Esperion Reports Fourth Quarter and Full Year 2023 Financial Results

February 27, 2024

– FY23 U.S. Net Product Revenue Grew 40% Y/Y to $78.3 Million; FY23 Total Revenue Grew 54% Y/Y to $116.3 Million –

– Q4 U.S. Net Product Revenue Grew 39% Y/Y to $20.8 Million; Q4 Total Revenue Grew 72% Y/Y to $32.3 Million –

– Q4 Retail Prescription Equivalents Grew 44% Y/Y and 8% Q/Q, with Momentum Expected into 1H 2024 –

– Resolved Litigation: Received $100 Million in January 2024 and Entitled to Additional $25 Million Pending EMA Label Determination; Hundreds of Millions of Dollars in Potential Cost Savings and Additional Revenue Streams –

– Recent Positive Interactions with FDA and EMA; Proposed Indications for Primary and Secondary Prevention of Cardiovascular Risk and Expanded LDL-C Indication Remain on Track for 1H 2024, with FDA PDUFA Date of March 31 –

– Conference Call and Webcast Today at 8:00 a.m. ET –

ANN ARBOR, Mich., Feb. 27, 2024 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a business update.

“We have recently made major strides as a company, which we believe position us for sustained growth in the short, medium, and long term,” said Sheldon Koenig, President and CEO. “First amongst these was reaching agreement with our valued European partner, DSE, to resolve the outstanding litigation and continue executing our strategy to strengthen our global franchise over time. Our agreement has had an immediate positive impact on our balance sheet, promises substantial cost savings in the years to come, and creates a roadmap for product lifecycle extension in Europe. We are pleased with the near- and long-term value this brings to our organization and look forward to DSE’s continued partnership and strong execution in Europe. We also continue to progress our other partnerships globally, including with Otsuka in Japan, and are on track to making this the blockbuster franchise we expect it to be.”

“We have continued to prioritize our commercial expansion based on our anticipated cardiovascular risk reduction labels from the FDA in March and the EMA in the second quarter. We are confident that our prospective labels will have a material impact on sales.”

“With the cash infusion from our settlement plus our recent capital raise, we are now exceptionally well positioned to fund our commercial launch, increase our coverage and market share, advance our preclinical pipeline, and bring our first-in-class therapies to millions of patients globally who need them. I am proud of our entire organization and its commitment to our long-term vision and look forward to updating you on our progress in the periods ahead.”

Fourth Quarter and Full Year 2023 Key Accomplishments and Recent Highlights

- Announced the resolution of pending litigation with Daiichi Sankyo Europe (DSE) in January 2024, which included near-term cash payments of $125 million and millions of dollars in anticipated manufacturing cost savings and additional potential revenue streams. The settlement provided for an amendment to the parties’ collaboration agreement and dismissal of their pending legal case. In addition to the near-term cash payments, the settlement terms provide for the transition of Esperion’s manufacturing and supply responsibilities in Europe and other territories to DSE, resulting in significant cost savings and efficiencies. The settlement agreement also expanded the parties’ collaboration agreement to include potential development and commercialization of a triple combination therapy in Europe, which could potentially extend patent exclusivity and corresponding revenue stream, to which Esperion would be entitled tiered royalties.

- Closed on a follow-on equity offering in January 2024, raising gross proceeds of $97.8 million. Proceeds will enable the Company to fund the ongoing commercialization efforts for NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe), research and clinical development of pipeline candidates, working capital, capital expenditures, and general corporate purposes.

- Announced FDA approval of an updated LDL-cholesterol lowering indication for NEXLETOL and NEXLIZET in December 2023, to include the treatment of primary hyperlipidemia as a qualifier for existing approved populations. In addition, the maximally tolerated qualifier for statin use was removed, and the prior limitation of use stating “the effect of NEXLIZET or NEXLETOL on cardiovascular morbidity and mortality has not been determined” was also removed. Of note, this labeling modification does not impact the full, pending label approvals for cardiovascular risk reduction indications for both drugs, which remain on track for anticipated approval on or before March 31, 2024.

