

**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 2, 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 1.01. Entry into a Material Definitive Agreement.

On January 2, 2019, Esperion Therapeutics, Inc. (the “Company”) entered into a License and Collaboration Agreement (the “Agreement”) with Daiichi Sankyo Europe GmbH (“DSE”). Pursuant to the Agreement, the Company will grant DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland (the “Territory”). DSE will be responsible for commercialization in the Territory. The Company will be responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including the Territory.

The Company and DSE will establish a joint collaboration committee (the “JCC”) to, among other powers and responsibilities, review and guide the implementation and management of development plans of the licensed products in the Territory, review the status of licensed products, approve of DSE’s request of certain clinical activities, address certain development and manufacturing matters of the licensed products in accordance with the terms of the Agreement, and perform other activities mutually agreed by the Company and DSE from time to time.

The Company will receive an upfront cash payment of \$150 million as well as \$150 million upon first commercial sales in the Territory. The Company is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the marketing authorization in the European Union for the cardiovascular risk reduction label, depending on the range of relative risk reduction in the Company’s CLEAR Outcomes study. In addition, the Company is eligible to receive additional sales milestone payments. Finally, the Company will receive tiered fifteen percent (15%) to twenty-five percent (25%) royalties on net Territory sales.

The Agreement will remain in effect, unless terminated earlier, until the last to expire royalty term under the Agreement. Each party has the right to terminate the Agreement for the other party’s material breach of its obligations under the Agreement, subject to cure rights. Additionally, DSE may terminate the Agreement in its sole discretion and in its entirety after a certain time period with sufficient prior written notice. The Company may also terminate the licenses of specified patent rights upon notice if DSE challenges the enforceability, validity, or scope of any patent rights belonging to the Company, unless DSE withdraws or causes the challenge to be withdrawn within a specified period. Either party to the Agreement may terminate the Agreement if the other party declares bankruptcy. Other termination rights are as specified in the Agreement. Upon termination, any license granted by the Company to DSE will terminate.

The Agreement includes customary representations and warranties on behalf of the Company and DSE as are customarily found in transactions of this nature, including representations and operative provisions as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

The foregoing description of the material terms of the Agreement is qualified in its entirety by reference to the complete text of the Agreement, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission.

Item 8.01. Other Events.

On January 4, 2019, the Company issued a press release announcing the entry into the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 4, 2019

SIGNATURES

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 4, 2019

Esperion Therapeutics, Inc.

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



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Esperion Announces Agreement with Daiichi Sankyo Europe (DSE) to Commercialize Bempedoic Acid in Europe

— Esperion to Receive \$300 Million in Upfront and Near-term Milestones —
 — Up to \$900 Million in Total Milestones —
 — Substantial Tiered Royalties —

— Esperion Partnering with a European CV Sales Organization Exceeding 1000 and One of the Most Successful European-based Commercial Businesses —
 — Conference Call and Webcast on Friday, January 4 at 8:00 a.m. Eastern Time —

ANN ARBOR, Mich. Jan. 4, 2019 (GLOBE NEWSWIRE) — Esperion Therapeutics (NASDAQ: ESPR) today announced that they have entered into a licensing agreement with Daiichi Sankyo Europe (DSE) providing DSE with exclusive rights to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland. The agreement combines Esperion Therapeutics' first-in-class ATP Citrate Lyase (ACL) inhibitor, bempedoic acid, with Daiichi Sankyo's European commercial capabilities which includes more than 1000 professionals dedicated to the commercialization of cardiovascular (CV) products, as well as synergies with their existing portfolio of novel oral anticoagulant and antiplatelet products. This agreement seeks to distribute bempedoic acid and the bempedoic acid / ezetimibe combination pill to the millions of patients in these geographies that need additional low-density lipoprotein cholesterol (LDL-C) lowering after maximum tolerated statin therapy.

"Daiichi Sankyo is focused on innovative pharmaceutical products to address the unmet medical needs of patients including those with cardiovascular disease, the number one cause of death and disability globally," Ralf Goeddertz, Head of Business Development and Licensing at Daiichi Sankyo Europe. "The Esperion team has conducted a robust, 4,000 patient, high-quality development program to establish bempedoic acid as an efficacious and safe therapeutic option that will help millions of patients that do not reach LDL-C treatment goals."

“We are very pleased to partner with DSE to establish bempedoic acid as the most preferred LDL-C lowering treatment option after statins for patients and physicians in Europe. Daiichi Sankyo Europe’s 1000 person cardiovascular commercial organization has a strong history of successfully commercializing drugs, including their novel oral *anticoagulant*, LIXIANA®, and there is significant overlap among physicians targeted for bempedoic acid,” said Tim Mayleben, president and chief executive officer of Esperion. “This agreement represents the first step in the evolution of Esperion from a pioneering development-stage company to a successful commercial-stage company.”

Esperion completed its Phase 3 LDL-C development program of bempedoic acid and the bempedoic acid / ezetimibe combination pill in October 2018. The company plans to submit New Drug Applications (NDAs) to the Food and Drug Administration (FDA) during the first quarter of 2019 and Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) during the second quarter of 2019. FDA and EMA LDL-C approval decisions are expected during the first half of 2020. The global cardiovascular outcomes trial of bempedoic acid, CLEAR Outcomes, is ongoing and cardiovascular risk reduction results are expected during 2022.

Details of the Agreement and Financial Terms

Under the terms of the licensing agreement, Esperion will grant Daiichi Sankyo Europe exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland. Daiichi Sankyo Europe will be responsible for commercialization in the territories.

Esperion will receive an upfront cash payment of \$150 million as well as \$150 million upon first commercial sales in the territory. Esperion is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the Marketing Authorization in the EU for the CV Risk Reduction Label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, Esperion is eligible to receive additional sales milestone payments. Finally, Esperion will receive substantial tiered royalties on net territory sales.

Conference Call and Webcast Information

Esperion’s Lipid Management Team will host a conference call and webcast today, Friday, January 4, 2019 at 8:00 a.m. Eastern Time to discuss the details of the agreement with Daiichi Sankyo Europe. The call can be accessed by dialing (877) 312-7508 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing access code 5399439. A live audio webcast can be accessed on the investors and media section of the Esperion website at investor.esperion.com. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company’s website for approximately 90 days.

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 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 up-regulates 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 produced 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.

About Esperion

Esperion 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 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 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 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 regarding its global pivotal Phase 3 clinical development program for bempedoic acid and the bempedoic acid / ezetimibe combination pill, Esperion's timing and plans for submission of NDAs to the FDA and MAAs to the EMA and 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 pill, if approved, and the expected upcoming milestones described in this press release. 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 pill 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.

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