



After successfully helping to turn around Organon USA, Michael Novinski is now setting his sights on repositioning Emisphere to capitalize on the drug-delivery company's technology assets.

RESTRUCTURING FOR SUCCESS

What has been your role in the reorganization of Emisphere and what is your expertise in the area of restructuring?

NOVINSKI: I was brought into Emisphere to restructure the company. I've been in the industry for about 30 years and I have been through some very successful build-up situations, particularly at Organon USA. In 1992, the company had revenue of about \$125 million and was primarily hospital-based; in 1999 revenue reached \$1 billion and the company introduced a number of products. I've had a lot of experience moving products through their commercial and clinical development — I've been part of a lot of successes, I've also been part of some failures. I've brought at least 15 products to approval at the Food and Drug Administration.

SETTING A NEW COURSE

Why was it necessary to realign the company and how did you go about redirecting the focus?

NOVINSKI: There are a number of people who have a great deal of enthusiasm for Emisphere's technology, but after about 20 years there was quite a bit of frustration over the company's lack of productivity, from the shareholders and the board's standpoint. The impetus behind the change, therefore, was to take the technology to the next level. I came in late May 2007 and got the process under way by conducting an assessment of the organization. We looked very closely at the people, most importantly those at the top tier of management. We looked at the structure of the organization in terms of its communications. And we looked very closely at the processes — both the scientific processes by which the data were being produced and at the business pro-

Emisphere's President and CEO **MICHAEL NOVINSKI** Considers the Changes in Drug Delivery

Michael V. Novinski is President and CEO of Emisphere Technologies and a veteran of the life-sciences industry. Having played a leading role in helping the pharmaceutical company Organon USA to restructure and refocus its operations, he is now turning his attention to the drug delivery industry.

According to Mr. Novinski, if the drug delivery industry is going to continue to provide avenues by which it can facilitate new products coming to the marketplace, its organizations have to start to think, act, behave, and understand the market much more like its pharma company peers.

cesses. We then brought in a fairly senior scientific team and some key nonscientific members, and they in turn are now making their evaluations and decisions.

Next we looked very closely at the technology. We found that the technology appeared to favor certain molecules over others — molecules that had a wide therapeutic index, molecules that were water soluble, and molecules that were of a specific molecular weight. When we evaluated the data generated over time, these findings appeared to be sound. For example, the technology seems to perform best with molecules of a particular molecular weight, such as salmon calcitonin, where we have two products in Phase III with our partner Novartis.

Also guided by the criteria that came out of the technology assessment, we are putting a more aggressive preclinical program forward. The goal is to follow through with molecules that we believe may have a shortened commercial path.

ADAPTING IN CHANGING TIMES

What do you regard as the biggest issues facing the drug delivery industry?

NOVINSKI: Regardless of the type of delivery system being put forward, the regulations are much more stringent and difficult in terms of the approvals, and the criteria by which drug delivery technologies are evaluated are far more difficult than they were many years ago. Today, companies have to justify why they are bringing a particular delivery system forward, just as pharma companies have to justify a particular pharmaceutical product for a given treatment modality.

The decisions need to be justified from a cost standpoint, from a safety standpoint, and from an efficacy standpoint. The reality is that the success stories may become less frequent and the industry needs to ask itself what it has to do to continue to improve shareholder value.

CAREER Highlights

Michael V. Novinski became President and CEO of Emisphere Technologies in May 2007. Previously, he served as President of Organon USA with additional responsibility for worldwide business development and life-cycle management. While serving as Organon's Director of Marketing and later as VP of Marketing, he directed the launch of eight new brands in the U.S. market.

Mr. Novinski was elected to the board of Pharmaceutical Research and Manufacturers of America (PhRMA) in June 2004, and he has served in a variety of capacities for a number of organizations.

PROMOTING PARTNERSHIPS

What steps does the drug delivery industry need to take to reinvent itself?

NOVINSKI: Drug delivery leadership teams have to visualize how their technologies work with particular molecules, the benefits these can bring to the commercial marketplace, and whether the benefits can be justified. Before pharma companies embark on a collaboration or partnership they need answers to these questions, as well as whether a drug delivery technology provides a particular healthcare benefit when it's used with a certain treatment modality. There are emerging opportunities, outside of prescription pharmaceuticals, to address poorly absorbed molecules, such as the bio-nutritional area where specific nutrients, foods, or supplements and vitamins can be addressed and improved by delivery systems and mechanisms.

PARTNERING FOR SUCCESS

How will drug delivery partnerships evolve?

NOVINSKI: The pharmaceutical industry is under tremendous pressure to continue to produce and to increase shareholder value, and the drug delivery industry provides positive alternatives on ways to bring new products to market. A good partnership is one where both parties recognize what their role is in the partnership. Obviously, we're very good at being able to come up with ways to deliver molecules in perhaps a better fashion; pharmaceutical companies are very good at putting molecules together with the drug delivery mechanism and developing them from a clinical perspective into the commercial marketplace. But when one partner begins to think that it can do just as well as the other partner, there begins to be a clash and the partnership is less fruitful. ♦

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