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**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): **May 23, 2018**

**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))

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.

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**Item 8.01 Other Events**

On May 23, 2018, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces Third Pivotal Phase 3 Study of Bempedoic Acid Meets Primary Endpoint” (the “Press Release”). A copy of the Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 23, 2018.

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated May 23, 2018.</a>

**SIGNATURE**

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: May 23, 2018

Esperion Therapeutics, Inc.

By: /s/ Tim M. Mayleben  
Tim M. Mayleben  
President and Chief Executive Officer



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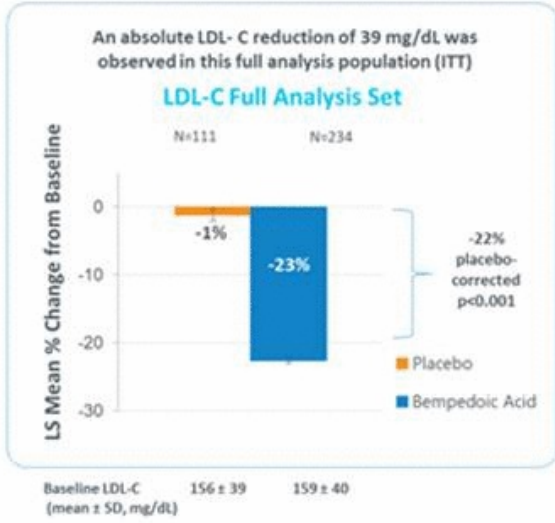
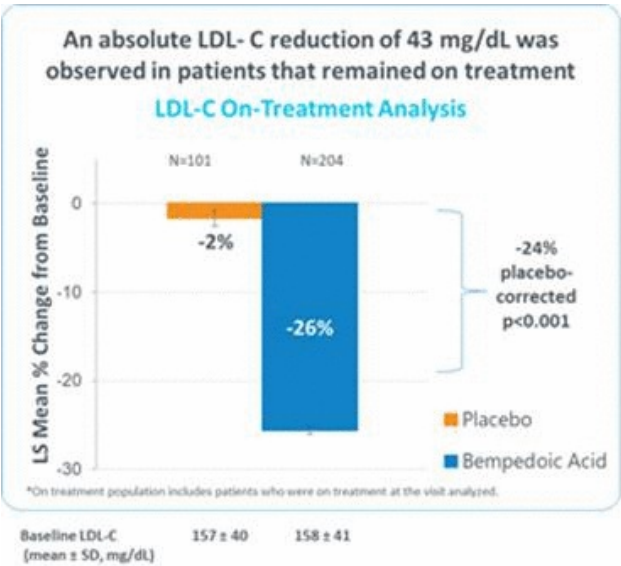
**Esperion Announces Third Pivotal Phase 3 Study of Bempedoic Acid  
 Meets Primary Endpoint**

- *Study 3 Achieves Additional 26% LDL-C Lowering on Background of Maximally Tolerated LDL-C Lowering Therapy in Patients Considered Statin Intolerant* —
- *Additional hsCRP Reduction of 25%* —
- *Cumulative Phase 2 / Phase 3 Demonstrates Broad Efficacy as well as Safety and Tolerability* —
- *Conference Call and Webcast on Wednesday, May 23, 2018, at 8:45 a.m. Eastern Time* —

Ann Arbor, Mich., — (Globe Newswire — May 23, 2018) — Esperion (NASDAQ: ESPR), the Lipid Management Company focused on developing and commercializing complementary, convenient, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced positive top-line results from the third of five pivotal Phase 3 studies (Study 3 or 1002-046) expected to be reported this year. This study evaluated the LDL-C lowering efficacy and the safety and tolerability of bempedoic acid 180 mg versus placebo in high-risk patients with atherosclerotic cardiovascular disease (ASCVD), or at high risk for ASCVD with hypercholesterolemia, inadequately treated with maximally tolerated background LDL-C lowering therapy who are only able to tolerate less than the approved daily starting dose of a statin and considered statin intolerant. Importantly, these results are consistent with the previously reported results in patients considered statin intolerant.

The 24-week study achieved LDL-C lowering totaling 26 percent in patients on bempedoic acid who remained on treatment at both week 12 and week 24 (an absolute reduction of 43 mg/dL) compared with placebo which had a decrease of two percent ( $p < 0.001$ ). The study met its primary endpoint with LDL-C lowering of 23 percent at 12 weeks in the intent to treat (ITT) analysis (an absolute reduction of 39 mg/dL), compared with placebo which had a decrease of one percent ( $p < 0.001$ ). Patients treated with bempedoic acid also achieved a significantly greater reduction of 25 percent in high-sensitivity C-reactive protein (hsCRP), an important marker of the underlying inflammation associated with cardiovascular disease, compared with placebo which had an increase of three percent ( $p < 0.001$ ).

