

# EMISPHERE TECHNOLOGIES INC

## **FORM 8-K** (Current report filing)

Filed 08/15/16 for the Period Ending 08/15/16

Address	240 CEDAR KNOLLS RD. SUITE 200 CEDAR KNOLLS, NJ 07927
Telephone	973-532-8000
CIK	0000805326
Symbol	EMIS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): August 15, 2016**

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**EMISPHERE TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

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**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.)

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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 August 15, 2016, Emisphere Technologies, Inc. (the "Company") issued a press release announcing results of operations for the quarterly period ended June 30, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01. **Other Events.**

On August 20, 2014, the Company entered into a series of agreements with MHR Capital Partners Master Account LP, MHR Capital Partners (100) LP, MHR Institutional Partners II LP, and MHR Institutional Partners IIA LP (collectively, "MHR"), including (a) the Second Amended and Restated Convertible Reimbursement Promissory Notes (the "Reimbursement Notes"), (b) a Senior Secured Loan Agreement (the "Loan Agreement"), and (c) a Royalty Agreement (the "Royalty Agreement").

The terms of the Reimbursement Notes and Loan Agreement require the Company to prepay amounts outstanding thereunder using 50% of certain proceeds (the "Proceeds") paid to the Company, including \$14 million received by the Company on October 26, 2015 in connection with certain licensing agreements with Novo Nordisk AS. Further, the terms of the Royalty Agreement require the Company to pay to MHR annual royalties on net sales of the Company's oral Eligen<sup>®</sup> B12 product ("Royalties").

On August 15, 2016, MHR agreed to further extend the payment of the Proceeds and Royalties to September 15, 2016. Copies of the Reimbursement Notes, Loan Agreement and Royalty Agreement were filed by the Company in its Quarterly Report on Form 10-Q for the quarter ending September 30, 2014, and a summary of their material terms was filed in the Company's Current Report on Form 8-K filed with the SEC on August 21, 2014.

Item 9.01 **Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Emisphere Technologies, Inc., dated August 15, 2016

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**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.

*August 15, 2016*

By: /s/ Alan L. Rubino

*Name: Alan L. Rubino*

*Title: President & Chief Executive Officer*

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**Exhibit Index**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press release of Emisphere Technologies, Inc., dated August 15, 2016



## Emisphere Reports Second Quarter 2016 Financial Results

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

**ROSELAND, N.J., August 15, 2016** — Emisphere Technologies, Inc. (OTCBB: EMIS) today reported financial results for the second quarter ended June 30, 2016, and provided an overview of corporate accomplishments and plans.

“During the first half of 2016, we continued to focus our efforts on business development initiatives, including advancing discussions with potential partners for a strategic transaction or alliance for our commercial oral Eligen B12™ product, the first and only prescription B12 replacement therapeutic,” said Alan L. Rubino, President and Chief Executive Officer of Emisphere. “In parallel, our Novo Nordisk A/S (NYSE: NVO) partnership continues on track with Phase 3a trials well underway evaluating oral semaglutide, a once daily type 2 diabetes treatment utilizing SNAC, one of our Eligen® Technology carriers. Efforts to secure new development partnerships centered around this unique, absorption enhancing delivery technology continue and there has been significant interest expressed by several pharmaceutical companies with the shared goal of creating new oral formulations to replace existing injectables.”

Mr. Rubino continued: “As a result of our strategic decision to partner Eligen B12™, we also successfully implemented several cost control measures which enabled us to significantly reduce our operating expenses and preserve our financial resources during the first half of the year. Looking ahead to the remainder of 2016, we will continue to aggressively explore, identify and advance discussions with potential partners and we look forward to keeping you updated on our progress.”

### FIRST HALF 2016 HIGHLIGHTS

**Exploring Strategic Partnership Opportunities for Oral Eligen B12™ in the U.S. and Internationally.** Eligen B12™ 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™ 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™ 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.

**Novo Nordisk Commenced Global Phase 3a Clinical Trials for Oral Semaglutide.** During the first half 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® 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.

