

ESPERION THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/22/17 for the Period Ending 02/22/17

Address	3891 RANCHERO DRIVE, SUITE 150 ANN ARBOR, MI 48108
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): **February 22 , 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))
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Item 2.02 Results of Operations and Financial Condition.

On February 22, 2017, Esperion Therapeutics, Inc. issued a press release announcing its financial results for the three months and year-ended December 31, 2016 (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 22, 2017.

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 22, 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 February 22, 2017.



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Esperion Provides Bempedoic Acid Development Program Update; Reports Fourth Quarter and Full Year 2016 Financial Results

Ann Arbor, Mich., — (Globe Newswire — February 22, 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 provided bempedoic acid development program updates and financial results for the fourth quarter and full year ended December 31, 2016.

“Last year, Esperion was focused on building a strong foundation for the development and initiation of our global pivotal Phase 3 clinical development program for bempedoic acid, which the team successfully initiated, including the CLEAR Outcomes cardiovascular outcomes trial,” said Tim M. Mayleben, president and chief executive officer of Esperion. “Our focus in 2017 will be on the timely completion of patient enrollment of these LDL-C lowering efficacy studies to enable us to report top-line results by mid-2018. We are encouraged by the early completion of patient enrollment in our long-term safety and tolerability study in January, and remain focused on completing patient enrollment across the remaining global pivotal Phase 3 studies.”

Development Program and Company Highlights

- November 2016: Publication of the definitive paper on the mechanism of action of bempedoic acid in the journal *Nature Communications*.
- December 2016: Initiation of three global pivotal Phase 3 studies and the **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes cardiovascular outcomes trial (CVOT) for bempedoic acid.
- January 2017: Early completion of patient enrollment in the global pivotal Phase 3 long-term safety and tolerability study (Study 1) of bempedoic acid.

Upcoming Milestones

- February 2017: Initiation of the open-label extension study of the global pivotal Phase 3 long-term safety and tolerability study (Study 1) to collect additional safety data. All patients in the open-label extension study will receive bempedoic acid.
 - March 2017:
 - Initiation of the Phase 2 “triplet oral therapy” study of bempedoic acid to further explore the complementary oral LDL-C lowering of bempedoic acid, ezetimibe and atorvastatin.
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- Brian A. Ference, M.D., M.Phil, M.Sc., F.A.C.C., Associate Professor of Medicine, Wayne State University School of Medicine, will present “Genetic Target Validation for ATP Citrate Lyase Inhibition” at the upcoming American College of Cardiology 66th Annual Scientific Session.

2016 Fourth Quarter and Full-Year Financial Results

As of December 31, 2016, cash and cash equivalents and investment securities available-for-sale totaled \$242.5 million compared with \$292.6 million at December 31, 2015.

Research and development expenses were \$24.9 million for the fourth quarter of 2016 and \$57.9 million for the year ended December 31, 2016, compared to \$8.0 million and \$29.8 million for the comparable periods in 2015. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, including the initiation of the three global pivotal Phase 3 studies and the CVOT in the fourth quarter of 2016.

General and administrative expenses were \$4.4 million for the fourth quarter of 2016 and \$18.3 million for the year ended December 31, 2016, compared to \$5.3 million and \$20.2 million for the comparable periods in 2015. The decrease in general and administrative expenses was primarily related to a reduction in pre-commercialization activities, partially offset by increases in costs to support public company operations, increases in the Company’s headcount, and other costs to support Esperion’s growth.

Esperion had a net loss of \$29.0 million for the fourth quarter of 2016 and \$75.0 million for the year ended December 31, 2016, compared to \$13.1 million and \$49.8 million for the comparable periods in 2015.

Esperion had approximately 22.6 million shares of common stock outstanding , with another 3.5 million issuable upon exercise of stock options and warrants and vesting of restricted stock units, and \$2.7 million of debt outstanding as of December 31, 2016 .

2017 Financial Outlook

Esperion expects full-year 2017 net cash used in operating activities to be approximately \$125 to \$135 million and its cash and cash equivalents and investment securities to be approximately \$105 to \$115 million at December 31, 2017. The Company estimates that current cash resources are sufficient to fund operations into early 2019 and through the announcement of top-line results from all global pivotal Phase 3 safety and efficacy studies.

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Completed Phase 1 and 2 studies in more than 800 patients treated with bempedoic acid have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy, approximately 50 percent in combination with ezetimibe, 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 considered “statin intolerant”. Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The Company has

two Phase 3 products in development: 1) bempedoic acid (monotherapy) an oral, once-daily pill, and 2) an, oral, once-daily fixed dose combination pill of bempedoic acid and ezetimibe (BA+EZ).

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 CVD; the leading cause of death around the world. Bempedoic acid, the Company's lead product candidate, is a targeted therapy that significantly reduces 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 therapeutic potential of, and clinical development plan for, bempedoic acid, including the Company's timing, designs, plans, and announcement of results regarding its global pivotal Phase 3 program for bempedoic acid, patient enrollment in the Company's Phase 3 clinical studies, the Company's Phase 2 triplet oral therapy study, the Company's cash position and liquidity outlook and the Company's plans for regulatory submission of bempedoic acid for an LDL-C lowering indication prior to the completion of a CVOT. 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 the Company's studies, including the risk that U.S. Food and Drug Administration may require additional studies or data, the impact of future changes in FDA's view of LDL-C lowering as a surrogate endpoint or standard-of-care treatment for patients with elevated LDL-C levels, that Esperion may need to change the design of its Phase 3 program, that positive results from a clinical study of bempedoic acid may not necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, that existing cash resources may be used more quickly than anticipated, that Esperion's global pivotal Phase 3 program for bempedoic acid may not produce sufficient safety or tolerability results or show meaningful change in LDL-C or other key lipid measures of patients, the CVOT may not demonstrate that bempedoic acid leads to cardiovascular risk reduction, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic acid, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. 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)

	December 31, 2016	December 31, 2015
Cash and cash equivalents	\$ 38,165	\$ 77,336
Working capital	197,988	208,769
Investments	204,324	215,240
Total assets	245,213	295,572
Total long-term debt	1,022	2,688
Common stock	23	23
Accumulated deficit	(229,200)	(154,222)
Total stockholders' equity	228,602	287,259

Esperion Therapeutics, Inc.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016 (Unaudited)	2015 (Unaudited)	2016 (Unaudited)	2015
Operating expenses:				
Research and development	\$ 24,881	\$ 7,956	\$ 57,868	\$ 29,802
General and administrative	4,404	5,278	18,282	20,238
Total operating expenses	29,285	13,234	76,150	50,040
Loss from operations	(29,285)	(13,234)	(76,150)	(50,040)
Interest expense	(78)	(121)	(376)	(520)
Other income, net	407	233	1,548	776
Net loss	\$ (28,956)	\$ (13,122)	\$ (74,978)	\$ (49,784)
Net loss per common share (basic and diluted)	\$ (1.29)	\$ (0.58)	\$ (3.33)	\$ (2.26)
Weighted average shares outstanding (basic and diluted)	22,554,418	22,515,136	22,544,475	22,019,818