

Esperion Provides Bempedoic Acid Franchise Development Program Updates; Reports Third Quarter 2018 Financial Results

November 1, 2018

ANN ARBOR, Mich., Nov. 01, 2018 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2018.

"The Lipid Management Team has made tremendous progress this year with positive top-line results reported from five pivotal Phase 3 studies. As we learned at our investor day in July, leading physicians and key opinion leaders have a highly favorable view of both bempedoic acid and the bempedoic acid / ezetimibe combination pill," said Tim M. Mayleben, president and chief executive officer of Esperion. "With results from the completed Phase 3 LDL-C lowering program in hand, we remain on-track to submit New Drug Applications for both drugs during the first quarter of 2019. We look forward to working with regulatory authorities to bring our convenient, cost-effective and complementary once-daily, oral bempedoic acid-based LDL-cholesterol lowering therapies to the millions of patients who are not reaching their LDL-C lowering goals with existing treatment options."

Recent Development Program Highlights

August 2018:

- Final Study 1 ([1002-040](#)) results were presented by Prof. Kausik Ray at the European Society of Cardiology Congress.
- Announced positive top-line results from the global, pivotal Phase 3 study ([1002FDC-053](#)) evaluating the safety and tolerability of the bempedoic acid 180 mg / ezetimibe 10 mg combination pill compared to bempedoic acid, ezetimibe or placebo in high-risk patients treated with maximally tolerated statins. The bempedoic acid / ezetimibe combination pill was observed to be safe and well tolerated in this study, and provided an additional 35 percent LDL-C lowering and 34 percent hsCRP reduction. In patients taking no statin background therapy, the bempedoic acid / ezetimibe combination pill lowered LDL-C by 43 percent.

October 2018:

- Announced positive top-line results from Study 2 ([1002-047](#)), the global, pivotal Phase 3 study of bempedoic acid 180 mg evaluating the LDL-C lowering efficacy and the safety and tolerability of bempedoic acid versus placebo in patients with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH) who are inadequately controlled with current lipid-modifying therapies, including maximally tolerated statin therapy. Bempedoic acid was observed to be safe and well-tolerated in this study and provided an additional 18 percent LDL-C lowering and 19 percent hsCRP reduction.
- Announced positive cumulative [results](#) from our Phase 3 LDL-C lowering development program of bempedoic acid. The program consisted of four pivotal, Phase 3, randomized, double-blind, placebo controlled studies which evaluated the LDL-C lowering efficacy and safety and tolerability of bempedoic acid 180 mg compared to placebo in high cardiovascular risk patients including ASCVD and/or HeFH patients. Bempedoic acid achieved all safety and tolerability objectives in the Phase 3 program and provided patients an additional 18% to 31% LDL-C lowering, 19% to 33% hsCRP reductions, as well as 0.19% to 0.31% hemoglobin A1c reductions.

Upcoming Milestones

November 2018:

- Presentation of final Study 3 (1002-046) results at the American Heart Association Scientific Sessions in Chicago.

First quarter 2019:

- NDA submissions of bempedoic acid and the bempedoic acid / ezetimibe combination pill to the US Food and Drug Administration.

Second quarter 2019:

- MAA submissions of bempedoic acid and the bempedoic acid / ezetimibe combination pill to the European Medicines Agency.
- Top-line results from the Phase 1 study of bempedoic acid sustained release (SR) in overweight subjects measuring traditional lipid parameters together with de novo lipogenesis.

2018 Financial Outlook

Esperion expects notably lower research and development expenses beginning this quarter due to the completion of the global pivotal Phase 3 LDL-C lowering development program of bempedoic acid and the bempedoic acid / ezetimibe combination pill in October 2018.

The company continues to expect 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.

2018 Third Quarter Financial Results

As of September 30, 2018, cash and cash equivalents and investment securities available-for-sale totaled \$164.4 million compared with \$273.6 million at December 31, 2017.

Research and development expenses were \$41.6 million for the third quarter of 2018 and \$122.0 million for the nine months ended September 30, 2018, compared to \$40.1 million and \$114.2 million for the comparable periods in 2017. The increase in research and development expenses was primarily related to clinical development costs for the bempedoic acid / ezetimibe combination pill and bempedoic acid, including costs to support the completion of three global pivotal Phase 3 studies for bempedoic acid and the pivotal Phase 3 study for the bempedoic acid / ezetimibe combination pill during the period, the ongoing CLEAR CVOT, and increases in our headcount and stock-based compensation expense.

