

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

August 2, 2018

ANN ARBOR, Mich., Aug. 02, 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 second quarter ended June 30, 2018.

"The Lipid Management Team has made tremendous progress during the first half of 2018, with positive top-line results reported from three pivotal Phase 3 studies and one Phase 2 study. Full results of completed Phase 3 studies are being prepared for presentation and publication, with full Study 4 results already presented and published last month. Additionally, at our recent Investor Day, key opinion leaders expressed their agreement that bempedoic acid is safe and well-tolerated, and has demonstrated clinically meaningful LDL-C lowering in completed Phase 2 and 3 studies," said Tim M. Mayleben, president and chief executive officer of Esperion. "We remain on-track to report top-line results for the final two pivotal Phase 3 studies at the end of August and September, as well as submit NDAs no later than the first quarter of 2019. We are on the cusp of delivering two once-daily, oral bempedoic acid-based LDL-cholesterol lowering therapies to the millions of patients who are inadequately treated with, or unable to gain access to, current LDL-C lowering therapies."

Second Quarter Development Program Highlights

May 2018:

- Announced positive top-line results from the global, pivotal Phase 3 long-term study (Study 1 or 1002-040) of bempedoic acid 180 mg evaluating the safety and tolerability of bempedoic acid versus placebo in very high-risk patients with atherosclerotic cardiovascular disease (ASCVD) 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 20 percent LDL-C lowering and 22 percent hsCRP reduction.
- Announced positive top-line results from the third global, pivotal Phase 3 study of bempedoic acid in patients with ASCVD or at high risk for ASCVD on background therapy of less than approved daily starting doses of statins (high CV risk patients considered statin intolerant). Bempedoic acid was observed to be safe and well-tolerated in this study, and provided an additional 26 percent LDL-C lowering and 25 percent hsCRP reduction.

June 2018:

- Presented full Study 4 (1002-048) results at the International Symposium on Atherosclerosis in Toronto and simultaneously published in [Atherosclerosis](#).

Upcoming Milestones

August 2018:

- Top-line results expected from the 12-week, pivotal Phase 3 Study ([1002FDC-053](#)) of the bempedoic acid / ezetimibe combination pill in ASCVD patients on maximally tolerated statin background therapy.
- Present Study 1 (1002-040) results at the European Society of Cardiology (ESC) meeting in Munich, Germany.

September 2018:

- Top-line results expected from the 52-week, pivotal Phase 3 Study 2 ([1002-047](#)) of bempedoic acid in ASCVD patients on maximally tolerated statin background therapy.

2018 Financial Outlook

Esperion expects notably lower research and development expenses, beginning 4Q18, as the global pivotal Phase 3 development program will have been completed.

The company expects 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 Second Quarter Financial Results

As of June 30, 2018, cash and cash equivalents and investment securities available-for-sale totaled \$201.8 million compared with \$273.6 million at

December 31, 2017.

Research and development expenses were \$39.5 million for the second quarter of 2018 and \$80.5 million for the six months ended June 30, 2018, compared to \$38.2 million and \$74.1 million for the comparable periods in 2017. As expected, 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 during the period, the ongoing CLEAR CVOT, and increases in our headcount and stock-based compensation expense.

General and administrative expenses were \$7.0 million for the second quarter of 2018 and \$12.9 million for the six months ended June 30, 2018, compared to \$5.4 million and \$10.4 million for the comparable periods in 2017. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, modest increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Esperion had a net loss of \$45.7 million for the second quarter of 2018 and \$91.9 million for the six months ended June 30, 2018, compared to \$43.3 million and \$83.9 million, respectively, for the comparable periods in 2017.

Esperion had approximately 26.8 million shares of common stock outstanding, with another 4.5 million issuable upon exercise of stock options and warrants and vesting of restricted stock units, and \$0.2 million of debt outstanding as of June 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 3,009 patients with ASCVD on maximally tolerated statin therapy, with top-line results reported in May 2018, and expected in September 2018, respectively;
- Two pivotal studies evaluating bempedoic acid (Studies 3 & 4) in 614 patients with ASCVD, or at high risk for ASCVD, who are considered statin intolerant, with top-line results reported in May 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 statin therapy, with top-line results expected 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 no later than the first quarter of 2019. Additionally, Esperion plans to submit Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) no later than 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. Previously completed Phase 2 data demonstrated that this safe and well tolerated combination results in a 48 percent lowering of LDL-C, and a 26 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 1, Phase 2 and Phase 3 studies conducted in more than 4,100 patients, and over 2,700 patients treated with bempedoic acid have produced 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.

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 up to 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. The vast majority of these patients 9.5 million, 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 complementary, convenient, 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 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 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)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 24,380	\$ 34,468
Working capital	153,919	170,780
Investments	177,424	239,151
Total assets	210,881	277,835
Common stock	27	26
Accumulated deficit	(488,151)	(396,291)
Total stockholders' equity	175,917	244,691

Esperion Therapeutics, Inc.

Statement of Operations

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 39,524	\$ 38,248	\$ 80,464	\$ 74,108
General and administrative	6,956	5,412	12,910	10,441
Total operating expenses	46,480	43,660	93,374	84,549
Loss from operations	(46,480)	(43,660)	(93,374)	(84,549)
Other income, net	750	323	1,514	671
Net loss	\$ (45,730)	\$ (43,337)	\$ (91,860)	\$ (83,878)
Net loss per common share (basic and diluted)	\$ (1.71)	\$ (1.92)	\$ (3.44)	\$ (3.72)
Weighted average shares outstanding (basic and diluted)	26,786,796	22,591,326	26,696,495	22,577,317

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

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

 Primary Logo

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