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Interviews & News!

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Aradigm Is On Their Way To Accomplishing Their Vision Of Becoming A Leading Company In Developing Treatments For Severe Respiratory Diseases



Healthcare
Specialty Pharmaceutical
(ARDM-OTC: BB)

Aradigm Corporation

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Igor Gonda, Ph.D.
President and CEO

BIO:

Igor was appointed President and Chief Executive Officer in August 2006. He has been a Director on Aradigm's Board of Directors since September 2001 and was Chairman of the Company's Scientific Advisory Board until August 2006. Prior to joining Aradigm Igor was the Chief Executive Officer and Managing Director of Acrux Limited, a publicly traded specialty pharmaceutical company in Melbourne, Australia. From October 1995 until July 2001, Igor was Vice President, Research and Development and then Chief Scientific Officer both at Aradigm.

From February 1992 to September 1995, Igor was a Senior Scientist and Group Leader at Genentech, Inc. Prior to that, Dr. Gonda held academic positions in the United Kingdom and Australia. Igor has a B.Sc. in Chemistry and a Ph.D. in Physical Chemistry from Leeds University, UK.

Company Profile:

Aradigm is an emerging specialty pharmaceutical company focused on the development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Current activities include partnered and self-initiated development programs addressing the treatment of cystic fibrosis, bronchiectasis, pulmonary hypertension, inhalation anthrax infections and smoking cessation.

In addition, Aradigm's AERx(R) insulin Diabetes Management System (iDMS), which has been licensed to Novo Nordisk for development and commercialization in return for royalties, is in Phase 3 testing for Type 1 and Type 2 diabetes. Under the agreements with Novo Nordisk, Novo Nordisk is responsible for all further clinical, manufacturing and commercial development, while Aradigm and Novo Nordisk continue to cooperate and share in technology development, as well as intellectual property development and defense.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Gonda, you have been CEO of Aradigm for about a year, what was your vision when you became CEO and where are you today?

Dr. Gonda: "My vision was to turn Aradigm into a leading company treating severe respiratory disease in the US. That was the vision that the Board and I discussed before I came here. I was very excited to be able to come and implement the vision and turn it to a mission to become such a company."

CEOCFO: How has that progressed over the past year?

Dr. Gonda: "We have started development of the lead product for the treatment of severe infections associated with cystic fibrosis and other obstructive lung disease such as bronchiectasis. The treatment is based on a well-known antibiotic. By getting the antibiotic directly into the lung, we believe that we can achieve the same or better efficacy as the oral or injected antibiotic with a much lower dose because we are giving the treatment directly to the lung. We should have efficacy without the side-effects that are associated with the oral or injected treatment."

CEOCFO: What is the market for severe lung diseases and why did you decided to make that your focus?

Dr. Gonda: "Aradigm has a long history of being a pioneer in the development of medications by inhalation. In the past, the business model has been to do the initial development of the technology and some of the products internally in-house and then partner these with larger companies who have the marketing and sales capabilities. The result of this effort has been two major partnerships in late stage development. One of them, Novo Nordisk is a global leading company in the area of treatment of diabetes, and that company is now in the last stages of development stage, Phase 3 with inhaled insulin,

which was initially developed by Aradigm and is now in the hands of Novo Nordisk. The product is expected to be launched in 2010. Another example of Aradigm's initial product is a needlefree injector that injects the treatment for migraine. It is a product that is now in the hands of a private company called Zogenix and the expected launch of the product is in 2009. TPartnering was the original business model with Aradigm and that led to the late stage product partnerships that we now have. However, we believe that we can leverage the expertise and the intellectual property portfolio of Aradigm. The people that we have here are experts at developing the products that specifically deliver medication by inhalation, which is attractive for the treatment of severe respiratory disease. Interestingly the markets for respiratory disease are very large and the mild to moderate disease is treated quite well by the existing therapy. However, disproportionately large sums of money are spent on patients who end up in the emergency units of hospitals, patients with severe disease that is not controlled well. Examples of these are patients with severe asthma and cystic fibrosis."

CEOCFO: Are you also looking into the prevention of respiratory disease?

Dr. Gonda: "Yes we are and there are two areas where we may be able to contribute significantly in future. One of them is the product that is related to the antibiotic treatment that I mentioned, the product that will be given by inhalation in a novel formulation that keeps an antibiotic drug in the lung for a prolonged period of time. There has been some data in animals indicating this so-called liposome formulation of the antibiotic is very effective to prevent and treat inhaled anthrax. The efficacy was demonstrated in an animal model of this infection. The treatment with our product would be used in an emergency situation where there is a suspected terrorism attack, either one that has already occurred or one that is likely to occur and the people at risk would be inhaling this medication in order to prevent the development of the disease caused by the infection. The other

area that we are very interested in is probably one of the greatest opportunities for preventative respiratory medicine in general and that is the treatment for tobacco smoking addiction. As you may know, the market for tobacco products is enormous compared to the market for the smoking cessation therapy, so there is a huge market opportunity and we do not believe that this opportunity in preventative medicine has been adequately explored. We are developing an interesting approach to this and that is giving smokers "clean" inhaled nicotine in the form of a fine water mist that would provide them with very similar blood level profiles of nicotine that would address the issue of their craving for nicotine. By gradually reducing these blood levels of nicotine in these patients using a special design of our "clean" inhaled nicotine product, we expect that we would be able to wean them off smoking. We just com-

