



March 29, 2016

## Emisphere Reports Fourth Quarter and Full Year 2015 Financial Results

### The Company to Host Conference Call Today at 8:30 AM ET

ROSELAND, N.J., March 29, 2016 (GLOBE NEWSWIRE) -- Emisphere Technologies, Inc. (OTCBB:EMIS) today reported financial results for the fourth quarter and full fiscal year ended December 31, 2015, and provided an overview of corporate accomplishments and plans.

"The last twelve months have been a pivotal time for Emisphere," said Alan L. Rubino, President and Chief Executive Officer of Emisphere. "Novo Nordisk A/S (NYSE:NVO), our most advanced collaborative partner, has commenced Phase 3a development with oral semaglutide, a once daily treatment for Type 2 diabetes which utilizes SNAC, one of our Eligen<sup>®</sup> Technology carriers. We expanded on our collaborative partnership with Novo Nordisk during the fourth quarter of 2015 with the execution of a new license agreement for the development of oral formulations targeting major metabolic disorders. These collaborations provide important validation for our Eligen<sup>®</sup> Technology and its ability to facilitate absorption from the gastrointestinal tract."

Mr. Rubino continued: "We launched oral Eligen B12<sup>™</sup> Rx in March 2015 to positive physician and patient reception. Throughout the year we evaluated our commercial operations and resources in light of product sales levels, and determined that the product's full market potential may best be achieved by entering into a strategic transaction or collaboration with a third party in the United States and internationally. We are now squarely focused on following that path and also seeking value creating partnerships for our Eligen<sup>®</sup> Technology carriers."

### 2015 AND RECENT HIGHLIGHTS

- 1 **Novo Nordisk commenced global Phase 3a clinical trials for oral semaglutide.** During the first quarter of 2016, Novo Nordisk commenced Phase 3a testing for oral semaglutide, which utilizes Emisphere's absorption-enhancing monosodium N-[8-(2-hydroxybenzoyl) amino] caprylate (SNAC) carrier. Novo Nordisk plans to conduct ten clinical trials enrolling approximately 9,300 patients with Type-2 diabetes in this Phase 3a program. The advancement of oral semaglutide into Phase 3a development represents a significant milestone for both Emisphere and the Eligen<sup>®</sup> Technology platform and supports the Company's belief that products developed using Eligen<sup>®</sup> carriers have the potential to overcome bioavailability challenges commonly associated with the oral administration of peptides and certain other compounds.
- 1 **Signed Expansion Development and License Agreement with Novo Nordisk to develop oral formulations targeting metabolic indications.** In October 2015, Emisphere and Novo Nordisk entered into a new license agreement 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<sup>®</sup> Technology. Emisphere received a \$5.0 million upfront licensing fee, and is eligible to receive up to \$207 million in development and sales milestone payments in addition to royalties on sales of each successfully commercialized product under this agreement.
- 1 **Amended the GLP-1 License Agreement with Novo Nordisk.** This third amendment provides for, among other things, a payment of \$9.0 million to Emisphere from Novo Nordisk as prepayment of a product development milestone in exchange for a reduction in certain future royalty payments that would have otherwise become payable to the Company under its 2008 GLP-1 Development License Agreement with Novo Nordisk.
- 1 **Launched Eligen B12<sup>™</sup> in the U.S. market.** Eligen B12<sup>™</sup> is the first and only once-daily oral prescription medical food tablet shown to normalize B12 levels without the need for an injection. Eligen B12<sup>™</sup> is indicated for the dietary management of patients who have a medically-diagnosed vitamin B12 deficiency, associated with a disease or condition that cannot be managed by a modification of the normal diet alone. Eligen B12<sup>™</sup> utilizes Emisphere's SNAC carrier to chaperone B12 through the gastric lining and directly into the bloodstream even in the absence of intrinsic factor, a protein made in the stomach that normally facilitates B12 absorption.
- 1 **Global Eligen<sup>®</sup> Technology Business Development Initiatives Continue .** During 2015, Emisphere commenced a

comprehensive business development initiative designed to identify and secure new Eligen<sup>®</sup> Technology partnerships. Eligen<sup>®</sup> Technology is a proven delivery system technology that is applicable to a broad range of chemical entities and has been shown to increase the benefit of the therapy by improving bioavailability or absorption or by decreasing time to onset of action. The Company currently owns rights to an extensive portfolio of carriers with strong patent protection. The current focus of the business development initiative is on next generation, smaller proteins and peptides, proven and/or approved drug compounds, and the development of new oral formulations to replace injectables.

