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

ANN ARBOR, Mich., Aug. 04, 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 second quarter ended June 30, 2016.

"The Esperion team is focused on the fourth quarter initiation of our global pivotal Phase 3 CLEAR LDL-C lowering efficacy studies in patients with hypercholesterolemia and the global CLEAR Outcomes trial in statin intolerant patients," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "We also look forward to sharing top-line results from our Phase 1 and Phase 2 clinical studies of bempedoic acid added-on to high-dose statins in September."

Development Program and Company Highlights

- June 2016:
  - Esperion announced global clinical development and regulatory plans for the bempedoic acid statin intolerance program following discussions with the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA). The clinical program has two major components: 1) the global pivotal Phase 3 Cholesterol Lowering via BEmpedoic Acid, an ACL-inhibiting Regimen (CLEAR) LDL-C lowering efficacy and safety studies in patients with hypercholesterolemia, and 2) the global CLEAR Outcomes cardiovascular outcomes trial (CVOT) in patients with elevated LDL-C levels who are unable to tolerate statins (statin intolerance).
  - Esperion received acceptance for filing of an Investigational New Drug Application by the FDA for the fixed-dose combination (FDC) of 180 mg of bempedoic acid and 10 mg of ezetimibe.
- July 2016:
  - Esperion initiated a Phase 1 (1002-034) bioavailability study for the FDC.

Upcoming Milestones

- September 2016:
  - Esperion plans to announce top-line results from the Phase 1 (1002-037) and Phase 2 (1002-035) clinical studies of bempedoic acid and high-dose statins.
- Q4 2016:
  - Esperion plans to initiate the global pivotal Phase 3 CLEAR LDL-C lowering efficacy studies and the global CLEAR Outcomes trial.

2016 Second Quarter Financial Results

As of June 30, 2016, cash and cash equivalents and investment securities available-for-sale totaled $274.8 million compared with $292.6 million at December 31, 2015.

Research and development expenses were $9.7 million for the second quarter of 2016 and $19.5 million for the six months ended June 30, 2016, compared to $7.2 million and $14.6 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 $4.6 million for the second quarter of 2016 and $9.7 million for the six months ended June 30, 2016, compared to $5.3 million and $9.3 million for the comparable periods in 2015. The decrease in general and administrative expenses for the second quarter of 2016 was primarily attributable to a reduction in pre-commercialization activities and the increase in general and administrative expenses for the six months ended June 30, 2016, was primarily attributable to increases in costs to support public company operations, increases in headcount, which includes increased stock-based compensation expense, and other costs to support Esperion's growth.

Esperion had a net loss of $14.0 million for the second quarter of 2016 and $28.6 million for the six months ended June 30, 2016, compared to $12.4 million and $23.9 million, respectively, for the comparable periods in 2015.

Esperion had approximately 22.5 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 $3.5 million of debt outstanding as of June 30, 2016.

2016 Financial Outlook

Esperion expects full-year 2016 net cash used in operating activities in 2016 will be approximately $65 to $75 million and that its cash and cash equivalents and investment securities to be approximately $220 million at December 31, 2016. The Company estimates that current cash resources are sufficient to fund operations into 2019 and the anticipated announcement of top-line results from the global pivotal Phase 3 CLEAR LDL-C lowering efficacy and safety studies.

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 700 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 24 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, without muscle-related side effects. 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 FDC with ezetimibe, with a particular focus on patients with elevated LDL-C who are unable to tolerate statin therapy. It is estimated that approximately 5-20 percent of patients who are prescribed statins are considered 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 those with statin intolerance. 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 timing of announcement of top-line results from the Company's Phase 1 (1002-037) and Phase 2 (1002-035) clinical studies, the Company's timing and plans regarding its Phase 3 program and CVOT, in each case including that submissions for an LDL-C lowering indication could be filed in the United States and Europe, and the Company's expected cash and liquidity position and 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 patient enrollment in the Company's studies, 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 a clinical study of bempedoic acid 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. 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)

	June 30, 2016	December 31, 2015
Cash and cash equivalents	$ 48,768	$ 77,336
Working capital	201,453	208,769
Investments	226,047	215,240
Total assets	277,466	295,572
Total long-term debt	1,871	2,688
Common stock	23	23
Accumulated deficit	(182,842)	(154,222)
Total stockholders' equity	267,960	287,259

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 9,698	$ 7,209	$ 19,489	$ 14,599
General and administrative	4,633	5,253	9,664	9,288
Total operating expenses	14,331	12,462	29,153	23,887
Loss from operations	(14,331)	(12,462)	(29,153)	(23,887)
Interest expense	(99)	(135)	(209)	(269)
Other income, net	395	202	742	295
Net loss	$ (14,035)	$ (12,395)	$ (28,620)	$ (23,861)
Net loss per common share (basic and diluted)	$ (0.62)	$ (0.55)	$ (1.27)	$ (1.11)
Weighted average shares outstanding (basic and diluted)	22,541,455	22,465,175	22,536,438	21,531,509

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