

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **June 24, 2023**

Esperion Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-35986
(Commission File Number)

26-1870780
(I.R.S. Employer
Identification No.)

3891 Ranchero Drive, Suite 150
Ann Arbor, MI
(Address of principal executive offices)

48108
(Zip Code)

Registrant's telephone number, including area code: **(734) 887-3903**

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ESPR	NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On June 24, 2023, Esperion Therapeutics, Inc. (the “Company”) announced the results from its pre-specified, primary prevention CLEAR Outcomes subgroup analysis, which were presented at the 83rd American Diabetes Association Scientific Sessions and simultaneously published in the *Journal of the American Medical Association*. A copy of the press release is being furnished herewith as Exhibit 99.1.

The information contained in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Information.*Business Update*

The Company is filing information for the purpose of supplementing and updating certain aspects of the description of its business from that described under the heading, “Item 1. Business” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (the “SEC”) on February 21, 2023. The updated disclosure is set forth below:

On June 24, 2023, the Company announced the results from its pre-specified, primary prevention CLEAR Outcomes subgroup analysis. The primary prevention patient population included 4,206 statin-intolerant patients from the CLEAR Outcomes trial (30% of the total 13,970 patients) who had no prior cardiovascular events, LDL-C level greater than or equal to 100 mg/dL at the start of the study, and who were at high risk for cardiovascular events.

Results from this primary prevention analysis show significant reduction in cardiovascular risk, including a 36% risk reduction of MACE-3 (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death), and a 30% risk reduction of MACE-4 (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke, coronary revascularization and cardiovascular death) in the primary prevention population.

Forward-Looking Statements

This Form 8-K contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding expected operational expenses, expected revenue of our commercial products, future operations, expected milestone payments from partners, commercial products and expected growth, clinical development and regulatory submissions, 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 the Company’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 the Company’s commercial products, clinical activities and results, supply chain, commercial development and launch plans, and the risks detailed in the Company’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.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated June 24, 2023.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 26, 2023

Esperion Therapeutics, Inc.

By: /s/ Sheldon L. Koenig
Sheldon L. Koenig
President and Chief Executive Officer

Esperion Presents Results from CLEAR Outcomes Primary Prevention Analysis at 83rd American Diabetes Association Scientific Sessions

- 30% risk reduction of MACE-4 composite of death from cardiovascular causes, and >25% risk reduction across four key secondary endpoints in primary prevention population, including 27% reduction in all-cause mortality –
- Bempedoic acid is the first LDL-lowering therapy since statins to demonstrate cardiovascular risk reduction in a primary prevention population –
 - Of the patients included in the primary prevention population, nearly two-thirds were diabetic –
 - Results simultaneously published in the *Journal of the American Medical Association (JAMA)* –

ANN ARBOR, Mich., June 24, 2023 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) announced the results from the pre-specified, primary prevention CLEAR Outcomes subgroup analysis at the 83rd American Diabetes Association (ADA) Scientific Sessions.

Results from this primary prevention analysis show a significant reduction in cardiovascular risk, including a 36% risk reduction of MACE-3 (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death), and a 30% risk reduction of MACE-4 (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke, coronary revascularization and cardiovascular death) in the primary prevention population. The data were simultaneously published in the renowned peer-reviewed *Journal of the American Medical Association (JAMA)*. The article, entitled “Bempedoic Acid for Primary Prevention of Cardiovascular Events in Statin-Intolerant Patients,” can be found [here](#).

“We are thrilled with the results from the primary prevention analysis of the CLEAR Outcomes study presented at the ADA Scientific Sessions and simultaneously published in the *Journal of the American Medical Association*,” said Sheldon Koenig, President and CEO of Esperion. “This analysis represents a significant opportunity to expand how many people can benefit from bempedoic acid, to the tune of 70 million patients. This large subgroup analysis supports the use of bempedoic acid, available as NEXLETOL[®] or in combination with ezetimibe as NEXLIZET[®], in the primary prevention population, for those patients at high risk for atherosclerotic cardiovascular disease (ASCVD) or a cardiovascular event. Now, more than ever, we believe that bempedoic acid offers an evidence-based option for patients who are not on statins and those not able to tolerate statins, as well as those who would benefit from primary or secondary cardiovascular event prevention strategies.”

