

EMISPHERE TECHNOLOGIES INC  
Form 8-K  
February 16, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 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

February 15, 2005

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Date of report (date of earliest event reported)

**EMISPHERE TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

Delaware

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(State or other jurisdiction of incorporation)

1-10615

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(Commission File Number)

13-3306985

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(I.R.S. Employer Identification Number)

765 Old Saw Mill River Road, Tarrytown, New York

10591

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(Address of principal executive offices)

(Zip Code)

914-347-2220

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(Registrant's telephone number, including area code)

N/A

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(Former name or former address, if changed since last report)

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

On February 15, 2005, Emisphere Technologies, Inc. issued a press release announcing results of operations for the fourth quarter and year ended December 31, 2004. The Company also highlighted its progress related to development programs using its proprietary *eligen*® oral drug delivery technology. A copy of the press release is furnished herewith and is incorporated by reference herein as Exhibit 99.1.

The information in this Current report and attached Exhibit are being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a) (2) of the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

**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.

Date:  
February 15, 2005

EMISPHERE TECHNOLOGIES, INC.

By:

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**Name: Elliot Maza**  
**Title: Chief Financial Officer**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>	
99.1	Press Release, issued February 15, 2005.	4

For further information contact:

**AT EMISPHERE TECHNOLOGIES, INC.**

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EMISPHERE TECHNOLOGIES ANNOUNCES FOURTH QUARTER AND  
YEAR END FINANCIAL RESULTS FOR 2004

**Tarrytown, NY February 15, 2005** --- Emisphere Technologies, Inc. (NASDAQ: EMIS) today announced results for the fourth quarter and year ended December 31, 2004. The Company also reviewed highlights of the year, including progress in commercializing its proprietary *eligen*® drug delivery technology.

**Fourth Quarter Results**

Emisphere reported a net loss of \$8.7 million, or \$0.47 per share, for the quarter ended December 31, 2004, compared to a net loss of \$9.2 million, or \$0.51 per share for the quarter ended December 31, 2003.

Total operating expenses were \$9.0 million for the 2004 fourth quarter, an increase of \$0.7 million, or 9%, compared to the same period last year. Total operating expenses include research and development costs of \$4.2 million, a decrease of \$0.6 million or 13%, compared to last year's fourth quarter and general and administrative expenses of \$3.6 million, an increase of \$1.5 million or 72%, compared to the same period last year. The 72% increase in general and administrative expenses is primarily due to an increase in legal fees related to litigation with Eli Lilly and Company. Excluding legal fees related to the Lilly litigation, general and administrative expenses for the fourth quarter were \$2.4 million, an increase of \$0.3 million or 15%, compared to the same period in 2003. This increase is primarily related to incremental legal and audit fees for certain non-recurring activities that occurred during the quarter.

Cash, cash equivalents and investments held as of December 31, 2004 were \$17.5 million, a net decrease of \$25.5 million from such amounts held on December 31, 2003.

## **Year End Results**

Emisphere reported a net loss of \$37.5 million, or \$2.04 per share, for the year ended December 31, 2004, compared to a net loss of \$44.9 million, or \$2.48 per share, for the year ended December 31, 2003.

Total operating expenses were \$34.2 million for the year ended December 31, 2004, a decrease of \$7.8 million, or 19%, compared to the year ended December 31, 2003. Total operating expenses include research and development costs of \$17.5 million, a decrease of \$3.5 million or 17%, compared to last year, and general and administrative expenses of \$11.8 million, an increase of \$2 million, or 21%, compared to last year. The 20% increase in general and administrative expenses is primarily due to an increase in legal fees related to the Lilly litigation.

Weighted average shares outstanding for the year ended December 31, 2004 and December 31, 2003, were 18.4 million and 18.1 million, respectively.