- A pre-specified, exploratory analysis of CLEAR Outcomes was presented at the 2023 American Heart Association Scientific Sessions. The exploratory analysis focused on vascular inflammation, as measured by the inflammatory marker hsCRP as a major determinant of atherosclerotic risk regardless of statin use. In the exploratory analysis, participants with baseline hsCRP in the top 25% of all participants were 43% more likely to experience major adverse cardiovascular events

(MACE), twice as likely to experience cardiovascular death, and 121% more likely to experience all-cause mortality compared to those in the lowest 25%. In CLEAR Outcomes, patients who were randomized to bempedoic acid experienced a 21.6% reduction in hsCRP compared to placebo at 6 months. This analysis further differentiates bempedoic acid from other non-statin LDL-lowering therapies.

- Reported royalty revenue of $5.5 million in the fourth quarter, representing a year-over-year increase of 139%. Daiichi Sankyo Europe (DSE) launched in Spain and gained approval in the Czech Republic during the fourth quarter of 2023. Daiichi Sankyo Asia and South Central American (DS ASCA) launched in Hong Kong during the fourth quarter of 2023, marking the first territory in that region to launch.

- Our development program with Otsuka in Japan remains on track, with anticipated Japan New Drug Application (JNDA) filing in 2024, and approval and National Health Insurance (NHI) pricing in 2025.

- Preparing for regulatory filings in Canada and Australia.

Fourth Quarter and Fiscal Year 2023 Financial Results

Total revenue was $32.3 million for the three months ended December 31, 2023, and $116.3 million for the full year ended December 31, 2023, compared to $18.8 million and $75.5 million for the comparable periods in 2022, an increase of approximately 72% and 54%, respectively.

U.S. net product revenue was $20.8 million for the three months ended December 31, 2023, and $78.3 million for the full year ended December 31, 2023, compared to $15.0 million and $55.9 million for the comparable periods in 2022, an increase of 39% and 40%, respectively, driven by retail prescription growth of 44% and 30%.

Collaboration revenue was $11.5 million for the three months ended December 31, 2023, and $38.0 million for the full year ended December 31, 2023, compared to $3.9 million and $19.6 million for the comparable periods in 2022, an increase of approximately 195% and 94%, respectively, driven by increased royalty revenue and tablet shipments to international partners.

Research and development expense was $17.7 million for the three months ended December 31, 2023, and $86.1 million for the full year ended December 31, 2023, compared to $33.0 million and $118.9 million for the comparable periods in 2022, a decrease of 46% and 28%, respectively. The decrease is primarily related to the close-out of our CLEAR Outcomes study.

Selling, general and administrative expense was $45.4 million for the three months ended December 31, 2023, and $142.5 million for the full year ended December 31, 2023, compared to $24.1 million and $109.1 million for the comparable periods in 2022, an increase of 88% and 31%, respectively. The increase is related to higher legal and promotional costs in addition to increases in headcount. The Company incurred $13.1 million in legal litigation expenses in the three months ended December 31, 2023, reflecting one-time legal expenses related to litigation resolution.

The Company had net losses of $56.3 million for the three months ended December 31, 2023, and $209.2 million for the full year ended December 31, 2023, compared to net losses of $55.5 million and $233.7 million for the comparable periods in 2022, respectively.

Basic and diluted net losses per share was $0.50 for the three months ended December 31, 2023, and $2.03 for the full year ended December 31, 2023, compared to basic and diluted net losses per share of $0.76 and $3.52, for the comparable periods in 2022, respectively.

As of December 31, 2023, cash, cash equivalents, and investment securities available-for-sale totaled $82.2 million, compared with $166.9 million as of December 31, 2022. In addition, the Company improved its cash position in January 2024, resulting significantly from the cash proceeds of its follow-on equity offering, which raised approximately $90.8 million in net proceeds, and the joint settlement agreement with its European partner that resulted in a $100 million cash payment.

The Company ended the quarter with approximately 118.2 million shares of common stock outstanding, excluding 2.0 million treasury shares to be purchased in the prepaid forward transaction as part of the convertible debt financing.

2024 Financial Outlook
The Company expects full year 2024 operating expenses to be approximately $225 million to $245 million, including $20 million in non-cash expenses related to stock compensation.

Conference Call and Webcast Information
Esperion will host a webcast at 8:00 a.m. ET to discuss financial results and business progress. Please click here to pre-register to participate in the conference call and obtain your dial in number and PIN. You can also visit the Esperion website to listen to the call via live webcast. A recorded version will be available under the same link immediately following the conclusion of the conference call. Already registered? Access with your PIN here.

