CEOCFO Interviews & News!

ceocfointerviews.com – All rights reserved. – Issue: June 27, 2008

IntelGenx Technologies Is Focused On Providing Development Services To The Pharmaceutical Industry Using Their Proprietary Orally Administered Drug Delivery Technology

IntelGenx Corp.

Healthcare
Drug Delivery
(IGXT-OTC: BB)

IntelGenx Technologies Corp.

6425 Abrams
Ville Saint Laurent, QC H4S 1X9
Phone: 514-331-7440

Horst G. Zerbe, Ph.D.
Chairman, President and CEO

BIO:
Horst G. Zerbe, Ph.D., President and CEO, Prior to founding IntelGenx, he served as the president of Smartrix Technologies Inc. in Montreal, and as Vice President of R&D at LTS Lohmann Therapy Systems in West Caldwell, NJ. He holds over 40 patents in drug delivery related fields and has published numerous scientific papers in recognized journals. He is one of the co-inventors of the edible film technology.

Company Profile:
IntelGenx Technologies Corp. is a drug delivery company focused on the development of oral controlled-release products as well as novel rapidly disintegrating delivery systems. The company uses its unique multiple layer delivery system to provide zero-order release of active drugs in the gastro-intestinal tract. IntelGenx has also developed novel delivery technologies for the rapid delivery of pharmaceutically active substances in the oral cavity based on its experience with rapidly disintegrating films. The company's research and development pipeline includes products for the treatment of osteoarthritis, pain management, hypertension, and smoking cessation.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Dr. Zerbe, you describe IntelGenx as a unique drug delivery company; what is your focus today in general?
Dr. Zerbe: "Our focus is to provide pharmaceutical development services to the pharmaceutical industry using our proprietary drug-delivery technologies. We currently have three oral drug-delivery technologies in our portfolio that we use for our development projects. We currently have a total of twelve projects at various development stages."

CEOCFO: Please tell us about the technology.
Dr. Zerbe: "Our focus is on oral drug delivery. Our platform technologies include systems for controlled release and immediate release dosage forms. Our controlled-release technology is based on layered tablets that consist of a non-erodible layer containing the active drug and one or more erodible cover layers. Upon contact of the tablet with the gastro-intestinal fluid, the cover layers erode at a pre-determined rate. This "controlled erosion" controls the release of an active drug from the non-erodible active matrix layer. With this system, we achieve zero-order release for a broad variety of drugs.IntelGenx has an international patent application pending for this delivery system.

The second platform technology involves a rapidly disintegrating film for oral administration. This technology was initially derived from the breath-freshening films that have become very popular. IntelGenx is taking this technology a step further by incorporating active drugs into the film. Because of its unique properties, mainly the rapid disintegration in the oral cavity, this delivery platform is specifically suitable for indications that require a very rapid onset of action. With the oral film, we are able to create therapeutic plasma concentrations within one minute compared to conventional oral tablets, which require up to 30 minutes or more.

Finally, we have developed a new muco-adhesive tablet technology that we use for drugs requiring oral absorption in order to prevent metabolic deactivation of the drug by first-pass metabolism. The tablets adhere to the oral mucosa for a predetermined period of time during which the active is released in the oral mucosa and can enter directly into the systemic circulation."

CEOCFO: What is the benefit in terms of the regulatory process with the use of existing drugs?

Dr. Zerbe: "We can make generic copies of existing products and file Abbreviated New Drug Applications with the FDA. However, we prefer to focus on 505(b)(2) applications. These applications are New Drug Applications that improve upon active ingredients already on the market. One potential advantage of this approach is that the applicant may get three years of market exclusivity upon approval of the product. This can give the applicant a favorable position in the market place."

CEOCFO: Are you doing this through partnerships primarily?
Dr. Zerbe: "Yes."

CEOCFO: Please tell us more about your alliances.
Dr. Zerbe: We perform an initial prototype development of a product at our own expense. We may finish the development ourselves and then seek a commercialization partner or look for partners who are interested in helping to fund the remainder of the development for exclusive commercialization rights to the product. We also prefer to retain manufacturing rights. As far as payment for our services, we are open and flexible. Typically, we receive milestones upon successful achievement of stages of development. In addition, we receive royalties based on market performance. As I mentioned previously, we may seek relationships in which partners share in the development costs. The further along in development the higher the royalties we can seek. We did that recently with two projects. Two months ago, we announced an agreement with Cary Pharmaceuticals in which we acquired a 50% ownership position in the product, thus, entitling us to 50% of all of the revenues from the commercialization partner. In the second case, we entered into an arrangement with Dava Pharmaceuticals for the joint development of a generic anti-hypertensive product. At our own expense, we developed the product to proof of bioequivalence to the brand. Then we entered into a relationship with Dava Pharmaceuticals to finish the development and commercialization rights. In the agreement with DAVA, IntelGenx will receive milestone payments and royalties on net sales. This is the model we are trying to apply routinely with our future projects."

