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Emisphere Technologies seeks pill for success

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Michael Novinski, seen in his office at the Landmark at Eastview, took over as president and chief executive officer of Emisphere Technologies Inc. about a year ago. (Carucha L. Meuse/The Journal News)

EASTVIEW - On a recent warm spring morning, employees of Emisphere Technologies Inc. are gathered in a hallway at the biotechnology company's laboratories in the Landmark at Eastview complex, awaiting the company's president and chief executive, Michael Novinski.

It's an occasional ritual Novinski established after taking the reins of the two-decade-old company about a year ago in which he meets with employees to talk shop.

Novinski himself works in Cedar Knolls, N.J., where the company has its executive offices and is now headquartered. About 20 employees work there, while the bulk of Emisphere's employees, 60, working in research and development, remain in Westchester, where the company was founded in 1986 as Clinical Technologies Associates Inc.

The informal meetings are part of Novinski's relaxed management style, which seeks to break down formal barriers that often exist between management and workers - and a departure from the previous management's more rigid style, says company spokesman Bob Madison.

Creating a more inviting working atmosphere is far from Novinski's biggest task at Emisphere. After years of trials and millions of dollars spent on developing pill forms of injectable drugs to treat diabetes and blood clots, the company has yet to develop a marketable product.

But Novinski thinks the company is on the edge of a breakthrough, eyeing the second half of the year as the possible launch date of its first drug, an oral form of vitamin B-12 that delivers high dosages of the nutrient, similar to injection, using the company's eligen technology.

At least 5 million people a year in the United States receive some 40 million B-12 injections to treat a range of debilitating diseases, Emisphere says.

Eligen essentially chaperones the nutrient through the digestive system, where it would otherwise be destroyed, into the bloodstream. Pursuing a treatment for a vitamin deficiency is also a cheaper and shorter route to a commercially viable product, because the U.S. Food and Drug Administration approval process for vitamins and nutrients is less rigorous.

Novinski is equally excited about partnerships Emisphere has struck with Swiss drug giant Novartis Pharma AG to develop treatments for osteoporosis, or loss of bone mass, and osteoarthritis, or degenerative joint disease, also using eligen in combination with synthetic salmon calcitonin.

When it comes to joint disease, Novinski says, "We could have the first disease-modifying treatment for osteoarthritis," which affects 16 million to 20 million Americans.

The combination of synthetic salmon calcitonin and eligen has been shown to exert "a protective effect in at-risk or already affected joints to help maintain the quality of cartilage and reduce the progression of joint-space narrowing," Emisphere says. Injectable and nasal spray versions of salmon calcitonin currently exist, but those are prescribed only for osteoporosis.

Clinical trials have entered final stages to treat both diseases, which may result in FDA approval within a year or two.

With no marketable products to sell, Emisphere derives its revenue largely from collaborative agreements with pharmaceutical companies, such as Novartis, and feasibility studies. Last year, the company reported it lost \$16.9 million, or 76 cents a share, on revenue of \$4.1 million.

Novinski assumed leadership of Emisphere following the ouster in January 2007 of former Chairman and Chief Executive Officer Dr. Michael Goldberg, who presided over the company since 1990. No reason was given for Goldberg's dismissal, though he remained on Emisphere's board of directors until March.

Novinski joined Emisphere from Organon USA Inc., a Roseland, N.J.-based drug company that specializes in contraceptive, fertility and other drugs. It was acquired last year by drug giant Schering-Plough Corp.

Emisphere's ability to introduce its first product under Novinski's leadership could be the break the company has been looking for, says one analyst.

"Any commercial transaction that they do validates their entire platform," says Stephen G. Brozak, president of WBB Securities LLC in Westfield, N.J. "That's what matters."

If one product works, the potential is that they all work, says Brozak, whose firm has a prior banking relationship with Emisphere, but doesn't own any of its shares.

Further, he says, Novartis wouldn't likely invest hundreds of millions of dollars in Emisphere if it didn't believe the technology worked.

Though Brozak is bullish on Emisphere, the rest of Wall Street remains skeptical. Emisphere's stock has lost about half its value this year. It's a problem that Novinski himself says is troubling. The shares closed Friday at \$1.51, having fallen from a 52-week high of \$5.17 in October.

Even though the market as a whole has been turbulent this year, Novinski says, Emisphere remains a misunderstood company.

"We've achieved a great number of things over the course of the last 12 months," Novinski says. "But we have to produce and basically validate to the financial markets what we said we were going to do."



Vincenc Camaj, senior research associate, looks at samples to be processed in the lab at Emisphere Technologies in Eastview. The company, which is still seeking its first marketable product, is looking to use biotechnology to treat vitamin B-12 deficiencies. (Carucha L. Meuse/The Journal News)

HOW EMISPHERE'S ELIGEN TECHNOLOGY WORKS

Emisphere Technologies is developing an oral form of vitamin B-12 using its eligen technology, which would allow a pill to provide the same level of the nutrient as an injection. Millions of Americans get B-12 shots to treat a wide range of debilitating diseases.

Oral forms of the vitamin aren't as effective because they can't navigate the human body's digestive tract. Emisphere's eligen technology, however, has shown the ability in rats and dogs to shepherd the vitamin through the walls of the intestines, allowing it to penetrate the bloodstream and deliver doses equal to that of injection.

The technology has the potential to be useful in a wide range of conditions for which there are currently no treatments or for which the existing treatments are limited to injections.

For example, Novartis Pharma AG, the Swiss drug giant with which Emisphere is in a partnership, is in final phase studies of a drug that uses eligen technology to treat osteoarthritis, or degenerative bone disease, for which there currently is no treatment.

Source: Emisphere Technologies Inc.

On the Web

www.emisphere.com