- ▮ **Grant of Waivers and Extensions under Debt Facility, Convertible Notes and Reimbursement Notes.** During November 2015, the creditor under our debt facility, convertible notes and reimbursement notes agreed to waive any event of default resulting from our failure to satisfy the net sales milestones for the Eligen B12<sup>™</sup> product for the 2015 fiscal year specified in our credit facility and convertible notes. The creditor has also agreed to extend the date by which we are required to use 50% of the \$14 million received from Novo Nordisk to pre-pay certain loans and notes until April 6, 2016. We believe that our current cash balance will provide sufficient capital to continue operations through approximately June 2016. However, if the pre-payment obligation is further extended or waived, the Company will have sufficient cash to operate through approximately June 2017.

#### **FOURTH QUARTER 2015 FINANCIAL RESULTS**

Emisphere reported a net loss of \$10.1 million, or (\$0.18) per basic and diluted share, for the quarter ended December 31, 2015, compared to net income of \$0.4 million, or \$0.01 per basic and diluted share, for the quarter ended December 31, 2014.

The Company reported an operating loss of \$4.2 million for the fourth quarter 2015, compared to an operating loss of \$3.3 million for the same period in 2014.

Total operating expenses were \$3.6 million for the fourth quarter 2015, an increase of \$0.3 million or 9.9% compared to the same period in 2014. Total operating expenses include research and development costs of \$0.1 million compared to \$0.2 million in 2014, and selling, general and administrative expenses of \$3.5 million, an increase of \$0.5 million or 16.7% compared to the same period in 2014. Other expense for the fourth quarter of 2015 was \$6.5 million compared to other expense of \$3.4 million for the fourth quarter of 2014.

#### **FULL YEAR 2015 FINANCIAL RESULTS**

Emisphere reported a net loss of \$40.4 million, or (\$0.67) per basic and diluted share, for the year ended December 31, 2015, compared to a net loss of \$25.4 million, or (\$0.42) per basic and diluted share, for the year ended December 31, 2014.

Total operating expenses were \$17.6 million for the year ended December 31, 2015, compared to \$9.3 million for the year ended December 31, 2014, an increase of \$8.3 million or 89.3%. Total operating expenses include research and development costs of \$0.5 million (a decrease of \$0.7 million or 57.9% compared to 2014), and selling, general and administrative expenses of \$17.1 million (an increase of \$9.0 million or 110% compared to 2014).

Other expense for the year ended December 31, 2015, was \$22.9 million, compared to other expense of \$18.1 million for the year ended December 31, 2014. The \$4.8 million increase was due primarily to a \$2.0 million increase in the fair value of derivative instruments, and a \$2.7 million increase in interest expense.

During 2015, Emisphere recognized a state income tax benefit of approximately \$0.6 million as a result of proceeds from the sale of \$7.1 million of New Jersey net operating losses through the Technology Business Certificate Transfer Program, sponsored by the New Jersey Economic Development Authority.

Weighted average basic and diluted shares outstanding for the years ended December 31, 2015, and December 31, 2014, was 60,687,478.

#### **LIQUIDITY**

As of December 31, 2015, Emisphere had approximately \$12.9 million in cash, a net increase of \$9.2 million from December 31, 2014, approximately \$7.1 million working capital deficiency, a stockholders' deficit of approximately \$151.9 million and an accumulated deficit of approximately \$554.5 million.

