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# THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

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## **COMPANY INTERVIEW**

**MICHAEL V. NOVINSKI**  
Emisphere Technologies, Inc.

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# Emisphere Technologies, Inc. (EMIS)



**MICHAEL V. NOVINSKI**, President and Chief Executive Officer of Emisphere Technologies, Inc., joined the company in May 2007. Previously, Mr. Novinski was President of Organon USA, and prior to that, he was the Executive Vice President of Operations and Marketing for Organon International. In June 2004, he was elected to the Board of Directors for Pharmaceutical Research and Manufacturers of America. Mr. Novinski received his BS in Biology from Washington and Jefferson College.

## SECTOR – DRUG DELIVERY

**(AJM607) TWST: Please begin with a brief historical sketch of the company and a picture of the things you are doing at the present time?**

**Mr. Novinski:** Emisphere Technologies, Inc., which has been in business for nearly 20 years, is a biopharmaceutical company that focuses on developing oral forms of injectable drugs, either alone or with corporate partners, by applying our proprietary *eligen*<sup>®</sup> technology to these drugs. Emisphere's *eligen* technology improves the body's ability to absorb select molecules. Emisphere's carriers provide a demonstrated safe method of chaperoning molecules without impacting on their biological benefit. Many of these molecules are currently delivered by injection. In certain cases, their benefits are limited due to poor bioavailability, slow onset of action or variable absorption.

Our technology, which we like to think of as "carriers" or "chaperones," if you will, facilitates the transport of normally poorly bioavailable molecules across the GI epithelium into the bloodstream where they become active.

**TWST: Would you explain what you mean by carrier and chaperone system?**

**Mr. Novinski:** Many compounds that are currently administered via injection are poorly absorbed molecules. We put these molecules together with our carriers. They aren't bound; they are associated. We put them together in a tablet form, and when they are taken into the gastric epithelium and into the stomach, the carrier actually changes the permeability and the fluidity of the gastric epithelium, which is normally not fluid to these particular molecules. When our carriers alter this fluidity of the gastric mucosa, a therapeutic dose of the drug molecules passes through the epithelium into the bloodstream. Then, very quickly after the transfer, the gastric epithelium resumes its normal state.

**TWST: Is Emisphere's *eligen* meant to be an alternative to injection?**

**Mr. Novinski:** I think it's better to say that it is an extremely efficient technology where poorly absorbed molecules can be improved to reasonable and acceptable levels for bioavailability. This would include not only molecules that are injected, which are poorly absorbed via the GI track, but also the considerable number of molecules that are given perhaps via the oral route in very large doses that are poorly bioavailable.

Perhaps when added to this technology we can also lower the dose, improve the bioavailability and potentially even improve the efficacy of some compounds that are delivered via the oral route.

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***“We have two very exciting products with Novartis that are already well into Phase III and by the middle of this year, more than 5,000 patients are going to be taking the eligen technology along with Salmon Calcitonin for the treatment of osteoarthritis and osteoporosis. That’s very exciting.”***

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**TWST: What medical conditions are you addressing?**

**Mr. Novinski:** In trying to alleviate unmet medical needs, we are entering into some very, very exciting areas. In our late-stage pipeline, we are working with our partner Novartis on Phase III studies with our carrier and Salmon Calcitonin for the treatment of osteoarthritis. This is an exciting market that can address the needs of somewhere between 15 and 20 million managed Americans with osteoarthritis. There are no known treatment modalities to stop the progression of the disease, which means our Salmon Calcitonin product with Novartis could become the first global disease-modifying drug for osteoarthritis. We are also in Phase III for the treatment of osteoporosis, so we are involved in addressing two very interesting and exciting markets with this product.

