

# 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): **November 6, 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))

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 November 6, 2017, Esperion Therapeutics, Inc. issued a press release titled, "Esperion Announces Initiation of Pivotal Phase 3 Study for the Bempedoic Acid / Ezetimibe Combination Pill." 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 November 6, 2017.
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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated November 6, 2017.</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: November 6, 2017

Esperion Therapeutics, Inc.

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



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### **Esperion Announces Initiation of Pivotal Phase 3 Study for the Bempedoic Acid / Ezetimibe Combination Pill**

*— Top-Line Results Expected by the Fourth Quarter of 2018 —*

*— NDA Submission for LDL-C Lowering Indication for the Bempedoic Acid / Ezetimibe Combination Pill Expected by First Quarter 2019 —*

Ann Arbor, Mich., — (Globe Newswire — November 6, 2017) — Esperion Therapeutics, Inc. (NASDAQ: ESPR), the Lipid Management Company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced initiation of the pivotal Phase 3 study (1002FDC-053) to assess the efficacy and safety of the bempedoic acid / ezetimibe combination pill in patients with hypercholesterolemia and atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH), including high cardiovascular risk primary prevention patients, whose LDL-C is not adequately controlled despite receiving maximally tolerated lipid-modifying background therapy. Top-line results are expected by the fourth quarter of 2018.

“Initiating the pivotal Phase 3 study for the bempedoic acid / ezetimibe combination pill puts us on track to report results from all five pivotal Phase 3 studies for the bempedoic acid franchise in 2018,” said Tim M. Mayleben, president and chief executive officer of Esperion. “The bempedoic acid / ezetimibe combination pill and bempedoic acid are the only convenient, complementary, cost-effective, once-daily, oral therapies in late-stage development for the millions of high-risk patients with hypercholesterolemia who are inadequately treated with, or unable to gain access to, current lipid-modifying therapies.”

The 12-week, pivotal Phase 3, randomized, double-blind, placebo-controlled, parallel-dose study will consist of four treatment arms evaluating the efficacy and safety of a once-daily, oral, fixed dose combination pill of 180 mg of bempedoic acid and 10 mg of ezetimibe versus placebo, 180 mg of bempedoic acid alone and 10 mg of ezetimibe alone. The study is expected to enroll approximately 350 patients at up to 125 U.S. sites. The co-primary objectives of the study are to assess LDL-C lowering efficacy in patients treated with the bempedoic acid / ezetimibe combination pill versus placebo, 180 mg of bempedoic acid and 10 mg of ezetimibe alone. Secondary objectives include assessing the safety and tolerability of the bempedoic acid / ezetimibe combination pill versus placebo, 180 mg of bempedoic acid and 10 mg of ezetimibe alone and effects on other risk markers, including high sensitivity C-reactive protein (hsCRP), non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apoB) and total cholesterol.

“As a physician, I am intrigued by the opportunity for these therapies to complement the standard of care and drive LDL-cholesterol levels even lower for my patients. Having a single pill that contains both bempedoic acid and ezetimibe that can be taken orally once daily would be a welcome addition to my treatment armamentarium,” said Christie M. Ballantyne, MD, Professor and Chief of Cardiology at Baylor College of Medicine and study investigator. “Patients need more oral LDL-cholesterol lowering options to help them reach

their goals, and both the fixed dose combination of bempedoic acid and ezetimibe, and bempedoic acid alone could satisfy their roles as patient-friendly, physician-friendly and payer-friendly choices.”

### **Bempedoic Acid / Ezetimibe Combination**

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination pill is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP Citrate Lyase (ACL) by bempedoic acid reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Inhibition of Niemann-Pick C1-Like 1 (NPC1L1) by ezetimibe results in reduced absorption of cholesterol from the gastrointestinal tract, thereby reducing delivery of cholesterol to the liver, which in turn upregulates LDL receptors. Previously completed Phase 2 data demonstrated that this safe and well tolerated combination results in a 48 percent lowering of LDL-C, a 26 percent reduction in high sensitivity C-reactive protein (hsCRP), and may potentially be associated with a lower occurrence of muscle-related side effects.

### **Bempedoic Acid**

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor, and may potentially be associated with a lower occurrence of muscle-related side effects. Completed Phase 1 and 2 studies conducted in approximately 1,300 patients, and over 800 patients treated with bempedoic acid, have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy 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 convenient, complementary, cost-effective, once-daily, oral therapies 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 are therefore considered to be statin intolerant. Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The company has two convenient, cost-effective, complementary, orally available, LDL-C lowering therapies in Phase 3 development: 1) a once-daily, oral bempedoic acid / ezetimibe combination pill, and 2) bempedoic acid, a once-daily, oral pill.

### **The Lipid Management Company**

Esperion Therapeutics, Inc. 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 reduce 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 therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination pill and bempedoic acid, including Esperion’s timing.

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designs, plans and announcement of results regarding the pivotal Phase 3 study (1002FDC-053). 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 pivotal Phase 3 study, that existing cash resources may be used more quickly than anticipated, that the pivotal Phase 3 study 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 and commercialization of the bempedoic acid / ezetimibe combination pill and bempedoic acid, 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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