

ESPERION THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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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): **June 26 , 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.

Item 8.01 Other Events

On June 26, 2017, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces FDA Confirmation of Regulatory Pathway to Approval for the Combination of Bempedoic Acid and Ezetimibe” (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 June 26, 2017.
	* * *
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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: June 26, 2017

Esperion Therapeutics, Inc.

By: /s/ Tim M. Mayleben

Tim M. Mayleben

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated June 26, 2017.



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

Investor Contact:
 Mindy Lowe
 Esperion Therapeutics, Inc.
 734.887.3903
 mlowe@esperion.com

Esperion Announces FDA Confirmation of Regulatory Pathway to Approval for the Combination of Bempedoic Acid and Ezetimibe

- *Complementary, Non-statin, Oral Bempedoic Acid / Ezetimibe Combination Therapy Demonstrates 48% Lowering of LDL-C and Significant hsCRP Reduction with Potential for Lower Occurrence of Muscle-Related Side Effects* —
- *Bempedoic Acid / Ezetimibe Combination Program to be Conducted Concurrently with Ongoing Global Pivotal Phase 3 Program for Bempedoic Acid* —
- *Phase 3 Bempedoic Acid / Ezetimibe Combination Bridging Study to Initiate by Fourth Quarter of 2017* —
- *On Track to Submit Both the Bempedoic Acid / Ezetimibe Combination and Bempedoic Acid Global Regulatory Filings for an LDL-C Lowering Indication by First Half of 2019* —
- *Conference Call and Webcast on Monday, June 26, 2017 at 4:30 p.m. Eastern Time* —

Ann Arbor, Mich., — (Globe Newswire — June 26, 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 the U.S. Food and Drug Administration (FDA) recently confirmed the regulatory pathway to approval for the once-daily, oral combination pill of bempedoic acid 180 mg and ezetimibe 10 mg.

Based on feedback received from the FDA, Esperion plans to initiate a single global pivotal Phase 3 bridging study (1002FDC-053) for the bempedoic acid / ezetimibe combination pill that will be conducted concurrently with the ongoing global pivotal Phase 3 program for bempedoic acid. The Phase 3 bridging study will support approval for an LDL-C lowering indication in both the U.S. and Europe. The randomized, double-blind, placebo-controlled study is expected to enroll up to 350 patients with hypercholesterolemia and with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH), including high cardiovascular risk primary prevention patients, whose LDL-C is not adequately controlled. The goal of this study is to evaluate the efficacy and safety of the bempedoic acid / ezetimibe combination, a convenient, cost-effective, once-daily, oral pill. Additional design details for this study will be provided upon initiation by the fourth quarter of 2017, with top-line results expected by the end of 2018.

In tandem with the NDA submission for bempedoic acid, the company plans to submit a New Drug Application (NDA) for an LDL-C lowering indication for the bempedoic acid / ezetimibe combination through the available abbreviated 505(b)(2) pathway by the first half of 2019. The company also expects to submit a Marketing Authorization Application (MAA) for an LDL-C lowering indication for the bempedoic acid / ezetimibe combination, consistent with the European Medicines Agency’s “Guideline on Clinical Development of Fixed Combination Medicinal Products,” in tandem with the MAA submission for bempedoic acid by the first half of 2019.

“Esperion now has two convenient, cost-effective, complementary, non-statin, once-daily, oral LDL-C lowering therapies in Phase 3 development both with confirmed regulatory pathways to approval and defined clinical development programs. The complementary mechanisms of action of bempedoic acid and ezetimibe provide a nearly 50 percent reduction in LDL-C lowering and this exciting therapy could become our most important therapy with the potential to address the LDL-C lowering needs of far more patients than bempedoic acid alone,” said Tim M. Mayleben, president and chief executive officer of Esperion. “We expect that these two distinct oral, non-statin LDL-C lowering therapies will complement existing standard of care oral therapies and provide patients, physicians and payers with much-needed options to conveniently and cost-effectively lower elevated LDL-C in patients who require additional LDL-C lowering. We look forward to initiating the bempedoic acid / ezetimibe combination clinical program, reporting top-line results and, most importantly, achieving the tandem global regulatory submissions for LDL-C lowering indications for both the bempedoic acid / ezetimibe combination and bempedoic acid by the first half of 2019.”

Conference Call and Webcast Information

Esperion’s lipid management team will host a conference call and webcast to discuss these updates. 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 40325639. 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.

Combination of Bempedoic Acid and Ezetimibe

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination 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 more than 1,000 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, 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 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 and bempedoic acid and the therapeutic potential of, and clinical development plan for, the bempedoic acid / ezetimibe combination and bempedoic acid. 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, 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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