Lexicon Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates

March 6, 2025

Topline Results for Phase 2b PROGRESS Study of Pilavapadin (LX9211) in Diabetic Peripheral Neuropathic Pain (DPNP); 10 mg dose to Advance into Phase 3 Development

Leaner organization focused on Advancing Strong Pipeline

Conference Call and Webcast at 5:00 pm ET

THE WOODLANDS, Texas, March 06, 2025 (GLOBE NEWSWIRE) -- Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months and year ended December 31, 2024, and provided an update on key corporate milestones and accomplishments.

“In 2024, Lexicon made progress on our Lead to Succeed strategy, resulting in a complete repositioning of the company to focus on advancing our R&D pipeline,” said Mike Exton, Ph.D., Lexicon’s chief executive officer and director. “With R&D efforts our core priority, we were pleased to report progress on three programs. First, we recently reported topline results from the PROGRESS Phase 2b study of pilavapadin, our novel non-opioid, oral, investigational therapy for neuropathic pain with potential to be the first new therapy for neuropathic pain in over two decades. We met our study objectives with respect to the 10 mg dose, which achieved meaningful pain reduction versus placebo and was well-tolerated, providing support for initiation of a Phase 3 program for pilavapadin in DPNP in 2025.”

“We are on track for an IND filing this year for LX9851 in obesity and other potential metabolic disorders. In parallel, we continue to build strong differentiating evidence for sotagliflozin, an SGLT1/2 inhibitor, and we are continuing to enroll a Phase 3 clinical trial in support of a potential broad indication in hypertrophic cardiomyopathy (HCM). These three pipeline opportunities are each in areas of significant unmet need, and have the potential for multiple indications, to be first or only new therapy to market, or to be meaningfully differentiated within their market.”

Fourth Quarter 2024 Business and Pipeline Highlights

Pilavapadin (LX9211) for DPNP

- Pilavapadin is an orally delivered, small molecule drug candidate for the treatment of DPNP. Pilavapadin has the potential to become the first oral non-opioid drug therapy approved in neuropathic pain in more than 20 years.
- Topline data in PROGRESS met the Company’s objective to identify a well-tolerated dose exhibiting meaningful pain reduction that is appropriate to advance into Phase 3 development. In the study, the 10 mg dose arm demonstrated meaningful separation in ADPS from both baseline and placebo and was well-tolerated, although the lack of separation in ADPS between the 20 mg dose arm and placebo resulted in the study not reaching statistical significance on its primary endpoint.
- The Company is moving toward an end of Phase 2 meeting with FDA and targeting initiation of U.S. and ex-U.S. Phase 3 trials in DPNP in 2025, while selecting a future medical meeting for release of additional clinical data later this year.

LX9851 for Obesity and Associated Cardiometabolic Disorders

- LX9851 is a novel, non-incretin oral development candidate that inhibits ACSL5 and is in preclinical development for obesity and weight management. LX9851 is progressing in IND-enabling studies and on track for a 2025 investigational new drug (IND) application submission.

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).
- Site initiation in the European Union and Latin America countries are well underway to further support the company’s trial execution timelines. All target sites are expected to be up and running by Q3.

INPEFA (sotagliflozin)

- Completed reprioritization of SG&A investment to cease active promotion while continuing to make product commercially

available.

Zynquista (sotagliflozin)

- Discontinued preparation for potential Zynquista launch in type 1 diabetes following receipt of complete response letter from FDA.

Data and Publications Highlights

- Continued to focus on generating clinical data to support differentiation of sotagliflozin, including most recent publication in *The Lancet Diabetes & Endocrinology* analyzing the ability of sotagliflozin to reduce the risks of life-threatening cardiovascular outcomes.
- The findings from the study, "Reduction in Major Adverse Cardiovascular Events with Sotagliflozin: A Prespecified Analysis of the SCORED Randomized Trial," concluded that the ischemic benefit of sotagliflozin on both heart attack (myocardial infarction, or MI), and stroke reduction has not been observed with other SGLT inhibitors.