“These findings demonstrate the importance of lowering LDL cholesterol in people who are at high risk of having a heart attack, but who have not had one to date,” noted Stephen Nicholls, MD, Director of the Victorian Heart Hospital and Institute and Monash University, Melbourne, Australia. “Many of these patients could not tolerate statins and needed a new option, and CLEAR Outcomes demonstrated that bempedoic acid proved to be effective not only in lowering LDL cholesterol, but also in lowering the rate of cardiovascular risk in primary prevention patients.”

JoAnne Foody, MD, FACC, FAHA, Chief Medical Officer of Esperion commented, “Patients at high risk of cardiovascular disease without a history of ASCVD, including those with diabetes, have few proven lipid lowering therapies that reduce cardiovascular risk. Bempedoic acid’s novel ATP citrate lyase inhibition is the first LDL-C lowering mechanism since statins to demonstrate cardiovascular risk reduction in primary prevention patients in a cardiovascular outcomes trial. Other non-statin LDL-C lowering therapies, such as ezetimibe and PCSK9s, have only been studied in secondary prevention (ASCVD) populations. We believe this analysis from CLEAR Outcomes supports the use of bempedoic acid earlier in the treatment paradigm to achieve LDL-C goals and reduce cardiovascular risk in a broad range of primary and secondary prevention patients.”

Key Highlights from the Primary Prevention Analysis:

The primary prevention patient population included 4,206 statin-intolerant patients from the CLEAR Outcomes trial (30% of the total 13,970 patients) who had no prior cardiovascular events, LDL-C level greater than or equal to 100 mg/dL at the start of the study, and who were at high risk for cardiovascular events (“primary prevention group”). Patients were randomized to receive oral bempedoic acid 180 mg daily (n=2,100) or placebo (n=2,106). Notable groups represented in this analysis included 59% (n=2,481) female, 18.5% (n=777) Hispanic/Latino ethnicity, and 66.1% (n=2,781) patients with diabetes.

For the primary endpoint, bempedoic acid demonstrated the following versus placebo:

- 30% reduced risk [hazard ratio (HR) 0.70 (95% CI 0.55-0.89)] of the primary efficacy endpoint of MACE-4
 - o This equates to 43 patients being treated with bempedoic acid to prevent one primary cardiovascular event

For key secondary endpoints, bempedoic acid demonstrated the following versus placebo:

- 39% reduced risk for cardiovascular mortality; HR 0.61 (95% CI 0.41-0.92)
- 39% reduced risk of myocardial infarction; HR 0.61 (95% CI 0.39-0.98)
- 36% reduced risk of MACE-3; HR 0.64 (95% CI 0.48-0.84)
- 27% reduced risk for all-cause mortality; HR 0.73 (95% CI 0.54-0.98)

Bempedoic Acid Effects on LDL Cholesterol and High-Sensitivity C-Reactive Protein:

- 21.5% reduction in high sensitivity C-reactive protein (hsCRP) after 12 months of treatment vs. placebo
- 21.3% reduction in LDL-C after 6 months of treatment vs. placebo

Adverse events in this primary prevention subpopulation were consistent with those seen in the overall study population and included higher incidences of hyperuricemia (12.1% vs. 6.3%), gout (2.6% vs. 2.0%), and cholelithiasis (2.5% vs. 1.1%) for those receiving bempedoic acid versus placebo.

INDICATION

Bempedoic acid is indicated as an adjunct 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 bempedoic acid on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Hyperuricemia: Bempedoic acid 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 bempedoic acid at the first sign of tendon rupture. Avoid bempedoic acid in patients who have a history of tendon disorders or tendon rupture.

Adverse Reactions: In 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.

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

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

Please see full Prescribing Information [here](#).

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.

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.

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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