Our loss from operations was \$18.1 million, \$9.3 million and \$7.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. Our net loss was \$40.4 million, \$25.4 million and \$20.9 million for the years ended December 31, 2015,

2014 and 2013, respectively. Our net cash provided (outlays) from operations and capital expenditures were (\$2.8), (\$8.4) million and \$3.1 million for the years ended December 31, 2015, 2014 and 2013, respectively. Net cash provided include receipts of deferred revenue of \$14.6, \$0.0 million and \$10.0 million for 2015, 2014, and 2013, respectively. Our stockholders' deficit was \$151.9 million and \$112.0 million as of December 31, 2015 and 2014, respectively. As of December 31, 2015, the Company's obligations included approximately \$46.5 million (face value) under its Second Amended and Restated Convertible Notes (the "Convertible Notes"), approximately \$22.8 million (face value) under a loan agreement dated August 20, 2014 (the "Loan Agreement"), approximately \$0.8 million (face value) under its Second Amended and Restated Reimbursement Notes (the "Reimbursement Notes"), and approximately \$2.1 million (face value) under its Second Amended and Restated Bridge Notes (the "Bridge Notes"). The Convertible Notes and the Loan Agreement are subject to various sales, operating and manufacturing performance criteria.

In the event that we do not satisfy annual net sales targets of Eligen B12™ by December 31 for each fiscal year beginning 2015 through 2019, we will be in default under the Loan Agreement and Convertible Notes, provided that we are not granted a waiver. On November 10, 2015, the creditor under our Loan Agreement 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.

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 the Expansion License Agreement, and \$9 million as payment in connection with the third amendment to the GLP-1 License Agreement. Under terms of its loan agreements, the Company is obligated to pre-pay certain loans and notes using 50% of any extraordinary receipts, such as the \$14 million received from Novo Nordisk. The creditor under our Loan Agreement and Reimbursement Notes has agreed to extend the date by which we are required to use 50% of the \$14 million received from Novo Nordisk to pre-pay certain loans and notes until April 6, 2016. However, because such pre-payment deadline has not been extended beyond one year from December 31, 2015, we have classified \$7.0 million of the loans and notes as a current liability as of December 31, 2015.

We believe that our current cash balance will provide sufficient capital to continue operations through approximately June 2016. However, if the pre-payment obligation is further extended or waived, the Company will have sufficient cash to operate through approximately June 2017. The Company's future capital requirements beyond June 2016 (or June 2017, in the event the pre-payment obligation is further extended or waived) and its financial success depend largely on its ability to raise additional capital, including by leveraging existing and securing new partnering opportunities for Eligen B12™ and for the Eligen® technology.

If the Company fails to generate sufficient capital from operations, strategic transactions, new or existing partnering opportunities, or other sources prior to June 2016 (or June 2017, in the event the pre-payment obligation is further extended or waived), it will need to raise capital and risks default under the terms of its existing indebtedness. If it cannot raise new capital, it could be forced to cease operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Consequently, the audit reports prepared by its independent registered public accounting firm relating to its financial statements for the years ended December 31, 2015, 2014 and 2013 include an explanatory paragraph expressing substantial doubt about its ability to continue as a going concern.

## **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](http://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# 76758582. 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 Tuesday, March 29, 2016 at 11:30 AM ET through 11:59 PM ET on April 18, 2016, by calling (855) 859-2056 (United States and Canada) or (404) 537-3406 (International), and entering Conference ID# 76758582.

## **ABOUT ELIGEN B12™**

Eligen B12™ is indicated for the dietary management of patients who have a medically-diagnosed vitamin B12 deficiency, 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 levels 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™ is classified by the U.S. Food and Drug Administration as a medical food. A medical food is a prescription product formulated to be consumed or administered orally under medical supervision for the treatment of a disease or condition that cannot be managed by a modification of the normal diet alone.