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In this study in statin-intolerant patients, bempedoic acid was observed to be safe and well-tolerated and with no fatalities observed in either group. Importantly, muscle-related adverse events were lower in the bempedoic acid group than in the placebo group. There were no clinically relevant differences in the occurrence of adverse events (AEs) and no differences between the treatment group and the placebo group in discontinuations due to muscle-related AEs which are commonly associated with statin intolerance. Serious adverse events (SAEs) in the bempedoic acid arm were 6.0 percent compared to 3.6 percent in the placebo arm. None of the SAEs were deemed to be related to bempedoic acid by the study investigator. Discontinuations due to AEs were 18.4 percent and 11.7 percent, respectively, for the treatment and placebo groups; importantly, there was no single class of events or event that was responsible for the difference. The rate of elevations in liver function tests in this study was 0.43 percent, repeated and confirmed. This is consistent with the 0.56 percent rate observed across the entire program and with all other previously approved and successful oral LDL-C lowering therapies, including statins and ezetimibe.

Treatment Emergent Adverse Events (AEs)	% (Number) of Patients	
	Bempedoic acid N=234	Placebo N=111
<b>Overview of AEs in All Patients (patient incidence)</b>		
Any AE(s)	64.1% (150)	56.8% (63)
Serious AE(s)*	6.0% (14)	3.6% (4)
Discontinuation due to AE(s)	18.4% (43)	11.7% (13)
Fatal Adverse Events – Unrelated to Study Treatment	0	0

Safety Population  
\*No SAE reported as related to study medication

“The dataset from this study is reassuring and highly consistent with what we’ve seen previously with bempedoic acid. For the millions of patients with hypercholesterolemia who are considered statin intolerant and have limited treatment options, bempedoic acid provides meaningful LDL-cholesterol lowering and statin-like reductions in hsCRP,” said Professor Dr. med Ulrich Laufs,

member of Esperion’s Phase 3 Executive Committee and Director of the Department of Cardiology at Leipzig University. “The medical community is in need of a new oral therapy which is effective, well tolerated and convenient for this complex patient population who may have run out of other options.”

### Cumulative Results of Bempedoic Acid

Analysis of the cumulative Phase 2 and Phase 3 results from more than 4,000 total patients have demonstrated broad efficacy as well as safety and tolerability for bempedoic acid in high-risk patients with ASCVD, or at high risk for ASCVD with hypercholesterolemia, and are inadequately treated with maximally tolerated background LDL-C lowering therapy or are considered statin intolerant. Bempedoic acid has provided LDL-C lowering of an additional 20 to 24 percent for those on background statin therapy, and 23 to 30 percent for patients not taking statins. Patients treated with bempedoic acid have also achieved a reduction of 22 to 40 percent in hsCRP. There were no clinically relevant differences between the bempedoic acid and placebo groups in the occurrence of AEs with 67.8 percent and 66.1 percent, respectively; or SAEs with 9.2 percent and 8.9 percent for the bempedoic acid and placebo groups, respectively. Discontinuations due to AEs were 9.5 percent and 6.9 percent, respectively, for the treatment and placebo groups; importantly, there was no single class of events or event that was responsible for the difference. Bempedoic acid showed no meaningful difference from placebo in muscle-related AEs. The occurrence of fatal adverse events was 0.5 percent and 0.2 percent for the treatment group and placebo group, respectively. None of these events were deemed to be related to study treatment by the study investigator.

Treatment Emergent Adverse Events (AEs)	% (Number) of Patients	
	Bempedoic Acid N=2668	Placebo/Active Control N=1338
Overview of AEs in All Patients (patient incidence)		
Any AE(s)	67.8% (1809)	66.1% (884)
Serious AE(s)*	9.2% (245)	8.9% (119)
Discontinuation of Study Drug due to AE(s)	9.5% (253)	6.9% (92)
Fatal Adverse Events – Unrelated to Study Treatment	0.5% (14)	0.2% (2)

Safety Analysis Set Population  
\*No SAE reported as related to study medication  
Includes data from Phase 2 (003, 005, 006, 007, 008, 009, 014, 035, 038, 039) and Phase 3 (Study 1, Study 3, Study 4)

“These results add to the already substantial body of evidence that bempedoic acid can be an important new complementary and convenient, once-daily oral treatment option for patients with ASCVD, or at a high risk for ASCVD, in need of additional LDL-cholesterol lowering, especially those considered statin intolerant,” said Tim M. Mayleben, president and chief executive officer of Esperion. “We eagerly anticipate the pivotal Phase 3 study results for our lead product candidate, the bempedoic acid / ezetimibe combination pill, in late August, and the fourth and final pivotal Phase 3 study of bempedoic acid, Study 2, in late September. Both studies include ASCVD patients on maximally tolerated statin therapy. The medical community is awaiting new, once-daily oral therapies that complement existing oral drugs to provide the LDL-C lowering and hsCRP reductions that their high-risk patients need, the value that payers appreciate, and the convenience and tolerability that patients want and deserve.”

Esperion plans to present full results from this study at an upcoming medical conference and to publish in a major medical journal.

