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

November 6, 2019

ANN ARBOR, Mich., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today provided bempedoic acid franchise development program updates and financial results for the third quarter ended September 30, 2019.

"The Esperion Lipid Management Team continues to lay a strong and durable foundation for what we believe are highly anticipated approvals and launches of 2020 – bempedoic acid and the bempedoic acid / ezetimibe combination tablet. We're especially proud to have completed enrollment in the landmark CLEAR cardiovascular outcomes trial with over 14,000 statin intolerant patients," said Tim M. Mayleben, president and chief executive officer of Esperion. "Our excitement and confidence continue to grow as we near the potential approval and commercial launch of our cost-effective, convenient, once-daily, oral LDL-C lowering therapies for the millions of patients on maximally tolerated statins who need additional LDL-C lowering."

Recent Development Program Highlights

August 2019:

- Announced positive top-line results from Phase 2 clinical study (1002-058) evaluating the efficacy and safety of the bempedoic acid / ezetimibe combination tablet compared to ezetimibe and placebo in 179 patients with both hypercholesterolemia and type 2 diabetes randomized 1:1:1 to receive bempedoic acid 180 mg / ezetimibe 10 mg combination tablet, ezetimibe 10 mg or placebo. The data reflected that the bempedoic acid / ezetimibe combination tablet significantly lowered low-density lipoprotein cholesterol (LDL-C) by 40 percent compared to placebo (p<0.001), reduced high-sensitivity C-reactive protein (hsCRP) by 25 percent (p<0.001), had no worsening of glycemic control, and with a rate of overall adverse events (AEs) that was comparable to placebo.

September 2019:

- Announced completion of enrollment in the CLEAR Cardiovascular Outcomes Trial with over 14,000 patients (original target enrollment of 12,600). The trial is designed to evaluate whether treatment with bempedoic acid reduces the risk of cardiovascular events (as measured by the 4-component MACE endpoint) in patients with statin intolerance (or "statin averse") who have cardiovascular disease or are at high risk for cardiovascular disease.

Upcoming Milestones

November 2019:

- A presentation and poster of pooled analyses from the Phase 3 LDL-C lowering development program of bempedoic acid will be presented at the American Heart Association Scientific Sessions in Philadelphia.

First quarter 2020:

- February 21, 2020 PDUFA target date for bempedoic acid and February 26, 2020 PDUFA target date for the bempedoic acid / ezetimibe combination tablet.

Second quarter 2020:

- European Commission marketing authorisation decisions anticipated for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet MAAs.

2019 Financial Outlook

Esperion updated the full-year 2019 outlook for a net increase in cash of approximately $70 to $80 million (previously $90 to $100 million). The change primarily results from one-time factors including 1) incremental costs associated with exceeding our patient enrollment target for the landmark CLEAR Outcomes Cardiovascular Outcomes Trial (CVOT) during the quarter (14,032 patients considered statin intolerant compared with the original target of 12,604 patients), and 2) incremental costs associated with accelerating certain commercial product manufacturing activities into 2019 that were previously planned for the calendar year 2020. The net increase in cash is driven by the following components:

Collaboration and license agreement cash source	$150 million
Oberland Capital revenue-based funding cash source	$125 million
R&D cash used	$135 million to $140 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 and Oberland Capital revenue-based funding agreement, and bempedoic acid and the bempedoic acid / ezetimibe combination tablet commercial sales, will be sufficient to fund operations through profitability.

2019 Third Quarter Financial Results

As of September 30, 2019, cash, cash equivalents, restricted cash and investment securities available-for-sale totaled $244.8 million compared with $136.3 million at December 31, 2018.

Revenue was $1.0 million for the third quarter of 2019 and $147.4 million for the nine months ended September 30, 2019, compared to $0.0 million for the comparable periods in 2018. Revenue was primarily attributable to the initial recognition of the upfront payment from the Daiichi Sankyo Europe (DSE) collaboration agreement.

