Sotagliflozin in Hypertrophic Cardiomyopathy (HCM)

Expect Topline Data in Q2 2025 from PROGRESS Phase 2b Study of LX9211 in Diabetic Peripheral Neuropathic Pain (DPNP)

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, August 1, 2024 – Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended June 30, 2024 and provided an update on key corporate milestones.

"This past quarter has resulted in important progress for the company," said Mike Exton, Ph.D., Lexicon's chief executive officer and director.

"We believe our novel set of commercial and pipeline opportunities, derived from our unique genomics target discovery platform Genome5000, have the potential to transform our company and significantly improve the healthcare treatment landscape in their respective therapeutic areas. Entering the second half of 2024, our first and most important priority will be closely evaluating our business strategy, resources and goals to ensure we are optimally positioned to promote the long-term success and growth of Lexicon," continued Dr. Exton.

Second Quarter 2024 Pipeline Highlights

INPEFA (sotagliflozin) for Heart Failure

- The INPEFA launch in heart failure continues to progress and market access discussions remain ongoing. Net sales for the quarter were $1.6 million.

ZYNQUISTA (sotagliflozin) for Type 1 Diabetes

- Lexicon resubmitted its NDA for ZYNQUISTA as an adjunct to insulin in adults with type 1 diabetes and CKD on June 20, 2024. FDA notified the company that it considers the resubmission to be a complete response to its 2019 action letter regarding the NDA and provided a PDUFA goal date of December 20, 2024. Preparations are underway for an early 2025 launch.

Sotagliflozin for HCM

- Lexicon has commenced the SONATA Phase 3 study of sotagliflozin in HCM, with multiple sites open for recruitment.

LX9211 for DPNP

- Patient enrollment remains on track in the PROGRESS Phase 2b dose optimization study of LX9211 in DPNP. LX9211 has the potential to become the first non-opioid drug therapy approved in neuropathic pain in more than 20 years. Topline data from the PROGRESS study is anticipated in Q2 2025.

LX9851 for Obesity and Weight Management

- Utilizing Lexicon's unique Genome 5000 targeting program, the company selected ACSL5-inhibitor LX9851, a novel, oral development candidate for obesity and weight management, for further preclinical development and is commencing IND-enabling studies.

Publications and Data

Lexicon had a significant presence at recent medical meetings including the 84th Scientific Sessions of the American Diabetes Association (ADA) in June 2024 and the Annual Congress of the Heart Failure Association of the European Society of Cardiology (ESC) in May 2024, as well as publications in Diabetes Care, JACC and Journal of Managed Care + Specialty Pharmacy (JMCP).

Second Quarter 2024 Financial Highlights

Revenues: Revenues for the second quarter of 2024 increased to $1.6 million from $0.3 million for the corresponding period from 2023, reflectingthe continued commercialization of INPEFA.

Research and Development (R&D) Expenses: Research and development expenses for the second quarter of 2024 increased to $17.6 million from $14.5 million for the corresponding period in 2023 primarily due to higher external clinical research expense, salaries and benefits.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the second quarter of 2024 increased to $39.2 million from $30.0 million for the corresponding period in 2023. The increase in 2024 reflects the significant investment in the commercial launch of INPEFA, including sales force and related marketing costs.

Net Loss: Net loss for the second quarter of 2024 was $53.4 million, or $0.17 per share, as compared to a net loss of $44.9 million, or $0.22 per share, in the corresponding period in 2023. For the second quarters of 2024 and 2023, net loss included non-cash, stock-based compensation expense of $4.9 million and $3.8 million, respectively.

Cash and Investments: As of June 30, 2024, Lexicon had $310.0 million in cash and investments, as compared to $170.0 million as of December 31, 2023, reflecting the company's March 2024 equity financing.

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 7023126. 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.

Click here for full Prescribing Information.

https://www.lexpharma.com/inpefa-US-PI.pdf

About Lexicon Pharmaceuticals

Lexicon is a biopharmaceutical company with a mission of pioneering medicines that transform patients' lives. Through the Genome5000™ program, Lexicon's unique genomics target discovery platform, 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, 2023, 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,**	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Net product revenue	$ 1,617	$ 291	$ 2,710	$ 291
Royalties and other revenue	30	26	67	49
Total revenues	1,647	317	2,777	340
Operating expenses:				
Cost of sales	166	8	197	8
Research and development, including stock-based compensation of $1,679, $1,302, $3,273 and $2,505, respectively	17,643	14,541	32,015	26,567
Selling, general and administrative, including stock-based compensation of $3,180, $2,513, $5,888 and $4,725, respectively	39,192	30,008	71,252	49,147
Total operating expenses	57,001	44,557	103,464	75,722
Loss from operations	(55,354)	(44,240)	(100,687)	(75,382)
Interest and other expense	(2,211)	(1,960)	(7,159)	(3,781)
Interest income and other, net	4,136	1,296	6,020	2,325
Net loss	$ (53,429)	$ (44,904)	$ (101,826)	$ (76,838)
Net loss per common share, basic and diluted	$ (0.17)	$ (0.22)	$ (0.37)	$ (0.39)
Weighted average common shares outstanding, basic and diluted	310,836	204,783	278,113	196,942

Consolidated Balance Sheet Data *(In thousands)*	**As of June 30, 2024**	**As of December 31, 2023**
Cash and investments	$ 309,964	$ 170,026
Property and equipment, net	1,954	1,987
Goodwill	44,543	44,543
Total assets	373,356	229,429
Long-term debt, net	99,499	99,508
Accumulated deficit	(1,868,665)	(1,766,839)
Total stockholders' equity	239,980	93,110

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