

EMISPHERE TECHNOLOGIES INC

FORM 8-K (Current report filing)

Filed 11/15/16 for the Period Ending 11/14/16

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 & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): November 14, 2016

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))
-
-

Item 2.02 **Results of Operations and Financial Condition**.

On November 14, 2016, Emisphere Technologies, Inc. (the “Company”) issued a press release announcing results of operations for the quarterly period ended September 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, Emisphere Technologies, Inc. (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[®] B12 product (“Royalties”).

On November 15, 2016, MHR agreed to further extend the payment of the Proceeds and Royalties to December 1, 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 November 14, 2016

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.

November 15, 2016

By: */s/ Alan L. Rubino*

Name: Alan L. Rubino

Title: President & Chief Executive Officer

Exhibit Index

**Exhibit
No.**

Description

99.1 Press release of Emisphere Technologies, Inc., dated November 14, 2016



Emisphere Reports Third Quarter 2016 Financial Results

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

ROSELAND, N.J., November 14, 2016 — Emisphere Technologies, Inc. (OTCBB: EMIS) today reported financial results for the third quarter ended September 30, 2016, and provided an overview of corporate accomplishments and plans.

“To date in 2016, we have made significant progress toward our key corporate objectives of securing a strategic alliance or transaction for Eligen B12 and new oral formulation development partnerships for our innovative Eligen[®] Technology,” said Alan L. Rubino, President and Chief Executive Officer of Emisphere. “Our discussions continue to advance with potential partners, both the U.S. and internationally, for the ongoing global commercialization of oral Eligen B12. We believe that Eligen B12 is a best-in-class product with a largely untapped patient base.”

Mr. Rubino continued, “On the financial front, we significantly reduced our operating expenses versus the same period a year ago, and we continue to look for opportunities to increase efficiency, reduce overhead, and extend our cash runway as we build a strong foundation for 2017.”

YEAR TO DATE 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. Emisphere is currently in discussions with several potential partners for a strategic alliance or transaction for Eligen B12[™].

Novo Nordisk Commenced Global Phase 3a Clinical Trials for Oral Semaglutide. During 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 has stated that data from the oral semaglutide Phase 3a program is expected to be reported beginning in late 2017.

Novo Nordisk Continues Feasibility Studies under our Development and License Agreement to Develop Oral Formulations Targeting Metabolic Indications. Emisphere and Novo Nordisk entered into a 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[®] 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® Technology Business Development Initiatives Continue. Emisphere continues to pursue its 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 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™ product for the 2015 fiscal year specified in our Loan and Royalty Agreements. We do not anticipate meeting the annual sales target at December 31, 2016, however, the Company is currently in discussions with the creditor for a permanent waiver of this condition. 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 November 15, 2016. We believe that our current cash balance will provide sufficient capital to continue operations through November, 2016. However, if the pre-payment obligation is further extended or waived, the Company will have sufficient cash to operate through December, 2017.

THIRD QUARTER 2016 FINANCIAL RESULTS

Emisphere reported a net loss of \$5.2 million, or (\$0.09) per basic and diluted share, for the quarter ended September 30, 2016, compared to net loss of \$4.4 million, or (\$0.07) per basic and diluted share, for the quarter ended September 30, 2015.

The Company reported an operating loss of \$2.0 million for the third quarter of 2016, compared to an operating loss of \$4.7 million for the same period in 2015.

Total operating expenses were \$1.6 million for the third quarter 2016, a decrease of \$3.1 million or 66% compared to the same period in 2015. Total operating expenses include research and development costs of \$0.08 million compared to \$0.09 million in 2015, and selling, general and administrative expenses of \$1.5 million, a decrease of \$3.1 million or 67% compared to the same period in 2015. Other non-operating expense for the third quarter 2016 was \$3.2 million compared to other non-operating income of \$0.2 million for the third quarter 2015.

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



YEAR TO DATE FINANCIAL RESULTS

For the nine months ended September 30, 2016, Emisphere reported a net loss of \$14.5 million, or (\$0.24) per basic and diluted share, compared to net loss of \$30.3 million, or (\$0.50) per basic and diluted share, for the same period last year.

The Company reported an operating loss of \$6.7 million for the nine months ended September 30, 2016, compared to an operating loss of \$13.9 million for the same period in 2015.

Total operating expense for the nine months ended September 30, 2016 was \$6.2 million, a decrease of \$7.8 million or 56%. Total operating expenses for the nine months ended September 30, 2016 include research and development costs of \$0.26 million compared to \$0.38 million in 2015, and selling, general and administrative expenses of \$5.9 million, a decrease of \$7.7 million or 57% compared to the same period in 2015. Other expense for the nine months ended September 30, 2016 was \$7.9 million compared to \$16.4 million for the same period in 2015.

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

LIQUIDITY

On September 30, 2016 Emisphere had approximately \$7.5 million in cash, a net decrease of \$5.4 million from December 31, 2015, a stockholders' deficit of approximately \$166.2 million and an accumulated deficit of approximately \$569.1 million.