## **2004 Product Development and Licensing Highlights**

### **Oral Heparin**

On August 4, Emisphere announced that it selected a soft gelatin capsule formulation of unfractionated Heparin (UFH) that demonstrated delivery of Heparin in humans. Emisphere selected this formulation following evaluation of results from a previous clinical trial comparing various oral dosage formulations of EMISPHERE® Heparin/SNAC to the Company's liquid UFH formulation it had previously tested in the PROTECT Phase III liquid oral Heparin trial.

In January 2005, Emisphere met with the U.S. Food and Drug Administration (FDA) to discuss the Company's clinical testing program for its oral Heparin product. At the meeting, the FDA indicated its willingness to consider the safety database from the Company's previous Phase III PROTECT study. The FDA also indicated that after review of an intended Phase III protocol, the Company may be able to continue Phase III development with respect to the recently selected solid dosage form. The Company is working to finalize a new Phase III protocol for submission to the FDA for a pivotal clinical trial to be conducted principally in the United States to evaluate oral Heparin as a prophylactic to prevent blood clots in patients at risk for deep vein thrombosis. It is reported that annual sales of injectable heparin exceed \$3 billion.

### **Novartis -- Human Growth Hormone License and Parathyroid Hormone Option Agreements**

In September, Emisphere announced that it entered into a licensing agreement with Novartis Pharma AG to develop an oral formulation of recombinant human growth hormone (rhGH). The companies formed the agreement following successful completion of pre-clinical feasibility studies for rhGH with Emisphere's *eligen*® technology that demonstrated clinically significant delivery of rhGH in laboratory animals. Emisphere has identified several carriers that can deliver therapeutically sufficient levels of rhGH to the blood stream and has selected a lead carrier for rhGH that has been the subject of extensive formulation and preclinical safety studies. Under the terms of the new agreement, Emisphere received an unrefundable upfront payment and may be entitled to additional milestone payments of up to \$33 million during the course of product development, and sales based royalties starting in single digit rates and increasing to double-digit rates. It is reported that annual sales of injectable growth hormone exceed \$1.7 billion.

In December, Novartis acquired an option from Emisphere to license Emisphere's *eligen*® technology for the development and commercialization of an oral form of parathyroid hormone (PTH). The license is dependent upon a successful outcome of the Lilly litigation which concerns the termination of the existing oral PTH collaboration between Emisphere and Lilly. The litigation arose from certain breaches of the PTH agreement that Emisphere believes were committed by Lilly. Lilly is seeking to keep the rights to the PTH program and Emisphere is seeking to terminate the program. Closing arguments have been heard and the matter is awaiting a decision by the court.

In conjunction with this contingent option and license, Emisphere received \$10 million from Novartis in exchange for a 5 year convertible note, bearing interest at 3% for the first two years, 5% for the next two years and 7% for the final year of the term of the note. Interest may be paid in cash or accrued as additional principal. The note is convertible at Emisphere's option at any time, subject to certain conditions, in whole or in part into the Company's common stock at the market price prevailing at the time of conversion. Emisphere has the right to prepay the note, including accrued interest, in cash or stock at any time prior to maturity. It is reported that annual sales of injectable PTH exceed \$238 million.

In 2000 Emisphere and Novartis entered into a license agreement for the development of oral salmon calcitonin for the treatment of osteoporosis and other indications. Novartis recently completed a 277 patient Phase IIa study evaluating oral calcitonin in post menopausal women. Based on the data from that study, Novartis has initiated a parallel program to develop oral salmon calcitonin for the treatment of osteoarthritis.

#### **Roche Collaboration**

In November, Emisphere entered into a licensing agreement with Roche to develop oral formulations of undisclosed small molecule compounds approved for use in the field of bone-related diseases. The agreement followed successful pre-clinical studies, and a human feasibility study incorporating Emisphere's *eligen*® delivery technology. Emisphere received a nonrefundable upfront fee and may be entitled to receive up to \$18.5 million in milestone payments for each product developed using *eligen*® technology.

