

ESPERION THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/20/18 for the Period Ending 02/20/18

Address	3891 RANCHERO DRIVE, SUITE 150 ANN ARBOR, MI, 48108
Telephone	734-887-3903
CIK	0001434868
Symbol	ESPR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 20, 2018**

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 20, 2018, Esperion Therapeutics, Inc. issued a press release announcing its financial results for the three months and year-ended December 31, 2017 (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 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 20, 2018.

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 20, 2018

Esperion Therapeutics, Inc.

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



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

Investor Contact:
 Audrey Gross
 W2O Group
 212.301.7214
 agross@w2ogroup.com

Esperion Provides Bempedoic Acid Franchise Development Program Updates; Reports Fourth Quarter and Full Year 2017 Financial Results

Ann Arbor, Mich., — (Globe Newswire — February 20, 2018) — Esperion (NASDAQ: ESPR), the Lipid Management Company focused on developing and commercializing complementary, convenient, cost-effective, 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 full year ended December 31, 2017.

“The past year was significant and reflective of the meaningful progress made by our Lipid Management Team through the achievement of positive regulatory interactions, clinical trial execution resulting in rapid patient enrollment in the global pivotal Phase 3 program for bempedoic acid and the bempedoic acid / ezetimibe combination pill, and completion of a follow-on public offering funding our programs through the expected approvals for an LDL-C lowering indication,” said Tim Mayleben, president and chief executive officer of Esperion. “With the first of our Phase 3 studies expected to report top-line results in March, we are confident 2018 will be the most transformational and defining year in our company’s history. We look forward to reporting top-line results from all five pivotal Phase 3 studies of the bempedoic acid franchise throughout this very exciting year.”

Fourth Quarter Development Program and Company Highlights

- November 2017: Announced design and initiated the pivotal Phase 3 study (1002FDC-053) for the bempedoic acid / ezetimibe combination pill.

Upcoming Milestones

- March 2018:
 - Top-line results expected from the pivotal Phase 3 Study 4 (1002-048) of bempedoic acid in atherosclerotic cardiovascular disease (ASCVD) patients on ezetimibe and low dose statin background therapy (high CV risk patients considered statin intolerant);
 - Top-line results expected from the Phase 2 study (1002-039) of bempedoic acid added-on to a once-monthly injectable PCSK9 inhibitor.
 - May 2018:
 - Top-line results expected from the pivotal Phase 3 Study 1 (1002-040) of bempedoic acid in ASCVD and/or heterozygous familial hypercholesterolemia (HeFH) patients on maximally tolerated statin background therapy;
 - Top-line results expected from the pivotal Phase 3 Study 3 (1002-046) of bempedoic acid in ASCVD patients on background therapy of less than approved daily starting doses of statins (high CV risk patients considered statin intolerant).
-

- August 2018:
 - Top-line results expected from the pivotal Phase 3 study (1002FDC-053) of the bempedoic acid / ezetimibe combination pill in ASCVD and/or HeFH patients on maximally tolerated statin background therapy.
- September 2018:
 - Top-line results expected from the pivotal Phase 3 study 2 (1002-047) of bempedoic acid in ASCVD and/or HeFH patients on maximally tolerated statin background therapy.

CLEAR Outcomes Global Cardiovascular Outcomes Trial Enrollment Update

Esperion initiated in December 2016 its global cardiovascular outcomes trial (CVOT) known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes (1002-043). The CLEAR Outcomes study is currently enrolling patients with hypercholesterolemia and high cardiovascular disease risk and only those who can be considered statin intolerant. Patient enrollment is proceeding as planned and remains on track to fully enroll by mid-2019. Top-line results from this study are expected to support our submissions for a cardiovascular disease risk reduction indication in the U.S. and Europe by 2022.

2017 Fourth Quarter and Full-Year Financial Results

As of December 31, 2017, cash and cash equivalents and investment securities available-for-sale totaled \$273.6 million compared with \$242.5 million at December 31, 2016.

Research and development expenses were \$33.4 million for the fourth quarter of 2017 and \$147.6 million for the year ended December 31, 2017, compared to \$24.9 million and \$57.9 million for the comparable periods in 2016. The increase in research and development expenses was primarily related to the further clinical development of the bempedoic acid / ezetimibe combination pill and bempedoic acid, including costs to support the global pivotal Phase 3 studies, the CVOT, and further increases in our headcount and stock-based compensation expense.

General and administrative expenses were \$5.3 million for the fourth quarter of 2017 and \$21.4 million for the year ended December 31, 2017, compared to \$4.4 million and \$18.3 million for the comparable periods in 2016. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Esperion had a net loss of \$37.9 million for the fourth quarter of 2017 and \$167.0 million for the year ended December 31, 2017, compared to \$29.0 million and \$75.0 million, respectively, for the comparable periods in 2016.

Esperion had approximately 26.3 million shares of common stock outstanding, with another 4.4 million issuable upon exercise of stock options and warrants and vesting of restricted stock units, and \$1.0 million of debt outstanding as of December 31, 2017.

2018 Financial Outlook

Esperion expects full-year 2018 net cash used in operating activities to be approximately \$135 to \$145 million and its cash and cash equivalents and investment securities to be approximately \$130 to \$140 million at December 31, 2018. The Company estimates that current cash resources are sufficient to fund operations through the expected approvals of the bempedoic acid / ezetimibe combination pill and bempedoic acid in the first quarter of 2020.

Bempedoic Acid / Ezetimibe Combination Pill

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 the LDL receptors. Previously completed Phase 2 data demonstrated that this safe and well tolerated combination results in a 48 percent lowering of LDL-C, and 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 1,300 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 complementary, convenient, cost-effective, once-daily, oral therapies to significantly reduce elevated levels of LDL-C in high-risk patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies. It is estimated that 40 million patients with hypercholesterolemia in the U.S. are taking statins, approximately 12 million of those patients are at high-risk with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH) and with LDL-C that is not adequately controlled despite receiving maximally tolerated lipid-modifying background therapy. The 12 million high-risk patients include patients only able to tolerate less than the lowest approved daily starting dose of their statin and are considered statin intolerant. Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The company has two bempedoic acid-based 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 is the Lipid Management Company passionately committed to developing and commercializing complementary, convenient, 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 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 pill and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination pill and bempedoic acid, including Esperion's timing, designs, plans and announcement of results, the global pivotal Phase 3 clinical development program for bempedoic acid, the expected upcoming milestones described in this press release, and our 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, 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, 2017</u>	<u>December 31, 2016</u>
Cash and cash equivalents	\$ 34,468	\$ 38,165
Working capital	170,780	197,988
Investments	239,151	204,324
Total assets	277,835	245,213
Total long-term debt	—	1,022
Common stock	26	23
Accumulated deficit	(396,291)	(229,200)
Total stockholders' equity	244,691	228,602

Esperion Therapeutics, Inc.

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Operating expenses:				
Research and development	\$ 33,439	\$ 24,881	\$ 147,603	\$ 57,868
General and administrative	5,257	4,404	21,379	18,282
Total operating expenses	38,696	29,285	168,982	76,150
Loss from operations	(38,696)	(29,285)	(168,982)	(76,150)
Interest expense	(32)	(78)	(198)	(376)
Other income, net	837	407	2,192	1,548
Net loss	\$ (37,891)	\$ (28,956)	\$ (166,988)	\$ (74,978)
Net loss per common share (basic and diluted)	\$ (1.44)	\$ (1.29)	\$ (6.98)	\$ (3.33)
Weighted average shares outstanding (basic and diluted)	26,222,397	22,554,418	23,933,273	22,544,475

#