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

May 3, 2024

Commercial launch of INPEFA® (sotagliflozin) for Heart Failure continues to progress

Resubmission of NDA for ZYNQUISTA ™(sotagliflozin) in Type 1 Diabetes expected mid-year 2024

Start-up ongoing for Phase 3 study of sotagliflozin in Hypertrophic Cardiomyopathy, with enrollment expected to begin mid-year 2024

Enrollment in Phase 2b PROGRESS study of LX9211 in Diabetic Peripheral Neuropathic Pain on track for expected Q2 2025 topline data

Conference Call and Webcast at 5:00 pm Eastern Time

The Woodlands, Texas, May 2, 2024 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended March 31, 2024 and provided an update on key corporate milestones.

“We have made tremendous progress as a company in the first quarter of 2024, both in our commercial launch and in our deep and innovative research and development pipeline,” said Lonnel Coats, Lexicon’s chief executive officer. “Lexicon has never been stronger, and the company’s future has never been brighter.”

“We continue to make progress on the INPEFA heart failure launch, with the expansion of market access we expect to begin around the middle of this year enabling an inflection in the second half of the year,” said Jeffrey Wade, Lexicon’s president and chief financial officer. “The first quarter also saw significant strides in our product pipeline. We are advancing a potential near-term, substantial market opportunity with a planned mid-year resubmission of our New Drug Application (NDA) for ZYNQUISTA as an adjunct to insulin in people with type 1 diabetes and chronic kidney disease (CKD). We commenced the start-up of our Phase 3 study of sotagliflozin in hypertrophic cardiomyopathy (HCM), an area of high unmet need with very few treatment options, with enrollment expected to begin around the middle of the year. And enrollment remains on track in PROGRESS, a Phase 2b study of LX9211 in diabetic peripheral neuropathic pain (DPNP), with the potential for LX9211 become the first new, non-opioid drug approved for neuropathic pain in over two decades.”

“Finally, our Genome5000™ gene knockout drug discovery engine continues to produce with the selection of our LX9851 development candidate for obesity and weight management, now entering IND-enabling studies. We are well capitalized with our recent successful financing, and we are committed to remaining financially disciplined as we make targeted investments to execute on these opportunities for growth and expansion in 2024 and beyond.”

First Quarter 2024 Pipeline Highlights

INPEFA (sotagliflozin) for Heart Failure

- The INPEFA launch in heart failure continues to progress, with favorable feedback from healthcare providers and ongoing negotiations with payers regarding expanded market access. Net sales for the quarter were $1.1 million reflecting 63 percent growth from the previous quarter. Market access remains at approximately 40% overall and is expected to expand in the second half of 2024.

ZYNQUISTA (sotagliflozin) for Type 1 Diabetes

- Following recent feedback from the FDA, Lexicon is preparing to resubmit its NDA for ZYNQUISTA as an adjunct to insulin in people with type 1 diabetes and CKD, expected mid-year 2024. Glycemic control is critical for patients with type 1 diabetes to manage the progression to CKD. It is estimated that CKD impacts an estimated 20 to 25 percent of people with type 1 diabetes.

Sotagliflozin for HCM

- Lexicon is initiating a Phase 3 study of sotagliflozin in HCM, with an expected study start mid-year 2024. It is estimated that approximately one million patients suffer ongoing and persistent symptoms from HCM that negatively impact their quality of life.

LX9211 for DPNP

- Patient enrollment remains on track in the PROGRESS Phase 2b dose optimization study. The PROGRESS study marks initiation of the late-stage development program for AAK1 inhibitor LX9211, with the potential for LX9211 to become the first new, 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

- Lexicon selected ACSL5-inhibitor LX9851, a novel, oral development candidate for obesity and weight management, and is commencing IND-enabling studies.

