

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): **January 9, 2017**

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))
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Item 8.01 Other Events

On January 8, 2017, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces Initiation of Three Pivotal Phase 3 Studies for Bempedoic Acid” (the “Phase 3 Press Release”). A copy of the Phase 3 Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

On January 9, 2017, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces Initiation of Global Cardiovascular Outcomes Trial for Bempedoic Acid” (the “CVOT Press Release”). A copy of the CVOT Press Release is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Phase 3 Press Release dated January 8, 2017.
99.2	CVOT Press Release dated January 9, 2017.

* * *

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: January 9, 2017

Esperion Therapeutics, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Phase 3 Press Release dated January 8, 2017.
99.2	CVOT Press Release dated January 9, 2017.



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Esperion Announces Initiation of Three Pivotal Phase 3 Studies for Bempedoic Acid

Global Phase 3 Program Top-Line Results Expected Mid-2018

Ann Arbor, Mich., — (Globe Newswire — January 8, 2017) — Esperion Therapeutics, Inc. (NASDAQ: ESPR), the lipid management company focused on developing and commercializing complementary oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced the initiation of the three remaining global pivotal Phase 3 LDL-C lowering efficacy studies of bempedoic acid in atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH) and patients considered “statin intolerant” with hypercholesterolemia who are inadequately treated with current lipid-modifying therapies.

“We are pleased our three global pivotal Phase 3 efficacy studies are now actively enrolling. With the global pivotal Phase 3 long-term safety study now nearly fully-enrolled, we remain on track to deliver top-line results from all of our pivotal studies in the Phase 3 program by mid-2018,” said Tim. M. Mayleben, president and chief executive officer of Esperion. “With Dr. Christie Ballantyne as chairman of our Phase 3 Executive Committee, the global Phase 3 clinical development program has been rigorously designed to support a LDL-C lowering label as an adjunct to diet and maximally tolerated statin therapy in high cardiovascular disease (CVD) risk patients in the U.S., with the European label expected to include specific language regarding the use of bempedoic acid in patients who are considered ‘statin intolerant’. We believe that bempedoic acid has high potential to provide a new, complementary, oral, once-daily LDL-C lowering therapy that could transform the lives of high CVD risk patients with hypercholesterolemia.”

Global Pivotal Phase 3 LDL-C Lowering Program

The global Phase 3 clinical development program initiated in January 2016 with a global pivotal 52-week long-term safety study.

The Company today announced the initiation of the three remaining global pivotal LDL-C lowering efficacy studies. The overall Phase 3 program — including the ongoing long-term safety study and the three LDL-C lowering efficacy studies in high CVD risk patients (ASCVD, HeFH and “statin intolerant”) — is designed to enroll over 3,200 high CVD risk patients with hypercholesterolemia on optimized background lipid-modifying therapy, specifically patients with ASCVD and/or HeFH who have LDL-C levels of ≥ 100 mg/dL; and patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and considered “statin intolerant” who have LDL-C levels of ≥ 100 mg/dL. Global regulatory submissions for an LDL-C lowering indication are expected by the first half of 2019 for a New Drug Application to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).

Top-line results from the global Phase 3 program in its entirety are expected by mid-2018.

Global Pivotal Phase 3 Study 1 (1950 ASCVD and/or HeFH patients): 52-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the long-term safety of 180 mg of bempedoic acid versus placebo — initiated in January 2016 — is expected to enroll approximately 1,950 patients with hypercholesterolemia (with ASCVD and/or HeFH) at high CVD risk and whose LDL-C is not adequately controlled with current lipid-modifying therapies. Additional safety data will be obtained from an open-label extension study initiating later this month.

Global Pivotal Phase 3 Study 2 (750 ASCVD and/or HeFH patients): 52-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of 180 mg of bempedoic acid versus placebo. This study is expected to enroll 750 patients with hypercholesterolemia (with ASCVD and/or HeFH) at high CVD risk and whose LDL-C is not adequately controlled with current lipid-modifying therapies. The study will be conducted at approximately 125 sites in the U.S., Canada and Europe. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo. Secondary objectives include evaluating the 24-week LDL-C lowering efficacy, and 52-week safety and tolerability of bempedoic acid versus placebo. Effects on other risk markers, including non-high-density lipoprotein cholesterol (non-HDL-C), total cholesterol, apolipoprotein B (apoB) and high sensitivity C-reactive protein (hsCRP), will also be evaluated.

Global Pivotal Phase 3 Study 3 (300 patients considered “statin intolerant”): 24-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of 180 mg of bempedoic acid versus placebo. This study is expected to enroll 300 patients with hypercholesterolemia on optimized background lipid-modifying therapy, including patients considered “statin intolerant.” The study will be conducted at approximately 70 sites in the U.S. and Canada. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo. Secondary objectives include evaluating the 24-week LDL-C lowering efficacy, safety and tolerability of bempedoic acid versus placebo and effects on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP.