**Novo Nordisk Continues Feasibility Studies under our Development and License Agreement 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.

**Global Eligen<sup>®</sup> Technology Business Development Initiatives Continue.** During the first half 2016, Emisphere continued to pursue its 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 Loan Agreement, Convertible Notes and Reimbursement notes agreed to waive any event of default resulting from our failure to satisfy the net sales milestone for the Eligen B12<sup>™</sup> product for the 2015 fiscal year specified in our Loan and Royalty Agreements. 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 (the "Loan Prepayment") until August 16, 2016. We believe that our current cash balance will provide sufficient capital to continue operations through September 2016. However, if the pre-payment obligation is further extended or waived, the Company will have sufficient cash to operate through September 2017.

## SECOND QUARTER 2016 FINANCIAL RESULTS

Emisphere reported a net loss of \$7.5 million, or (\$0.12) per basic and diluted share, for the quarter ended June 30, 2016, compared to net income of \$7.1 million, or \$0.12 per basic share and (\$0.04) per diluted share, for the quarter ended June 30, 2015.

The Company reported an operating loss of \$2.0 million for the second quarter 2016, compared to an operating loss of \$4.6 million for the same period in 2015.

Total operating expenses were \$1.6 million for the second quarter 2016, a decrease of \$3.0 million or 66% compared to the same period in 2015. Total operating expenses include research and development costs of \$0.10 million compared to \$0.10 million in 2015, and selling, general and administrative expenses of \$1.5 million, a decrease of \$3.1 million or 68% compared to the same period in 2015. Other non-operating expense for the second quarter of 2016 was \$5.5 million compared to other non-operating income of \$11.7 million for the second quarter 2015.

Weighted average basic and diluted shares outstanding for the three months ended June 30, 2016, was 60,687,478. Weighted average basic and diluted shares outstanding for the three months ended June 30, 2015, was 60,687,478 and 123,445,160, respectively.



## YEAR TO DATE FINANCIAL RESULTS

For the six months ended June 30, 2016, Emisphere reported a net loss of \$9.3 million, or \$(0.15) 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.

The Company reported an operating loss of \$4.7 million for the six months ended June 30, 2016, compared to an operating loss of \$9.2 million for the same period in 2015.

Total operating expense for the six months ended June 30, 2016 was \$4.6 million, a decrease of \$4.7 million or 50%. Total operating expenses for the six months ended June 30, 2016 include research and development costs of \$0.2 million compared to \$0.3 million in 2015, and selling, general and administrative expenses of \$4.4 million, a decrease of \$4.6 million or 51% compared to the same period in 2015. Other expense for the six months ended June 30, 2016 was \$4.7 million compared to \$16.6 million for the same period in 2015.

Weighted average basic and diluted shares outstanding for the six months ended June 30, 2016 and June 30, 2015 was 60,687,478.

## LIQUIDITY

As of June 30, 2016, Emisphere had approximately \$8.7 million in cash, a net decrease of \$4.2 million from December 31, 2015, a stockholders' deficit of approximately \$161.1 million and an accumulated deficit of approximately \$563.9 million.

As of June 30, 2016, the Company's obligations included approximately \$49.7 million (face value) under its Second Amended and Restated Convertible Notes (the "Convertible Notes"), approximately \$24.3 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 \$2.3 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.

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 prepayment of a product development milestone and in exchange for a reduction in certain future royalty payments that may have become due and payable under the terms of our GLP-1 Development License Agreement with Novo Nordisk. Under the terms of our loan agreements, we are 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 August 16, 2016. Because the Loan Prepayment deadline has not been extended beyond one year from June 30, 2016, we have classified \$7.0 million of the loans and notes as a current liability as of June 30, 2016.

