

With a Computer Based Technology that Uses Algorithms to Predict Where Proteins Will Misfold or Become Partially Unfolded, Amorfix Life Sciences Ltd is Developing Targeted Monoclonal Antibody Therapeutics that Specifically Bind to Diseased Cells but Not Normal Cells Creating Products with a Greater Safety Profile



Healthcare
Diagnostics and Monoclonal Anti-
body Therapeutics
(AMF-TSX)



Dr. Robert Gundel, Ph.D., M.B.A.
President and CEO

BIO:

Dr. Gundel has extensive industry experience from executive management positions at a number of leading biopharmaceutical companies prior to joining Amorfix in January 2010. Previously, Dr. Gundel was the Chief Scientific Officer at Heat Biologics, the Vice President and Head of Research at Elusys Therapeutics Inc., the Chief Scientific Officer at Arius

Research, Inc., the Vice President, Preclinical Research and Scientific Corporate Development at XOMA (US), LLC., and Vice President, Pharmacology and Preclinical Research at Chiron Corporation. Earlier, Dr. Gundel also worked at Bayer Corporation as Director of Pharmacology after beginning his career in pharmaceutical R&D at Boehringer Ingelheim Pharmaceuticals, Inc.

Dr. Gundel earned his M.B.A. from Saint Mary's College, and his Ph.D. in physiology from New York Medical College. He has participated in over 45 national and international scientific meetings as an invited speaker and/or session chairperson. He has published more than 130 abstracts, articles in peer reviewed journals and book chapters. He has served on the editorial board of several journals and is a co-inventor on several issued U.S. patents.

Dr Gundel is also a member of Amorfix's Board of Directors.

Company Profile:

Amorfix Life Sciences Ltd. (TSX: AMF) is a product development company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including Alzheimer's Disease (AD), cancers, and ALS. Amorfix utilizes its computational discovery platform, ProMIS™, to predict novel Disease Specific Epitopes ("DSEs") on the molecular surface of misfolded proteins. Cancer immunotherapies have in the past been directed against targets which are also present on normal cells, whereas Amorfix's innovative ProMIS

platform identifies targets present only on cancer cells, retaining efficacy with improved safety. Amorfix's lead programs include therapeutics and companion diagnostics for cancers, antibodies and vaccines to DSEs in ALS, as well as AD and ALS diagnostic tests. Amorfix's proprietary Epitope Protection™ technology enables it to specifically identify very low levels of misfolded proteins in a biological sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated beta-Amyloid in brain tissue, CSF and blood from animal models of AD, months prior to observable amyloid formation and the development of a human screening test for AD and a blood test to diagnose ALS. For more information about Amorfix, visit www.amorfix.com.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Dr. Gundel, what attracted you to Amorfix, and what strengths do you bring to the table that the company needed when you became CEO?

Dr. Gundel: There were several things that really attracted me to Amorfix including the technology, the therapeutic space the company works in and the small company culture and environment. The technology is truly innovative and represents an entirely new approach to the identification of therapeutic targets that enables the development of drugs that are specific to diseased cells and do not affect normal cells. This approach is extremely important in treating a disease like cancer because it repre-

sents a way to kill the cancer but leave the normal functioning cells intact and untouched. The technology, called ProMIS discovery, is a computer based algorithm that predicts areas where proteins will either misfold when they are originally produced inside the cell, or once they are produced and expressed outside of the cell, will partially unfold. Our technology identifies those areas and we use this information to generate monoclonal antibodies that will bind exclusively to the novel areas that are exposed due to the partial unfolding. This enables us to develop therapeutics that are specific to diseased cells and will not bind to normal cells because it is only the diseased cells that expresses the misfolded or partially unfolded form of the protein. That is the concept that attracted me to the company. It is a way to develop therapeutics that will be much more effective at treating disease and have a much better safety profile. In addition, Amorfix also has technology for developing diagnostics for diseases that are known to be associated with aggregated misfolded proteins. Misfolded proteins represent a very small portion of the total amount of protein found in an excess of normally folded proteins; sometimes more than a million to one excess. This makes detecting them and measuring them very difficult. Our technology masks the normally folded proteins and so enables us to detect and measure those very small amounts of misfolded proteins found in a variety of samples including blood and cerebrospinal fluid and is the basis of our diagnostic programs. The Epitope protection technology allows us to find the needle in the haystack.

I have been working in the pharmaceutical industry for more than 30 years. I have worked for both big pharma companies as well as small company start-ups and have just about seen it all. Drug development is a complicated process for a variety of reasons and there is really nothing short of having years of experience to

understand it and excel at it. This is what I bring to the table at Amorfix.