Publications and Data

Lexicon had a significant presence at recent medical meetings including the American Society of Nephrology (ASN) in January 2024, International Conference on Advanced Technologies & Treatments for Diabetes in March 2024 and American College of Cardiology in April 2024:

- Beta-Hydroxybutyrate Levels and Risk of Diabetic Ketoacidosis in Adults with Type 1 Diabetes Treated with Sotagliflozin.
- Sotagliflozin and Kidney Outcomes, Kidney Function, and Albuminuria in T2DM and CKD: A Secondary Analysis of the SCORED Trial
- Sotagliflozin, A Dual SGLT1 and SGLT2 Inhibitor, in Patients with Type 1 Diabetes and Chronic Kidney Disease: A Post-hoc Analysis of the inTandem3 Study.
- Sotagliflozin Reduces Stroke Outcomes in Patients with Diabetes and Chronic Kidney Disease
- Sotagliflozin, a Dual SGLT 1 and 2 Inhibitor, Modulated Expression of Glucose Transport and Inflammatory Proteins in Endothelial Cells following Angiotensin II Stimulation
- Sotagliflozin, a First-in-Class SGLT1/2 Inhibitor, Inhibits Clotting Potential in the Vessel via Inhibition of Platelet Activation, Integrin Activation, and Aggregation in Human Platelets
- Temporal Shift in Heart Failure Medications Prescribed to Hospitalized Patients According to Sex and Age. Results from Two Large US Integrated Health System

First Quarter 2024 Financial Highlights

Revenues: Revenues for the first quarter of 2024 were $1.1 million, primarily from the commercialization of INPEFA.

Research and Development (R&D) Expenses: Research and development expenses for the first quarter of 2024 increased to $14.4 million from $12.0 million for the corresponding period in 2023, primarily due to higher external research and development expenses.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the first quarter of 2024increased to $32.1 million from $19.1 million for the corresponding period in 2023. The increase in 2024 reflects the significant investment in the commercial launch of INPEFA, including salaries and benefits associated with the addition of the INPEFA sales force and other increased headcount as well as increased travel and marketing costs.

Net Loss: Net loss for the first quarter of 2024 was $48.4 million, or $0.20 per share, as compared to a net loss of $31.9 million, or $0.17 per share, in the corresponding period in 2023. For the first quarters of 2024 and 2023, net loss included non-cash, stock-based compensation expense of $4.3 million and $3.4 million, respectively.

Cash and Investments: As of March 31, 2024, Lexicon had $355.6 million in cash and investments, as compared to $170.0 millionas of December 31, 2023 reflecting the issuance of convertible preferred stock in March 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 5993982. 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 March 31,**	
	2024	**2023**
	(Unaudited)	
Revenues:		
Net product revenue	$ 1,093	$ —
Royalties and other revenue	37	24
Total revenues	1,130	24
Operating expenses:		
Cost of sales	31	—
Research and development, including stock-based compensation of $1,594 and $1,203, respectively	14,372	12,026
Selling, general and administrative, including stock-based compensation of $2,708 and $2,212, respectively	32,060	19,140
Total operating expenses	46,463	31,166
Loss from operations	(45,333)	(31,142)
Interest and other expense	(4,948)	(1,821)
Interest income and other, net	1,884	1,029
Net loss	$ (48,397)	$ (31,934)
Net loss per common share, basic and diluted	$ (0.20)	$ (0.17)
Shares used in computing net loss per common share, basic and diluted	245,390	189,014

Consolidated Balance Sheet Data *(In thousands)*	**As of March 31, 2024**	**As of December 31, 2023**
Cash and investments	$ 355,598	$ 170,026
Property and equipment, net	1,843	1,987
Goodwill	44,543	44,543
Total assets	417,219	229,429
Long-term debt, net	99,874	99,508
Accumulated deficit	(1,815,236)	(1,766,839)
Total stockholders' equity	288,867	93,110

For Investor Inquiries:

Lisa DeFrancesco
Lexicon Pharmaceuticals, Inc.
lexinvest@lexpharma.com

For Media Inquiries:

Alina Cocuzza
Lexicon Pharmaceuticals, Inc.
acocuzza@lexpharma.com