# 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): January 8, 2023

# **Esperion Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

Delaware 001-35986

(State or other jurisdiction of incorporation) (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 ollowing provisions:	intended to simultaneously satisfy th	he filing obligation of the registrant under any of the
Written communications pursuant to Rule 425 under th	e Securities Act (17 CFR 230.425)	
Soliciting material pursuant to Rule 14a-12 under the E	Exchange Act (17 CFR 240.14a-12)	
Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchange Act (17	7 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17	7 CFR 240.13e-4(c))
ecurities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ESPR	NASDAQ Stock Market LLC
ndicate by check mark whether the registrant is an emerg ecurities Exchange Act of 1934.	ing growth company as defined in R	ule 405 of the Securities Act of 1933 or Rule 12b-2 of the
		Emerging growth company
f an emerging growth company, indicate by check mark is r revised financial accounting standards provided pursual	· ·	e the extended transition period for complying with any new Act.

#### Item 2.02. Results of Operations and Financial Condition.

On January 8, 2023, Esperion Therapeutics, Inc. issued a press release announcing preliminary 2022 results and upcoming corporate milestones. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 2.02 by reference.

The information in 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, as amended (the "Exchange Act") 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description	
<u>99.1</u>	Press Release dated January 8, 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: January 9, 2023 Esperion Therapeutics, Inc.

By: /s/ Sheldon L. Koenig

Sheldon L. Koenig

President and Chief Executive Officer

# **Esperion Outlines Upcoming Milestones and Announces Preliminary Fourth Quarter 2022 Financial Results**

- Based on the robustness of the CLEAR Outcomes data across primary and secondary endpoints, Company anticipates global regulatory submissions in 1H 2023 and believes it is entitled to receive milestone payments from partners upon regulatory approvals –
- Fourth quarter 2022 U.S. net product revenue estimated between \$14.4 to \$15.1 million, FY growth between 38% and 40% year over year
  - New partnership with RFK Racing to increase brand awareness and drive accelerated growth -
    - Company presenting at J.P. Morgan 41st Annual Healthcare Conference -

**ANN ARBOR, Mich., January 8, 2023** (GLOBE NEWSWIRE) – Esperion (NASDAQ: ESPR) today announced preliminary, unaudited fourth-quarter 2022 financial results and highlighted key upcoming anticipated milestones which represent continued execution of the Company's transformational plan.

"Esperion stands committed to our strategic vision of driving accelerated growth and expansion of our bempedoic acid franchise, with the ultimate goal of reducing LDL cholesterol and improving cardiovascular outcomes, particularly in patients who are unable to tolerate or reach their goals with statins," said Sheldon Koenig, Esperion's president and chief executive officer. "With the robust CLEAR Outcomes data being presented and supporting regulatory submissions in the first half of 2023, we are poised to deliver significant value for shareholders in the coming months, as we look forward to potential label expansion and believe we will be entitled to receive partner milestone payments upon regulatory approvals. In line with our goal of increasing cardiovascular health awareness, we are also pleased to announce a new partnership with RFK Racing, which will provide ample opportunities for community engagement and education to their large and diverse consumer base. We look forward to building on our momentum in 2023 and beyond as we seek to maximize our opportunity with NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) and drive the franchise towards blockbuster status."

#### **Preliminary Q4 2022 Financial Results**

Preliminary, unaudited fourth-quarter 2022 net U.S. product sales are expected to be between \$14.4 to \$15.1 million; FY growth between 38% and 40% year over year.

As of December 31, 2022, cash and investment securities available-for-sale totaled approximately \$167 million and there were approximately 74.6 million shares of common stock outstanding, excluding the 2.0 million treasury shares to be purchased in the prepaid forward transaction as part of the convertible debt financing.

The preliminary unaudited results described in this press release are estimates only and are subject to revision until the Company reports its full financial results for the fourth guarter and full year 2022 in late February.

# **Regulatory and Milestone Updates from Partners**

Esperion anticipates submission of the CLEAR Outcomes package to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in the first half of 2023. Regulatory submissions will be supported by positive CLEAR Outcomes data, which met the major adverse cardiovascular events (MACE-4) primary endpoint as well as several key secondary endpoints. Based on the robustness of the CLEAR Outcomes data, the Company believes it would be entitled to receive milestone payments from collaborative partners upon inclusion of cardiovascular risk reduction data in the US and European labels.

## **RFK Racing Partnership**

Esperion is also announcing a new partnership with RFK Racing, which is part of the company's multi-dimensional approach to advance consumer awareness about the benefits of lowering LDL cholesterol and improving cardiovascular health. This 12-month, 360° marketing platform is focused on national consumer awareness, community engagement and patient education. The campaign will target the 10+ million RFK Racing fanbase, millions of whom report being diagnosed with high cholesterol and are more likely than non-fans to be diagnosed with and currently treating cardiovascular conditions. Awareness and education events will include the big race in February, sponsorship of the RFK Fan Day 5K road race, and other events throughout 2023.

#### **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**

Esperion works hard to make our medicines easy to get, easy to take, and easy to have. We discover, develop, and commercialize innovative medicines and combinations to lower cholesterol, especially for patients whose needs aren't being met by the status quo. Our entrepreneurial team of industry leaders is inclusive, passionate and resourceful. We are singularly focused on managing cholesterol so you can improve your health easily. For more information, please visit esperion.com and follow us on Twitter at www.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 expected operational expenses, expected revenue of our commercial products, future operations, expected milestone payments from partners, commercial products and expected growth, clinical development, 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, 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.

#### Contact:

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