Research and development expenses were $48.3 million for the third quarter of 2019 and $137.4 million for the nine months ended September 30, 2019, compared to $41.6 million and $122.0 million for the comparable periods in 2018. The increase was primarily attributable to clinical development costs for bempedoic acid, including costs to support the ongoing CLEAR Outcomes Trial, commercial product manufacturing supply as we approach anticipated approval, and increases in our headcount and stock-based compensation expense.

General and administrative expenses were $18.5 million for the third quarter of 2019 and $44.1 million for the nine months ended September 30, 2019, compared to $9.0 million and $21.9 million for the comparable periods in 2018. The increase 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 loss of $68.4 million for the third quarter of 2019 and a net loss of $35.2 million for the nine months ended September 30, 2019, compared to a net loss of $49.9 million and a net loss of $141.8 million for the comparable periods in 2018.

Esperion had approximately 27.2 million shares of common stock outstanding, with another 5.3 million issuable upon exercise of stock options and vesting of restricted stock units, and $128.4 million of the revenue interest liability outstanding as of September 30, 2019.

Bempedoic Acid

Bempedoic acid is our lead, non-statin, oral, once-daily, low-density lipoprotein cholesterol (LDL-C) lowering therapeutic candidate, currently under regulatory review by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). With a targeted mechanism of action, bempedoic acid is a first-in-class, ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptor. Bempedoic acid has been observed to reduce 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, demonstrated up to 18 percent placebo corrected LDL-C lowering when used with moderate- and high-intensity statins and 21 to 28 percent placebo corrected LDL-C lowering when used with low dose or no background statin.

Bempedoic Acid / Ezetimibe Fixed Dose 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 fixed dose combination tablet is a non-statin, orally available, once-daily, LDL-C lowering therapeutic candidate, currently under review by the FDA and EMA. Inhibition of ATP Citrate Lyase (ACL) by bempedoic acid lowers LDL-C by reducing cholesterol biosynthesis and 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. Phase 3 data demonstrated that this combination resulted in a 29 percent placebo corrected 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 high sensitivity C-reactive protein (hsCRP).

CLEAR Cardiovascular Outcomes Trial

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 Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of 14,032 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

Esperion Therapeutics' Commitment to Patients with Hyperlipidemia

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[1] In the United States, 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[2].

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.

Esperion Therapeutics

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. 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 tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, the therapeutic potential of, and the clinical development plan for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose 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 tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, if approved. 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.

References

[1] Esperion market research on file: research project interviewing 350 physicians. Esperion Therapeutics, Inc. Sept-Oct 2018.

[2] Data on file: analysis of NHANES database. Esperion Therapeutics, Inc. 2018.

Esperion Therapeutics, Inc.

Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 211,978	$ 36,973
Working capital	195,942	78,299
Investments	31,883	99,293
Restricted cash	928	—
Total assets	255,270	143,451
Revenue interest liability	128,420	—
Common stock	27	27
Accumulated deficit	(633,320)	(598,101)
Total stockholders' equity	68,512	79,118

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,	
	2019	2018	2019	2018
Revenues:				
Collaboration revenue	$ 981	$ —	$ 147,382	$ —
Total Revenues	981	—	147,382	—
Operating expenses:				
Research and development	$ 48,281	$ 41,551	$ 137,377	$ 122,015
General and administrative	18,468	9,011	44,142	21,921
Total operating expenses	66,749	50,562	181,519	143,936
Loss from operations	(65,768)	(50,562)	(34,137)	(143,936)
Interest expense	(3,996)	—	(3,996)	(28)
Other income, net	1,387	651	2,914	2,193
Net loss	$ (68,377)	$ (49,911)	$ (35,219)	$ (141,771)
Net loss per common share – basic and dilutive	$ (2.52)	$ (1.86)	$ (1.30)	$ (5.30)
Weighted average shares outstanding – basic and dilutive	27,171,769	26,804,026	26,995,661	26,732,733

Investor Contact:
Alex Schwartz
Esperion
734-249-3386
aschwartz@esperion.com

Media Contact:
Elliot Fox
W2Opure
212-257-6724
efox@purecommunications.com