November 16, 2015

Emisphere Reports Third Quarter 2015 Financial Results

Management to Host Conference Call Today at 8:30 AM ET

ROSELAND, N.J., Nov. 16, 2015 (GLOBE NEWSWIRE) -- Emisphere Technologies, Inc. (OTCBB:EMIS) today reported financial results for the third quarter ended September 30, 2015, and provided a corporate update.

"During the third quarter, we made great strides in commercializing the Eligen® technology. There were two important developments with our partner, Novo Nordisk A/S (NYSE:NVO). Novo Nordisk announced it will initiate a global phase 3a development program with oral semaglutide, a once daily Type 2 diabetes treatment utilizing SNAC, one of our Eligen technology carriers," said Alan L. Rubino, President and Chief Executive Officer of Emisphere. "We also entered into an agreement with Novo Nordisk to develop and commercialize oral formulations of certain of Novo Nordisk's investigational molecules targeting major metabolic disorders, including diabetes and obesity, using our Eligen technology. Novo Nordisk has been an important partner for many years and their continuing development of once daily oral semaglutide and the expanded partnership further validate the Eligen technology's ability to facilitate absorption from the gastrointestinal tract."

Mr. Rubino continued: "We continue to see steady growth of Eligen B12™ sales in the U.S. and we remain focused o advancing our global business development efforts. Our goal is to continue building new, high-value partnerships for both Eligen B12 and our Eligen technology platform. We look forward to updating you on our progress."

YEAR TO DATE HIGHLIGHTS

- **Novo Nordisk announced its decision to advance oral semaglutide (GLP-1) into a global phase 3a development program** using Emisphere's absorption-enhancing excipient, SNAC. Novo Nordisk plans to initiate the PIONEER global phase 3a program, consisting of seven trials and approximately 8,000 patients with Type 2 diabetes.
- **Entered into an agreement with Novo Nordisk** to develop and commercialize oral formulations of four classes of Novo Nordisk's investigational molecules targeting major metabolic disorders, including diabetes and obesity, using Emisphere's oral Eligen technology. Emisphere received a $5.0 million upfront licensing fee, and is eligible to receive up to $207.5 million in development and sales milestone payments in addition to royalties on sales of each successfully commercialized product under this agreement.
- **Amended our GLP-1 License Agreement with Novo Nordisk** to provide for, among other things, a payment of $9.0 million as prepayment of a product development milestone and in exchange for a reduction in certain future royalty payments.
- **Commercial Rollout of Eligen B12 Continues in the U.S.** Emisphere recently launched Eligen B12, the first once-daily oral prescription medical food tablet shown to normalize B12 levels without the need for an injection in patients who have a medically-diagnosed vitamin B12 deficiency. Physician and patient reception has been positive and Eligen B12 is achieving excellent medical outcomes. Emisphere continues to refine its field force and other promotional efforts to increase awareness and drive adoption.
- **Global Eligen Technology Business Development Initiatives Continuing.** During the third quarter of 2015, Emisphere continued to focus on smaller, next-generation proteins and peptides; proven and/or approved drug compounds; and the development of new oral formulations to replace injectables.
- **Grant of Waiver under Debt Facility and Convertible Notes.** On November 10, 2015, the creditor under our debt facility and convertible notes agreed to waive any event of default resulting from our failure to satisfy the net sales milestones for the Eligen B12™ product for the 2015 fiscal year specified in our credit facility and convertible notes.

THIRD QUARTER 2015 FINANCIAL RESULTS

Revenue for the third quarter ended September 30, 2015, was $130,000 compared to no revenue for the third quarter ended September 30, 2014. The increase in revenue was due to sales revenues from Eligen B12, which was launched in March 2015.

Total operating expense for the third quarter of 2015 was $4.7 million compared to $2.1 million for the same period in 2014, an increase of $2.6 million or 124 percent. Total operating expenses include research and development (R&D) and sales, general and administrative (SG&A) costs. For the third quarter of 2015, R&D expenses were $94,000 compared to $229,000 for the same period in 2014. For the third quarter of 2015, SG&A expenses were $4.6 million compared to $1.9 million for the same period in 2014. The increase in total operating expenses is due primarily to increased sales, and marketing and other commercial costs in connection with the introduction of the oral Eligen B12 product in the U.S. during 2015.

For the third quarter ended September 30, 2015, Emisphere reported a net loss of $4.4 million, or $0.07 per basic and diluted share, compared to net loss of $14.4 million, or $0.24 per basic and diluted share, for the same period last year.

YEAR TO DATE FINANCIAL RESULTS

Revenue for the nine months ended September 30, 2015, was $225,000 compared to no revenue for the nine months ended September 30, 2014. The increase in revenue was due to sales revenues from Eligen B12.

