

ESPERION THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 05/04/17 for the Period Ending 05/04/17

Address	3891 RANCHERO DRIVE, SUITE 150 ANN ARBOR, MI 48108
Telephone	734-887-3903
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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): **May 4, 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 2.02 Results of Operations and Financial Condition.

On May 4, 2017, Esperion Therapeutics, Inc. issued a press release announcing its financial results for the three months ended March 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 May 4, 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: May 4, 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 May 4, 2017.



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Esperion Provides Bempedoic Acid Development Program Updates; Reports First Quarter 2017 Financial Results

Ann Arbor, Mich., — (Globe Newswire — May 4, 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 first quarter ended March 31, 2017.

“With FDA having confirmed the pathway to approval for an LDL-C lowering indication for bempedoic acid, we remain on track to submit the NDA and MAA global regulatory filings by the first half of 2019. We expect to begin reporting top-line results from our global pivotal Phase 3 studies starting in the second quarter of 2018,” said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. “Our near-term focus is the completion of patient enrollment in our Phase 3 LDL-C lowering efficacy studies, and later this quarter we look forward to announcing details of our clinical development and regulatory strategy for our doublet pill, the fixed dose combination of bempedoic acid and ezetimibe.”

Development Program and Company Highlights

- February 2017: Initiated 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 (1002-050) will receive bempedoic acid.
- March 2017:
 - U.S. Food and Drug Administration (FDA) confirmed the ongoing global pivotal Phase 3 LDL-C lowering program is adequate to support approval for an LDL-C lowering indication for bempedoic acid;
 - Brian A. Ference, M.D., M.Phil, M.Sc., F.A.C.C., Associate Professor of Medicine, Wayne State University School of Medicine, presented “Genetic Target Validation for ATP Citrate Lyase Inhibition,” at the American College of Cardiology 66th Annual Scientific Session;
 - Initiated the Phase 2 triplet oral therapy study (1002-038) to further explore the complementary oral LDL-C lowering of bempedoic acid, ezetimibe and atorvastatin.

Upcoming Milestones

- June 2017:
 - Announce the clinical development and regulatory pathway for the doublet pill, the fixed dose combination of bempedoic acid 180 mg and ezetimibe 10 mg (BA+EZ).
 - 2H 2017:
 - Initiate and announce the design of a Phase 2 study of bempedoic acid added-on to a PCSK9i;
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- Announce top-line results of the Phase 2 triplet oral therapy study (1002-038);
- Complete patient enrollment of the three ongoing global pivotal Phase 3 LDL-C lowering efficacy studies (Studies 2, 3 and 4);
- Dr. Brian A. Ference to publish results from the Mendelian randomization studies that genetically validate ACL inhibition in a top-tier medical journal.

2017 First Quarter Financial Results

As of March 31, 2017, cash and cash equivalents and investment securities available-for-sale totaled \$207.8 million compared with \$242.5 million at December 31, 2016.

Research and development expenses were \$35.9 million for the first quarter of 2017, compared to \$9.8 million for the comparable period in 2016. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, including costs to support the global pivotal Phase 3 LDL-C lowering program and the cardiovascular outcomes trial (CVOT), and further increases in our headcount and stock-based compensation expense.

General and administrative expenses were \$5.0 million for the first quarter of 2017 and 2016. Decreases in stock-based compensation expense were offset by increases in costs to support public company operations and other costs to support our growth.

Esperion had a net loss of \$40.5 million for the first quarter of 2017, compared to \$14.6 million for the comparable period in 2016.

Esperion had approximately 22.6 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 \$2.3 million of debt outstanding as of March 31, 2017.

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 through the announcement of top-line results from all global pivotal Phase 3 safety and efficacy studies and into early 2019.

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, and may potentially be associated with a lower occurrence of 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 has 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 bempedoic acid, 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 Phase 3 long-term safety and tolerability program and CVOT for bempedoic acid, and the Company's expected cash and liquidity position and outlook. Any express or implied statements contained in this press release that are not statements of historical fact, including interpretation of guidance given by the FDA, 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, changes in the FDA guidance for regulatory approval, delays or failures in the Company's studies, including risks regarding the FDA's interpretation of the Company's clinical trial results, the risk that U.S. Food and Drug Administration may require additional studies or data, 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 be sufficient for FDA approval or 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 Phase 3 long-term safety and tolerability program for bempedoic acid may not produce sufficient safety or tolerability results or show meaningful change in LDL-C, that the CVOT may not demonstrate that bempedoic acid leads to cardiovascular risk reduction or other key lipid measures of patients, if approved that Esperion's product could have labeling restrictions that impact its marketing and adoption, 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. The FDA guidance described in this release was given as of a specific date and the FDA could change its position on the clinical endpoints or other standards for review/approval. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Actual results could differ from those described therein. 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>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Cash and cash equivalents	\$ 19,867	\$ 38,165
Working capital	166,408	197,988
Investments	187,937	204,324
Total assets	214,612	245,213
Total long-term debt	585	1,022
Common stock	23	23
Accumulated deficit	(269,844)	(229,200)
Total stockholders' equity	192,422	228,602

Esperion Therapeutics, Inc.

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

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2017</u>	<u>2016</u>
Operating expenses:		
Research and development	\$ 35,860	\$ 9,791
General and administrative	5,029	5,031
Total operating expenses	40,889	14,822
Loss from operations	(40,889)	(14,822)
Interest expense	(67)	(110)
Other income, net	415	347
Net loss	<u>\$ (40,541)</u>	<u>\$ (14,585)</u>
Net loss per common share (basic and diluted)	<u>\$ (1.80)</u>	<u>\$ (0.65)</u>
Weighted average shares outstanding (basic and diluted)	<u>22,563,152</u>	<u>22,532,031</u>

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