Global Pivotal Phase 3 Study 4 (225 patients considered “statin intolerant”): 12-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of 180 mg of bempedoic acid versus placebo as an add-on to 10 mg of ezetimibe. This study is expected to enroll 225 patients with hypercholesterolemia on optimized background lipid-modifying therapy, including ezetimibe, and patients considered “statin intolerant.” The study will be conducted at approximately 75 sites in the U.S., Canada and Europe. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo when added to ezetimibe. Secondary objectives include evaluating safety and tolerability of bempedoic acid when added to ezetimibe, and effects on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP.

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Completed Phase 1 and 2 studies in more than 800 patients treated with bempedoic acid have produced clinically relevant 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.

Esperion’s Commitment to Patients with Hypercholesterolemia

In the United States, 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. Esperion’s mission as the lipid management company is to provide patients and physicians with a new convenient and complementary oral therapy to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. It is estimated that 40 million patients in the U.S. are taking statins with approximately 5-20 percent of these patients only able to tolerate less than the lowest approved daily starting dose of their statin and considered “statin intolerant”. Esperion-discovered and developed, bempedoic acid is a

targeted LDL-C lowering therapy in Phase 3 development. The Company has two Phase 3 products in development: 1) bempedoic acid (monotherapy) an oral, once-daily pill, and 2) an, oral, once-daily fixed dose combination pill of bempedoic acid and ezetimibe (BA+EZ)).

The Lipid Management Company

Esperion Therapeutics, Inc. is the lipid management company focused on developing and commercializing convenient and complementary 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 CVD; the leading cause of death around the world. Bempedoic acid, the Company's lead product candidate, has a targeted mechanism of action that significantly reduces 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 therapeutic potential of, and clinical development plan for, bempedoic acid, including the Company's timing, designs, plans, and announcement of results regarding its global Phase 3 program and timing of an NDA submission for bempedoic acid, in each case including that submissions for an LDL-C lowering indication could be filed in the United States and Europe prior to the completion of a cardiovascular outcomes trial, or CVOT. 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 the Company's studies, including in patient enrollment, the risk that FDA may require additional studies or data that Esperion may need to change the design of its Phase 3 program, the impact of future changes in FDA's view of LDL-C lowering as a surrogate endpoint or standard-of-care treatment for patients with elevated LDL-C levels, that positive results from a clinical study of bempedoic acid may not necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, that existing cash resources may be used more quickly than anticipated, the CVOT may not demonstrate that bempedoic acid leads to cardiovascular risk reduction, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic acid, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. 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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Esperion Announces Initiation of Global Cardiovascular Outcomes Trial for Bempedoic Acid

Ann Arbor, Mich., — (Globe Newswire — January 9, 2017) — Esperion Therapeutics, Inc. (NASDAQ: ESPR), the lipid management company focused on developing and commercializing complementary oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced the initiation of the 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. The study is expected to enroll over a 30-month period with a total estimated study duration of approximately 4.75 years. The expected average treatment duration will be 3.5 years with a minimum treatment duration of approximately 2.25 years. Patients enrolling in the study will be required to have a history of, or be at high-risk for, CVD with LDL-C levels between 100 mg/dL and 190 mg/dL despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL.

“The start of the CLEAR Outcomes CVOT is one of the last and most exciting steps in the development of bempedoic acid, and we are very pleased to have begun dosing patients,” said Tim M. Mayleben, president and chief executive officer of Esperion. “We worked closely with Dr. Steven Nissen and the team at the Cleveland Clinic to develop this well-powered study to demonstrate the potential benefit of bempedoic acid in reducing events in a patient population with a significant unmet need — patients with hypercholesterolemia considered ‘statin intolerant’ who are at high-risk for CVD. We believe bempedoic acid has the potential to provide a well-tolerated, complementary, once-daily, oral therapy for patients with “statin intolerance” and other high-risk patient populations with hypercholesterolemia.”

The primary efficacy endpoint of the event-driven global study is the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, hospitalization for unstable angina, or coronary revascularization; also referred to as “five-component MACE”). Similar to other CVOTs, CLEAR Outcomes is designed to provide greater than 85 percent power to detect an approximately 14 percent relative risk reduction in the primary endpoint in the bempedoic acid treatment group as compared to the placebo group, and is expected to complete with a minimum of 1,437 patients experiencing the primary endpoint.

The Company expects to submit a New Drug Application (NDA) for cardiovascular risk reduction to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), on the basis of a successful completion of the CLEAR Outcomes CVOT, by 2022.

Bempedoic Acid

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