Total operating expense for the nine months ended September 30, 2015 was $14.0 million compared to $6.0 million for the same period in 2014, an increase of $8.0 million or 133 percent. Total operating expenses include research and development and sales, general and administrative costs. For the nine months ended September 30, 2015, R&D expenses were $382,000 compared to $880,000 for the same period in 2014. SG&A expenses were $13.6 million compared to $5.1 million for the same period in 2014. The increase in total operating expenses is due primarily to increased sales, and marketing and other commercial costs in connection with the introduction of the oral Eligen B12 product in the U.S. during 2015.

For the nine months ended September 30, 2015, Emisphere reported a net loss of $30.3 million, or $0.50 per basic and diluted share, compared to net loss of $25.8 million, or $0.43 per basic and diluted share, for the same period last year.

Weighted average basic and diluted shares outstanding for the periods ended September 30, 2015 and September 30, 2014 were 60,687,478.

LIQUIDITY

As of September 30, 2015, Emisphere had approximately $1.4 million in cash, a net decrease of $2.3 million from December 31, 2014; approximately $8.5 million working capital deficiency; a stockholders' deficit of approximately $142.0 million; and an accumulated deficit of approximately $544.4 million. On July 1, 2015, Emisphere borrowed $2.0 million in original principal amount on its $20.0 million secured credit facility. On October 26, 2015, we received a total payment of $14 million from Novo Nordisk pursuant to, and consisting of, $5 million as payment for entry into a license agreement and $9 million as payment in connection with the third amendment to the existing GLP-1 License Agreement with Novo Nordisk.

Management believes that with the funding made available from an existing loan agreement, the new license agreement, and the GLP-1 Amendment, the Company will have sufficient capital to continue to execute its Eligen B12 commercialization plans and to continue operations through approximately July 2016. The Company's future capital requirements beyond July 2016 and financial success depend largely on the commercial success of the Eligen B12 prescription product and the Company's ability to continue to leverage existing partnerships and secure new partnering opportunities.

CONFERENCE CALL AND WEBCAST INFORMATION

The live webcast of the conference call can be accessed through the Company's web site at www.emisphere.com. The call can also be accessed by dialing (877) 303-9483 (United States and Canada) or (760) 666-3584 (international), and entering Conference ID# 78510550. In addition, an archive of the webcast can be accessed through the same link and an audio replay of the call will be available beginning at 11:30 am ET on Monday, November 16, 2015, through 11:59 pm ET on December 6, 2015, by calling (855) 859-2056 (United States and Canada) or (404) 537-3406 (International), and entering Conference ID# 78510550.

ABOUT ELIGEN B12™

Eligen B12 is indicated for the dietary management of patients who have a medically-diagnosed vitamin B12 deficiency that is associated with a disease or condition that cannot be managed by a modification of the normal diet alone. Eligen B12 is designed so that patients only need to take a single oral tablet (cyanocobalamin 1000 mcg/salcaprozate sodium [SNAC] 100 mg) of B12 daily.

Eligen B12 is the first and only prescription medical food that has been shown to normalize vitamin B12 to levels that are comparable to an intramuscular (IM) injection of B12. In a study that compared the impact of Eligen B12 and IM B12 on plasma B12 levels in 50 patients with demonstrated B12 deficiency (serum B12 < 350 pg/mL), both products normalized B12 levels by Day 15 (first observation) and maintained normal levels over the duration of the study (three months). In a study that compared

bioavailability in 20 healthy subjects of Eligen B12 with that of a standard oral B12 supplement, the bioavailability of Eligen B12 was 5.09 percent compared with 2.16 percent, which is more than double the bioavailability of the conventional over-the-counter oral B12 supplement formulation at the same dose.

Eligen B12 was developed as a medical food as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

For more information, visit www.eligenb12.com.

ELIGEN B12™ IMPORTANT SAFETY INFORMATION

Those with an allergy to B12, cobalt or any ingredients of Eligen B12 should not take this product. Eligen B12 should not be taken by people who have Leber's disease, which physicians may refer to as hereditary optic nerve atrophy. Cyanocobalamin (B12) can lead to optic nerve damage (and possibly blindness) in people with Leber's disease. Note that Eligen B12 has not been studied in patients below 18 years of age.

ABOUT EMISPHERE'S ELIGEN® TECHNOLOGY

Emisphere's proprietary Eligen® technology facilitates the absorption of difficult-to-deliver small and large molecules that typically are only available as injectables, without altering their chemical form, biological integrity or pharmacological properties, making it possible to avoid injections for drug administration. Eligen technology offers improved safety, broad applicability, stand-alone delivery, versatility of formulation and ease of manufacture.

