

# THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

## GenVec, Inc. (GNVC)



**DR. PAUL H. FISCHER**, Ph.D., has served as President, Chief Executive Officer and a Director of GenVec, Inc., since 1996. Prior to joining GenVec, he was Executive Vice President of Research and Development with Oncologix, Inc. — now Antigenics, Inc. — a biotechnology company. Previously he served as Manager, Cancer Research, at Pfizer, Inc. Dr. Fischer received his B.S. in biology from the University of Denver and his Ph.D. in pharmacology from the University of California at San Francisco. He performed his post-doctoral research in pharmacology at Yale University School of Medicine. Prior to joining Pfizer, he also served as an Assistant Professor of pharmacology at the University of Missouri School of Medicine and an Associate Professor of

human oncology at the University of Wisconsin. Dr. Fischer serves on numerous community, academic, and professional organizations and boards.

### SECTOR — BIOTECHNOLOGY

**TWST:** Tell us a little bit about GenVec.

**Dr. Fischer:** GenVec was founded in 1992 to explore the potential of gene-based medicines, which was a very forward-looking concept back then. From the outset, we have tackled difficult problems because we believe the new technology should address hard-to-meet medical needs. Those have included things such as new cancer treatments and, more recently, efforts to prevent infectious diseases. It's really gratifying for us now to have our lead product candidate, TNFerade™, now in Phase III testing in pancreatic cancer, a disease for which there is no effective therapy.

In addition, we've had substantial efforts — all of which are supported by outside funding focused on the application of our core adenovector technology — for the development of new vaccines. These programs are important to us for multiple reasons: They reduce our cash needs because they are fully funded; they also accelerate the development of new technology, which has been critical for us to stay ahead of our competitors and generate new product opportunities. That portion of the businesses is doing well and has continued to grow over the last several years.

Most recently, we've had a leading-edge program in hearing loss emerge. This program is also based on our core gene delivery technology. Hearing loss is a major problem without effective drug therapy, and we are excited about the potential our technology has to address this serious unmet medical need.

**TWST:** One of the technologies you have is adenovector. What is that?

**Dr. Fischer:** First, I'd like to explain the clinical problem, and then I'll tell you how our technology solves it. There is a potent protein, tumor necrosis factor-alpha (TNF-alpha), known to stimulate the immune system and have significant anti-tumor properties. For a number of years it was studied clinically, but when the protein was given in the bloodstream it would cause too many harmful side effects to be useful. Thus, the protein looked promising but because of drug delivery problems, it couldn't be used effectively.

Our goal was to find a way to solve the TNF-alpha toxicity problem. Through our innovative technology, we were able to deliver the gene to the tumor. Delivery of the gene allows cells in the tumor to produce TNF-alpha locally at the site of the disease without leading to high levels of TNF-A in the bloodstream. With this technology, we are able to express the anti-cancer protein without the toxicity that could occur when TNF-alpha is administered in the bloodstream. This is an example of how GenVec's technology can be used — a gene stimulates the production of a protein locally, creating a therapeutic effect without toxicity.

**TWST:** Why is this particularly beneficial for pancreatic cancer?

**Dr. Fischer:** TNFerade is particularly useful in pancreatic cancer because we are able to deliver a very strong anti-cancer protein to fight a very serious tumor without major side effects for the patients. We

combine this treatment with the best available therapy, which is radiation combined with a drug known as fluorouracil, and then follow it with treatment of the metastatic disease with another chemotherapy drug called gemcitabine. The results to date have supported the concept that improved local therapy would, in fact, show better overall survival in patients with locally advanced pancreatic cancer. We're very encouraged that TNFerade appears to help control pancreatic cancer and improve survival in those suffering from this hard-to-treat disease.

**TWST: Did GenVec develop this technology in-house or did you acquire it?**

**Dr. Fischer:** GenVec's vector-related or gene delivery technology has been built internally at GenVec, and the company was founded with that idea in mind. The core gene delivery technology used here, including manufacturing, characterization and production, is proprietary. Over the years we've filed numerous patents, and we continue to advance the technology.

