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): **August 29, 2019**

Esperion Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35986**	**26-1870780**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3891 Ranchero Drive, Suite 150 **Ann Arbor, MI**	**48108**
(Address of principal executive offices)	(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ESPR	NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 August 29, 2019, Esperion Therapeutics, Inc. issued a press release titled, "Esperion Announces Positive Top-Line Results from Phase 2 Study of Bempedoic Acid / Ezetimibe Combination Tablet in Patients with Hypercholesterolemia and Type 2 Diabetes" (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

Exhibit No.	Description
99.1	Press Release dated August 29, 2019.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

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: August 29, 2019

Esperion Therapeutics, Inc.

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

Exhibit 99.1

Investor Contact:
Alex Schwartz
Esperion
734-249-3386
aschwartz@esperion.com

Media Contact:
Elliot Fox
W2Opure
212-257-6724
efox@purecommunications.com

Esperion Announces Positive Top-Line Results from Phase 2 Study of Bempedoic Acid / Ezetimibe Combination Tablet in Patients with Hypercholesterolemia and Type 2 Diabetes

— Bempedoic Acid / Ezetimibe Combination Tablet Achieved Robust 40% Placebo Corrected LDL-C Lowering —
— Provided 25% hsCRP Reduction —
— No Worsening of Glycemic Control —
— Overall Adverse Events Comparable to Placebo —
— Conference Call and Webcast on Thursday, August 29 at 8:00 a.m. Eastern Time —

ANN ARBOR, Mich., Aug. 29, 2019 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced positive top-line results from the Phase 2 bempedoic acid / ezetimibe combination tablet study (1002-058). This was a randomized, double-blind, parallel group study assessing the efficacy and safety of the bempedoic acid / ezetimibe combination tablet compared to ezetimibe and placebo in 179 patients with both hypercholesterolemia and type 2 diabetes. Patients enrolled were on stable background diabetes medications and washed out of lipid modifying therapies.

The 12-week study met its primary endpoints as well as key secondary endpoints, including that the bempedoic acid / ezetimibe combination tablet:

- Significantly lowered LDL-C by 40 percent compared to placebo ($p<0.001$);
- Reduced high-sensitivity C-reactive protein (hsCRP), an important marker of inflammation associated with cardiovascular disease, by 25 percent ($p<0.001$);
- No worsening of glycemic control;
- Overall adverse events (AEs) comparable to placebo;
- Had no increase in muscle-related AEs, serious adverse events, discontinuations due to AEs or elevations in liver function tests (LFTs);
- Achieved LDL-C levels of <70 mg/dl and an LDL-C reduction of >50 percent in approximately 40 percent of patients.

“The LDL-C lowering and hsCRP reductions seen with the bempedoic acid / ezetimibe once-daily combination oral tablet, without worsening glycemic parameters, are very important to physicians like me who frequently manage patients with both hypercholesterolemia and type 2 diabetes. In addition, the substantial reductions in apolipoprotein B and non-HDL-C observed in this study may be particularly important for patients with hypercholesterolemia and type 2 diabetes,” said Dr. Harold Bays, Medical Director and President of the Louisville Metabolic and Atherosclerosis Research Center. “Patients benefit from having more therapeutic options, especially ones that improve multiple cardiovascular disease risk factors.”

Safety and Tolerability of Bempedoic Acid / Ezetimibe Combination Tablet Over 12 Weeks

The results showed no clinical differences between the bempedoic acid / ezetimibe combination tablet, placebo, and ezetimibe patient groups in the occurrence of:

- Adverse events with 43 percent, 37 percent, and 30 percent, respectively;
- Serious adverse events (SAEs) with 0 percent, 2 percent, and 2 percent, respectively;
- Discontinuations due to AEs with 0 percent, 0 percent, and 2 percent, respectively;
- No elevations in liver function tests (ALT/AST) (>3X the upper limit of normal, repeated and confirmed) were observed.

