

**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): **February 28, 2019**

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 2.02 Results of Operations and Financial Condition.

On February 28, 2019, Esperion Therapeutics, Inc. issued a press release announcing its financial results for the three months and year-ended December 31, 2018 (the “Press Release”). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information set forth under Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On February 28, 2019, Esperion Therapeutics, Inc. issued a press release titled, “Esperion Announces Submissions of Two NDAs and Official Completion of Two MAA Validations for Both Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet”. A copy of the 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	<u>Press Release dated February 28, 2019.</u>
99.2	<u>Press Release dated February 28, 2019.</u>

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: February 28, 2019

Esperion Therapeutics, Inc.

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



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Esperion Provides Bempedoic Acid Franchise Development Program Updates; Reports Fourth Quarter and Full Year 2018 Financial Results

ANN ARBOR, Mich., Feb. 28, 2019 (GLOBE NEWSWIRE) — Esperion (NASDAQ:ESPR), the Lipid Management Company focused on developing and commercializing complementary, cost-effective, convenient, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today provided bempedoic acid franchise development program updates and financial results for the fourth quarter and year ended December 31, 2018.

“2018 was an exciting and incredibly productive year for our Lipid Management Team highlighted by positive top-line results reported from five pivotal Phase 3 studies. Already in 2019, we’ve continued this momentum by completing an EU commercialization agreement with Daiichi Sankyo Europe (DSE) and submitting our NDAs and MAAs to FDA and EMA, respectively,” said Tim M. Mayleben, President and Chief Executive Officer of Esperion. “Our team of Lipid Management experts will be working closely with regulatory authorities throughout 2019 to bring our LDL-cholesterol lowering therapies to the millions of patients who are not reaching their LDL-C lowering goals with existing treatment options.”

Recent Development Program Highlights

October 2018:

- Announced positive top-line results from Study 2 (1002-047), the global, pivotal Phase 3 study of bempedoic acid 180 mg evaluating the LDL-C lowering efficacy and the safety and tolerability of bempedoic acid versus placebo in patients with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH) who are inadequately controlled with current lipid-modifying therapies, including maximally tolerated statin therapy. Bempedoic acid was observed to be safe and well-tolerated in this study and provided consistent LDL-C lowering and hsCRP reductions.
 - Announced positive cumulative results from our Phase 3 LDL-C lowering development program of bempedoic acid. The program consisted of four pivotal, Phase 3, randomized, double-blind, placebo-controlled studies which evaluated the LDL-C
-

lowering efficacy and safety and tolerability of bempedoic acid 180 mg compared to placebo in high cardiovascular risk patients including ASCVD and/or HeFH patients. Bempedoic acid achieved all safety and tolerability objectives in the Phase 3 program and provided patients an additional 18% to 31% LDL-C lowering, 19% to 33% hsCRP reductions, as well as 0.19% to 0.31% hemoglobin A1c reductions.

November 2018:

- Final Study 3 (1002-046) results were presented by Dr. med Ulrich Laufs at the American Heart Association Scientific Sessions.

January 2019:

- Announced a collaboration agreement with Daiichi Sankyo Europe (DSE) to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland. DSE's European sales organization includes over 1,000 professionals dedicated to the commercialization of cardiovascular products and has a strong history of successful cardiovascular commercial launches. Payments to Esperion under the agreement included \$150 million upfront, \$150 million upon first commercial sale in the territory, up to \$600 million in additional regulatory and commercial milestones payments as well as 15% to 25% tiered royalties on net territory sales.

February 2019:

- Announced the submission of two New Drug Applications (NDAs) for bempedoic acid and the bempedoic acid / ezetimibe combination tablet to the U.S. Food and Drug Administration (FDA). The bempedoic acid NDA was submitted to the FDA on February 20, 2019 and the bempedoic acid / ezetimibe combination tablet NDA was submitted to the FDA on February 26, 2019.
- Announced that the European Medicines Agency (EMA) has completed formal validation of Esperion's two Marketing Authorization Applications (MAAs) and officially started the review procedure for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet. The MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet were submitted to the EMA on February 11, 2019.