*"I want to be sure that investors and potential partners fully appreciate that our core technology allows us to explore multiple programs and product opportunities. Due to the funding and validation that comes from our vaccine programs, we are able to use our technology in a variety of different applications, including our late-stage cancer program, which could significantly drive the value for investors."*

With some products, such as TNFerade, we in-licensed the therapeutic gene, TNF-alpha, and used our technology to access the benefits of the gene. In most cases, the core technology is GenVec's and then we bring in other elements, such as genes, as needed to enhance potential products.

**TWST: So it's a combination — you go out and look for things to aid what you've already developed.**

**Dr. Fischer:** Yes, absolutely.

**TWST: You've discussed using the adenovector technology for cancer, specifically pancreatic cancer. What other applications are there for that technology?**

**Dr. Fischer:** First and foremost are GenVec's vaccine applications. One of the main things people in the vaccine field are looking for is a better way to get the immune response to protect against future infection, and GenVec's technology is very good at that. Instead of delivering a therapeutic protein, such as tumor necrosis factor, we're actually delivering the gene that codes for a foreign protein — something from an unwanted virus such as HIV — so that the body says, "Hey, I don't like that protein, I'm going to react to it, I'll turn on an immune reaction to it." Our technology is better than most when it comes to activating the cellular arm, and it's also very good at activating the antibody response. For this reason, vaccine experts will come to us and say, "We'd like to use your technology for our disease," which has led to collaborations in the animal health field with, for example, foot-and-mouth disease as well as in the human health field, addressing important human diseases such as HIV and malaria.

In addition to vaccines, we also use our technology in our hearing loss and balance disorder program. When people suffer from hearing loss and balance disorders it is because cells in the inner ear have been damaged by loud noises, age or drugs. Once these cells die, the body is not able to regenerate them. However, an excellent researcher at Baylor University in Texas has discovered a gene that seems to stimulate cells to form these hair cells in the inner ear, and we have in-licensed that technology and combined it with our gene delivery technology. Through support of

grants and other NIH funding, we have been able to show in animal models that we can regenerate the inner ear hair cells by using a gene to turn on the regeneration of these hair cells and restore hearing. Needless to say, this is a tremendous unmet medical need, and GenVec's technology may be one of the only technologies that can solve this problem.

**TWST: You've discussed several technologies that GenVec has in-licensed. Does GenVec also out-license technology?**

**Dr. Fischer:** Historically, that's been an important part of GenVec's strategy. We've always believed collaborations are valuable and can have the potential to accelerate drug development. Collaborations continue to be a very important part of our business strategy. For example, all of our vaccine programs are collaborative, and these collaborations help us to develop our technology and explore a variety of indications. Our vaccine collaborations are very important to us, and we're in the process of looking for corporate collaborations for our TNFerade and hearing loss programs.

**TWST: Have there been oncology trials conducted using TNFerade?**

**Dr. Fischer:** Yes, we have studied the drug extensively over a number of years in different indications. We have studied the use of the drug in cancers, such as esophageal, rectal, head and neck, and pancreatic. All of these indications have shown interesting early results, but we have focused our attention on studying the use of TNFerade in pancreatic cancer.

To date we have seen very promising results in the Phase III TNFerade study in pancreatic cancer, known as the PACT trial. Encouraging interim data from the PACT trial were released in late 2009. These data show that patients in the TNFerade arm of the trial have an approximately 25% less chance of dying, which is a very meaningful number when comparing to FDA-approved oncology therapies on the market. We anticipate seeing new data from this study in the first quarter of 2010.

**TWST: What kind of reception are you getting for the cancer therapies?**

**Dr. Fischer:** People are extremely interested in GenVec's cancer therapies because for many of these diseases the standard treatments haven't worked well, and the results of our trials have been promising. Additionally, scientists, oncologists and patients are all seeking less toxicity in cancer treatments, which makes TNFerade — a treatment that doesn't seem to add significant toxicities to the standard therapy — very appealing.

