

**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): **March 15, 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 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:

As previously disclosed, on March 4, 2023, the Company announced the full results from its Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial. CLEAR Outcomes was a global study of nearly 14,000 patients with or at risk for cardiovascular disease who were unable to maximize or tolerate a statin. The study showed that NEXLETOL significantly reduced the risk of hard MACE-4 and MACE-3 by 13% and 15%, respectively, and significantly reduced the risk of heart attack and coronary revascularization by 23% and 19%, respectively, as compared to placebo. These results were seen in a broad population of primary and secondary prevention patients who are unable to maximize or tolerate a statin. The proportions of patients experiencing adverse events and serious adverse events were similar between the active and placebo treatment groups. Bempedoic acid (contained in NEXLEOL and NEXLIZET® (bempedoic acid and ezetimibe) tablets) now becomes the first LDL-C lowering therapy since statins proven to lower hard ischemic events, not only in those with ASCVD but also in the large number of primary prevention patients for whom limited therapies exist.

The Company believes that it remains on track to submit regulatory filings to the FDA and EMA in the first half 2023. Based on the robustness of the CLEAR Outcomes data, the Company believes it would be entitled to receive \$300 million in partner milestone payments upon inclusion of cardiovascular risk reduction data in the EU label, for which payment is tied to the magnitude of the risk percentage reduction included in the label (among other requirements) and ranges from \$200 million for the inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate that, based on the CLEAR Outcomes data, is equal or greater than 15% but less than 20% to \$300 million if such risk reduction in the EU label that correlates with a relative risk reduction rate is equal or greater than 20%, and up to \$140 million in partner milestone payments upon the achievement of other regulatory milestones, including inclusion of certain required cardiovascular risk reduction data in the US label. The Company has had communications with Daiichi Sankyo Europe (DSE) regarding potential milestone payments in which DSE has conveyed that it disagrees with the Company’s assessment that the CLEAR Outcomes data would support the Company’s right to receive any milestone payments upon inclusion of certain required cardiovascular risk reduction data in the EU label, because the CLEAR Outcomes study showed a 12.98% reduction in MACE-4, the primary endpoint of the trial. The Company strongly disagrees and continues to believe that, pursuant to Section 9.2 of the Company’s license and collaboration agreement with DSE, which refers only to cardiovascular risk reduction and not to any primary endpoint, it would be entitled to receive such payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the CLEAR Outcomes trial demonstrating a significant reduction of fatal and non-fatal myocardial infarction by 23%. If necessary, the Company intends to enforce its contractual rights and seek the milestone payments it believes it is entitled to. Even if the Company is successful in enforcing its rights, there could be a delay in the Company’s receipt of the milestone payments as a result of any dispute relating to such payments. Any failure to receive or any delay in receipt of the milestone payments may significantly impact the Company’s future capital needs.

In addition, while the Company believes it would be entitled to receive such funds upon meeting the foregoing requirements, the Company cautions that receipt of any milestone payment amounts is subject to risks and uncertainties, including the Company obtaining the relevant regulatory approvals and marketing authorizations, the approval of the required EU and US labels, the absence of any material disagreements or disputes with regulators or our collaboration partners and the ultimate timing and payment of such milestone payment amounts by our collaboration partners. In addition, while the Company expects that it will be entitled to the foregoing milestone payments, its inability to receive some or all of its milestone payments and other royalty amounts from its collaboration partners may significantly impact its future capital needs.

### **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.

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**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: March 15, 2023

Esperion Therapeutics, Inc.

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

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