

# ESPERION THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

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Address	3891 RANCHERO DRIVE, SUITE 150 ANN ARBOR, MI, 48108
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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 2, 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 2, 2018, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces Positive Top-Line Results from Pivotal Phase 3 Long-Term Safety Study of Bempedoic Acid” (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 2, 2018.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated May 2, 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 2, 2018

Esperion Therapeutics, Inc.

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



Media Contact:  
 Elliot Fox  
 W2O Group  
 212.257.6724  
 efox@w2ogroup.com

Investor Contact:  
 Audrey Gross  
 W2O Group  
 212.301.7214  
 agross@w2ogroup.com

## Esperion Announces Positive Top-Line Results from Pivotal Phase 3 Long-Term Safety Study of Bempedoic Acid

— *Met Primary Endpoint of Safety and Tolerability in Largest and Longest Duration Study* —

— *Bempedoic Acid Achieved Additional 20% On-Treatment LDL-C Lowering on Background Maximally Tolerated Statin Therapy* —  
 — *Additional hsCRP Reduction of 22% on Background Maximally Tolerated Statin Therapy* —  
 — *Conference Call and Webcast on Wednesday, May 2, 2018, at 8:30 a.m. Eastern Time* —

Ann Arbor, Mich., — (Globe Newswire — May 2, 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 second pivotal, Phase 3 study (Study 1 or 1002-040), the long-term safety study of bempedoic acid 180 mg, in this case evaluating the safety, tolerability and efficacy of bempedoic acid versus placebo in high-risk patients with atherosclerotic cardiovascular disease (ASCVD) who are inadequately controlled with current lipid-modifying therapies, including maximally tolerated statin therapy.

The study included 2,230 patients and met the primary endpoint of safety and tolerability and the key efficacy endpoint with on-treatment LDL-C lowering of an additional 20 percent at twelve weeks ( $p < 0.001$ ) (18 percent ( $p < 0.001$ ) in the intent to treat analysis). Patients treated with bempedoic acid also achieved a significant reduction of 22 percent in high-sensitivity C-reactive protein (hsCRP), an important marker of the underlying inflammation associated with cardiovascular disease.

“We know from the Phase 2 program that bempedoic acid demonstrates consistent and complementary LDL-cholesterol lowering and hsCRP reductions when added to currently available therapies. As expected, these new data confirm the long-term safety and tolerability profile of bempedoic acid, even in high cardiovascular risk patients on maximally tolerated statins, especially when looking at muscle-related adverse events,” said Christie M. Ballantyne, M.D., chairman of Esperion’s Phase 3 Executive Committee and Professor and Chief of Cardiology at Baylor College of Medicine in Houston. “Physicians are in need of additional convenient, once-daily, oral therapies, such as bempedoic acid, to complement currently available, once-daily, oral therapies for patients with ASCVD. These results suggest that bempedoic acid could be an important new oral treatment option for a very broad range of patients.”

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## Long-Term Safety and Tolerability of Bempedoic Acid over 52 Weeks

In this 52-week study, bempedoic acid was observed to be safe and well-tolerated. There were no clinically relevant differences between the bempedoic acid and placebo groups in the occurrence of adverse events (AEs) with 78.5 percent and 78.7 percent, respectively; or serious adverse events (SAEs) with 14.5 percent and 14.0 percent, respectively. Discontinuations due to AEs were 10.9 percent and 7.1 percent, respectively for the bempedoic acid and placebo groups; discontinuations due to muscle-related AEs were 2.2 percent and 1.9 percent, respectively in the bempedoic acid and placebo groups. In the study, 0.54 percent of patients treated with bempedoic acid and 0.13 percent of patients in the placebo group had elevations in liver function tests (ALT/AST) of greater than three times the upper limit of normal, repeated and confirmed. The cumulative number of patients now treated with bempedoic acid in Phase 2 and Phase 3 clinical trials totals 2,434. Of these, 0.58 percent had elevations in liver function tests greater than three times the upper limit of normal, repeated and confirmed. This rate of elevations in liver function test is consistent with the rate observed in all other previously approved oral LDL-C-lowering therapies, including statins and ezetimibe.