A live webcast can be accessed on the investors and media section of the Esperion website. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 90 days.

INDICATION
NEXLETOL /NEXLIZET is indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

IMPORTANT SAFETY INFORMATION
NEXLIZET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets. Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported with ezetimibe, a component of NEXLIZET.

Hyperuricemia: Bempedoic acid, a component of NEXLIZET and NEXLETOL, may increase blood uric acid levels which may lead to gout. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, especially in patients with a

history of gout. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.

Tendon Rupture: Bempedoic acid, a component of NEXLIZET and NEXLETOL, is associated with an increased risk of tendon rupture or injury. Tendon rupture occurred within weeks to months of starting NEXLIZET or NEXLETOL. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure, and patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Avoid NEXLIZET or NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

The most common adverse reactions in clinical trials of bempedoic acid (a component of NEXLIZET and NEXLETOL) in ≥2% of patients and greater than placebo, were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

Adverse reactions reported in ≥2% of patients treated with ezetimibe (a component of NEXLIZET) and at an incidence greater than placebo in clinical trials were upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity fatigue, and influenza.

In clinical trials of NEXLIZET, the most commonly reported adverse reactions (incidence ≥3% and greater than placebo) observed that not observed in clinical trials of bempedoic acid or ezetimibe, were urinary tract infection, nasopharyngitis, and constipation.

Discontinue NEXLIZET or NEXLETOL when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. Because of the potential for serious adverse reactions in a breast-fed infant, breastfeeding is not recommended during treatment with NEXLIZET or NEXLETOL. Report pregnancies to the Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Esperion Therapeutics
At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life's work. For more information, visit esperion.com and esperionscience.com and follow us on X at twitter.com/EsperionInc.

CLEAR Cardiovascular Outcomes Trial
CLEAR Outcomes is part of the CLEAR clinical research program for NEXLETOL® (bempedoic acid) Tablet and NEXLIZET® (bempedoic acid and ezetimibe) Tablet. The CLEAR Program seeks to generate important clinical evidence on the safety and efficacy of bempedoic acid, a first in a class ATP citrate lyase inhibitor contained in NEXLETOL and NEXLIZET and its potential role in addressing additional critical unmet medical needs. More than 60,000 people will have participated in the program by the time of its completion. The CLEAR Program includes 5 label-enabling Phase III studies as well as other key Phase IV studies with the potential to reach more than 70 million people with or at risk for CVD based on elevated LDL-C.

Forward-Looking Statements
This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding marketing strategy and commercialization plans, current and planned operational expenses, future operations, commercial products, clinical development, including the timing, designs and plans for the CLEAR Outcomes study and its results, plans for potential future product candidates, financial condition and outlook, including expected cash runway, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including, without limitation, the net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, the outcomes and anticipated benefits of legal proceedings and settlements, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Esperion disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

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Esperion Therapeutics, Inc.

Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 82,248	$ 124,775
Investments	—	42,086

Working capital	44,841	154,375
Total assets	205,796	247,939
Revenue interest liability	274,778	243,605
Convertible notes, net of issuance costs	261,596	259,899
Common stock	118	75
Accumulated deficit	(1,549,284)	(1,340,036)
Total stockholders' deficit	(454,994)	(323,778)

Esperion Therapeutics, Inc.

Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 20,760	$ 14,967	$ 78,335	$ 55,863
Collaboration revenue	11,490	3,851	37,999	19,612
Total Revenues	32,250	18,818	116,334	75,475
Operating expenses:				
Cost of goods sold	11,452	4,160	43,267	26,967
Research and development	17,742	33,033	86,107	118,927
Selling, general and administrative	45,423	24,138	142,523	109,082
Total operating expenses	74,617	61,331	271,897	254,976
Loss from operations	(42,367)	(42,513)	(155,563)	(179,501)
Interest expense	(15,057)	(14,329)	(58,976)	(56,810)
Other income, net	1,080	1,355	5,291	2,652
Net loss	$ (56,344)	$ (55,487)	$ (209,248)	$ (233,659)
Net loss per common share – basic and diluted	$ (0.50)	$ (0.76)	$ (2.03)	$ (3.52)
Weighted-average shares outstanding – basic and diluted	112,403,358	73,487,416	103,106,616	66,407,242