

EMISPHERE TECHNOLOGIES INC

FORM 8-K (Current report filing)

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Address	240 CEDAR KNOLLS RD. SUITE 200 CEDAR KNOLLS, NJ 07927
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): March 29, 2017

EMISPHERE TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

000-17758
(Commission
File Number)

13-3306985
(I.R.S. Employer
Identification No.)

4 Becker Farm Road
Suite 103, Roseland, New Jersey
(Address of principal executive offices)

07068
(Zip Code)

Registrant's telephone number, including area code: 973-532-8000

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 **Results of Operations and Financial Condition**.

On March 29, 2017, Emisphere Technologies, Inc. issued a press release announcing results of operations for the fourth quarter and year ended December 31, 2016. A copy of the press release is furnished herewith and is incorporated by reference herein as Exhibit 99.1.

Item 9.01 **Financial Statements and Exhibits**.

Exhibit
No.

Description

99.1 Press Release of Emisphere Technologies, Inc., dated March 29, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Emisphere Technologies, Inc.

March 29, 2017

By: */s/ Alan L. Rubino*

Name: Alan L. Rubino

Title: President and Chief Executive Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Emisphere Technologies, Inc., dated March 29, 2017



Emisphere Reports Fourth Quarter and Full Year 2016 Financial Results

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

ROSELAND, N.J., March 29, 2017 —Emisphere Technologies, Inc. (OTCBB: EMIS) today reported financial results for the fourth quarter and full fiscal year ended December 31, 2016, 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. “With our most advanced partner, Novo Nordisk A/S (NYSE:NVO), commencing Phase 3a development with oral semaglutide, a once daily treatment for Type 2 diabetes which utilizes SNAC, one of our Eligen[®] Technology carriers. We expanded on the Novo Nordisk partnership during the fourth quarter of 2015 with the execution of a new license agreement for the potential development of four new oral formulations targeting major metabolic disorders, and have been working on expanding this key collaboration to continue the validation for our Eligen[®] Technology and its ability to facilitate absorption from the gastrointestinal tract.”

Mr. Rubino continued: “We launched oral Eligen B12[™] Rx in 2015 to positive physician and patient reception. During the fourth quarter 2015, several major Pharma and Consumer Healthcare Companies expressed interest in licensing or acquiring Eligen B12[™]. Throughout the launch 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 continue to work extensively with potential suitors who have strong commercial capability across various market segments.

“Other than the Eligen B12 interactions outlined above, we have refocused business development efforts with major R&D companies as we continue to seek new value creating partnerships for our Eligen[®] Technology carriers.”

2016 AND RECENT HIGHLIGHTS

- ***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 initiated 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[®] Technology platform and supports the Company’s belief that products developed using Eligen[®] carriers have the potential to overcome bioavailability challenges commonly associated with the oral administration of peptides and certain other compounds.
- ***Global Eligen[®] Technology Business Development Initiatives Continue*** . During 2016, Emisphere launched a comprehensive business development initiative designed to identify and secure new Eligen[®] Technology partnerships. Eligen[®] Technology is a proven delivery system technology that is applicable to a broad range of chemical entities and has shown to increase the benefit of the therapy by improving bioavailability and absorption, or by decreasing time to onset of action. We have initiated new collaborations with R&D companies and have commenced moving new molecules into feasibility testing to



determine the potential to translate these injectable API's into oral formulations. 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 injectable therapeutics.

- **Modifications under Debt Facility, Convertible Notes and Reimbursement Notes.** During December 2016, the creditor under our debt facilities waived certain obligations under these facilities, including, among other things, the permanent waiver of the requirement to prepay \$7 million of our debt obligations with proceeds received from Novo Nordisk in connection with the 2015 license, reduce by \$7 million the principal amount under our debt facilities on the first commercial sale of a product licensed under our GLP-1 License Agreement with Novo Nordisk, waive any events of default as a result of the our failure to meet certain sales targets, waive the cash sweep of 50% of proceeds from the license, distribution or sale of any of our products other than B12.

FOURTH QUARTER 2016 FINANCIAL RESULTS

Emisphere reported a net income of \$4.5 million for the quarter ended December 31, 2016, compared to a net loss of \$10.1 million for the quarter ended December 31, 2015.

