

Esperion Therapeutics, Inc.
Form 8-K
January 12, 2015

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): **January 12, 2015**

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

Edgar Filing: Esperion Therapeutics, Inc. - Form 8-K

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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 7.01 Regulation FD Disclosure.

On January 12, 2015, Esperion Therapeutics, Inc. (the "Company") announced the submission to FDA of the responses to the PPAR and 240 mg Partial Clinical Holds for ETC-1002. In 2009, upon submission of the original IND for ETC-1002, the FDA had determined that ETC-1002 was a potential peroxisome proliferator activated receptor (PPAR) agonist and as a result was subject to a partial clinical hold. The partial clinical hold permits clinical studies of up to six months in duration for ETC-1002, but also required the Company to evaluate the drug candidate in two-year rat and mouse carcinogenicity studies before initiating clinical studies longer than six months. In addition, based upon early preclinical toxicology results, the FDA limited the Company's ability to dose ETC-1002 above 240 mg in its clinical studies. The Company has dosed ETC-1002 at doses between 40 mg and 240 mg in the clinical program to date (11 completed clinical studies) and has achieved the desired efficacy within this dose range. Based upon the satisfactory safety and efficacy results achieved, Phase 3 planning is underway and clinical trials in the final stage of testing will include doses of ETC-1002 within the historical range.

On January 12, 2015, Esperion Therapeutics, Inc. announced that the abstract "ETC-1002 Lowers LDL-C More Than Ezetimibe in Patients with Hypercholesterolemia with or without Statin Intolerance" (ETC-1002-008) has been accepted for presentation at the American College of Cardiology Scientific Session March 14-16, 2015.

On January 12, 2015, Esperion Therapeutics, Inc. announced that the United States Adopted Names (USAN) Council has assigned "bempedoic acid" as the non-proprietary name for ETC-1002.

The information in Item 7.01 of this Report on Form 8-K is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

* * *

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: January 12, 2015

Esperion Therapeutics, Inc.

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