Upcoming Milestones

Third quarter 2019:

- Enrollment completion in the CLEAR Outcomes study

Second half 2019:

- Top-line results from the 12-week, Phase 2 study (1002-058) of the bempedoic acid / ezetimibe combination tablet in patients with elevated LDL-C and type 2 diabetes mellitus
 - Pivotal Phase 3 trial initiation of bempedoic acid in patients with elevated LDL-C and type 2 diabetes, to support a glycemic control indication in adults with type 2 diabetes mellitus as well as HbA1c data inclusion
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2019 Financial Outlook

Esperion expects 2019 net cash used in operations to be \$25 to \$35 million, driven by the following components:

Collaboration and license agreement cash source	\$150 million
R&D cash used	\$115 million to \$120 million
SG&A cash used	\$60 million to \$65 million

Esperion expects that current cash resources, coupled with expected milestone payments under the European commercial collaboration agreement, as well as bempedoic acid and the bempedoic acid / ezetimibe combination tablet commercial sales, are sufficient to fund operations until operating cash flow is positive.

2018 Fourth Quarter and Full-Year Financial Results

As of December 31, 2018, cash and cash equivalents and investment securities available-for-sale totaled \$136.3 million compared with \$273.6 million at December 31, 2017. This amount does not include the \$150.0 million upfront payment resulting from the Daiichi Sankyo Europe agreement that was announced on January 4, 2019.

Research and development expenses were \$49.5 million for the fourth quarter of 2018 and \$171.5 million for the year ended December 31, 2018, compared to \$33.4 million and \$147.6 million for the comparable periods in 2017. The increase in research and development expenses was primarily related to clinical development costs for the bempedoic acid / ezetimibe combination tablet and bempedoic acid, including costs to support the completion of four global pivotal Phase 3 studies for bempedoic acid and the pivotal Phase 3 study for the bempedoic acid / ezetimibe combination tablet during the period, the ongoing CLEAR CVOT, and increases in our headcount and stock-based compensation expense.

General and administrative expenses were \$11.2 million for the fourth quarter of 2018 and \$33.1 million for the year ended December 31, 2018, compared to \$5.3 million and \$21.4 million for the comparable periods in 2017. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, including costs to support pre-commercialization activities, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Esperion had a net loss of \$60.0 million for the fourth quarter of 2018 and \$201.8 million for the year ended December 31, 2018, compared to \$37.9 million and \$167.0 million, respectively, for the comparable periods in 2017.

Esperion had approximately 26.8 million shares of common stock outstanding, with another 5.3 million issuable upon exercise of stock options and warrants and vesting of restricted stock units as of December 31, 2018.

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 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 the LDL receptors. Phase 3 data demonstrated that this safe and well-tolerated combination results in a 35 percent lowering of LDL-C when used with maximally tolerated statins, a 43 percent lowering of LDL-C when used as a monotherapy, and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ATP Citrate Lyase 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 2 and Phase 3 studies conducted in almost 4,800 patients, and approximately 3,100 patients treated with bempedoic acid, have demonstrated an additional 20 percent LDL-C lowering when used with maximally tolerated statins, up to 30 percent LDL-C lowering as monotherapy, 35 percent LDL-C lowering in combination with ezetimibe when used with maximally tolerated statins and up to 48 percent LDL-C lowering in combination with ezetimibe as monotherapy.

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. The company 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 intolerant.” 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 intolerant — leaving them at high risk for cardiovascular events. 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.

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 complementary, cost-effective, convenient, 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 tablet, 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 Statement: Esperion

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 tablet and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination tablet and bempedoic acid, 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, 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, the expected upcoming milestones described in this press release, and Esperion's cash position and financial outlook. 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 DSE is able to successfully commercialize the bempedoic acid / ezetimibe combination tablet and bempedoic acid, if approved, 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.

Esperion Therapeutics, Inc.

Balance Sheet Data
(In thousands)
(Unaudited)

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash and cash equivalents	\$ 36,973	\$ 34,468
Working capital	78,299	170,780
Investments	99,293	239,151
Total assets	143,451	277,835
Common stock	27	26
Accumulated deficit	(598,101)	(396,291)
Total stockholders' equity	79,118	244,691

Esperion Therapeutics, Inc.

Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Year Ended</u> <u>December 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses:				
Research and development	\$ 49,473	\$ 33,439	\$ 171,488	\$ 147,603
General and administrative	11,176	5,257	33,097	21,379
Total operating expenses	60,649	38,696	204,585	168,982
Loss from operations	(60,649)	(38,696)	(204,585)	(168,982)
Other income, net	610	805	2,775	1,994
Net loss	\$ (60,039)	\$ (37,891)	\$ (201,810)	\$ (166,988)
Net loss per common share (basic and diluted)	\$ (2.24)	\$ (1.44)	\$ (7.54)	\$ (6.98)
Weighted average shares outstanding (basic and diluted)	26,818,331	26,222,397	26,754,308	23,933,273



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Esperion Announces Submissions of Two NDAs and Official Completion of Two MAA Validations for Both Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet

ANN ARBOR, Mich., Feb. 28, 2019 (GLOBE NEWSWIRE) — Esperion (Nasdaq: ESR) today announced that the company has successfully completed important and key global marketing applications including the submission of two New Drug Applications (NDAs) for bempedoic acid and the bempedoic acid / ezetimibe combination tablet to the U.S. Food and Drug Administration (FDA). Bempedoic acid and the bempedoic acid / ezetimibe combination tablet are being developed as complementary, cost-effective, convenient, once-daily, oral therapies for the treatment of patients with elevated low-density lipoprotein cholesterol (LDL-C) who need additional LDL-C lowering despite the use of currently accessible therapies. Based on Esperion's bempedoic acid submission date of February 20, 2019 as well as the bempedoic acid / ezetimibe combination tablet submission date of February 26, 2019, the Company expects to receive notification from FDA on whether the submissions were filed for review in May 2019.

Esperion also announced that the European Medicines Agency (EMA) has completed formal validation of Esperion's two Marketing Authorization Applications (MAAs) and officially started the review procedure for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet. The MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet were submitted to the EMA on February 11, 2019. The MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet are being reviewed via the centralised procedure with an opinion of the Committee for Medicinal Products for Human Use (CHMP) expected by Day 210 (plus the standard clock-stops for response to the List of Questions). After the adoption of a CHMP opinion, a final decision regarding the MAA is carried out by the European Commission.

"The NDA submissions and completion of the MAA validations for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet are truly inspirational accomplishments for our

team of Lipid Management Experts and we would like to thank the patients, families and healthcare providers who participated in our clinical studies, as well as our colleagues, investigators and clinical trial sites for their help in the development of these innovative medicines,” said Tim M. Mayleben, President and Chief Executive Officer of Esperion. “We look forward to working closely with regulatory authorities as we continue to advance our once-daily, oral bempedoic acid-based therapies to help the millions of patients who are inadequately treated with, or unable to gain access to, current LDL-C lowering therapies.”

Esperion’s Global Pivotal Phase 3 LDL-C Lowering Program to Support FDA and EMA Submissions

Esperion completed its global, pivotal, Phase 3 clinical development program and announced positive cumulative results in October 2018. The program evaluated the safety, tolerability and consistent, complementary LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination tablet 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 included five studies of approximately 4,000 patients, four for bempedoic acid and one for the bempedoic acid / ezetimibe combination tablet.

- Two pivotal studies evaluated bempedoic acid (Studies 1 and 2) in 3,008 patients with ASCVD on maximally-tolerated statins, with top-line results reported in May 2018 and October 2018, respectively;
- Two pivotal studies evaluated bempedoic acid (Studies 3 and 4) in 613 patients with ASCVD, or at a high risk for ASCVD, considered statin intolerant, with top-line results reported in May 2018 and March 2018, respectively;
- One pivotal study evaluated the bempedoic acid / ezetimibe combination tablet (053 Study) in 382 patients with ASCVD, or at high risk for ASCVD, on maximally tolerated statins, with top-line results reported in August 2018.

Bempedoic acid and the bempedoic acid / ezetimibe combination tablet new drug applications have been submitted to the United States Food and Drug Administration, as well as are under regulatory review for marketing authorization by the European Medicines Agency.

Bempedoic Acid / Ezetimibe Combination Tablet

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