The Company reported an operating loss of \$1.2 million for the fourth quarter 2016, compared to an operating loss of \$4.2 million for the same period in 2015.

Total operating expenses were \$1.4 million for the fourth quarter 2016, a decrease of \$2.2 million or 61.1% compared to the same period in 2015. Total operating expenses include research and development costs of \$0.1 million compared to \$0.1 million in 2015, and selling, general and administrative expenses of \$1.2 million, a decrease of \$2.3 million or 65.8% compared to the same period in 2015. Other income for the fourth quarter of 2016 was \$5.7 million compared to an other non-operating loss of \$6.5 million for the fourth quarter of 2015. The change from other expense to other income for the fourth quarter 2016 was due primarily to a decrease in fair value of derivative instruments of \$12.9 million and a \$0.7 million increase in interest expense.

FULL YEAR 2016 FINANCIAL RESULTS

Emisphere reported a net loss of \$10.0 million, or \$0.17 per basic and diluted share, for the year ended December 31, 2016, compared to a net loss of \$40.4 million, or \$0.67 per basic and diluted share, for the year ended December 31, 2015.

Total operating expenses were \$7.5 million for the year ended December 31, 2016, compared to \$17.6 million for the year ended December 31, 2015, a decrease of \$10.1 million or 57.4%. Total operating expenses include research and development costs of \$0.4 million (a decrease of \$0.1 million or 20.0% compared to 2015), and selling, general and administrative expenses of \$7.2 million (a decrease of \$10 million or 58.4% compared to 2015).

Other expense for the year ended December 31, 2016, was \$2.2 million, compared to other expense of \$22.9 million for the year ended December 31, 2015. The \$20.7 million decrease was due primarily to a \$23.1 million decrease in the fair value of derivative instruments, and a \$2.4 million increase in interest expense.



Weighted average basic and diluted shares outstanding for the years ended December 31, 2016, and December 31, 2015, was 60,687,478.

LIQUIDITY

As of December 31, 2016, Emisphere had approximately \$6.1 million in cash, a net decrease of \$6.8 million from December 31, 2015, approximately \$3.2 million working capital deficiency, a stockholders' deficit of approximately \$161.4 million and an accumulated deficit of approximately \$564.6 million.

Our net loss was \$10.0 million, \$40.4 million and \$25.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. Our net cash provided (outlays) from operations and capital expenditures were (\$6.8), (\$2.8) million and (\$8.4) million for the years ended December 31, 2016, 2015 and 2014, respectively. Net cash provided (outlays) include receipts of deferred revenue of (\$0.01) million, \$14.6 million and \$0.0 million for 2016, 2015, and 2014, respectively. Our stockholders' deficit was \$161.4 million and \$151.9 million as of December 31, 2016 and 2015, respectively.

As of December 31, 2016, the Company's obligations included approximately \$53 million (face value) under its Second Amended and Restated Convertible Notes (the "Convertible Notes"), approximately \$26 million (face value) under a loan agreement entered into on 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 \$2.4 million (face value) under its Second Amended and Restated Bridge Notes (the "Bridge Notes").

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 was obligated to pre-pay certain loans and notes using 50% of any extraordinary receipts, such as the \$14 million received from Novo Nordisk. Under the terms of the Loan Agreement and Convertible Notes Emisphere is required to satisfy annual net sales targets of Eligen B12™. On December 8, 2016, we entered into various agreements whereby, among other things, 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 2016 fiscal year and all future periods specified in our Loan Agreement and Convertible Notes. The creditor also agreed to irrevocably waive the Company's obligation to pre-pay \$7 million of certain loans and notes resulting from the \$14 million cash receipt from Novo Nordisk.

Management has concluded that due to the conditions described above, there is substantial doubt about the entity's ability to continue as a going concern. We have evaluated the significance of the conditions in relation to our ability to meet our obligations and believe that our current cash balance will provide sufficient capital to continue operations through approximately March 2018. While our plan is to raise capital from commercial operations and/or product partnering opportunities to address our capital deficiencies and meet our operating cash requirements, there is no assurance that our plans will be successful. If we fail to generate sufficient capital from commercial operations or partnerships, we will need to seek capital from other sources and risk default.



under the terms of our existing loans. We cannot assure you that financing will be available on favorable terms or at all. Additionally, if additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders. Furthermore, despite our optimism regarding the Eligen[®] Technology, even in the event that the Company is adequately funded, there is no guarantee that any of our products or product candidates will perform as hoped or that such products can be successfully commercialized.