CEO CFO: What is a misfolded protein?

Dr. Gundel: There is a whole set of machinery inside the cell that puts amino acids together in the right sequence to form proteins. It is important that everything is assembled correctly such that the protein assumes the proper three-dimensional structure and part of the cell machinery acts as quality control to ensure that each protein has the proper configuration. The function of the protein is dependent on this three-dimensional structure and when the protein is not assembled correctly it becomes "misfolded" and does not have the proper structure and, subsequently, the proper function. Normally these misfolded proteins are identified by the

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cell and reprocessed into their normal configuration or destroyed. In diseases such as ALS, Alzheimer's Disease and cancer, the normal quality control system in cells becomes overwhelmed and unable to keep up with the amount of misfolded proteins produced. As a result, the misfolded protein escapes the normal control system. When a protein is misfolded or becomes partially unfolded, it either loses its function entirely or gains a different function and that is the basis behind a variety of different diseases that fall under the umbrella of misfolded protein diseases.

CEO CFO: What is Amorfix doing with the knowledge that you have developed?

Dr. Gundel: On the diagnostics front, we have two big programs that we are working on. One is for Alzheimer's disease and the other is for ALS. The protein that we are focused on for

Alzheimer's disease is called Abeta amyloid. It turns out that in Alzheimer's disease the Abeta protein is misfolded and forms clumps of protein that eventually accumulate in the brain leading to the characteristic plaque formation and dementia symptoms. Currently, the only way Alzheimer's disease is definitively diagnosed is by autopsy where these distinctive plaques can be seen. Our diagnostic can detect and measure these clumps of Abeta protein in cerebrospinal fluid and thus represents a way to identify patients with early-stage Alzheimer's disease. This is the only diagnostic that measures the aggregated form of Abeta which is a hallmark of Alzheimer's disease. We believe the immediate utility of this diagnostic is to aid in the improvement of clinical trials for testing new therapeutics for the treatment of

Alzheimer's disease. Currently, the mis-diagnosis rate for Alzheimer's disease can be as high as 30% which is problematic and basically means that up to 3 of 10 subjects enrolled in a study might not actually have the disease but rather some other form of dementia. Our diagnostic can significantly improve those statistics as well as identify patients with early-stage disease. These

are patients much more likely to benefit from therapeutic intervention and, therefore, the most desirable to enroll in a clinical trial. The rule is that, in most cases, the earlier one can diagnose and begin treatment of a disease, the better the chances are of a successful outcome.

Our ALS diagnostic program involves another misfolded protein called super oxide dismutase-1 (SOD1). This protein, in its native form acts as an anti-oxidant and protects neurons. In its misfolded form SOD1 has the exact opposite activity. It becomes a pro-oxidant and actually kills neurons. Our diagnostic will measure misfolded SOD1 in the blood of ALS patients and offers an entirely new way to diagnose the disease. The situation with ALS is desperate and a new way to diagnose the disease is needed. Today ALS is diagnosed based on

symptoms and, basically, by a process of elimination of other potential neurological diseases. This process takes time, which for ALS patients is a very costly thing. The normal survival time is only 3 to 5 years after diagnosis. Our diagnostic will be a very simple blood test which can be administered early-on in the disease process. It has the potential to revolutionize the way ALS is diagnosed and treated.

CEO CFO: Where are you in the process?

Dr. Gundel: For our Alzheimer's disease diagnostic, we just completed an analysis of over two hundred clinical samples. The data show very good specificity and sensitivity with our assay, meaning that the number of false positives and false negatives are low. We are now looking for a pharma partner or other suitable partner to take this assay and assist in the commercialization for clinical trials and to continue the development of the assay to be used as a diagnostic. As I said earlier, this assay could be used for enrollment criteria for patients going into Alzheimer's disease studies as a way of improving clinical studies. Alzheimer's disease is one of the most active areas of clinical investigation with almost 900 clinical studies in progress right now. We feel our diagnostics could greatly improve the quality and outcome of some of these studies, meaning that they would be more accurate and better reflective of what is actually happening in Alzheimer's disease. So, that is our first plan to market this diagnostic. Longer term, we want to find a development partner to help complete all the clinical studies required to have this approved by the FDA for use as a general diagnostic.

CEO CFO: How do you get the attention of the right people that might partner with you?

