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

August 8, 2019

ANN ARBOR, Mich., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today provided bempedoic acid franchise development program updates and financial results for the second quarter ended June 30, 2019.

“This year continues the momentum we’ve come to expect from our team of Lipid Management Experts. Already in 2019, we completed precedent setting agreements with Daiichi Sankyo Europe and Oberland Capital which validated the economic value of the global bempedoic acid franchise. We also achieved the filing and acceptance of New Drug Applications in the US and Marketing Authorization Applications in the EU for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet,” said Tim M. Mayleben, president and chief executive officer of Esperion. “We look forward to accelerating this momentum in the months ahead as we prepare to bring our convenient, once-daily oral LDL-cholesterol lowering therapies to the millions of patients who are not reaching their LDL-C lowering goals despite the use of currently accessible therapies.”

Recent Development Program Highlights

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.

June 2019:

- Entered into a $200 million revenue interest purchase agreement with an investor group led by Oberland Capital Management LLC (Oberland Capital). This agreement extends Esperion’s cash runway through profitability. Payments to Esperion under the agreement include $125 million upfront received in June, $25 million upon FDA approval, and $50 million at Esperion’s option after launch. The initial mid-single digit repayment rate on U.S. revenue will step down to less than one percent rate upon certain revenue achievements. Esperion reacquires 100% revenue rights upon repayment completion.

Upcoming Milestones

Third quarter 2019:

- Top-line results from the 12-week, Phase 2 clinical study (1002-058) of the bempedoic acid / ezetimibe combination tablet in 179 patients with elevated LDL-C and type 2 diabetes mellitus (elevated HbA1c levels).
- Completion of enrollment in the 12,604 patient CLEAR Cardiovascular Outcomes study.

2019 Financial Outlook

Esperion expects full-year 2019 net increase in cash of approximately $90 to $100 million, 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	$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 and Oberland Capital revenue-based funding agreement, and bempedoic acid and the bempedoic acid / ezetimibe combination tablet commercial sales, are sufficient to fund operations until operating cash flow is positive.

2019 Second Quarter Financial Results

As of June 30, 2019, cash, cash equivalents, restricted cash and investment securities available-for-sale totaled $302.2 million compared with $136.3 million at December 31, 2018.

Revenue was $1.0 million for the second quarter of 2019 and $146.4 million for the six months ended June 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 $42.8 million for the second quarter of 2019 and $89.1 million for the six months ended June 30, 2019, compared to $39.5 million and $80.5 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 CVOT as we approach full enrollment in the study, commercial product

manufacturing supply as we approach anticipated approval, regulatory submissions and increases in our headcount and stock-based compensation expense.

General and administrative expenses were $13.5 million for the second quarter of 2019 and $25.7 million for the six months ended June 30, 2019, compared to $7.0 million and $12.9 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 $54.2 million for the second quarter of 2019 and a net gain of $33.2 million for the six months ended June 30, 2019, compared to a net loss of $45.7 million and a net loss of $91.9 million for the comparable periods in 2018.

Esperion had approximately 27.0 million shares of common stock outstanding, with another 5.4 million issuable upon exercise of stock options and vesting of restricted stock units, and $124.4 million of the revenue interest liability outstanding as of June 30, 2019.

Bempedoic Acid

Bempedoic acid is our lead, non-statin, 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 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 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 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 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[1]. 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.

The Lipid Management Company

Esperion is the Lipid Management Company passionately committed to developing and commercializing convenient, cost-effective, complementary, 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 are being developed 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 ability to access capital from Oberland Capital and its related repayment obligations, 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.

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)

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 274,344	$ 36,973
Working capital	252,809	78,299
Investments	26,882	99,293
Restricted cash	928	-
Total assets	308,814	143,451
Revenue interest liability	124,409	-
Common stock	27	27
Accumulated deficit	(564,943)	(598,101)
Total stockholders' equity	129,334	79,118

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,	
	2019	2018	2019	2018
Revenues:				
Collaboration revenue	$ 982	$ —	$ 146,401	$ —
Total Revenues	982	—	146,401	—
Operating expenses:				
Research and development	$ 42,788	$ 39,524	$ 89,096	$ 80,464
General and administrative	13,492	6,956	25,674	12,910
Total operating expenses	56,280	46,480	114,770	93,374
Income (loss) from operations	(55,298)	(46,480)	31,631	(93,374)
Other income, net	1,077	750	1,527	1,514
Net income (loss)	$ (54,221)	$ (45,730)	$ 33,158	$ (91,860)
Net income (loss) per common share - basic	$ (2.01)	$ (1.71)	$ 1.23	$ (3.44)
Net income (loss) per common share - diluted	$ (2.01)	$ (1.71)	$ 1.16	$ (3.44)
Weighted average shares outstanding - basic	26,968,818	26,786,796	26,906,149	26,696,495
Weighted average shares outstanding - diluted	26,968,818	26,786,796	28,518,015	26,696,495

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