We are also involved in the area of diabetes, which is a bit more early stage. We are investigating the use of our compound with Glucagon-like peptides, GLP-1 and PYY, for the potential treatment of diabetes. We are also looking at the technology using analogs of GLP-1. If you talk to most of the experts and people involved in the treatment of diabetes, they do believe that the future treat-

ment is going to be with GLP-1 or GLP-1-type analogs. The problem with the GLP-1 or GLP-1 analogs is that they are all currently administered via injection. We are involved with potential oral delivery in a very early stage.

Another medical condition we are addressing is vitamin B12 deficiency. B12 is a molecule that is very poorly absorbed for a number of reasons. In the United States alone there are 40 million injections given per year, in addition to large numbers of tablets of various strengths — somewhere in the magnitude of 600 million to 700 million tablets annually. The B12 taken in the tablets is not absorbed, though, in any substantive way. For this reason, many B12 deficient patients must take the injection route. We have completed two animal studies involving B12 and hope to be conducting studies in humans by mid-year. We are looking to potentially commercialize this opportunity for an oral vitamin B12 sometime in 2009.

**TWST: What is the competitive landscape like and what are your competitive advantages?**

**Mr. Novinski:** I think the competitive landscape for the technology is actually extremely limited at this stage. We seem to be our own competitors when you look at the history of the company. There are very few technologies, if any at all, that really can stand side-by-side with the *eligen* technology that is now being brought forward by Emisphere. The limiting factor in the past has probably been an understanding of the technology and matching the technology with the correct molecules, making sure that there was the proper chemistry there. That was probably one of the biggest factors in the company’s lack of success in the past.

**TWST: What are the main items on your agenda as you look out over the next three years or so?**

**Mr. Novinski:** There are two goals for the organization: The number one goal that the company has set forward is to bring our technology to the commercial level. I think a lot of people have asked the question, can you take this delivery platform out of the experimental stage and into the commercial marketplace? We are indeed working to commercialize the technology and that's one of the reasons I believe that the B12 opportunity is critical. The number two goal of the organization is to build its pipeline through high-value partnerships. We are looking to not only build on our current successful partnership with Novartis on two late-stage products, but we are looking to add three new partnerships during 2008 that will fall under our early and mid-stage product development pipeline.

**TWST: What possible challenges or problems worry you most?**

**Mr. Novinski:** I don't think that it's a secret that the company is in the process of reorganizing. We are making a number of changes and we have put several new processes in place. We have looked to reduce costs and improve functions, always with an eye to finding the best way to bring our technology to the commercial level, build partnerships and improve our position and cash flow situation. I think that's probably the most significant question we have in front of us. If we are going to bring this technology to the commercial level, how are we going to do it, given that we've had some constraints when it came to cash flow?

**TWST: What were the reasons for the company's lack of success in the past and what changes will you be making?**

**Mr. Novinski:** Emisphere spent an enormous amount of time, money and resources on two particular molecules, insulin and heparin, that were not necessarily the best fit for our technol-

ogy. The company spent years and literally tens of millions of dollars trying to take both of these injectable products to the oral form of delivery at a level that would be considered acceptable to the FDA for its appropriate treatments. The issue is that essentially neither of these molecules fit the criteria as well as other molecules do. The reason for that is the therapeutic index for both insulin and heparin is very, very narrow. You can compare that to the treatment for osteoporosis and osteoarthritis, which is essentially administration for a chronic condition taken over a long period of time. But for insulin and heparin, if you are talking about treating Type 2 diabetes, or if you are talking about, for heparin, treating a DVT, you have a very narrow therapeutic window. With any oral delivery mechanism, there is always going to be some variability, and this technology is no exception. When you take something orally, the GI track is a very complicated place. A lot of things can occur that could affect the delivery of the molecule to the body at any given time. Therefore, if you are delivering molecules with very specific needs, like insulin and heparin, you have to be very specific every time and, quite frankly, variability is just basically unacceptable for these particular two areas of treatment.