**TWST: What made you decide to look at the problem of hearing loss?**

**Dr. Fischer:** Researchers recognized that critical cells in the inner ear were not able to regenerate after being damaged. When we learned of a protein that could regenerate these cells, we realized that if we could somehow deliver the gene that coded for the protein, regeneration of these cells may be possible. We really believe — and continue to be encouraged by the early data we've seen in animal models — that our technology has the potential to be groundbreaking in this field.

**TWST: When will we see that therapy on the market?**

**Dr. Fischer:** It is very difficult to project that. It typically takes 10 years for clinical trials and FDA approval. We are encouraged by the wonderful animal data that we've seen in hearing loss, and we're in business discussions with companies about hearing loss. It might be possible to get into initial early clinical testing possibly within a couple of years because the proof of concept looks very powerful. But there are a lot of steps in terms of manufacturing and safety study, so it is difficult to project an exact time frame. However, we are confident this technology will see the clinic, and we hope to see promising results.

**TWST: What are the leading drug candidates for you on the vaccine side, and what are the expected timelines?**

**Dr. Fischer:** For most of the vaccine programs, we work with collaborators who make many of the decisions concerning the clinical development pathway. For this reason, it is difficult for us to predict or estimate timelines for these programs. We are encouraged by the progress we continue to make in all of our vaccine programs, and we're grateful for the support we receive from our collaborators. It is this funding and support that helps us to move potential product candidates forward while continuing to develop our technology.

**TWST: You work on both human and animal applications. Is the regulatory process different for each of those?**

**Dr. Fischer:** Our internal clinical efforts are focused on the development of human therapeutics, principally TNFerade. Our collaborators have directed the clinical testing in the various vaccine programs. Our expertise has centered on the design and manufacture of the various vaccine candidates. Leadership in the animal health arena has come from our collaborators in the FMD program.

**TWST: What about GenVec makes it a good addition to a portfolio?**

**Dr. Fischer:** There are several things that make GenVec a good addition to a portfolio. One of the most important things to recognize is that GenVec's proprietary technology is the foundation for the company's diverse pipeline. Validation of GenVec's core technology also comes through our multiple funded vaccine programs. These collaborations accelerate the development of our technology, provide significant revenues and generate potential product opportunities. In addition, a key value-driver is our late-stage TNFerade program in pancreatic cancer, a program in which we will have data available in the first quarter of 2010. Another important aspect of GenVec is our breakthrough program in

hearing loss, an affliction from which many suffer but for which there is no medical treatment. This program is potentially a very valuable asset for GenVec. As you can see, we have a very diverse pipeline with a variety of programs that can provide value for investors.

**TWST: Tell us about your background.**

**Dr. Fischer:** My background is in pharmacology, which is the development and design of drugs, with a particular emphasis in cancer. For a number of years, my background focused on the early testing and discovery of new cancer drugs. I was an Associate Professor of human oncology at the University of Wisconsin School of Medicine and then moved to head the cancer program at Pfizer. Subsequent to that, I was the Head of Research at a company focused solely in oncology, Oncologix. In 1995 I came to GenVec as the Head of Development, and in 1996 I was appointed the CEO and Director of the company.

**TWST: Is there anything else that you'd like to add?**

**Dr. Fischer:** I want to be sure that investors and potential partners fully appreciate that our core technology allows us to explore multiple programs and product opportunities. Due to the funding and validation that comes from our vaccine programs, we are able to use our technology in a variety of different applications, including our late-stage cancer program, which could significantly drive the value for investors.

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

**DR. PAUL H. FISCHER**  
 President, CEO & Director  
 GenVec, Inc.  
 65 West Watkins Mill Road  
 Gaithersburg, MD 20878  
 (240) 632-0740  
 (877) 943-6832 — TOLL FREE  
 (240) 632-0735 — FAX  
[www.genvec.com](http://www.genvec.com)