Esperion Reports First Quarter 2024 Financial Results

May 7, 2024

– Q1 Total Revenue Grew 467% Y/Y to $137.7 Million, Reflecting Strong Growth Globally –

– Q1 U.S. Net Product Revenue Grew 46% Y/Y to $24.8 Million –

– Q1 Retail Prescription Equivalents Grew 43% Y/Y and 6% Q/Q, Increased Momentum from Label Expansions Expected Throughout 2024 –

– Received U.S. FDA Approval of Broad New Label Expansions for NEXLETOL® (bempedoic acid) Tablet and NEXLIZET® (bempedoic acid and ezetimibe) Tablet, Becoming the First LDL-C Lowering Non-Statins to Prevent Heart Attacks and Reduce Cardiovascular Risk in Primary and Secondary Prevention Patients –

– Received Positive Opinion from the Committee for Medical Products for Human Use (CHMP); European Commission Decision for Expanded Labels Anticipated in Q2 2024 –

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

ANN ARBOR, Mich., May 07, 2024 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today reported financial results for the first quarter ended March 31, 2024, and provided a business update.

“We are proud of our strong start to 2024 and the continued momentum and growth we again delivered in the first quarter,” said Sheldon Koenig, President and CEO. “We posted retail prescription equivalent growth of 43% year-over-year, generated our highest level of revenue yet, and ended the quarter with a cash balance that positions us to capitalize on our new label and deliver long term value growth.”

“We also received FDA approval of our highly anticipated label expansions for NEXLETOL and NEXLIZET, which we believe positions us for a meaningful uptick in growth. As the only oral LDL-cholesterol (LDL-C) lowering non-statins approved for reducing cardiovascular risk in both primary and secondary prevention patients, our expanded labels will enable us to potentially reach more than 70 million new patients in need of an alternative therapy. We believe this approval brings us closer to bridging the statin gap, which encompasses an underserved patient population that is unable to reach their LDL-C goal on current therapies alone.”

“We have prioritized investment in our commercial strategy, including ramping up our sales force, launching our new Lipid Lurker consumer campaign, developing a suite of new promotional materials, and initiating partnerships to provide improved interim access with the payer and patient communities. We’re also pleased to report utilization management criteria updates that will be made by two major payers in the next two months that covers 40 million lives, and anticipate additional payers aligning with our new labels on a weekly basis. Looking to our global ex-U.S. franchise., our partner Daiichi Sankyo Europe (DSE) continued to drive increased sales across newly launched territories, signaling the growth potential of these products globally. In summary, with our reinforced commercial infrastructure and recent payer wins, we are poised for significant growth and I look forward to sharing our progress in the coming quarters.”

First Quarter 2024 Key Accomplishments and Recent Highlights

- Granted expanded label from the FDA for NEXLETOL and NEXLIZET on March 22, 2024. The label expansion added prevention of heart attacks and reduction of cardiovascular risk as indications and expanded the LDL-C lowering indication to include use with or without a statin. The updates to the label expand accessibility by approximately 70 million patients in the U.S.

- Initiated new commercial initiatives to increase patient awareness of NEXLETOL and NEXLIZET’s expanded labels. Expanded our sales force to 150 representatives in the U.S. and developed new promotional materials and tools to supplement salesforce efforts. Initiated partnerships to provide interim patient access while working with payers to update utilization management criteria and streamline transition to the new and expanded labels.

- Received positive opinions from the Committee for Medical Products for Human Use (CHMP) of the European Medical Agency (EMA) on March 22, 2024. The opinions were based on the updated label of NILEMDO® (bempedoic acid) and NUSTENDI® (bempedoic acid / ezetimibe fixed dose combination), which were recommended for the reduction of LDL-C and cardiovascular risk. The European Commission is expected to deliver its determination on the pending label update applications in the second quarter of 2024.

- Reported royalty revenue of $6.6 million in the first quarter, representing a year-over-year increase of 164%. DSE launched in the Netherlands, Czech Republic, and Slovakia during the first quarter of 2024. Daiichi Sankyo Company, Limited (“DS ASCA”) received approvals in Thailand and Myanmar during the first quarter of 2024.

- Presented prespecified subgroup analyses from the CLEAR Outcomes trial at ACC 2024. The subgroup analyses evaluated key underserved and understudied populations, including patients with obesity, women, and Hispanics/Latinx.

CLEAR Outcomes enrolled 48% women and 17% Hispanic/Latinx patients, setting a new standard for diversity and inclusion in clinical trials. NEXLETOL demonstrated a 23% reduction in major adverse cardiovascular events (MACE-4) versus placebo in obese patients and had clinical benefits in women and Hispanic/Latinx patients with and without cardiovascular disease.