#### **Elan Agreement - New Terms for Note Repayment**

In December, Emisphere entered into an agreement to prepay its outstanding note to Elan Corporation PLC in cash and stock. Under terms of the new agreement, Emisphere paid Elan \$13 million and issued to Elan 600,000 shares of common stock. Elan has agreed to extinguish the Note in exchange for the payment of an additional \$13 million and the issuance of a warrant to purchase an additional 600,000 shares of common stock if paid by March 31, 2005. Alternatively, Emisphere may elect to pay the additional \$13 million to Elan in installments through June 30, 2005, but in that case would issue to Elan an additional 600,000 shares in lieu of the warrant. If neither of these options is elected by Emisphere, the note would revert to its original terms plus interest and certain penalties. The accrued value of the note on the date of the agreement was approximately \$44 million and the amount payable at maturity in July 2006 in the absence of this new agreement would be \$55 million.

Michael Goldberg, M.D., Chairman and Chief Executive Officer of Emisphere, commented on the Company's 2004 accomplishments: 2004 was a year of progress and validation for Emisphere and its *eligen*® technology. The Company formed three licensing agreements, including a new relationship with Roche, demonstrating the value of our scientific expertise and patented technology. In addition, based on data from a Phase IIa study, Novartis has decided to expand our existing salmon calcitonin collaboration to include development of that drug for the treatment of osteoarthritis. This added indication significantly increases our potential royalties from that product. We continue to make strides in our insulin program and have finalized the design of a 90-day oral insulin study involving 100 or more patients. We are working with the FDA to outline a late-stage protocol for our oral Heparin product and pending agreement from the FDA, expect to initiate a Phase III study this year utilizing our newly created solid dosage formulation. Financially, we are pleased that we have completed a successful negotiation of the Elan note and are now working on a number of strategies to address our cash needs and strengthen our financial position to support our operations and clinical plans. We have reduced our burn rate and look forward in 2005 to earning potential cash milestones from our existing partnerships and those that we concluded in 2004. We have identified a number of potential financing opportunities and will select the most appropriate alternative taking into account the preferences of all our stakeholders. Overall, we are very pleased with our accomplishments over the past year, and will continue to focus on advancing our clinical programs and our technology in 2005.

#### Conference Call Information

Emisphere will hold a teleconference to discuss its 2004 fourth quarter and year end financial results on February 15, 2005 at 10:30AM EST. A replay of the teleconference will be made available for one week and will be accessible two hours following the end of the call.

The live conference call dial-in number is: 800-231-5571 (U.S./Canada)  
973-582-2703 (international)

To access a replay of the call: 877-519-4471 (U.S./Canada)  
973-341-3080 (international)  
Conference ID: 5657500

Emisphere will simultaneously be webcasting this teleconference. To access the live broadcast in listen-only mode or the subsequently archived recording please go to the investor relations portion of the Company's website at [www.emisphere.com](http://www.emisphere.com) or to [http://www.corporate-ir.net/ireye/ir\\_site.zhtml?ticker=EMIS&script=1010&item\\_id=920511](http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=EMIS&script=1010&item_id=920511). Please visit these sites at least five minutes prior to start time for instructions.

#### About The *eligen*® Technology

Emisphere's broad-based oral drug delivery technology platform, known as the *eligen*® technology, is based on the use of proprietary, synthetic chemical compounds, known as EMISPHERE® delivery agents, or carriers. These molecules facilitate or enable the transport of the therapeutic macromolecules across biological membranes such as those of the gastrointestinal tract, and exert their desired pharmacological effect. Emisphere's *eligen*® technology makes it possible to orally deliver a therapeutic molecule without altering its chemical form or biological integrity.



**About Emisphere Technologies, Inc.**

Emisphere Technologies, Inc. is a biopharmaceutical company pioneering the oral delivery of otherwise injectable drugs. Emisphere's business strategy is to develop oral forms of injectable drugs, either alone or with corporate partners, by applying its proprietary *eligen*® technology to those drugs or licensing its *eligen*® technology to partners who typically apply it directly to their marketed drugs. Emisphere's *eligen*® technology has enabled the oral delivery of proteins, peptides, macromolecules and charged organics. Emisphere and its partners have advanced oral formulations or prototypes of salmon calcitonin, Heparin, insulin, parathyroid hormone, human growth hormone and cromolyn sodium into clinical trials. Emisphere has strategic alliances with world-leading pharmaceutical companies. For further information, please visit <http://www.emisphere.com>.