“The bempedoic acid / ezetimibe combination tablet provided 40% LDL-C lowering, 25% hsCRP reductions, and did not worsen glycemic control in patients with both hypercholesteremia and type 2 diabetes on a background of no statin therapy. These results build upon the pivotal, Phase 3 bempedoic acid / ezetimibe combination tablet data announced last August, where the majority of patients were on background statin therapy,” said Tim M. Mayleben, president and chief executive officer of Esperion. “We have increasing confidence that our convenient, once-daily, oral therapies could become an important, cost-effective treatment option for millions of patients in the U.S. who are not at their LDL-C goal.”

Design of Phase 2 Study (1002-058)

Study 1002-058 was a 12-week, randomized, double-blind, parallel group, multicenter study to evaluate the efficacy and safety of bempedoic acid 180 mg / ezetimibe 10 mg combination tablet compared to ezetimibe 10 mg and placebo in patients with hypercholesterolemia and type 2 diabetes being treated with stable diabetes medication and washed out of lipid modifying therapy. The study was conducted at 28 sites in North America. A total of 179 patients were randomized 1:1:1 to receive bempedoic acid 180 mg / ezetimibe 10 mg combination tablet, ezetimibe 10 mg or placebo. The co-primary objectives included assessments of LDL-C lowering of the bempedoic acid / ezetimibe combination tablet versus ezetimibe and placebo. The secondary objectives included assessments of hemoglobin A1c (HbA1c), high-sensitivity C-reactive protein (hsCRP), non-HDL-C, total cholesterol (TC), and apolipoprotein B (apoB) after 12 weeks of treatment as well as characterizing the safety and tolerability of the bempedoic acid / ezetimibe combination tablet versus ezetimibe and placebo.

Conference Call and Webcast Information

Esperion's Lipid Management Team will host a conference call and webcast today, August, 29, 2019, at 8:00 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 the access code 8065776. 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.

Bempedoic Acid

Bempedoic acid is our lead, non-statin, orally available, once-daily, LDL-C lowering therapeutic candidate, currently under review by the U.S. Food and Drug Administration (FDA). With a targeted mechanism of action, bempedoic acid is a first-in-class, 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 3 studies conducted in more than 4,000 patients, with over 2,600 patients treated with bempedoic acid, demonstrated up to 18 percent placebo corrected LDL-C lowering when used with moderate- and high-intensity statins and 21 to 28 percent placebo corrected LDL-C lowering when used with low dose or no background statin.

Bempedoic Acid / Ezetimibe Combination Tablet

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination tablet is a non-statin, orally available, once-daily, LDL-C lowering therapeutic candidate, currently under review by the FDA. 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 the LDL receptors. Phase 3 data demonstrated that this combination resulted in a 29 percent placebo corrected LDL-C lowering when used with maximally tolerated statins, a 44 percent LDL-C lowering when used with no background statin (post-hoc analysis), and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

CLEAR Outcomes

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. Esperion 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 averse." The CVOT — known as 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 over 1,000 sites in approximately 30 countries.

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., 96 million people, or more than 37 percent of the adult population, have elevated LDL-C. There are approximately 18 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 averse — leaving them at high risk for cardiovascular events[1]. More than 50 percent of ASCVD patients who are not able to reach their LDL-C goals with statins alone need less than a 40 percent reduction to reach their LDL-C threshold[2].

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, cost-effective, complementary, 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 bempedoic acid / ezetimibe combination tablet are targeted therapies that are being developed 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 bempedoic acid and the bempedoic acid / ezetimibe combination tablet and the therapeutic potential of, clinical development plan for, bempedoic acid and the bempedoic acid / ezetimibe combination tablet, including Esperion's timing, designs, plans and announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, timing for the review and approval of the NDAs and the MAAs, 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 tablet, 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 or EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that notwithstanding the completion of Esperion’s Phase 3 clinical development program for LDL-C lowering, the FDA or EMA may require additional development in connection with seeking regulatory approval, 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 any forward-looking statements contained in this press release, other than to the extent required by law.

References

[1] Esperion market research on file: research project interviewing 350 physicians. Esperion Therapeutics, Inc. Sept-Oct 2018.
[2] Data on file: analysis of NHANES database. Esperion Therapeutics, Inc. 2018.