As of September 30, 2016, our financial obligations included approximately \$49.7 million (face value) under our Second Amended and Restated Convertible Notes (the "Convertible Notes"), approximately \$24.3 million (face value) under a loan agreement entered into on August 20, 2014 (the "Loan Agreement"), approximately \$0.8 million (face value) under our Second Amended and Restated Reimbursement Notes (the "Reimbursement Notes"), and approximately \$2.3 million (face value) under our Second Amended and Restated Bridge Notes (the "Bridge Notes"). The Convertible Notes and the Loan Agreement are subject to annual net sales performance targets.

Under the terms of the Loan Agreement, the Company borrowed an aggregate of \$20.0 million to finance the development, manufacturing, marketing and sales of our oral Eligen B12 Rx Product. The loan facility will mature on December 31, 2019 and bears interest at a rate of 13% per year. In the event that the Company does not satisfy the 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. We do not anticipate meeting the annual net sales target by December 31, 2016, however, the Company is currently in discussions with the creditor for a permanent waiver of this condition.

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 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 November 15, 2016. Because the Loan Prepayment deadline has not been extended beyond one year from September 30, 2016, we have classified \$7.0 million of the loans and notes as a current liability as of September 30, 2016.

We believe that our current cash balance will provide sufficient capital to continue operations through November 2016. However, if the pre-payment obligation is further extended or waived, the Company will have sufficient cash to operate through approximately December 2017. The Company's future capital requirements beyond November 2016 (or December 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[®] 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 November 2016 (or December 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. 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# 9336783. 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, November 14, 2016 at 11:30 AM ET through 11:30 AM ET on November 21, 2016, by calling (855) 859-2056 (United States and Canada) or (404) 537-3406 (International), and entering Conference ID# 9336783.



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, 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.



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
973.532.8000
arubino@emisphere.com

Alan Gallantar, Acting CFO
973.532.8005
agallantar@emisphere.com



EMISPHERE TECHNOLOGIES INC.
CONDENSED BALANCE SHEETS
SEPTEMBER 30, 2016 AND DECEMBER 31, 2015
(in thousands, except share and per share data)

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,514	\$ 12,898
Accounts Receivable, net	232	455
Inventories	85	1,340
Prepaid expenses and other current assets	194	1,081
Total Current Assets	8,025	15,774
Equipment and leasehold improvements, net	1	12
Security deposits	24	24
Total assets	<u>\$ 8,050</u>	<u>\$ 15,810</u>
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	\$ 773	\$ 2,121
Notes payable, related party	7,000	7,000
Accrued interest, related party	2,545	—
Deferred Revenue, current portion	629	631
Royalty payable, related party	208	208
Derivative instruments		
Related party	11,983	12,690
Others	—	205
Total current liabilities	23,138	22,855
Notes payable, related party, net of related discount	57,309	54,172
Derivative instruments, related party	38,016	35,071
Deferred revenue	55,616	55,616
Royalty payable – related party	173	—
Deferred lease liability and other liabilities	7	14
Total liabilities	<u>174,259</u>	<u>167,728</u>
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, 2016 and December 31, 2015	610	610
Additional paid-in-capital	406,198	405,944
Accumulated deficit	(569,065)	(554,520)
Common stock held in treasury, at cost; 289,732 shares	(3,952)	(3,952)
Total stockholders' deficit	<u>(166,209)</u>	<u>(151,918)</u>
Total liabilities and stockholders' deficit	<u>\$ 8,050</u>	<u>\$ 15,810</u>



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

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Net revenue	\$ 204	\$ 130	\$ 863	\$ 225
Cost of goods sold	41	58	139	138
Write-off of slow moving inventory	560	—	1,214	—
Gross profit (loss)	(397)	72	(490)	87
Costs and expenses:				
Research and development	80	94	260	382
General and administrative expenses	1,381	1,352	4,043	4,181
Selling expenses	137	3,291	1,868	9,414
Depreciation and amortization	3	3	11	10
Total costs and expenses	1,601	4,740	6,182	13,987
Operating loss	(1,998)	(4,668)	(6,672)	(13,900)
Other non-operating income (expense):				
Other income	3	1	12	8
Change in fair value of derivative instruments				
Related party	(436)	2,334	20	(9,783)
Other	—	232	205	(188)
Interest expense related party	(2,772)	(2,321)	(8,110)	(6,391)
Total other non-operating income (expense)	(3,205)	246	(7,873)	(16,354)
Net loss	\$ (5,203)	\$ (4,422)	\$ (14,545)	\$ (30,254)
Net loss per share, basic and diluted	\$ (0.09)	\$ (0.07)	\$ (0.24)	\$ (0.50)
Weighted average shares outstanding, basic and diluted	60,687,478	60,687,478	60,687,478	60,687,478