Dr. Gundel: One of the challenges is increasing the visibility of the company. We press release all important business-related events and important scientific discoveries. We also attend scientific conferences. For instance, in Alzheimer's disease there is the ICAD Conference that occurs once a year. That is one of the big international meetings that all of the Alz-

heimer's researchers attend and all the Pharma companies working in the area of Alzheimer's disease are represented. We use that meeting to present our progress on our Alzheimer's disease program and network with various companies for possible collaborations and business deals. We also communicate our message through various media channels, publications and industry organized partnering events. It certainly is one of the challenges for us as a small biotech company in Canada, to get the word out on our programs. I am hoping that this publication will help a great deal.

CEO CFO: What else are you working on at Amorfix?

Dr. Gundel: We have made considerable progress developing our product portfolio of new cancer treatments. We use the ProMIS discovery technology to generate therapeutics that selectively kill tumors while leaving normal cells intact. One of the big issues with cancer treatments today is the adverse side effects from treatment. Our technology enables us to generate therapeutics that will have good anti-tumor activity without the dose-limiting side effects seen with most other cancer treatments. We are advancing our lead program to a proof of concept study in animal models of cancer as quickly as possible and expect to be initiating these studies in the second quarter this year.

CEO CFO: Have you considered licensing your technology?

Dr. Gundel: Yes, that is a major part of our business strategy. We licensed our ALS therapeutics technology in 2010. We are seeking to establish strategic alliances with other pharmaceutical companies for co-development of some of our programs. We will bring our programs to a certain stage of development and then partner them out or out-license to a big company that can take them through to commercialization. We are also looking to partner with companies that could use our technology to develop diagnostics and therapeutics outside of our focus disease areas; so called platform technology deals. In those cases, we can either collaborate

with them or out-license the technology to them altogether.

CEO CFO: How does Amorfix manage working on several fronts, with several products?

Dr. Gundel: One of the most important things is to remain focused. We have a lot of projects going but we are very focused. Our organization is lean and mean. One hears this all the time, but we really are. We have a process in place where we eliminate anything that does not look like it has a chance of making it all the way as early in the development process as possible. That way we do not waste time and money on programs that have a low probability of success. We are constantly evaluating our programs and making adjustments as we go along. It is definitely a challenge to make the hard decisions on our programs but it is critical to our success. I think the real challenge is obviously funding, especially in today's environment. It is really tough out there right now. My analogy of being the head of a small company is as follows: you are driving a car and you have a quarter of a tank of gas and 300 miles to go. What can you do to make sure that you get there? The first thing you can do is make sure the car you are driving gets great gas mileage; so you try to maximize the amount of mileage that you can get with what you have. I mentioned that our company is lean, mean and very focused, so we absolutely have done that. The other thing you need to do is to make sure that the road map that you have and the directions that you are following are accurate and are going to get you where you need to be at the end of the day. You need to make sure that the path that you are taking is the right one. Problematic for sure because there is no GPS for drug development. We have an organization that is very focused. Our burn rate is at a minimum and we move our programs forward in the direction that we think we need to be moving in. It is a little nerve racking at times, but certainly challenging and rewarding when you get it right.

CEO CFO: What is the financial picture like for Amorfix Life Sciences today?

Dr. Gundel: We have just completed a private placement, so the financial picture is actually pretty good. We determined how much funding we needed to drive our programs past some of the critical milestones, what I call "strategic inflection points." One is the proof of concept in animal models for our cancer therapeutic program. Once we have that proof of concept data, we believe the floodgates will open and a lot of big pharma companies will become aware of our technology and will want to partner and work with us. Our Alzheimer's disease diagnostic is ready for prime time and we are actively involved in partnering discussions with a number of companies. We will be raising enough cash to get us to where we need to be to complete business deals.

CEOCFO: Why should Amorfix Life Sciences stand out for potential investors?

Dr. Gundel: There are a number of things that distinguish Amorfix from our competitors. Our proprietary technology enables us to do things that other companies cannot. We are developing important diagnostics and therapeutics in disease areas that have large unmet medical need and large commercial market opportunities. I believe we are a very undervalued company right now. Most of our projects have short term milestones and strategic inflection points which means added value for our shareholders in a short period of time. -In short, I see the company as a great investment opportunity at the present time.

CEOCFO: Final thoughts, what should people remember most about Amorfix?

Dr. Gundel: Amorfix is a company with unique and valuable technology that provides a competitive advantage over other companies that are working in the same space. We have strong science and an emerging pipeline of novel diagnostic and therapeutics that have the potential to become blockbuster commercial products. We have an exceptional management team and experienced Board of Directors. You have to have the right team in place to make it all happen. I believe we have that at Amorfix.



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