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***"We want to commercialize our technology as soon as possible. We believe there is an opportunity to do so as early as next year, and that during the course of this year we are going to be able to build our early and mid-stage pipeline with additional partnerships."***

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I think what they found in pursuing these particular molecules was that they just didn't allow for the levels of safety and efficacy to be reached, or were acceptable for these particular

treatment modalities. It's just inherent to oral delivery of molecules and with this technology that there is going to be some variability. If you compare that with the treatment of osteoarthritis or B12 administration, there may be some variability, but it is not as significant, because some of it is absorbed now or one hour later, and that kind of timing is not crucial. Overall, the molecule is being delivered over a period of time, which becomes fairly consistent as opposed to the oral delivery of oral heparin and oral insulin. That's why I say that I don't believe that they necessarily had a great understanding of the technology.

When I came aboard in mid-2007 there were three things that we did. First, we evaluated people and processes. Second, we evaluated the technology. Number three is, we put together both a long- and short-term plan for success. When you look at the people and processes, we put a lot of procedures in place to make sure that the organization had proper controls, that spending was occurring at proper levels and that communication was occurring with the appropriate staff and within the proper departments. We then brought in a different scientific team, added expertise from consultants, assessed the technology and established criteria for development. What we have learned is that the molecules that were being explored in the past didn't really meet the criteria where the technology actually performed best. At the end of the day, that's what counts. We established the criteria, and then we established the list. We looked at molecules that perhaps would work best with the technology. Oral heparin and oral insulin didn't really fall on the list for the reasons that I discussed, and some molecules that came on list were actually quite surprising. Some of the molecules were prescription drugs and some that were turning up on the list were

not. This is where B12 came in, because it does not necessarily have to be a prescription drug to be a molecule that is poorly absorbed. This process started in the third quarter of 2007, about four months after I got here, and then we directed our efforts in more aggressive, preclinical programs and developed our technology with products that we felt met the criteria.

**TWST: How far along do you feel that you are in this process of change?**

**Mr. Novinski:** I think that from the organizational standpoint, I am very satisfied with the basic infrastructure of the company. I think that perhaps from a people standpoint there may be some adjustments that may occur, but these are changes that would occur in any organization. I think that the infrastructure from the staffing perspective is sound and that the processes that have been put in place are sound. I don't think we need to do much there. We do have to improve on some areas like communications, but I think that will go from a level of mediocrity to a level of high success. So from the people and the processes standpoint, I think we are pretty much there.

From the technology assessment position, I think that we are probably halfway there. I think that we are going to have to make a bit more of an investment in understanding the technology to be able to list those molecules that meet the criteria and we might be able to alter the criteria a little bit as well. From a planning perspective, I think that we have probably only just begun. We have started an aggressive preclinical program. We have a nice opportunity with B12, and we have some good late-stage development projects with Novartis. But, quite frankly, when you look at how broadly our technology could possibly be applied, I think we are only at the beginning of the planning process.

**TWST: What would you reasonably expect the company to look like in a broad way in about three years?**

**Mr. Novinski:** I think that we are going to probably stay within the niche of being an early-stage research biopharmaceutical company that is in the drug delivery area. From the commercial opportunities that we have, we could actually grow into this area and you could possibly see the company emerge into a full-fledged commercial operation. That's definitely a distinct possibility. But I think, most important, what we need to do is solidify the company, the technology and the application of the technology. I would like to see an organization with very, very talented people and sound processes. I predict that from a financial standpoint Emisphere, will be very strong.

**TWST: What might be some year-by-year milestones or indicators that investors could look for?**

**Mr. Novinski:** I think year-by-year, even quarter-by-quarter, what they should be on the lookout for are the development milestones and those particular goals that we are putting forward toward achieving them, not only for this year but for the years ahead. Potential investors should also look for the publication of data in the completed studies of osteoporosis and osteoarthritis. They should look for the data that is coming out in the area of diabetes treatment, as well as for the completion of the pre-clinical data with B12, and our movement to the area of human clinical trials for B12. At the end of the year they should be looking for a submission to the FDA. Then, next year, more of the same.

