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

May 8, 2019

ANN ARBOR, Mich., May 08, 2019 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today provided bempedoic acid franchise development program updates and financial results for the first quarter ended March 31, 2019.

“The potential of bempedoic acid is being broadly realized as evidenced by publication and presentation of Phase 3 clinical study results in the New England Journal of Medicine, the American College of Cardiology 2019 Scientific Sessions and other industry leading platforms. This high-profile external validation of the potential of bempedoic acid to meet the LDL-C lowering needs of the millions of patients with high LDL-C despite the use of currently accessible therapies confirms the beliefs of our Lipid Management Team,” said Tim M. Mayleben, president and chief executive officer of Esperion. “We will continue to work closely with regulatory authorities to bring our LDL-C lowering therapies to physicians, payers and their patients.”

Recent Development Program Highlights

January 2019:

- Entered into a license and collaboration agreement (the LCA) with Daiichi Sankyo Europe (DSE) to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland. Payments to Esperion under the agreement include $150 million upfront upon execution of the LCA, $150 million upon first commercial sale in the territory (as defined by the LCA), up to $600 million in additional regulatory and commercial milestones payments as well as 15% to 25% tiered royalties on net territory sales.

February 2019:

- Submitted two New Drug Applications (NDAs) for bempedoic acid and the bempedoic acid / ezetimibe combination tablet to the U.S. Food and Drug Administration (FDA).
- Completed the formal validation process with the European Medicines Agency (EMA) of Esperion’s two Marketing Authorization Applications (MAAs) and officially started the review procedure for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet. The MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet were submitted to the EMA on February 11, 2019.

March 2019:

- Publication of bempedoic acid Study 1 (1002-040) results in *The New England Journal of Medicine*. The research was authored by Professor Kausik Ray.
- Presentation of Study 2 (1002-047) results at the American College of Cardiology 2019 Scientific Sessions by Dr. Anne C Goldberg.
- Publication of bempedoic acid Study 3 (1002-046) results in *The Journal of American Heart Association*. The research was authored by Dr. med Ulrich Laufs.

May 2019:

- Acceptance for filing and review of the NDAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet by the FDA with a target action Prescription Drug User Fee Act (PDUFA) date of February 21, 2020 and February 26, 2020, respectively. The FDA has communicated that there is no current plan to hold an advisory committee meeting to discuss the applications.
- Results from the initial clinical study of the 100 mg sustained release formulation of bempedoic acid demonstrated consistent (29%) LDL-C lowering (with approximately one-half the active pharmaceutical ingredient of the current 180 mg bempedoic acid tablet) as well as favorable safety and PK parameters. These results provide initial proof-of-concept for the sustained release formulation of bempedoic acid to increase efficacy, extend the patent life of the bempedoic acid franchise into 2038 while utilizing a 505(b)(2) regulatory pathway to approval, and reduce manufacturing costs.

Upcoming Milestones

Second quarter 2019:

- Esperion to host Analyst and Investor Day on May 30th

Third quarter 2019:

- Completion of enrollment in the 12,604 patient CLEAR Cardiovascular Outcomes study

Second half 2019:

- Top-line results from the 12-week, Phase 2 clinical study (1002-058) of the bempedoic acid / ezetimibe combination tablet in 242 patients with elevated LDL-C and type 2 diabetes mellitus
- Pivotal Phase 3 trial initiation of bempedoic acid in patients with elevated LDL-C and type 2 diabetes, to support a glycemic control indication in adults with both hypercholesterolemia and type 2 diabetes mellitus

2019 Financial Outlook

Esperion expects full-year 2019 net cash used in operations to be $25 to $35 million, driven by the following components:

Collaboration and license agreement cash source	$150 million
R&D cash used	$115 million to $120 million
SG&A cash used	$60 million to $65 million

Esperion expects that current cash resources, coupled with expected milestone payments under the European commercial collaboration agreement, as well as bempedoic acid and the bempedoic acid / ezetimibe combination tablet commercial sales, are sufficient to fund operations until operating cash flow is positive.

