

DRUG DELIVERY

Executive



EMISPHERE



Michael V. Novinski
President & CEO
Emisphere
Technologies, Inc.

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The “New” Emisphere: Impacting the Future of Drug Delivery

Emisphere Technologies, Inc., (NASDAQ: EMIS), with corporate headquarters in Cedar Knolls, NJ, and its Scientific Center in Tarrytown, NY, is a biopharmaceutical company that has developed a broad-based proprietary drug delivery platform known as the eligen[®] technology. This technology makes it possible to deliver a therapeutic molecule orally without altering its chemical form or biological integrity. The key benefit of the eligen technology is that it improves the ability of the body to absorb diverse molecules by means other than injection. Drug Delivery Technology recently interviewed Michael V. Novinski, President and Chief Executive Officer of Emisphere, to discuss the company’s technology, product pipeline, and its future strategic direction.

Q: The last time we spoke with Emisphere was in 2002. How have things changed throughout the past 6 years?

A: I took over the reigns of Emisphere in May 2007. Since then, I am pleased to say, a “new” company has emerged. We determined that we needed to take steps to enhance the effectiveness of the organization, including an evaluation of our technology and an assessment of the company overall. So we put together a plan, which we are executing, beginning with a restructuring of Emisphere across the board to facilitate communication and better management. I re-staffed the organization at the senior level. These critical additions included Michael R.

Garone, Chief Financial Officer; Paul Lubetkin, Vice President, General Counsel and Corporate Secretary; and Gary I. Riley, DVM, PhD, Vice President, Nonclinical Development and Applied Biology. In conjunction with adding staff in key management roles, we have established necessary business processes for adequate control. We cut costs through productivity gains and headcount reduction, and eliminated excess overhead, such as by moving our corporate headquarters to Cedar Knolls and subleasing part of our more expensive scientific space in Tarrytown. We have also put in place the necessary scientific processes to improve rigidity and reliability of data, and have re-evaluated our eligen technology.

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Q: What can you tell our readers about your eligen delivery platform?

A: Emisphere's eligen technology improves the body's ability to absorb select molecules, leading to significant, not merely incremental, improved oral bioavailability. Emisphere's synthetic chemical carriers provide a demonstrated safe method of chaperoning molecules across biological membranes, such as those of the gastrointestinal tract, without impacting their benefit. The main properties that we are interested in seeing in the drugs that we use with eligen are water-soluble drugs that have poor permeability characteristics that are the small- or medium-size molecules with a weight of less than 10,000 or 10 kd. The eligen technology can be applied to the oral route of administration as well other delivery pathways, such as buccal, rectal, inhalation, intra-vaginal, or transdermal. One of the first things I did when taking the helm at Emisphere was to reassess our technology. That reassessment convinced us that, when it is applied properly, the

technology can be life-changing for many patients and bring enormous benefits to healthcare treatment. The eligen delivery system can enhance overall healthcare, including patient accessibility and compliance, while benefiting the commercial pharmaceutical marketplace – and driving our company's valuation.

Q: Can you give us an example of an application of your eligen technology?

A: In early February, Emisphere announced the results of animal studies that demonstrated proof-of-concept that absorption of oral vitamin B12 using Emisphere's eligen technology was 15 to 30 times greater than with the same dose of oral vitamin B12 administered alone. In March, we released the results of a second phase of animal studies demonstrating that our eligen technology enhanced the absorption of oral B12 at considerably lower doses than the previous study and, most importantly, at levels that are more physiologically relevant.

Confirming the original study, overall absorption of B12 using eligen technology was 18 times greater than with the same dose administered alone. Simply put, oral delivery of Vitamin B12 using eligen technology is more efficient, more convenient, and less costly than B12 injections. Vitamin B12 deficiency is a significant health issue. Nearly 40% of the US population is B12 deficient, according to research done by Tufts University in Boston. This includes a sizable number of patients who are severely deficient and are currently being treated. Further, a vast number of people are completely unaware that they are B12 deficient and will eventually need treatment. Currently, some 5 million people in the US are taking more than 40 million injections of B12 per year to treat a variety of debilitating medical conditions, which can include pernicious anemia, neurological changes, fatigue, weakness, and other symptoms. Another 5 million are consuming more than 600 million tablets of B12 orally. And the worldwide market is, at least, double these numbers.

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Q: What other products are currently in your pipeline?

A: Prioritizing our pipeline for products most likely to succeed with highest return represents the core of the company's value proposition and creates significant opportunities for growth. This includes marquee products that demonstrate the most promise through unmet market needs. Emisphere's pipeline includes product candidates that are in, or have reached, clinical development and a variety of preclinical research and development programs, both independently and in collaboration with major pharmaceutical companies. In addition to an improved formulation of oral Vitamin B12, which I've discussed, promising marquee products in the pipeline include oral Salmon Calcitonin for osteoarthritis and osteoporosis, currently in development with Novartis Pharma AG and its development partner Nordic Bioscience. Novartis is conducting two Phase III clinical studies for osteoarthritis, with enrollment in the first trial to be completed by the third quarter of 2008 and enrollment for the second Phase III trial to be complete mid-2009.

Osteoporosis Phase III trials are also ongoing, with enrollment completion expected in the first half of 2008. Among these Phase III studies, there will be more than 5,000 clinical study patients using the eligen technology in 2008. Approximately 10 million Americans are being treated for osteoporosis, with an additional 34 million at risk of developing the disease because of low bone mass. In addition, about 21 million Americans have osteoarthritis. Our Salmon Calcitonin product could be the first disease-modifying treatment ever available to treat osteoarthritis. In addition to oral Vitamin B12 and calcitonin, we are conducting early research using our eligen technology and GLP-1, a potential treatment for type 2 diabetes. A second, early stage human study of an oral formulation that combines PYY and GLP-1 has commenced. We expect publication of the first study in medical journals sometime mid-year, with the results from the second study available to the public around the same time. We are confident that our current pipeline presents us with numerous opportunities to explore and exploit our technology, which we intend to do to the fullest.

Q: How would you characterize your strategy for ensuring the company's financial health and viability for the future?

A: Among our primary strategies is to establish and pursue products for internal commercial development against reasonable investments. In terms of our product development criteria, we are looking at large markets (greater than \$1 billion) in which we can address unmet medical needs through clearly differentiated product profile benefits. We also maintain a commitment to enhancing existing high-value partnerships with leading pharmaceutical companies as well as forming new ones. These collaborations will not only bolster our pipeline development, but will also improve the company's overall financial position. We believe that as we move forward and get closer to realizing the commercialization of our technology, our stock price will reflect a higher value, while we make a substantial impact on the future of drug delivery. ♦