



November 3, 2016

Esperion Therapeutics Provides Bempedoic Acid Development Program Updates; Reports Third Quarter 2016 Financial Results

ANN ARBOR, Mich., Nov. 03, 2016 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), a pharmaceutical company focused on developing and commercializing oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today provided bempedoic acid (ETC-1002) development program updates and financial results for the third quarter ended September 30, 2016.

"With the delivery of positive top-line results from the clinical studies of bempedoic acid in combination with high-dose statins, we will enroll patients with hypercholesterolemia on maximally tolerated lipid-modifying therapy, including patients on any statin at any dose, into our global pivotal Phase 3 program," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "While we continue to rapidly enroll patients into the global long-term safety study, we look forward to initiating the global pivotal Phase 3 LDL-C lowering efficacy studies and cardiovascular outcomes trial for bempedoic acid before year-end. With our available cash resources, we remain focused on delivering top-line results from our Phase 3 efficacy and long-term safety studies by mid-2018."

Development Program and Company Highlights

- | October 2016:
 - | Esperion announced positive top-line results of the Phase 1 (1002-037) and Phase 2 (1002-035) clinical studies of bempedoic acid in combination with high-dose statins.
 - | Esperion amended and expanded the global Phase 3 CLEAR Harmony (1002-040) 52-week, long-term safety study to include 1,950 patients with hypercholesterolemia on maximally tolerated lipid modifying therapy, including patients on any statin at any dose.
 - | Esperion announced high-level design details for three global pivotal Phase 3 CLEAR LDL-C lowering efficacy studies of bempedoic acid — 1002-046, 1002,047, and 1002-048.
 - | Esperion announced the proposed global pivotal Phase 3 clinical development plan is expected to support global regulatory submissions for an LDL-cholesterol lowering indication in patients with hypercholesterolemia on maximally tolerated background lipid modifying therapy who require additional LDL-cholesterol lowering, with a special focus on patients considered "statin intolerant".

Upcoming Milestones

- | Q4 2016:
 - | Esperion plans to initiate the three global pivotal Phase 3 CLEAR LDL-C lowering efficacy studies and the global CLEAR Outcomes cardiovascular outcomes trial.
 - | Esperion plans to publish the definitive scientific paper on the mechanism of action for bempedoic acid in a top-tier journal.

2016 Third Quarter Financial Results

As of September 30, 2016, cash and cash equivalents and investment securities available-for-sale totaled \$259.7 million compared with \$292.6 million at December 31, 2015.

Research and development expenses were \$13.5 million for the third quarter of 2016 and \$33.0 million for the nine months ended September 30, 2016, compared to \$7.2 million and \$21.8 million for the comparable periods in 2015. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, which includes increases in the Company's headcount and stock-based compensation expense.

General and administrative expenses were \$4.2 million for the third quarter of 2016 and \$13.9 million for the nine months ended September 30, 2016, compared to \$5.7 million and \$15.0 million for the comparable periods in 2015. The decrease in general and administrative expenses was primarily related to a reduction in pre-commercialization activities, partially offset by increases in costs to support public company operations, increases in the Company's headcount, and other costs to support Esperion's growth.

Esperion had a net loss of \$17.4 million for the third quarter of 2016 and \$46.0 million for the nine months ended September 30, 2016, compared to \$12.8 million and \$36.7 million, respectively, for the comparable periods in 2015.

Esperion had approximately 22.6 million shares of common stock outstanding, with another 3.4 million issuable upon exercise of stock options and warrants and vesting of restricted stock units, and \$3.1 million of debt outstanding as of September 30, 2016.

2016 Financial Outlook

Esperion expects full-year net cash used in operating activities in 2016 will be approximately \$65 million and that its cash and cash equivalents and investment securities to be approximately \$225 million at December 31, 2016. The Company expects to announce top-line results from the global pivotal Phase 3 CLEAR LDL-C lowering efficacy and safety studies in mid-2018, and that current cash resources are sufficient to fund operations into early 2019.

About Bempedoic Acid

Bempedoic acid is a first-in-class ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Phase 1 and 2 studies conducted previously 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 to 22 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 is to provide patients and physicians with a new oral therapy to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. Esperion-discovered and developed, bempedoic acid is an oral LDL-C lowering therapy in Phase 3 development. The Company plans to develop bempedoic acid as a monotherapy as well as a fixed dose combination (FDC) with ezetimibe, with a particular focus on patients inadequately treated with current lipid-modifying therapies. It is estimated that approximately 5-20 percent of patients who are prescribed statins are only able to tolerate less than the lowest approved daily starting dose of their statin ("statin intolerant").

About Esperion Therapeutics

Esperion Therapeutics, Inc. is a pharmaceutical company focused on developing and commercializing oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the 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, the Company's lead product candidate, significantly reduces 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 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 program and timing of an NDA submission for bempedoic acid, in each case including that submissions for an LDL-C lowering indication could be filed in the United States and Europe prior to the completion of a cardiovascular outcomes trial, or CVOT, its upcoming milestones, and its 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 the Company's studies, including in patient enrollment, the risk that FDA may require additional studies or data that Esperion may need to change the design of its Phase 3 program, the impact of future changes in FDA's view of LDL-C lowering as a surrogate endpoint or standard-of-care treatment for patients with elevated LDL-C levels, that positive results from prior clinical studies of bempedoic acid, including from 1002-035 and 1002-037, may not 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, the CVOT may not demonstrate that bempedoic acid leads to cardiovascular risk reduction, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic acid, as well as other risks detailed in Esperion's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the

year ended December 31, 2015 and subsequently filed Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. 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, 2016	December 31, 2015
Cash and cash equivalents \$	47,140	77,336
Working capital	205,307	208,769
Investments	212,607	215,240
Total assets	263,791	295,572
Total long-term debt	1,451	2,688
Common stock	23	23
Accumulated deficit	(200,244)	(154,222)
Total stockholders' equity	254,180	287,259

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,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 13,498	\$ 7,247	\$ 32,987	\$ 21,846
General and administrative	4,214	5,672	13,878	14,960
Total operating expenses	<u>17,712</u>	<u>12,919</u>	<u>46,865</u>	<u>36,806</u>
Loss from operations	<u>(17,712)</u>	<u>(12,919)</u>	<u>(46,865)</u>	<u>(36,806)</u>
Interest expense	(89)	(130)	(298)	(399)
Other income, net	399	248	1,141	543
Net loss	<u>\$ (17,402)</u>	<u>\$ (12,801)</u>	<u>\$ (46,022)</u>	<u>\$ (36,662)</u>
Net loss per common share (basic and diluted)	<u>\$ (0.77)</u>	<u>\$ (0.57)</u>	<u>\$ (2.04)</u>	<u>\$ (1.68)</u>
Weighted average shares outstanding (basic and diluted)	<u>22,550,438</u>	<u>22,494,075</u>	<u>22,541,137</u>	<u>21,854,685</u>

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