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



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. If we fail to generate sufficient additional capital from sales of oral Eligen B12 or to obtain substantial cash inflows from existing or new partners or other sources prior to September 2016 (or September 2017, in the event the prepayment obligations is further extended or waived), we could be forced to cease operations. 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. These conditions raise substantial doubt about our ability to continue as a going concern. Consequently, the audit reports prepared by our independent registered public accounting firm relating to our financial statements for the years ended December 31, 2015, 2014 and 2013 include an explanatory paragraph expressing substantial doubt about our 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# 59804462. 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 Monday, August 15, 2016 at 11:30 AM ET through 11:59 PM ET on August 22, 2016, by calling (855) 859-2056 (United States and Canada) or (404) 537-3406 (International), and entering Conference ID# 59804462.

#### **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 of 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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Alan Gallantar, Acting CFO  
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**EMISPHERE TECHNOLOGIES INC.**  
**CONDENSED BALANCE SHEETS**  
**JUNE 30, 2016 AND DECEMBER 31, 2015**  
(in thousands, except share and per share data)

	June 30, 2016 (unaudited)	December 31, 2015
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,740	\$ 12,898
Accounts Receivable, net	246	455
Inventories	656	1,340
Prepaid expenses and other current assets	448	1,081
Total Current Assets	10,090	15,774
Equipment and leasehold improvements, net	4	12
Security deposits	24	24
Total assets	<u>\$ 10,118</u>	<u>\$ 15,810</u>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 878	\$ 2,121
Notes payable, related party	7,000	7,000
Deferred Revenue, current portion	677	631
Royalty payable, related party	208	208
Derivative instruments		
Related party	12,274	12,690
Others	—	205
Total current liabilities	21,037	22,855
Notes payable, related party, net of related discount	57,113	54,172
Derivative instruments, related party	37,289	35,071
Deferred revenue	55,616	55,616
Royalty payable – related party	141	—
Deferred lease liability and other liabilities	9	14
Total liabilities	<u>171,205</u>	<u>167,728</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>Stockholders' deficit:</b>		
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 June 30, 2016 and December 31, 2015	610	610
Additional paid-in-capital	406,117	405,944
Accumulated deficit	(563,862)	(554,520)
Common stock held in treasury, at cost; 289,732 shares	(3,952)	(3,952)
Total stockholders' deficit	<u>(161,087)</u>	<u>(151,918)</u>
Total liabilities and stockholders' deficit	<u>\$ 10,118</u>	<u>\$ 15,810</u>



**EMISPHERE TECHNOLOGIES, INC.**  
**CONDENSED STATEMENT OF OPERATIONS**  
**For the three and six months ended June 30, 2016 and 2015**  
(in thousands, except share and per share data)  
(unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Net revenue	\$ 286	\$ 88	\$ 659	\$ 94
Cost of goods sold	46	55	98	80
Write-off of slow moving inventory	654	—	654	—
Gross profit (loss)	(414)	33	(93)	14
Costs and expenses:				
Research and development	89	59	180	287
General and administrative expenses	1,322	1,528	2,662	2,820
Selling expenses	137	3,007	1,731	6,132
Depreciation and amortization	3	3	8	7
Total costs and expenses	1,551	4,597	4,581	9,246
Operating loss	(1,965)	(4,564)	(4,674)	(9,232)
Other non-operating income (expense):				
Other income	4	3	9	7
Change in fair value of derivative instruments				
Related party	(2,993)	13,493	456	(12,117)
Other	83	433	205	(420)
Interest expense related party	(2,642)	(2,229)	(5,338)	(4,070)
Total other non-operating income (expense)	(5,548)	11,700	(4,668)	(16,600)
Net income (loss)	\$ (7,513)	\$ 7,136	\$ (9,342)	\$ (25,832)
Net income (loss) per share, basic	\$ (0.12)	\$ 0.12	\$ (0.15)	\$ (0.43)
Net income (loss) per share, fully diluted	\$ (0.12)	\$ (0.04)	\$ (0.15)	\$ (0.43)
Weighted average shares outstanding, basic	60,687,478	60,687,478	60,687,478	60,687,478
Weighted average shares outstanding, diluted	60,687,478	123,445,160	60,687,478	60,687,478