2019 First Quarter Financial Results

As of March 31, 2019, cash, cash equivalents, restricted cash and investment securities available-for-sale totaled $229.7 million compared with $136.3 million at December 31, 2018.

Revenue was $145.4 million for the first quarter of 2019, compared to $0.0 million for the comparable period in 2018. Revenue was attributable to the initial recognition of the upfront payment from the DSE collaboration agreement.

Research and development expenses were $46.3 million for the first quarter of 2019, compared to $40.9 million for the comparable period in 2018. The increase in research and development expenses was primarily related to the clinical development costs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, including costs to support the ongoing CLEAR CVOT, regulatory submissions and increases in our headcount.

General and administrative expenses were $12.2 million for the first quarter of 2019, compared to $6.0 million for the comparable period in 2018. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, including costs to support pre-commercialization activities, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Esperion had a net gain of $87.4 million for the first quarter of 2019, compared to a net loss of $46.1 million for the comparable period in 2018.

Esperion had approximately 26.9 million shares of common stock outstanding, with another 5.3 million issuable upon exercise of stock options and warrants and vesting of restricted stock units as of March 31, 2019.

Bempedoic Acid

Bempedoic acid is our lead, non-statin, complementary, orally available, once-daily, LDL-C lowering therapy. With a targeted mechanism of action, bempedoic acid is a first-in-class, 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 high sensitivity C-reactive protein (hsCRP), a key marker of inflammation associated with cardiovascular disease. Completed Phase 3 studies conducted in more than 4,000 patients, with over 2,600 patients treated with bempedoic acid, have produced an additional 18 percent LDL-C lowering when used with moderate- and high-intensity statins and 28 percent LDL-C lowering when used with no background statin.

Bempedoic Acid / Ezetimibe Combination Tablet

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination tablet is a 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. Phase 3 data demonstrated that this combination results in a 29 percent LDL-C lowering when used with maximally tolerated statins, a 44 percent LDL-C lowering when used with no background statin (post-hoc analysis), and a 34 percent reduction in hsCRP.

CLEAR Outcomes

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. Esperion 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 averse." The CVOT — known as 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 over 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., 96 million people, or more than 37 percent of the adult population have elevated LDL-C. There are approximately 18 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 averse — leaving them at high risk for cardiovascular events. More than 50 percent of ASCVD patients who are not able to reach their LDL-C goals with statins alone need less than a 40 percent reduction to reach their LDL-C threshold.

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, cost-effective, convenient, 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 bempedoic acid / ezetimibe combination tablet 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 bempedoic acid and the bempedoic acid / ezetimibe combination tablet and the therapeutic potential of, clinical development plan for, bempedoic acid and the bempedoic acid / ezetimibe combination tablet, including Esperion's timing, designs, plans and announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, timing for the review and approval of the NDAs and the MAAs 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 tablet, if approved, Esperion’s cash position and financial outlook, and the expected upcoming milestones described in this press release. 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 notwithstanding the completion of Esperion’s Phase 3 clinical development program for LDL-C lowering, the FDA or EMA may require additional development in connection with seeking regulatory approval, 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)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 174,836	$ 36,973
Working capital	175,196	78,299
Investments	53,692	99,293
Restricted cash	1,193	-
Total assets	236,482	143,451
Common stock	27	27
Accumulated deficit	(510,722)	(598,101)
Total stockholders' equity	175,010	79,118

Esperion Therapeutics, Inc.

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Collaboration revenue	$ 145,419	$ -
Total Revenues	145,419	-

Operating expenses:		
Research and development	46,308	40,940
General and administrative	12,182	5,954
Total operating expenses	58,490	46,894
Income (loss) from operations	86,929	(46,894)
Other income, net	450	764
Net income (loss)	$ 87,379	$ (46,130)
Net income (loss) per common share - basic	$ 3.26	$ (1.73)
Net income (loss) per common share - diluted	$ 3.07	$ (1.73)
Weighted average shares outstanding - basic	26,842,785	26,605,189
Weighted average shares outstanding - diluted	28,449,767	26,605,189

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