### **Design of Global Pivotal Phase 3 Study 3 (1002-046)**

The 24-week, global pivotal Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the LDL-C lowering efficacy and safety of bempedoic acid 180 mg/day versus placebo added to background lipid-modifying therapy in patients with hypercholesterolemia who are considered statin intolerant. The study was conducted at 67 sites in the U.S. and Canada. A total of 345 patients were randomized 2:1 to receive bempedoic acid or placebo. The primary efficacy objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Secondary objectives included evaluating the 24-week LDL-C lowering efficacy of bempedoic acid versus placebo, the safety and tolerability of bempedoic acid versus placebo, and its effects on other risk markers after 12 weeks of treatment, including hsCRP.

### **Conference Call and Webcast Information**

Esperion's lipid management team will host a conference call and webcast today, Wednesday, May 23, 2018, at 8:45 a.m. Eastern Time to discuss these Phase 3 study results. The call can be accessed by dialing (877) 312-7508 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing access code 9199635. A live audio webcast can be accessed on the investors and media section of the Esperion website at investor.esperion.com. 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.

### **About Esperion's Global Pivotal Phase 3 LDL-C Lowering Program**

Esperion initiated its global, pivotal, Phase 3 clinical development program in January 2016 to evaluate the safety, tolerability and consistent, complementary LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination pill in patients with atherosclerotic cardiovascular disease (ASCVD), or who are at a high risk for ASCVD, with hypercholesterolemia who continue to have elevated levels of LDL-C despite the use of maximally-tolerated statins and ezetimibe, leaving them at high risk for cardiovascular events. The program includes five studies in approximately 4,000 patients, four for bempedoic acid and one for the bempedoic acid / ezetimibe combination pill.

- Two pivotal studies evaluating bempedoic acid (Studies 1 & 2) in 3,000 patients with ASCVD on maximally-tolerated statin therapy, with top-line results reported in May 2018, and expected in September 2018, respectively;
- Two pivotal studies evaluating bempedoic acid (Studies 3 & 4) in 600 patients with ASCVD, or at a high risk for ASCVD, considered statin intolerant, with top-line results reported in this press release and March 2018, respectively;
- One pivotal study evaluating the bempedoic acid / ezetimibe combination pill (053 Study) in 350 patients with ASCVD, or at high risk for ASCVD, on maximally-tolerated statin therapy, with top-line results expected in August 2018.

Esperion plans to submit New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for bempedoic acid and the bempedoic acid / ezetimibe combination pill for LDL-C-lowering indications no later than the first quarter of 2019. Additionally, Esperion

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plans to submit Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) no later than the second quarter of 2019.

### **Bempedoic Acid**

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ATP Citrate Lyase (ACL) inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Similar to statins, bempedoic acid also reduces hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 1, Phase 2 and Phase 3 studies conducted in more than 4100 patients, and over 2,700 patients treated with bempedoic acid, have produced LDL-C lowering results of up to 30 percent as monotherapy, approximately 50 percent in combination with ezetimibe and an incremental 20+ percent when added to stable statin therapy.

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. The company initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered “statin intolerant.” The CVOT — known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes — is an event-driven, global, randomized, double-blind, placebo-controlled study expected to enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at more than 600 sites in approximately 30 countries.

### **Esperion’s Commitment to Patients with Hypercholesterolemia**

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack or stroke. In the U.S., 78 million people, or more than 20 percent of the population, have elevated LDL-C; an additional 73 million people in Europe and 30 million people in Japan also live with elevated LDL-C. There are approximately 13 million people in the U.S. with atherosclerotic cardiovascular disease (ASCVD) who live with elevated levels of LDL-C despite taking maximally-tolerated lipid-modifying therapy — including individuals considered statin intolerant — leaving them at high risk for cardiovascular events. The vast majority of these patients, 9.5 million, require less than 30 percent additional LDL-C lowering to achieve treatment goals.

Esperion’s mission as the Lipid Management Company is to deliver once-daily, oral therapies that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

### **The Lipid Management Company**

Esperion is the Lipid Management Company passionately committed to developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease; the leading cause of death around the world. Bempedoic acid and the company’s lead product candidate, the bempedoic acid / ezetimibe combination pill, are targeted therapies that have been shown to significantly lower elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with

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current lipid-modifying therapies. For more information, please visit [www.esperion.com](http://www.esperion.com) and follow us on Twitter at <https://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 the regulatory approval pathway for the bempedoic acid / ezetimibe combination pill and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination pill and bempedoic acid, including Esperion's timing, designs, plans and announcement of results regarding its global pivotal Phase 3 clinical development program for bempedoic acid and the bempedoic acid / ezetimibe combination pill, Esperion's timing and plans for submission of NDAs to the FDA and MAAs to the EMA and Esperion's expectations for the market for therapies to lower LDL-C, including the market adoption of bempedoic acid and the bempedoic acid / ezetimibe combination pill, if approved. 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, delays or failures in Esperion's studies, that positive results from a clinical study of bempedoic acid may not be sufficient for FDA or EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that existing cash resources may be used more quickly than anticipated, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. 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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