Esperion Reports Second Quarter 2023 Financial Results

August 1, 2023

– Q2 U.S. Net Product Revenue Grew 49% Y/Y to $20.3 Million –

– Q2 Retail Prescription Equivalents Grew 26% Y/Y; Q2 New to Brand Prescriptions Grew 28% Q/Q –

– Submitted Applications for Expanded Indications in the U.S. and Europe; Label Changes Expected in 1H 2024 –

– Presented New CLEAR Outcomes Analysis, Demonstrating Significant Cardiovascular Risk Reduction of Bempedoic Acid in Primary Prevention Population, Increasing Addressable Market to 70 Million Patients in U.S. –

ANN ARBOR, Mich., Aug. 01, 2023 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today reported financial results for the second quarter ended June 30, 2023, and provided a business update.

“We posted strong results in the second quarter of 2023, reflecting continued prescription growth and an unwavering commitment to execution of our strategic plan,” said Sheldon Koenig, President and Chief Executive Officer of Esperion. “Following the presentation of our CLEAR Outcomes results in March, we subsequently filed regulatory applications in both the U.S. and Europe to meaningfully expand the current indications and remove restrictions for use of NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe). This was a significant accomplishment and one that positions us for regulatory approval of label expansion in both jurisdictions in the first half of next year, which we believe will serve as a catalyst for further growth and ultimately result in blockbuster status for our novel therapies.”

“In addition, we presented new and meaningful data from our landmark trial at several medical conferences during the quarter. Of note, an unprecedented analysis highlighting significant cardiovascular risk reduction in a primary prevention patient population from CLEAR Outcomes was featured at the American Diabetes Association (ADA) Meeting and simultaneously published by the *Journal of the American Medical Association* (JAMA). Many patients without ASCVD but who are at high risk for ASCVD events have not had a new lipid-lowering option proven to lower cardiovascular risk since statins. Our impressive outcomes data clearly demonstrate the effectiveness of bempedoic acid not only in secondary prevention patients, but also in the primary prevention population, meaningfully expanding the number of patients who could benefit from NEXLETOL and NEXLIZET to achieve their LDL-C goals and reduce their cardiovascular risk. These results continue to demonstrate the significant benefits of our therapies as the clear next step in treatment after statins,” he concluded.

Second Quarter 2023 Key Accomplishments and Recent Highlights

- Announced the submission of its Supplemental New Drug Applications (sNDAs) for NEXLETOL and NEXLIZET to the Food and Drug Administration (FDA), and the submission of an application for expanded indication for NILEMDO® (bempedoic acid) and NUSTENDI® (bempedoic acid and ezetimibe) to the European Medicines Agency (EMA). Both applications seek the addition of bempedoic acid for use in cardiovascular risk reduction in patients with or at high risk for atherosclerotic cardiovascular disease. The Company anticipates approvals in both the U.S. and Europe in the first half of 2024.
- Presented key results from CLEAR Outcomes primary prevention analysis at the 83rd American Diabetes Association (ADA) Scientific Sessions, with simultaneous publication of the data in the renowned peer-reviewed *Journal of the American Medical Association (JAMA*). Bempedoic acid is the first LDL-lowering therapy since statins to demonstrate cardiovascular risk reduction in a primary prevention population, patients who have not yet had a cardiovascular event, but who are at high risk for one. This data expands the Company’s addressable market to 70 million patients in the U.S. alone.
- Presented additional data from CLEAR Outcomes comparing the cardiovascular risk reduction benefits of bempedoic acid treatment with statins at the Endocrine Society Meeting (ENDO 2023). Results demonstrated that the cardiovascular risk reduction benefit of bempedoic acid treatment is comparable to that of statins based on an analysis of per unit decrease in LDL-C, using the Cholesterol Treatment Trialists’ (CTT) methodology.
- Acceptance of two late-breaker presentations at the European Society of Cardiology (ESC) Congress 2023 in August: Clear Outcomes Total Events Analysis, presented by Stephen J Nicholls, and Clear Outcomes Analysis by Glycaemic Status, presented by Kausik K Ray.

Second Quarter and YTD 2023 Financial Results

Total revenue for the second quarter ended June 30, 2023, was $25.8 million and $50.1 million for the six months ended June 30, 2023, compared to $18.8 million and $37.7 million for the comparable periods in 2022, an increase of 37% and 33%, respectively.

U.S. net product revenue for the second quarter ended June 30, 2023, was $20.3 million and $37.3 million for the six months ended June 30, 2023, compared to $13.6 million and $26.9 million for the comparable periods in 2022, an increase of 49% and 39%, respectively, driven by retail prescription growth of 26% and 21%.

Collaboration revenue for the second quarter ended June 30, 2023, was $5.5 million and $12.8 million for the six months ended June 30, 2023, compared to $5.3 million and $10.7 million for the comparable periods in 2022, an increase of 4% and approximately 20%, respectively, driven by

increased royalty revenue, partially offset by timing of tablet shipments to international partners.

Research and development expenses for the second quarter ended June 30, 2023, were $22.1 million and $53.5 million for the six months ended June 30, 2023, compared to $32.4 million and $56.8 million for the comparable periods in 2022, a decrease of 32% and 6%, respectively. The decrease is primarily related to lower costs related to our CLEAR Outcomes study following the announcement and presentation of the full study results in March 2023.