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pleted the dosing in the first clinical trial. We expect that we will be able to announce the data before too long. I think that this could be a very valuable product to prevent people from developing severe respiratory disease and other health problems that are related to tobacco smoking."

CEOCFO: Very rich pipeline!

Dr. Gonda: "We are very selective in what we take. We are very careful to have expertise and intellectual property."

CEOCFO: What is the financial picture for Aradigm?

Dr. Gonda: "The financial situation is quite healthy. We were very fortunate that the vision of the company was supported in a recent public offering that we conducted in January. We raised over \$33 million net, which at the end of last quarter provided us with a balance of over \$51 million in cash. Our quarterly burn rate is now below \$6 million. We have got a

good financial position to enable us to advance these products in development before we need to raise money again. We hope that we will be able to take inhaled liposomal antibiotic approach for cystic fibrosis all the way to the market, possibly with one more fund raising."

CEOCFO: What is ahead the next couple of years for the company?

Dr. Gonda: "The internal development of products for cystic fibrosis is ultimately going to drive the value of the company. The focus internally will be on the anti-effective for cystic fibrosis and other infections associated with lung disease. I expect that much of the news, much of the investment and internal effort will be associated with that. We would like to become the leading company in the USA helping pulmonologists who treat severe respiratory disease. We are looking at additions to this product portfolio that

would be consistent with our strategy. We also are hopeful that our partners will continue successfully with the late stage development of the products, namely Novo Nordisk, who are in nine Phase III clinical trials to treat diabetes with inhaled insulin using technology that was initially developed at Aradigm.

We are expecting that gradually results of the clinical trials will be published as we approach the Novo Nordisk launch of this product. We think it will be a great help to many diabetes patients who are not treated with insulin currently because they are afraid of injecting or are not taking as many injections as they should be taking because it is inconvenient. It is a great opportunity and we expect revenues to Aradigm to be on average about 5% of net sales of this product."

CEOCFO: Is your management team in place?

Dr. Gonda: "Currently we have the right management team I believe to conduct the development of the products that are in our pipeline. As we approach the commercial phase of the development, obviously we will need to add people particularly in the marketing and sales side. We also made the strategic decision that we will not be building factories and we

will not be conducting commercial scale manufacturing. We announced today that we have signed a contract manufacturing agreement with Enzon for the liposomal antibiotic. Enzon is a well known public company that already has a liposomal product on the market, so they have experience in manufacturing for the kind of products that our inhaled liposomal antibiotic is. We will not have to build a large manufacturing organization in Aradigm, but we will need marketing and salespeople and other infrastructure associated with marketing and sales.”

CEOCFO: Why should potential investors be looking at Aradigm and be willing to invest in the company?

Dr. Gonda: “Our business plan is a somewhat unusual business plan. We

have a two-pronged approach to revenues, one of them is the legacy of partnerships in drug delivery and I mentioned the Novo Nordisk AERx partnership in diabetes, that is currently already in Phase 3 development, as an example. There is also a possibility that there will be further partnerships, outside diabetes, where basically the partners take on all the future costs of the development of products and we license to them the AERx technology. In addition, the development of Aradigm is in the direction to become a specialty pharmaceutical company leading the treatment of severe respiratory disease. Companies such as Pathogenesis have validated that business model in the past and those companies have done very well, in fact, they were so successful that they were bought by larger

companies. Now most of these small companies are no longer in existence so we seem to be able to fill the gap with specializations and developing the relationship in this segment of market.”

CEOCFO: What should people take away from this interview?

Dr. Gonda: “Aradigm is a company that has a strategic plan in place for a market that has been previously validated. We have competitive products in development and we have a strong cash position to be able to advance further development of our products toward the market.”

PostScript: After completing the interview with the CEO Igor Gonda, Aradigm announced two partnerships in respiratory disease: a deal with Lung Rx, a subsidiary of United Therapeutics, to use the palm-size AERx Essence inhaler for the treatment of pulmonary arterial hypertension, a severe debilitating and life threatening disease. In addition to license fees and milestone payments, Aradigm can earn up to 10% royalties. The second collaboration is also using the same technology, AERx Essence, and it is with Cydex Inc, on the development of products for the treatment of asthma and chronic obstructive pulmonary disease. The two companies will split the partnering and sales revenues in a ratio 60:40.



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