**Safe Harbor Statement Regarding Forward-looking Statements**

*The statements in this release and oral statements made by representatives of Emisphere relating to matters that are not historical facts (including without limitation those regarding the timing or potential outcomes of research collaborations or clinical trials, any market that might develop for any of Emisphere's product candidates and the sufficiency of Emisphere's cash and other capital resources) are forward-looking statements that involve risks and uncertainties, including, but not limited to, the likelihood that future research will prove successful, the likelihood that any product in the research pipeline will receive regulatory approval in the United States or abroad, the ability of Emisphere and/or its partners to develop, manufacture and commercialize products using Emisphere's drug delivery technology, Emisphere's ability to fund such efforts with or without partners, 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" in Emisphere's Annual Report on Form 10-K (file no. 1-10615) filed on March 29, 2004.*

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**EMISPHERE TECHNOLOGIES, INC.**

## Selected Financial Information

For the three and twelve months ended December 31, 2004 and 2003

(in thousands, except share and per share data)

**Condensed Statements of Operations**

	For the three months ended December 31,		For the twelve months ended December 31,	
	2004	2003	2004	2003
	(unaudited)	(unaudited)	(unaudited)	
<b>Revenue</b>	\$ 1,773	\$ (34)	\$ 1,953	\$ 400
<b>Costs and expenses:</b>				
Research and development	4,181	4,799	17,462	21,026
General and administrative expenses	3,635	2,114	11,766	9,794
Restructuring		(6)		(79)
Loss on impairment of long-lived assets		100		5,439
Depreciation and amortization	1,148	1,216	4,941	5,806
Total costs and expenses	8,964	8,223	34,169	41,986
<b>Operating loss</b>	<b>(7,191)</b>	<b>(8,257)</b>	<b>(32,216)</b>	<b>(41,586)</b>
<b>Other (expense) and income:</b>				
Investment and other income	178	352	846	1,882
Interest expense	(1,693)	(1,339)	(6,152)	(5,165)
Total other (expense) and income	(1,515)	(987)	(5,306)	(3,283)
<b>Net Loss</b>	<b>\$ (8,706)</b>	<b>\$ (9,244)</b>	<b>\$ (37,522)</b>	<b>\$ (44,869)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.47)</b>	<b>\$ (0.51)</b>	<b>\$ (2.04)</b>	<b>\$ (2.48)</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>18,536,950</b>	<b>18,170,831</b>	<b>18,411,240</b>	<b>18,077,402</b>

**Condensed Balance Sheets**

	<b>December 31, 2004</b>	<b>December 31, 2003</b>
	<b>(unaudited)</b>	
<b>Assets:</b>		
Cash, cash equivalents, and investments	\$ 17,550	\$ 35,187
Accounts receivable	120	326
Prepaid expenses and other current assets	2,516	1,098
<b>Total current assets</b>	<b>20,186</b>	<b>36,611</b>
Equipment and leasehold improvements, net	10,007	14,005
Land, building and equipment held for sale, net	3,589	3,618
Purchased technology, net	2,273	2,512
Investments		7,821
Other assets	237	1,482
<b>Total assets</b>	<b>\$ 36,292</b>	<b>\$ 66,049</b>
<b>Liabilities and Stockholders (Deficit) Equity:</b>		
Current liabilities	\$ 7,328	\$ 3,371
Notes payable	39,332	38,345
Capital lease obligation - L/T	245	469
Deferred lease liability - L/T	661	1,057
Stockholders (deficit) equity	(11,274)	22,807
<b>Total liabilities and stockholders (deficit) equity</b>	<b>\$ 36,292</b>	<b>\$ 66,049</b>

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