Treatment Emergent Adverse Events (AEs)	% (Number) of Patients	
	Bempedoic Acid N=1,487	Placebo N=742
<b>Overview of AEs in All Patients (patient incidence)</b>		
Any AE(s)	78.5% (1167)	78.7% (584)
Serious AE(s)	14.5% (216)	14.0% (104)
Discontinuation due to AE(s)	10.9% (162)	7.1% (53)
Fatal Adverse Events – Unrelated to Study Treatment	0.9% (13)	0.3% (2)

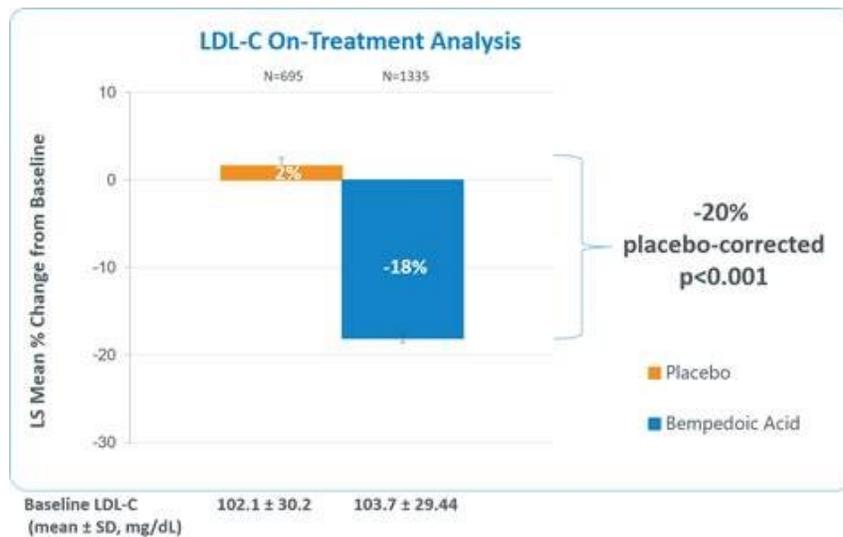
Safety Analysis Set Population

“In this study, the largest in our Phase 3 program, bempedoic acid was observed to be safe and well tolerated over a 52-week period, while providing clinically and statistically significant LDL-cholesterol lowering and reductions in hsCRP when added on to maximally tolerated statin therapy,” said Tim M. Mayleben, president and chief executive officer of Esperion. “In the coming months, results from our three remaining pivotal Phase 3 studies are expected to further validate the safety, efficacy and tolerability profile of bempedoic acid and the bempedoic acid / ezetimibe combination pill, definitively establishing these once-daily oral therapies as convenient and complementary to existing treatments for the 13 million people in the U.S. with ASCVD who live with elevated levels of LDL-cholesterol despite taking maximally-tolerated lipid-modifying therapy and remain at high risk for further cardiovascular disease or events, including heart attack and stroke.”

### LDL-C Lowering and hsCRP Reduction

The study met its key efficacy endpoint with on-treatment LDL-C lowering of 20 percent at 12 and 24 weeks, and 16 percent at 52 weeks ( $p < 0.001$ ). The LDL-C lowering for the bempedoic acid group at 12 weeks was 18 percent from baseline, as compared to an LDL-C increase of two percent for the placebo group. The intent to treat LDL-C lowering totaled 18 percent ( $p < 0.001$ ) at 12 weeks. These results were comparable across statin treatment groups. Patients treated with bempedoic acid also achieved a significant reduction of 22 percent in hsCRP, compared to the placebo group which had an increase of three percent ( $p < 0.001$ ).

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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 1 (1002-040)

The 52-week, global, pivotal Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the long-term safety and tolerability of bempedoic acid 180 mg/day versus placebo in high-risk patients with ASCVD and/or heterozygous familial hypercholesterolemia (HeFH). LDL-C levels of at least 70 mg/dL who are inadequately controlled with current lipid-modifying therapies, including maximally tolerated statin therapy. The study was conducted at 117 sites in the U.S., Canada and Europe. A total of 2,230 patients were randomized 2:1 to receive bempedoic acid or placebo. The secondary objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Tertiary objectives were to assess the effect of bempedoic acid on other lipid parameters and risk markers, including hsCRP.

An open-label extension study (1002-050) was initiated in early 2017 and is fully enrolled with 1,462 patients.

### Conference Call and Webcast Information

Esperion's lipid management team will host a conference call and webcast today, Wednesday, May 2, 2018, at 8:30 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 8390264. A live audio webcast can be accessed on the investors and media section of the Esperion website at [investor.esperion.com](http://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 this press release, 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 expected in May 2018 and reported in 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 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 1,600 patients, and over 1,000 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.

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## **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 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 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

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any forward-looking statements contained in this press release, other than to the extent required by law.

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