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# 90730730. 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 Wednesday, March 29, 2017 at 11:30 AM ET through 11:59 PM ET on April 5, 2017, by calling (855) 859-2056 (United States and Canada) or (404) 537-3406 (International), and entering Conference ID# 90730730.

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.

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 is a Drug Delivery Company whose core business strategy is to partner its proprietary drug delivery technology and license Eligen B12. Our thirty-year history has made us the established leader in converting injectable therapeutics into advanced oral formulations. Utilizing our experience in researching, developing and manufacturing a number of fully characterized carriers in our extensive library, our partners leverage our expertise to employ our unique intracellular delivery mechanism to advance their portfolio and create differentiated line extensions. Our capabilities range from early proof of concept, to extensive development and commercial capabilities.

Emisphere's technology can enhance the clinical profile of both pre-market and currently marketed products. Further, our broad-based proprietary oral drug delivery platform provides significant increases in bioavailability, facilitates the enhanced absorption of small and large molecules without altering their chemical form, and maintains their biological integrity or pharmacological properties. Finally, it is especially useful for oral delivery of peptides, proteins, oligonucleotides and oligosaccharides. 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 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.

COMPANY CONTACTS:

Alan L. Rubino, CEO
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EMISPHERE TECHNOLOGIES, INC.
BALANCE SHEETS

	December 31, 2016 2015 (In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,085	\$ 12,898
Accounts receivable, net	301	455
Inventories	67	1,340
Prepaid expenses and other current assets	107	1,081
Total current assets	6,560	15,774
Equipment and leasehold improvements, net	—	12
Security deposit	24	24
Total assets	\$ 6,584	\$ 15,810
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	\$ 869	\$ 2,121
Notes payable, related party	—	7,000
Deferred revenue, current portion	513	631
Royalty payable—related party	—	208
Derivative instruments:		
Related party	8,343	12,690
Others	—	205
Total current liabilities	9,725	22,855
Notes payable, related party net of related discount	67,589	54,172
Derivative instruments—related party	34,851	35,071
Royalty payable—related party	206	—
Deferred revenue	55,616	55,616
Deferred lease liability and other liabilities	5	14
Total liabilities	167,992	167,728
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$.01 par value; authorized 4,000,000 shares at December 31, 2016 and 2015; issued and outstanding at December 31, 2016 and 2015	—	—
Common stock, \$.01 par value; authorized 400,000,000 shares at December 31, 2016 and 2015 issued 60,977,210 shares (60,687,478 outstanding) at December 31, 2016 and 2015	610	610
Additional paid-in capital	406,495	405,944
Accumulated deficit	(564,561)	(554,520)
Common stock held in treasury, at cost; 289,732 shares	(3,952)	(3,952)
Total stockholders' deficit	(161,408)	(151,918)
Total liabilities and stockholders' deficit	\$ 6,584	\$ 15,810



EMISPHERE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2016	2015	2014
	(In thousands, except share and per share data)		
Net revenue	\$ 1,195	\$ 411	\$ —
Cost of goods sold	286	201	—
Write-off of slow moving inventory	1,214	691	—
Gross loss	(305)	(481)	—
Costs and expenses:			
Research and development	373	475	1,128
General and administrative	5,228	5,950	5,968
Selling expenses	1,923	11,176	2,194
Depreciation and amortization	12	14	15
Total costs and expenses	7,536	17,615	9,305
Operating loss	(7,841)	(18,096)	(9,305)
Other non-operating income (expense):			
Investment and other income	15	12	10
Change in fair value of derivative instruments:			
Related party	8,933	(13,950)	(12,172)
Others	205	34	300
Interest expense—related party	(11,353)	(8,966)	(6,232)
Total other non-operating income (expense)	(2,200)	(22,870)	(18,094)
Loss before income tax benefit	(10,041)	(40,966)	(27,399)
Income tax benefit	—	585	2,019
Net loss	\$ (10,041)	\$ (40,381)	\$ (25,380)
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.67)	\$ (0.42)
Weighted average shares outstanding, basic and diluted	60,687,478	60,687,478	60,687,478