General and administrative expenses were \$9.0 million for the third quarter of 2018 and \$21.9 million for the nine months ended September 30, 2018, compared to \$5.7 million and \$16.1 million for the comparable periods in 2017. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, including costs to support pre-commercialization activities, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Esperion had a net loss of \$49.9 million for the third quarter of 2018 and \$141.8 million for the nine months ended September 30, 2018, compared to \$45.2 million and \$129.1 million, respectively, for the comparable periods in 2017.

Esperion had approximately 26.8 million shares of common stock outstanding, with another 4.6 million issuable upon exercise of stock options and warrants and vesting of restricted stock units as of September 30, 2018.

About Esperion's Global Pivotal Phase 3 LDL-C Lowering Program

Esperion initiated its global, pivotal, Phase 3 clinical development program in January 2016 to evaluate the safety, tolerability and consistent, complementary LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination pill in patients with atherosclerotic cardiovascular disease (ASCVD), or who are at a high risk for ASCVD, with hypercholesterolemia who continue to have elevated levels of LDL-C despite the use of maximally-tolerated statins and ezetimibe, leaving them at high risk for cardiovascular events. The program includes five studies in approximately 4,000 patients, four for bempedoic acid and one for the bempedoic acid / ezetimibe combination pill.

- Two pivotal studies evaluating bempedoic acid (Studies 1 & 2) in 3,008 patients with ASCVD on maximally-tolerated statins, with top-line results reported in May 2018 and October 2018, respectively;
- Two pivotal studies evaluating bempedoic acid (Studies 3 & 4) in 613 patients with ASCVD, or at a high risk for ASCVD, considered statin intolerant, with top-line results reported in May 2018 and March 2018, respectively;
- One pivotal study evaluating the bempedoic acid / ezetimibe combination pill (053 Study) in 382 patients with ASCVD, or at high risk for ASCVD, on maximally tolerated statins, with top-line results reported in August 2018.

Esperion plans to submit New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for bempedoic acid and the bempedoic acid / ezetimibe combination pill for LDL-C lowering indications during the first quarter of 2019. Additionally, Esperion plans to submit Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) during the second quarter of 2019.

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. 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 (ACL) 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 Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (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.

Esperion's Commitment to Patients with Hypercholesterolemia

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack or stroke. In the U.S., 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. There are approximately 13 million people in the U.S. with atherosclerotic cardiovascular disease (ASCVD) who live with elevated levels of LDL-C despite taking maximally-tolerated lipid-modifying therapy — including individuals considered statin intolerant — leaving them at high risk for cardiovascular events. More than 6 million patients with ASCVD and/or HeFH on maximally tolerated statins require less than 30 percent additional LDL-C lowering to achieve treatment goals.

Esperion's mission as the Lipid Management Company is to deliver once-daily, oral therapies that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

The Lipid Management Company

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 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 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, 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, 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 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.

Esperion Therapeutics, Inc.

Balance Sheet Data (In thousands) (Unaudited)

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 26,755	\$ 34,468
Working capital	125,925	170,780
Investments	137,644	239,151
Total assets	174,030	277,835
Common stock	27	26
Accumulated deficit	(538,062)	(396,291)
Total stockholders' equity	131,745	244,691

Esperion Therapeutics, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 41,551	\$ 40,056	\$ 122,015	\$ 114,164
General and administrative	9,011	5,681	21,921	16,122
Total operating expenses	<u>50,562</u>	<u>45,737</u>	<u>143,936</u>	<u>130,286</u>
Loss from operations	(50,562)	(45,737)	(143,936)	(130,286)
Other income, net	651	518	2,165	1,189
Net loss	<u>\$ (49,911)</u>	<u>\$ (45,219)</u>	<u>\$ (141,771)</u>	<u>\$ (129,097)</u>
Net loss per common share (basic and diluted)	<u>\$ (1.86)</u>	<u>\$ (1.86)</u>	<u>\$ (5.30)</u>	<u>\$ (5.57)</u>
Weighted average shares outstanding (basic and diluted)	<u>26,804,026</u>	<u>24,311,844</u>	<u>26,732,733</u>	<u>23,161,847</u>

Investor Contact:

Alex Schwartz
Esperion
734-249-3386
aschwartz@esperion.com

Media Contact:

Elliot Fox
W2O Group
212-257-6724
efox@w2ogroup.com