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### Emisphere Relaunches After Turbulent Past

By Donna Young, Washington Editor

NEW YORK - **Emisphere** Technologies Inc. last year underwent a major restructuring, which included cutting employees, moving its corporate headquarters from Tarrytown, N.Y., to Cedar Knolls, N.J., and hiring Michael Novinski to lead the firm.

The 22-year-old company, Novinski told attendees at the BIO CEO & Investor Conference in New York, has emerged as a new firm focused on commercializing its eligen drug delivery platform, which is based on synthetic chemical carriers that transport macromolecules across biological membranes, such as those of the gastrointestinal tract, and products that are more likely to succeed with the highest return.

It's part of what the company is calling its relaunch, and comes, Novinski said, after years of "stumblings." **Emisphere** analyzed its organization from its staff to its processes to its technology, said Novinski, who was appointed CEO last May.

As a result of that evaluation, which is ongoing, the firm reduced its headcount by about 25 percent, Novinski told *BioWorld Today*. In addition, the company brought in new employees, including Gary Riley, vice president of nonclinical development and applied biology, who was most recently with Cambridge, Mass.-based Alkermes Inc. for 14 years before leaving to join **Emisphere**.

The reevaluation of **Emisphere** proprietary eligen technology, Riley said in an interview, involved determining which types of drugs for which the technology was best suited.

The firm is using a rational approach to drug selection and technology application that is based first on chemistry and then on pharmacological properties, he said.

"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 molecular weight of less than 10,000 or 10 kd, Riley explained. "Those are the core characteristics that we feel qualify a drug for consideration."

Drugs that are water soluble with low permeability are associated with poor bioavailability, he noted.

"The application of the eligen technology is targeted to improve that bioavailability," or to make the body better absorb drugs, Riley said.

Agents with a narrow therapeutic window and high molecular weight are not favorable characteristics for eligen, he noted.

In addition to aiding an oral drug to more rapidly be absorbed in the body, Riley said, eligen's technology helps drugs to rapidly be eliminated and to not accumulate in organs and tissues. **Emisphere's** "fundamental objective," Novinski said, is to "bring the eligen technology to the commercial marketplace as soon as possible." The company is targeting products for eligen that have markets of greater than \$1 billion and fill an unmet medical need, he said.

The firm has two oral products based on salmon calcitonin, a polypeptide hormone secreted by the parafollicular cells of the thyroid gland, in Phase III testing in collaboration with Novartis Pharma AG and its development partner Nordic Bioscience.

The products use **Emisphere's** eligen deliver technology to provide salmon calcitonin as an oral medication to treat osteoporosis and osteoarthritis. Calcitonin enables bones to retain more mass and functionality by inhibiting the bone-tissue resorbing activity of specialized bone cells called osteoclasts. Salmon calcitonin is about 30 times more potent than human calcitonin.

Novinski said the firms expect to complete enrollment of the worldwide, three-year Phase III salmon calcitonin osteoporosis study by the end of this quarter with 4,200 patients. The companies are conducting two separate Phase III trials of salmon calcitonin in more than 2,000 patients with osteoarthritis, with the first trial expected to complete enrollment by the third quarter of this year and the second study by next February, he added.

Novinski noted that about 10 million Americans are being treated for osteoporosis, with an additional 34 million at risk of developing the disease because of low a bone mass. In addition, he said, about 21 million Americans have osteoarthritis. **Emisphere's** salmon calcitonin product, Novinski said, "could be the first disease-modifying treatment ever" available to treat osteoarthritis. **Emisphere** also is partnering with Novartis Pharma to develop a recombinant human growth hormone and an oral parathyroid hormone using the New Jersey biotech's eligen technology.

**Emisphere** also is studying the use of its eligen technology to improve the bioavailability of vitamin B12. Recent results of animal studies showed that absorption of oral vitamin B12 with the eligen technology was 15-30 times greater than with the same dose of oral vitamin B12 administered alone. About 5 million people in the U.S. are administered 40 million injections of B12 annually to treat a variety of medical conditions, such as chronic fatigue syndrome, Novinski said. Another 5 million Americans consume more than 600 million B12 tablets per year, often with little clinical success, he added.

Providing patients with an oral form of B12 that is absorbed better fills a large unmet medical need, Novinski argued. **Emisphere** is anticipating starting a second animal study of its oral B12 product in March, with a formulation optimization study in June 2008, he noted. The company could start clinical trials in humans by the third quarter of this year, Novinski said. He noted that while the firm's Phase III salmon calcitonin programs are its top priority, **Emisphere's** B12 product may have a shorter pathway to the marketplace and may be the company's first commercialized product, which could improve the firm's financial situation.

In its third quarterly earnings report, **Emisphere** said that unless it raises substantial additional financing or secures funds from new or existing partners, it will not have sufficient resources to develop fully any new products or technologies.

The company's failure to raise capital before June "will adversely affect our business, financial condition and results of operations and could force us to reduce or cease our operations at some time in the future," the company said.

Novinski said the firm's financial problems could improve if its B12 product stays on track and all goes as planned with three new anticipated partnerships this year. **Emisphere** also expects to save at least \$1 million in office space expenses by moving its headquarters to New Jersey, he added.

The firm, he said, will do its best to minimize dilution, and plans to increase its visibility in the financial community, Novinski added. It reported revenue of \$3.7 million as of Sept. 30. The company also reported an additional \$11.9 million in income from its \$18 million settlement with Indianapolis-based Eli Lilly & Co. Per the terms of the settlement, Novinski said he could not confirm whether Lilly's \$18 million payment involved **Emisphere's** dispute that Lilly had violated the terms of its contract to develop an oral parathyroid hormone for osteoporosis using **Emisphere's** proprietary eligen technology. (See *BioWorld Today*, Jan. 13, 2006.)

"Both companies are satisfied that it has come to an end," Novinski said.