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Esperion Provides Bempedoic Acid Franchise Development Program Updates; Reports Third Quarter 2017 Financial Results

ANN ARBOR, Mich., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), the Lipid Management Company focused on developing and commercializing convenient, complementary, 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, 2017.

"We are entering the most transformative period in Esperion's history in a strong position. The bempedoic acid franchise continues to deliver highly positive clinical results, most recently with the all-oral regimen of the bempedoic acid / ezetimibe combination plus atorvastatin lowering LDL-C by 64% and reducing hsCRP by almost 50%. Patient enrollment was completed in September for the bempedoic acid pivotal Phase 3 LDL-C lowering studies, and the pivotal Phase 3 study of the bempedoic acid / ezetimibe combination pill has been initiated. Top-line results are on track to start reporting out by the second quarter of 2018 followed by NDA submissions by the first quarter of 2019," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "We are in a strong financial position and continue to make rapid progress on delivering 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 lipid-modifying therapies."

Development Program and Company Highlights

- August 2017:
  - Announced positive top-line results from the Phase 2 clinical study (1002-038) of the bempedoic acid / ezetimibe combination plus atorvastatin all-oral therapy;
  - Completed a follow-on public offering of $175 million, funding the Company through the expected regulatory approvals of the bempedoic acid / ezetimibe combination pill and bempedoic acid in the first quarter of 2020.
- September 2017: Completed enrollment in the global pivotal Phase 3 program for bempedoic acid.
- November 2017: Initiated and announced design of the pivotal Phase 3 study (1002FDC-053) of the bempedoic acid / ezetimibe combination pill.

Upcoming Milestones

- December 2017: Planned publication of results from Mendelian randomization studies that genetically validate ACL inhibition, the enzyme target of bempedoic acid.

2017 Third Quarter Financial Results

As of September 30, 2017, cash and cash equivalents and investment securities available-for-sale totaled $309.1 million compared with $242.5 million at December 31, 2016.

Research and development expenses were $40.1 million for the third quarter of 2017 and $114.2 million for the nine months ended September 30, 2017, compared to $13.5 million and $33.0 million for the comparable periods in 2016. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, including costs to support the global pivotal Phase 3 LDL-C lowering program and the cardiovascular outcomes trial (CVOT), and further increases in our headcount and stock-based compensation expense.

General and administrative expenses were $5.7 million for the third quarter of 2017 and $16.1 million for the nine months ended September 30, 2017, compared to $4.2 million and $13.9 million for the comparable periods in 2016. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, increases in our headcount, and other costs to support our growth.

Esperion had a net loss of $45.2 million for the third quarter of 2017 and $129.1 million for the nine months ended September 30, 2017, compared to $17.4 million and $46.0 million, respectively, for the comparable period in 2016.

Esperion had approximately 26.2 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, and $1.5 million of debt outstanding as of September 30, 2017.

2017 Financial Outlook

Esperion expects full-year 2017 net cash used in operating activities to be approximately $135 million and its cash and cash equivalents and investment securities to be approximately $272 million at December 31, 2017. 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.

Bempedoic Acid / Ezetimibe Combination

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 LDL receptors. Previously completed Phase 2 data demonstrated that this safe and well tolerated combination results in a 48 percent lowering of LDL-C, a 26 percent reduction in high sensitivity C-reactive protein (hsCRP), and may potentially be associated with a lower occurrence of muscle-related side effects.

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor, and may potentially be associated with a lower occurrence of muscle-related side effects. Completed Phase 1 and 2 studies conducted in approximately 1,300 patients, and over 800 patients treated with bempedoic acid, have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy and an incremental 20+ 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 as the Lipid Management Company is to provide patients and physicians with convenient, complementary, cost-effective, once-daily, oral therapies to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. It is estimated that 40 million patients in the U.S. are taking statins with approximately 5-20 percent of these patients only able to tolerate less than the lowest approved daily starting dose of their statin and are therefore considered to be statin intolerant. Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The company has two convenient, cost-effective, complementary, orally available, LDL-C lowering therapies in Phase 3 development: 1) a once-daily, oral bempedoic acid / ezetimibe combination pill, and 2) bempedoic acid, a once-daily, oral pill.

The Lipid Management Company

Esperion Therapeutics, Inc. 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 reduce 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 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, 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, 2017	December 31, 2016
Cash and cash equivalents	$ 21,024	$ 38,165
Working capital	171,826	197,988
Investments	288,064	204,324
Total assets	313,093	245,213
Total long-term debt	-	1,022
Common stock	26	23
Accumulated deficit	(358,400)	(229,200)
Total stockholders' equity	278,096	228,602

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,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 40,056	$ 13,498	$ 114,164	$ 32,987
General and administrative	5,681	4,214	16,122	13,878
Total operating expenses	45,737	17,712	130,286	46,865
Loss from operations	(45,737)	(17,712)	(130,286)	(46,865)
Interest expense	(44)	(89)	(166)	(298)
Other income, net	562	399	1,355	1,141
Net loss	$ (45,219)	$ (17,402)	$ (129,097)	$ (46,022)
Net loss per common share (basic and diluted)	$ (1.86)	$ (0.77)	$ (5.57)	$ (2.04)
Weighted average shares outstanding (basic and diluted)	24,311,844	22,550,438	23,161,847	22,541,137

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