ABOUT EMISPHERE

Emisphere is a commercial-stage pharmaceutical and drug delivery company that has recently commenced commercial operations. The Company launched its first prescription product, oral Eligen B12™, in the U.S. in March 2015 and is in partnership with global pharmaceutical companies to develop new formulations of existing products, as well as new chemical entities, using its Eligen® technology. Beyond Eligen B12, the Company utilizes its proprietary Eligen® technology to create new oral formulations of therapeutic agents. Emisphere's product pipeline includes prescription drug and medical food product candidates that are being developed in partnership or internally. For more information, please visit www.emisphere.com.

SAFE HARBOR STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements in this release or oral statements made by representatives of Emisphere relating to matters that are not historical facts are forward-looking statements that involve risks and uncertainties, including, but not limited to, the success of the Company's commercialization initiatives, the sufficiency of the Company's cash position, the Company's ability to enter into strategic partnerships, the Company's ability to capture market share for oral Eligen B12™ or any potential products, tl Company's ability and/or that of its partners to develop, manufacture and commercialize products using Emisphere's drug delivery technology, and other risks and uncertainties detailed in Emisphere's filings with the Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" identified in the documents Emisphere has filed, or will file, with the Securities and Exchange Commission ("SEC"). Copies of Emisphere's filings with the SEC may be obtained from the SEC Internet site at http://www.sec.gov. Emisphere expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Emisphere's expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based.

EMISPHERE TECHNOLOGIES, INC.
CONDENSED STATEMENT OF OPERATIONS
For the three and nine months ended September 30, 2015 and 2014
(in thousands, except share and per share data)
(unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenue, net of discounts and allowances	$ 130	$ —	$ 225	$ —

Cost of Revenue	58	—	138	—
Gross Profit	72	—	87	—
Costs and expenses:				
Research and development	94	229	382	880
Selling, General and administrative expenses	4,643	1,887	13,595	5,113
Depreciation and amortization	3	4	10	11
Total costs and expenses	4,740	2,120	13,987	6,004
Operating loss	(4,668)	(2,120)	(13,900)	(6,004)
Other non-operating income (expense):				
Other income (expense)	1	(3)	8	8
Change in fair value of derivative instruments				
Related party	2,334	(10,585)	(9,783)	(16,730)
Other	232	148	(188)	(35)
Interest expense related party	(2,321)	(1,813)	(6,391)	(4,722)
Total other non-operating income (expense)	246	(12,253)	(16,354)	(21,479)
Net loss before tax incentive	(4,422)	(14,373)	(30,254)	(27,483)
Income tax incentive	—	—	—	1,684
Net loss	$ (4,422)	$ (14,373)	$ (30,254)	$ (25,799)
Net loss per share, basic and diluted	$ (0.07)	$ (0.24)	$ (0.50)	$ (0.43)
Weighted average shares outstanding, basic and diluted	60,687,478	60,687,478	60,687,478	60,687,478

EMISPHERE TECHNOLOGIES INC.
CONDENSED BALANCE SHEETS
SEPTEMBER 30, 2015 AND DECEMBER 31, 2014
(in thousands, except share and per share data)

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,404	$ 3,683
Accounts Receivable	305	—
Inventory	2,054	2,068
Prepaid expenses and other current assets	722	188
Total Current Assets	4,485	5,939
Equipment and leasehold improvements, net	15	25
Security deposits	24	24
Total assets	$ 4,524	$ 5,988
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,672	$ 1,846
Deferred Revenue	382	—
Derivative instruments		
Related party	10,520	5,548
Others	427	239
Total current liabilities	13,001	7,633
Notes payable, related party, net of related discount	58,669	44,546
Accrued interest, related party	2,201	—
Derivative instruments		

Related party	30,889	24,133
Deferred revenue, non-current	41,616	41,616
Royalty payable	121	—
Deferred lease liability, non-current and other liabilities	12	10
Total liabilities	146,509	117,938
COMMITMENTS AND CONTINGENCIES		
Stockholders' deficit:		
Preferred stock, $.01 par value; 4,000,000 shares authorized; none issued and outstanding		
Common stock, $.01 par value; 400,000,000 shares authorized; issued 60,977,210 shares (60,687,478 outstanding) as of September 30, 2015 and December 31, 2014	610	610
Additional paid-in-capital	405,750	405,531
Accumulated deficit	(544,393)	(514,139)
Common stock held in treasury, at cost; 289,732 shares	(3,952)	(3,952)
Total stockholders' deficit	(141,985)	(111,950)
Total liabilities and stockholders' deficit	$ 4,524	$ 5,988

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Primary Logo

Source: Emisphere Technologies, Inc.