**TWST: Would you tell us about your own background and expertise, as well as that of your associates?**

**Mr. Novinski:** I've been in the business about 29 years. I started at Organon in 1979 as a

pharmaceutical sales representative after coming out of graduate school, and spent about three or four years in the sales and marketing area. I then moved over to Wyeth, where I spent 10 years in the international side of the business in international planning. I moved back to Organon in 1992 and we built that company from about \$125 million to approximately \$1.1 billion in eight years. We launched about 13 products. In the year 2000, I was appointed to the Board of Management for Organon Worldwide. I took charge of the company's international operations, which covered 54 countries. In 2003, I was asked to come back to the US and be President of Organon BioSciences USA. Then in 2007, when Organon BioSciences was purchased by Schering-Plough, I decided that I would move on and Emisphere was the right opportunity at the time. As far as my staff goes, I had looked to bring on board more specific experience in the disciplines that were necessary, like finance and legal and communications and human resources. I also looked to bring on people who had the experience in the pharmaceutical and the biopharmaceutical fields, and these are the individuals who are currently on my senior team.

**TWST: What occupies your own attention most on a day-by-day basis?**

**Mr. Novinski:** I think it's the commercialization of the technology. I am very, very focused on this particular area. I think it's the most important thing Emisphere can do over the next 12 months. I say that because the technology needs to come from the clinical experimental stage to the commercial level. At that point we will be able to demonstrate that in fact our technology can provide benefits to the population at large for whatever treatment it is we are talking about. I think the landscape for Emisphere is going to begin to change.

**TWST: What is your cash situation like right now?**

**Mr. Novinski:** Right now we have a cash situation where we're probably going to go through mid-third quarter of this year.

**TWST: How much attention are you giving to investor relations at the present time?**

**Mr. Novinski:** That's one of our major objectives. One of our goals is not only to communicate more properly, but also to communicate more often with our existing shareholder base. We are looking to expand the base of our current shareholders as well. I spend one day every week talking to various people in the financial world about Emisphere. This often includes spending time with investors on the phone on Saturday mornings.

**TWST: Are there many misunderstandings about the company?**

**Mr. Novinski:** Yes, and with that you have hit the nail on the head. I think that's a very solid question. I think there are many misunderstandings about Emisphere. I believe the company is misunderstood, and the technology is misunderstood, and I think the company somehow has been poorly positioned in the financial community along with these misunderstandings.

**TWST: What would be the two or three best reasons for the long-term investor to look closely at Emisphere?**

**Mr. Novinski:** I think there are a couple of reasons. Number one, I think we are closer to possibly commercializing our technology than most people realize. One should really understand the problem that exists in health care today with molecules that are very poorly absorbed, and, in fact, the number of advantages that our technology can bring forward to certain molecules. I think a lot of people do not understand how close we are to commercializing this technology and bringing it forward as a demonstration that vali-

dates the technology. That's number one. Number two, I don't think people understand the things that are going on with our late-stage pipeline. We have two very exciting products with Novartis that are already well into Phase III and by the middle of this year, more than 5,000 patients are going to be taking the *eligen* technology along with Salmon Calcitonin for the treatment of osteoarthritis and osteoporosis. That's very exciting. You don't get to that stage very often with two particular products and I think that that's probably something that people do not understand.

**TWST: Is there anything that you would like to add, especially regarding strategies, long-term objectives and reasons for an investor to look at the company?**

**Mr. Novinski:** What I would like to highlight is that the organization's goals are very simple, and that is we want to commercialize our technology as soon as possible. We believe there is an opportunity to do so as early as next year, and that during the course of this year we are going to be able to build our early and mid-stage pipeline with additional partnerships. It would be my goal to communicate to existing and potential shareholders to look at these milestones as Emisphere is emerging from what it has been in the past, and I think they will see a completely different company.

**TWST: Thank you. (MC)**

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