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

— Phase 3 Enrollment Progress Supports NDA Submissions for LDL-C Lowering Indications for Bempedoic Acid / Ezetimibe Combination Pill and Bempedoic Acid by the First Quarter 2019 —
— Conference Call and Webcast on Tuesday, August 8, 2017 at 8:30 a.m. Eastern Time —

ANN ARBOR, Mich., Aug. 08, 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 second quarter ended June 30, 2017. The company now expects to submit two New Drug Applications (NDAs) for LDL-C lowering indications for the bempedoic acid / ezetimibe combination pill and bempedoic acid by the first quarter of 2019.

Bempedoic Acid Global Pivotal Phase 3 Program Update

The ongoing Phase 3 program for bempedoic acid includes four global pivotal studies expected to enroll approximately 3,400 high CVD risk patients with hypercholesterolemia and atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH), or who are high risk primary prevention, on optimized background lipid-modifying therapy and with elevated levels of LDL-C. These patients are on two distinct types of background lipid-modifying therapy: 1) patients on their maximally tolerated statin therapy, and 2) patients only able to tolerate less than the lowest approved daily starting dose (e.g., patients considered statin intolerant).

Global Pivotal Phase 3 Study 1: This 52-week long-term safety and tolerability study was initiated in January 2016 and fully enrolled in January 2017 with 2,230 patients with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. Top-line results are expected to be announced by the second quarter of 2018.

Global Pivotal Phase 3 Study 2: This 52-week LDL-C lowering efficacy and safety study was initiated in December 2016 and will be fully enrolled mid-month with approximately 750 patients with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. Top-line results are expected to be announced by the third quarter of 2018.

Global Pivotal Phase 3 Study 3: This 24-week LDL-C lowering efficacy study was initiated in December 2016 and will be fully enrolled this month with approximately 300 high CVD risk patients with ASCVD and/or HeFH, or who are high risk primary prevention, whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered statin intolerant. Top-line results are expected to be announced by the second quarter of 2018.

Global Pivotal Phase 3 Study 4: This 12-week LDL-C lowering efficacy study was initiated in December 2016 and will be fully enrolled in September with approximately 225 high CVD risk patients with ASCVD and/or HeFH, whose LDL-C is not adequately controlled with current lipid-modifying therapies, including ezetimibe, and who are only able to tolerate the lowest approved daily starting dose of a statin and considered statin intolerant. Top-line results are expected to be announced by the second quarter of 2018.

"I'm pleased with the progress our team has made enrolling patients in all of our global pivotal Phase 3 LDL-C lowering efficacy studies. We are on track to complete enrollment for the Phase 3 program this quarter, and look forward to reporting top-line results from each of the four global pivotal Phase 3 studies in the second and third quarters of 2018," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "The Phase 3 pivotal study enrollment progress, together with FDA confirmation of the regulatory pathways to approval for both the bempedoic acid / ezetimibe combination pill and bempedoic acid supports our plans to submit both NDAs for LDL-C lowering indications by the first quarter of 2019."

Development Program and Company Highlights

- May 2017: Mary McGowan, M.D., Chief Medical Officer, presented "Bempedoic Acid Reduces LDL-C and is Well-Tolerated in Patients Receiving Atorvastatin 80 mg Background Therapy" at the 2017 National Lipid Association

Scientific Sessions.

- June 2017: The U.S. Food and Drug Administration (FDA) confirmed the abbreviated 505(b)(2) regulatory pathway to approval for the bempedoic acid / ezetimibe combination pill for an LDL-C lowering indication. The pivotal Phase 3 bridging study is expected to be initiated in the fourth quarter of 2017 and complete by the end of 2018 to support an NDA submission for an LDL-C lowering indication.

- July 2017: Initiated and announced the design of a Phase 2 study of bempedoic acid added-on to a PCSK9i.

- August 2017: Announced positive top-line results of Phase 2 study (1002-038) of the bempedoic acid / ezetimibe combination + atorvastatin oral therapy.

Upcoming Milestones

- Q4 2017:
  - Initiate and announce design of the bempedoic acid / ezetimibe combination pill global pivotal Phase 3 bridging study;
  - Dr. Brian A. Ference to publish in a top-tier medical journal results from Mendelian randomization studies that genetically validate ACL inhibition.

2017 Second Quarter Financial Results

As of June 30, 2017, cash and cash equivalents and investment securities available-for-sale totaled $181.1 million compared with $242.5 million at December 31, 2016.

Research and development expenses were $38.2 million for the second quarter of 2017 and $74.1 million for the six months ended June 30, 2017, compared to $9.7 million and $19.5 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 $5.4 million for the second quarter of 2017 and $10.4 million for the six months ended June 30, 2017, compared to $4.6 million and $9.7 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 $43.3 million for the second quarter of 2017 and $83.9 million for the six months ended June 30, 2017, compared to $14.0 million and $28.6 million, respectively, for the comparable period in 2016.

Esperion had approximately 22.6 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 $1.9 million of debt outstanding as of June 30, 2017.

2017 Financial Outlook

Esperion expects full-year 2017 net cash used in operating activities to be approximately $125 to $135 million and its cash and cash equivalents and investment securities to be approximately $105 to $115 million at December 31, 2017. The Company estimates that current cash resources are sufficient to fund operations through the announcement of top-line results from our global pivotal Phase 3 programs for the bempedoic acid / ezetimibe combination pill and bempedoic acid and into early 2019.

Conference Call and Webcast Information

Esperion's lipid management team will host a conference call and webcast to discuss these updates. The call can be accessed by dialing (877) 312-7508 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing access code 63709230. A live audio webcast can be accessed on the investors and media section of the Esperion website at investor.esperion.com. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 90 days.

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 more than 1,000 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 and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination and bempedoic acid, including expected enrollment timelines and status, 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)

	June 30,	December 31,

	2017	2016
Cash and cash equivalents	$ 20,373	$ 38,165
Working capital	139,953	197,988
Investments	160,715	204,324
Total assets	185,242	245,213
Total long-term debt	140	1,022
Common stock	23	23
Accumulated deficit	(313,181)	(229,200)
Total stockholders' equity	154,107	228,602

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,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 38,248	$ 9,698	$ 74,108	$ 19,489
General and administrative	5,412	4,633	10,441	9,664
Total operating expenses	43,660	14,331	84,549	29,153
Loss from operations	(43,660)	(14,331)	(84,549)	(29,153)
Interest expense	(55)	(99)	(122)	(209)
Other income, net	378	395	793	742
Net loss	$ (43,337)	$ (14,035)	$ (83,878)	$ (28,620)
Net loss per common share (basic and diluted)	$ (1.92)	$ (0.62)	$ (3.72)	$ (1.27)
Weighted average shares outstanding (basic and diluted)	22,591,326	22,541,455	22,577,317	22,536,438

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