For more information, visit [www.eligenb12.com](http://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

Emisphere Technologies, Inc. ("Emisphere" or the "Company") is a pharmaceutical and drug delivery company. The Company launched its first prescription product, oral Eligen B12™, in the U.S. in March 2015 and we are currently engaged in strategic discussions to optimize its economic value in the U.S. and global markets. Beyond Eligen B12™, the Company utilizes its proprietary Eligen® Technology to create new oral formulations of therapeutic agents. Emisphere is currently partnered with global pharmaceutical companies for the development of new orally delivered therapeutics. For more information, please visit [www.emisphere.com](http://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 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, the success of the Company's commercialization initiatives, the ability if the Company 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 STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2015	2014	2013
	(In thousands, except share and per share data)		
Net revenue	\$ 411	\$ -	\$ -
Cost of goods sold	892	-	-
Gross profit (loss)	(481)	-	-
Costs and expenses:			
Research and development	475	1,128	836
General and administrative	5,950	5,968	6,749
Selling expenses	11,176	2,194	-
Loss on disposal of fixed assets	-	-	10
Depreciation and amortization	14	15	9
Total costs and expenses	17,615	9,305	7,604
Operating loss	(18,096)	(9,305)	(7,604)

Other non-operating income (expense):			
Investment and other income	12	10	81
Change in fair value of derivative instruments:			
Related party	(13,950)	(12,172)	(8,491)
Others	34	300	58
Interest expense - related party	<u>(8,966)</u>	<u>(6,232)</u>	<u>(4,955)</u>
Total other non-operating income (expense)	<u>(22,870)</u>	<u>(18,094)</u>	<u>(13,307)</u>
Loss before income tax benefit (expense)	(40,966)	(27,399)	(20,911)
Income tax benefit (expense)	<u>585</u>	<u>2,019</u>	<u>(28)</u>
Net loss	\$ <u>(40,381)</u>	\$ <u>(25,380)</u>	\$ <u>(20,939)</u>
Net loss per share, basic and diluted	\$ <u>(0.67)</u>	\$ <u>(0.42)</u>	\$ <u>(0.35)</u>
Weighted average shares outstanding, basic and diluted	<u>60,687,478</u>	<u>60,687,478</u>	<u>60,687,478</u>

**EMISPHERE TECHNOLOGIES, INC.  
CONDENSED BALANCE SHEETS**

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
	<u>(In thousands, except share data)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 12,898	\$ 3,683
Accounts receivable, net	455	-
Inventories	1,340	2,068
Prepaid expenses and other current assets	<u>1,081</u>	<u>188</u>
Total current assets	15,774	5,939
Equipment and leasehold improvements, net	12	25
Other assets	<u>24</u>	<u>24</u>
Total assets	<u>\$ 15,810</u>	<u>\$ 5,988</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current		
Accounts payable and accrued expenses	\$ 2,121	1,846
Notes payable, related party net of related discount	7,000	-
Deferred revenue - current portion	631	-
Royalty payable - related party	208	-
Derivative instruments:		
Related party	12,690	5,548
Others	<u>205</u>	<u>239</u>
Total current liabilities	22,855	7,633
Notes payable, related party net of related discount	54,172	44,546
Derivative instruments - related party	35,071	24,133
Deferred revenue	55,616	41,616
Deferred lease liability and other liabilities	<u>14</u>	<u>10</u>
Total liabilities	167,728	117,938
Commitments and contingencies	-	-
Stockholders' deficit:		
Preferred stock, \$.01 par value; authorized 4,000,000 shares at December 31, 2015 and 2014; issued and outstanding at December 31, 2015 and 2014 - none	-	-
Common stock, \$.01 par value; authorized 400,000,000 shares at December 31, 2015 and 2014 issued 60,977,210 shares (60,687,478 outstanding) at December 31, 2015 and 2014	610	610

Additional paid-in capital	405,944	405,531
Accumulated deficit	(554,520)	(514,139)
Common stock held in treasury, at cost; 289,732 shares	<u>(3,952)</u>	<u>(3,952)</u>
Total stockholders' deficit	<u>(151,918)</u>	<u>(111,950)</u>
Total liabilities and stockholders' deficit	<u>\$ 15,810</u>	<u>\$ 5,958</u>

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 Primary Logo

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