CEOCFO: Is a better form of drug delivery a focus for the medical community?
Dr. Zerbe: "Yes it is. New products have become so expensive to develop that you have to maximize the new product from every aspect including the delivery system in order to recover development costs that were incurred in the process. Secondly, we see a clear trend in the pharmaceutical industry towards specialization. Big Pharma no longer invests their research dollars in drug delivery. They specialize on drug discovery, the development of new molecules, and subcontract much of the work revolving around the development of an appropriate delivery system. Typically, these drug delivery systems are being developed by companies like IntelGenx. We are a drug-delivery company specializing on all oral drug delivery systems, so this ongoing and progressing differentiation in the service portfolio of the pharmaceutical industry needs to be considered."

CEOCFO: What is the financial picture like today for IntelGenx?
Dr. Zerbe: "Currently, our revenues come exclusively from development fees and milestones that we received from our development and commercialization partners. Calendar year 2008 will be a break-through year for IntelGenx. We will be launching our first product, via a partner, that had been fully developed in our laboratories. The scheduled launch will be early in the third quarter. It is a prenatal vitamin combination that we developed for Azur Pharma. It will be marketed in the US through Azur Pharma's wholly-owned subsidiary. We expect to be cash flow positive by the end of 2008 or early in 2009. In 2009, we are projecting two more products on the market."

CEOCFO: Exciting times for you!
Dr. Zerbe: "Yes, it has been a lot of hard work, but now we believe that we have made it or are very close to making it."

CEOCFO: You have just listed on the TSX; what is the significance for Intelgenx?
Dr. Zerbe: "IntelGenx Corp. is a Canadian company, and the majority of our shareholders are Canadian and more familiar with the Canadian market. More importantly, many Canadian institutional investors invest only in companies that are listed on a Canadian Exchange. It is important for IntelGenx as a Canadian company to have the support of Canadian institutional investors. Earlier this year, we closed on a strategic financing that involved three major Canadian institutional investors. We believe that their participation in the company will raise the awareness amongst Canadian investors about our company."

CEOCFO: Please tell us about your latest clincial study results, they are certainly quite positive.
Dr. Zerbe: "One of our key projects involves the development of our antidepressant drug CPI-300 using our Versatab controlled-release tablet technology. We recently completed a food effect study, the first of two pivotal clinical studies required by FDA to submit a 505(b)(2) NDA. The results of that study demonstrated bioequivalency with the brand product for the relevant parameters AUC and Cmax. The company is now gearing

"Our focus is on oral drug delivery. Our platform technologies include systems for controlled release and immediate release dosage forms. Our controlled-release technology is based on layered tablets that consist of a non-erodible layer containing the active drug and one or more erodible cover layers. Upon contact of the tablet with the gastro-intestinal fluid, the cover layers erode at a pre-determined rate. This "controlled erosion" controls the release of an active drug from the non-erodible active matrix layer. With this system, we achieve zero-order release for a broad variety of drugs.IntelGenx has an international patent application pending for this delivery system."

- Horst G. Zerbe, Ph.D.

up for the final clinical study, a BA/BE study, and is on track for a 505(b)(2) submission in Q4/2008. We expect to launch the product in the second half of 2009."

CEOCFO: In closing, why should potential investors be interested in IntelGenx Technologies, and please tell us about your product pipeline.

Dr. Zerbe: "We have a solid product pipeline. All twelve of our projects are progressing towards commercialization. The furthest along is the prenatal vitamin mentioned previously. We have an elaborate process established for selecting projects. We try to include projects where the risk of failure is minimized. We believe that all twelve of our projects have a realistic chance of being successfully developed and reaching the market. As far as new projects,, we may come up with ideas ourselves or we may be contacted by existing or new clients. Factors we consider in selecting projects include the size of the opportunity. It must make sense economically for both IntelGenx and our partner. We also consider the probability of success. In addition, the regulatory pathway and hurdles need to be evaluated. We use only proven and accepted methods and ingredients. We have a low risk profile, something important for investors. In addition, we have a competent group and approach our projects aggressively. We have had impressive growth from the standpoint of headcount, sales, the number of projects and the number of patent and patent applications. Therefore, this rapid and impressive growth of the company should help convince potential investors to take a closer look at us."

"The second platform technology involves a rapidly disintegrating film for oral administration. This technology was initially derived from the breath-freshening films that have become very popular. IntelGenx is taking this technology a step further by incorporating active drugs into the film. Because of its unique properties, mainly the rapid disintegration in the oral cavity, this delivery platform is specifically suitable for indications that require a very rapid onset of action. With the oral film, we are able to create therapeutic plasma concentrations within one minute compared to conventional oral tablets, which require up to 30 minutes or more."

- Horst G. Zerbe, Ph.D.

IntelGenx Corp.

“Finally, we have developed a new mucoadhesive tablet technology that we use for drugs requiring oral absorption in order to prevent metabolic deactivation of the drug by first-pass metabolism. The tablets adhere to the oral mucosa for a predetermined period of time during which the active is released in the oral mucosa and can enter directly into the systemic circulation.” - Horst G. Zerbe, Ph.D.

IntelGenx Technologies Corp.
6425 Abrams
Ville Saint Laurent, QC H4S 1X9
Phone: 514-331-7440