

ESPERION THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 03/27/18 for the Period Ending 03/27/18

Address	3891 RANCHERO DRIVE, SUITE 150 ANN ARBOR, MI, 48108
Telephone	734-887-3903
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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): **March 27 , 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.

Item 8.01 Other Events

On March 27, 2018, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces Positive Top-Line Results from Phase 2 Study of Bempedoic Acid Added-On to a PCSK9 Inhibitor in Patients with Hypercholesterolemia” (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 March 27, 2018.
	* * *
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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 27, 2018.

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: March 27, 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

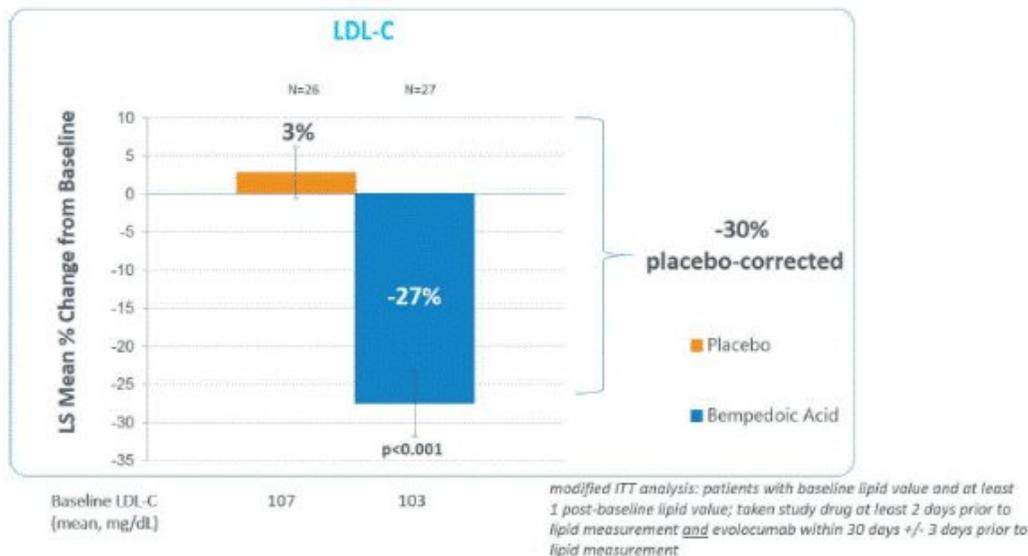
Investor Contact:
 Audrey Gross
 W2O Group
 212.301.7214
 agross@w2ogroup.com

Esperion Announces Positive Top-Line Results from Phase 2 Study of Bempedoic Acid Added-On to a PCSK9 Inhibitor in Patients with Hypercholesterolemia

— Study Met Primary Endpoint with 30% Additional LDL-C Lowering —
 — hsCRP Reduction of 34% —
 — Observed to be Safe and Well-Tolerated in This Study —
 — Conference Call and Webcast on Tuesday, March 27, 2018, at 8:30 a.m. Eastern Daylight Time —

Ann Arbor, Mich., — (Globe Newswire — March 27, 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 Phase 2 clinical study (1002-039) that evaluated the LDL-C lowering efficacy and safety of bempedoic acid 180 mg added-on to stable background therapy of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor in 58 patients with hypercholesterolemia.

The eight-week study met its primary endpoint with additional LDL-C lowering totaling 30 percent (p<0.001). The LDL-C lowering for the bempedoic acid group was 27 percent from baseline, as compared to an increase of three percent for the placebo group. Patients treated with bempedoic acid also achieved a significantly greater reduction of 34 percent in high-sensitivity C-reactive protein (hsCRP), an important marker of the underlying inflammation associated with cardiovascular disease, compared to the placebo group which had a reduction of two percent (p<0.029).



“Bempedoic acid has previously demonstrated the ability to complement currently available standard-of-care oral LDL-C lowering therapies, and the results of this Phase 2 study show that bempedoic acid can also be safely and effectively used in patients who require additional LDL-C lowering despite taking an injectable PCSK9 inhibitor,” said Tim M. Mayleben, president and chief executive officer of Esperion. “These Phase 2 results provide consistent evidence and further support that bempedoic acid is poised to become the broadly accessible, complementary, once-daily, oral LDL-C lowering therapy that is appealing to patients, physicians and payers.”

In this study, bempedoic acid was observed to be safe and well-tolerated. There were essentially no differences in the occurrence of adverse events (AEs) between the bempedoic acid and placebo groups, serious adverse events or muscle-related AEs. There were no discontinuations due to AEs or muscle-related AEs. No patients in either 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 completed Phase 2 and Phase 3 clinical trials totals 947. Of these, six patients (0.63 percent) had elevations in liver function tests. This rate of elevations in liver function tests is consistent with the rate observed in previous clinical trials and with all other previously approved oral LDL-C-lowering therapies, including statins and ezetimibe.

Treatment Emergent Adverse Events (AEs)	% (Number) of Patients	
	Placebo N=30	Bempedoic Acid N=28
Overview of AEs in All Patients (patient incidence)		
Any AE(s)	23.3% (7)	32.1% (9)
Serious AE(s)	0	3.6% (1)*
Discontinuation of Study Drug due to AE(s)	0	0
Fatal Adverse Events	0	0

Safety Population

*Influenza—considered by investigator to be unrelated to study drug

Design of Phase 2 Study 1002-039

This eight-week Phase 2, randomized, double-blind, placebo-controlled, multicenter study evaluated the efficacy and safety of bempedoic acid 180 mg/day in patients with hypercholesterolemia at screening (LDL-C \geq 160 mg/dL) who then received 12 weeks of background injectable evolocumab 420 mg administered every four weeks prior to randomization. A total of 59 patients from 21 sites in the U.S. and Canada were then randomized 1:1 to receive bempedoic acid or placebo added-on to evolocumab. The primary efficacy objective was to assess the eight-week LDL-C lowering efficacy of bempedoic acid versus placebo in patients on a PCSK9 inhibitor. Secondary objectives included evaluating the safety and tolerability of bempedoic acid versus placebo and its effects on other risk markers, including hsCRP.

Conference Call and Webcast Information

Esperion will host a conference call and webcast today, Tuesday, March 27, 2018, at 8:30 a.m. Eastern Time to discuss these Phase 2 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 8056235. 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 expected in early May and 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. Top-line results from Study 4 were reported in March 2018, and top-line results from Study 3 are expected in May 2018;
- 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 by the first quarter of 2019. Additionally, Esperion plans to submit Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) by the second quarter of 2019.

About 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 approximately 1,600 patients, and close to 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.

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 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 from studies in the 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, 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, including the risk that Esperion may need to change the design of its Phase 3 program, that existing cash resources may be used more quickly than anticipated, that the pivotal Phase 3 program may not produce sufficient safety or tolerability results or show meaningful change in LDL-C or other key lipid measures of patients, or the risk that other unanticipated developments or data could interfere with the scope of development, approval and commercialization of the bempedoic acid / ezetimibe combination pill and bempedoic acid, and the other 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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