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

November 13, 2024

Announced Exclusive Licensing Agreement with Viatris for Sotagliflozin in all Markets Outside of the U.S. and Europe

Completed ZYNQUISTA™ FDA Advisory Committee Meeting; PDUFA Goal Date December 20, 2024

Concluded Enrollment Screening For Phase 2b PROGRESS Study of LX9211 in Diabetic Peripheral Neuropathic Pain (DPNP); Topline Data Expected in Q1 2025

Executed Repositioning of INPEFA® (sotagliflozin); Net Sales of $1.7 Million in Q3 2024

Conference Call and Webcast at 5:00pm ET

THE WOODLANDS, TEXAS, NOV. 12, 2024 —Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended September 30, 2024 and provided an update on key corporate milestones.

"The past few months have been transformational for Lexicon. In addition to reaching significant milestones for several of our novel investigational medicines, we also entered into a new exclusive licensing agreement to expand the reach of sotagliflozin outside of the U.S. and Europe and strategically realigned our resources to support the wealth of opportunities in our pipeline," said Mike Exton, Ph.D., Lexicon's chief executive officer and director. "With an updated executive leadership team and strong clinical development, medical, and commercial capabilities concentrated in cardiometabolic disease, we are well positioned to embark on the next phase of our Lead to Succeed strategy. We look forward to continuing this momentum with the upcoming PDUFA target action date for ZYNQUISTA on December 20, 2024, and topline results of our Phase 2b clinical trial for LX9211 anticipated in the first quarter of next year."

Third Quarter 2024 Pipeline Highlights

Exclusive Licensing Agreement with Viatris for Sotagliflozin

- Announced an exclusive licensing agreement with Viatris for rights to sotagliflozin in all global markets outside of the U.S. and Europe.
- Received an upfront payment of $25 million, and eligible to receive $197 million in additional potential regulatory and sales milestones and tiered royalties ranging from low-double-digit to upper-teens percentages of annual net sales.

ZYNQUISTA (sotagliflozin) for Type 1 Diabetes

- Following the discussion and feedback from the recent Advisory Committee meeting held for ZYNQUISTA, the company continues to work toward the Prescription Drug User Fee Act (PDUFA) target action date of December 20, 2024.
- The Advisory Committee voted 11 to 3 that the benefits of ZYNQUISTA do not outweigh the risks in adults with type 1 diabetes (T1D) and chronic kidney disease (CKD), as defined in the voting question as having estimated glomerular filtration rate (eGFR) ≥45 to <60 mL/min.1.73 m2 or eGFR >60 mL/min/1.73 m2 and urine albumin-to-creatinine ratio (uACR) > 30mg/g. As part of the discussion, certain committee members expressed support for sotagliflozin in alternative sub-populations of people with T1D and CKD, where they believed the benefits potentially outweigh the risks. The advisory committee meeting also included substantial patient and medical community support for the approval of ZYNQUISTA and the potential for the first new adjunct to insulin in over 100 years.

INPEFA (sotagliflozin) for Heart Failure

- Continued to make progress on the INPEFA launch, with third-quarter net sales of $1.7 million and market access discussions ongoing. Experienced growth in demand with an increase of 18 percent in active INPEFA prescribers.
- Completed strategic repositioning and reprioritization of SG&A investment, including a reduction in field force by approximately 50 percent to focus on a targeted set of prescribers.

Sotagliflozin for HCM

- Enrollment is underway in SONATA HCM, a pivotal Phase 3 placebo-controlled study with a targeted enrollment of 500 patients with obstructive or nonobstructive hypertrophic cardiomyopathy (HCM).

LX9211 for DPNP

- LX9211 is an orally-delivered, small molecule drug candidate for the treatment for DPNP. LX9211 has the potential to become the first non-opioid drug therapy approved in neuropathic pain in more than 20 years.
- Completed patient screening ahead of schedule in the PROGRESS Phase 2b dose optimization study of LX9211 in DPNP. Topline data from the PROGRESS study is now anticipated in Q1 2025.

LX9851 for Obesity and Associated Cardiometabolic Disorders

- Data from recent Obesity Week 2024 presentations summarize the preclinical efficacy and mechanism of action of LX9851.
- Lexicon's ACSL5-inhibitor LX9851, a novel, non-incretin oral development candidate, is progressing in IND-enabling studies and is on track for a mid 2025 IND submission.

Third Quarter 2024 Financial Highlights

Revenues: Revenues for the third quarter of 2024 increased to $1.8 million from $0.2 million for the corresponding period from 2023 reflecting increased product revenues from sales of INPEFA.

Research and Development (R&D) Expenses: Research and development expenses for the third quarter of 2024 increased to $25.8 million from $17.6 million for the corresponding period in 2023 primarily due to investments in Phase 2 and 3 clinical trials, including the SONATA Phase 3 study of sotagliflozin in HCM and the PROGRESS Phase 2b study of LX9211 in DPNP.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the third quarter of 2024 increased to $39.6 million from $32.2 million for the corresponding period in 2023. The increase in 2024 reflects higher marketing costs in conjunction with the commercialization of INPEFA and the severance costs resulting from the partial reduction in the field force in September 2024.

Net Loss: Net loss for the third quarter of 2024 was $64.8 million, or $0.18 per share, as compared to a net loss of $50.5 million, or $0.21 per share, in the corresponding period in 2023. For the third quarters of 2024 and 2023, net loss included non-cash, stock-based compensation expense of $2.8 million and $3.9 million, respectively.

Cash and Investments: As of September 30, 2024, Lexicon had $258.4 million in cash and investments, as compared to $170.0 million as of December 31, 2023. The $25 million upfront payment under the exclusive licensing agreement with Viatris for sotagliflozin outside of the US and Europe was received in the fourth quarter of 2024.

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 1004487. 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 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 September 30,**		**Nine Months Ended September 30,**	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Net product revenue	$ 1,741	$ 148	$ 4,451	$ 438
Royalties and other revenue	9	14	76	64
Total revenues	1,750	162	4,527	502
Operating expenses:				
Cost of sales	71	7	268	15
Research and development, including stock-based compensation of $1,460, $1,337, $4,733, and $3,842, respectively	25,780	17,558	57,795	44,125
Selling, general and administrative, including stock-based compensation of $1,341, $2,561, $7,229, and $7,286, respectively	39,592	32,228	110,844	81,375
Total operating expenses	65,443	49,793	168,907	125,515
Loss from operations	(63,693)	(49,631)	(164,380)	(125,013)
Interest and other expense	(4,562)	(3,899)	(11,721)	(7,680)
Interest income and other, net	3,444	3,005	9,464	5,330
Net loss	$ (64,811)	$ (50,525)	$ (166,637)	$ (127,363)
Net loss per common share, basic and diluted	$ (0.18)	$ (0.21)	$ (0.54)	$ (0.60)
Weighted average common shares outstanding, basic and diluted	361,492	244,925	306,109	213,112

Consolidated Balance Sheet Data *(In thousands)*	**As of September 30, 2024**	**As of December 31, 2023**
Cash and investments	$ 258,369	$ 170,026
Property and equipment, net	2,135	1,987
Goodwill	44,543	44,543
Total assets	321,123	229,429
Long-term debt, net	99,895	99,508
Accumulated deficit	(1,933,476)	(1,766,839)
Total stockholders' equity	178,512	93,110

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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