- Initiated the technology transfer process for NILEMDO and NUSTENDI tablet manufacturing to DSE for its territories, which we expect to be completed in the second half of 2025. Additionally, as part of our amended partnership, we authorized DSE to proceed with commercialization of a triple formulation product comprising bempedoic acid, ezetimibe, and a statin, which, if approved, has the potential to meaningfully extend the product's lifecycle in Europe.

- Our collaboration with Otsuka in Japan remains on track, with Otsuka's phase III study expected to close out in Q2 2024, an anticipated Japan New Drug Application (JNDA) filing in late 2024, and approval and National Health Insurance (NHI) pricing in 2025.

First Quarter 2024 Financial Results

Total revenue was $137.7 million, compared to $24.3 million for the comparable period in 2023, an increase of approximately 467%.

U.S. net product revenue was $24.8 million, compared to $17.0 million for the comparable period in 2023, an increase of approximately 46%, driven by retail prescription growth of 43%.

Collaboration revenue was $113.0 million, compared to $7.3 million for the comparable period in 2023, an increase of 1,448%, driven by increased tablet sales to our international partners and sales growth within partner territories along with the settlement related milestone payment.

Research and development expenses were $13.4 million, compared to $31.4 million for the comparable period in 2023, a decrease of 57%. The decrease is primarily related to the close-out of our CLEAR Outcomes study.

Selling, general and administrative expenses were $42.0 million, compared to $29.9 million for the comparable period in 2023, an increase of 40%. The increase is primarily related to the ramp up of our sales force ahead of our commercial launch in addition to bonus payments and promotional costs.

Total net income for the quarter was $61.0 million, compared to a net loss of $61.7 million for the comparable period in 2023.

Basic net income per share was $0.36, compared to basic and diluted net loss per share of $0.79 for the comparable period in 2023. Diluted net income per share was $0.34.

As of March 31, 2024, cash and cash equivalents totaled $226.6 million, which includes our legal settlement and $90.7 million in net proceeds from our underwritten public offering in January 2024, compared with $82.2 million as of December 31, 2023.

The Company ended the quarter with approximately 187.9 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 still 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.

A live audio webcast can be accessed on the investor and media section of the Esperion website at esperion.com/investor-relations/events. 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
NEXLIZET and NEXLETOL are indicated:

- The bempedoic acid component of NEXLIZET and NEXLETOL is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
    - established cardiovascular disease (CVD), or
    - at high risk for a CVD event but without established CVD.
- As an adjunct to diet:
    - NEXLIZET, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.
    - NEXLETOL, in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.

IMPORTANT SAFETY INFORMATION
NEXLIZET and NEXLETOL are contraindicated in patients with a prior hypersensitivity to bempedoic acid or ezetimibe or any of the excipients.

Serious hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported.

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, returning to baseline following discontinuation of treatment. 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 may occur more frequently in patients over 60 years of age, in those taking corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Consider alternative therapy in patients who have a history of tendon disorders or tendon rupture.

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

The most common adverse reactions in the cardiovascular outcomes trial for bempedoic acid, a component of NEXLIZET and NEXLETOL, at an incidence of ≥2% and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

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 Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Please see full Prescribing Information for NEXLIZET and NEXLETOL.

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.

Esperion Contact Information:
Investors:
investorrelations@esperion.com

Media:
Tiffany Aldrich
corporateteam@esperion.com
(616) 443-8438

Esperion Therapeutics, Inc.

Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 226,609	$ 82,248
Working capital	201,094	44,841
Total assets	373,060	205,796
Revenue interest liability	279,883	274,778
Convertible notes, net of issuance costs	262,033	261,596
Common stock	188	118
Accumulated deficit	(1,488,262)	(1,549,284)
Total stockholders' deficit	(294,298)	(454,994)

Esperion Therapeutics, Inc.

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

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Product sales, net	$ 24,756	$ 17,031
Collaboration revenue	112,979	7,298
Total Revenues	137,735	24,329
Operating expenses:		
Cost of goods sold	10,075	11,652
Research and development	13,403	31,381
Selling, general and administrative	41,988	29,901
Total operating expenses	65,466	72,934
Income (loss) from operations	72,269	(48,605)
Interest expense	(14,024)	(14,387)
Other income, net	2,777	1,273
Net income (loss)	$ 61,022	$ (61,719)
Net income (loss) per common share - basic	$ 0.36	$ (0.79)
Net income (loss) per common share - diluted	$ 0.34	$ (0.79)
Weighted-average shares outstanding - basic	169,258,564	78,440,266
Weighted-average shares outstanding - diluted	189,641,251	78,440,266