Selling, general and administrative expenses for the second quarter ended June 30, 2023, were $34.0 million and $63.9 million for the six months ended June 30, 2023, compared to $29.6 million and $60.0 million for the comparable periods in 2022, an increase of 15% and approximately 7%, respectively, primarily related to upfront training costs for our contract sales force and higher legal costs.

The Company had net losses of $49.9 million for the second quarter ended June 30, 2023, and $111.7 million for the six months ended June 30, 2023, compared to net losses of $66.3 million and $123.1 million for the comparable periods in 2022, respectively.

Basic and diluted net losses per share was $0.46 for the second quarter ended June 30, 2023, and $1.19 for the six months ended June 30, 2023, compared to basic and diluted net losses per share of $1.05 and $1.98, for the comparable periods in 2022, respectively.

As of June 30, 2023, cash, cash equivalents, and investment securities available-for-sale totaled $138.5 million, compared with $166.9 million on December 31, 2022.

The Company ended the quarter with approximately 100.9 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.

Reiterating 2023 Financial Outlook

The Company still expects full year 2023 operating expenses to be approximately $225 million to $245 million, including $25 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 and NEXLIZET are indicated as adjuncts to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.
Limitations of Use: The effect of NEXLETOL and NEXLIZET on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION
Contraindications: NEXLETOL has no contraindications. 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.

Warnings and Precautions: Hyperuricemia: Bempedoic acid, a component of NEXLETOL and NEXLIZET, may increase blood uric acid levels. 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 is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid versus 0% of patients treated with placebo, and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Tendon rupture occurred within weeks to months of starting bempedoic acid. 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 NEXLETOL or NEXLIZET at the first sign of tendon rupture. Avoid NEXLETOL and NEXLIZET in patients who have a history of tendon disorders or tendon rupture.

Adverse Reactions: In NEXLETOL clinical trials, the most commonly reported adverse reactions were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Reactions reported less frequently, but still more often than with placebo, included benign prostatic hyperplasia and atrial fibrillation.

In the NEXLIZET clinical trial, the most commonly reported adverse reactions observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, a component of NEXLIZET, and occurring more frequently than with placebo, were urinary tract infection, nasopharyngitis, and constipation.

Adverse reactions reported in clinical trials of ezetimibe, and occurring at an incidence greater than with placebo, included upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza. Other adverse reactions reported in postmarketing use of ezetimibe included hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria; erythema multiforme; myalgia; elevated creatine phosphokinase; myopathy/rhabdomyolysis; elevations in liver transaminases; hepatitis; abdominal pain; thrombocytopenia; pancreatitis; nausea; dizziness; paresthesia; depression; headache; cholelithiasis; cholecystitis.

Drug Interactions*: Simvastatin and Pravastatin:* Concomitant use with bempedoic acid results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use of either NEXLETOL or NEXLIZET with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

Cyclosporine: Caution should be exercised when using NEXLIZET and cyclosporine concomitantly due to increased exposure to both ezetimibe and cyclosporine. Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine. In patients treated with cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by NEXLIZET.

Fibrates: Coadministration of NEXLIZET with fibrates other than fenofibrate is not recommended. Fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to cholelithiasis. If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered.

Cholestyramine: Concomitant use of NEXLIZET and cholestyramine decreases ezetimibe concentration. This may result in a reduction of efficacy. Administer NEXLIZET either at least 2 hours before, or at least 4 hours after, bile acid sequestrants.

Lactation and Pregnancy: It is not recommended that NEXLETOL or NEXLIZET be taken during breastfeeding. Discontinue NEXLETOL or NEXLIZET when pregnancy is recognized, unless the benefits of therapy outweigh the potential risks to the fetus. Based on the mechanism of action of bempedoic acid, NEXLETOL and NEXLIZET may cause fetal harm.

Please see full Prescribing Information here.

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 Twitter 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 impact of the ongoing COVID-19 pandemic on our business, revenues, results of operations and financial condition, the net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, the outcomes of legal proceedings, 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)

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 138,470	$ 124,775
Investments	—	42,086
Working capital	124,952	154,375
Total assets	234,626	247,939
Revenue interest liability	259,774	243,605

Convertible notes, net of issuance costs	260,738	259,899
Common stock	101	75
Accumulated deficit	(1,451,690)	(1,340,036)
Total stockholders' deficit	(371,978)	(323,778)

Esperion Therapeutics, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 20,293	$ 13,578	$ 37,324	$ 26,932
Collaboration revenue	5,493	5,263	12,791	10,745
Total Revenues	25,786	18,841	50,115	37,677
Operating expenses:				
Cost of goods sold	6,786	9,176	18,438	16,301
Research and development	22,099	32,432	53,480	56,751
Selling, general and administrative	33,959	29,609	63,860	59,990
Total operating expenses	62,844	71,217	135,778	133,042
Loss from operations	(37,058)	(52,376)	(85,663)	(95,365)
Interest expense	(14,537)	(14,266)	(28,924)	(28,328)
Other income, net	1,660	318	2,933	638
Net loss	$ (49,935)	$ (66,324)	$ (111,654)	$ (123,055)
Net loss per common share – basic and diluted	$ (0.46)	$ (1.05)	$ (1.19)	$ (1.98)
Weighted-average shares outstanding – basic and diluted	109,243,845	63,227,406	93,927,148	62,097,358