Fourth Quarter 2024 Financial Highlights

Revenues: Revenues for the fourth quarter of 2024 increased to $26.6 million from $0.7 million for the comparable period in 2023 and for the full year 2024 increased to $31.1 million from $1.2 million for the full year 2023. Revenues for both periods in 2024 reflect increased sales of INPEFA compared to 2023 and an upfront payment of $25.0 million received upon entering into the Viatris INPEFA licensing agreement in October 2024.

Research and Development (R&D) Expenses: Research and development expenses for the fourth quarter of 2024 increased to $26.7 million from $14.8 million for the comparable period in 2023. Full-year research and development expenses for 2024 increased to $84.5 million from $58.9 million for the full year 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 pilavapadin in DPNP.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the fourth quarter of 2024 decreased to $32.3 million from $32.6 million for the comparable period in 2023. Full-year 2024 selling, general and administrative expenses increased to $143.1 million from $114.0 million for the full year 2023. The increase in 2024 reflects higher marketing costs related to the commercialization of INPEFA and increased employee salaries and benefit costs prior to the reduction in our field force in late 2024 including severance costs associated with our strategic repositioning.

Net Loss: Net loss for the fourth quarter of 2024 was $33.8 million, or $0.09 per share, as compared to a net loss of $49.8 million, or $0.20 per share, in the corresponding period in 2023. For the fourth quarters of 2024 and 2023, net loss included non-cash, stock-based compensation expense of $1.5 million and $3.2 million, respectively. Net loss for the full year 2024 was $200.4 million, or $0.63 per share, as compared to a net loss of $177.1 million, or $0.80 per share, for the full year 2023. For the full years of 2024 and 2023, net loss included non-cash, stock-based compensation expense of $13.5 million and $14.3 million, respectively.

Cash and Investments: As of December 31, 2024, Lexicon had $238.0 million in cash and short-term investments, as compared to $170.0 million as of December 31, 2023.

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. A live audio webcast of the call can be accessed by visiting the Events page of the Company's investor relations website at https://investors.lexpharma.com/. Participants who wish to ask a question may register here to receive dial-in numbers and a unique pin to join the call. An archived version of the webcast will be available on the website for 30 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 December 31,**		**Years Ended December 31,**	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Net product revenue	$ 1,550	$ 672	$ 6,001	$ 1,110
Licensing revenue	25,000	—	25,000	—
Royalties and other revenue	4	30	80	94
Total revenues	26,554	702	31,081	1,204
Operating expenses:				
Cost of sales	348	70	616	85
Research and development, including stock-based compensation of $1,106, $1,297, $5,839 and $5,139, respectively	26,685	14,762	84,480	58,887
Selling, general and administrative, including stock-based compensation of $431, $1,915, $7,660, and $9,201, respectively	32,258	32,607	143,102	113,982
Total operating expenses	59,291	47,439	228,198	172,954
Loss from operations	(32,737)	(46,737)	(197,117)	(171,750)
Interest and other expense	(3,858)	(5,421)	(15,579)	(13,101)
Interest income and other, net	2,829	2,402	12,293	7,732
Net loss	$ (33,766)	$ (49,756)	$ (200,403)	$ (177,119)
Net loss per common share, basic and diluted	$ (0.09)	$ (0.20)	$ (0.63)	$ (0.80)
Weighted average common shares outstanding basic and diluted	361,492	244,925	320,031	221,130

Consolidated Balance Sheet Data *(In thousands)*	**As of December 31, 2024**	**As of December 31, 2023**
Cash and investments	$ 237,957	$ 170,026
Property and equipment, net	2,484	1,987
Goodwill	44,543	44,543
Total assets	298,420	229,429
Long-term debt, net.	100,298	99,508
Accumulated deficit	(1,967,242)	(1,766,839)
Total stockholders' equity	145,950	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