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Synthetic Affinity Molecules Alternative

Mark Shumbera
President

CEOCFO: *Mr. Shumbera, would you tell us the idea behind AM Biotechnologies?*
Mr. Shumbera: AM Biotech produces and designs synthetic affinity molecules called X-Aptamers. These affinity molecules can be used in place of monoclonal antibodies, which are widely used in the marketplace.

CEOCFO: *Where are monoclonal antibodies typically used and why go with your product?*
Mr. Shumbera: Monoclonal antibodies are biologically produced proteins that are used in many areas of life science. They can be used as a research tool, in a diagnostic test, or even as a drug. Generally, monoclonal antibodies have an affinity for a particular molecule also called an antigen. If you want to detect a certain molecule or manipulate it in some way, then you need an affinity molecule, such as a monoclonal antibody or its synthetic equivalent, an X-Aptamer.

CEOCFO: *Why use a synthetic product?*
Mr. Shumbera: You would want to use an X-Aptamer instead of a monoclonal antibody because X-Aptamers are synthetically produced, as opposed to monoclonal antibodies, which are produced in living systems in bio-reactors. In addition, monoclonal antibodies are expensive to produce, have a relatively short shelf life, are very susceptible to degradation when they are not refrigerated or frozen, and are restricted to physiological conditions. X-Aptamers, on the other hand, are produced by chemical synthesis rather than in living systems. As a result, X-Aptamers are ambient stable, are able to operate in a much broader range of conditions and are much less expensive to produce.

CEOCFO: *Why is it that not everyone is using* X-Aptamers*?*
Mr. Shumbera: The primary reason is that they are relatively new. They are based on a technology called aptamers, which has been around since only the early 1990's when the technology was discovered. Aptamers work pretty well but do not work well enough to replace monoclonal antibodies. X-Aptamers are game-changers because they are able to incorporate combinations of chemical functional groups that enhance the interaction with a target. This is not possible with aptamers. In addition, the binding affinity of an X-Aptamer and the specificity for its target is much better than a regular aptamer.

CEOCFO: *What have you developed at AM Biotech specifically?*
Mr. Shumbera: We have developed a process by which we can discover X-Aptamers. We have a micro-bead based process that enables us to include chemical modifications that are impossible with regular aptamer technology. We have also developed a number of unique reagents that are used to synthesize nucleic acid sequences; among them are the thiophosphoramidtes, which have proven to be very versatile even in fields other than aptamers, such as siRNA.

CEOCFO: *How do you decide on a target?*
Mr. Shumbera: The target is defined by our customer. Our customer may have a particular protein that is of interest; something that they want to quantify in a blood sample, for instance, to determine whether somebody has a particular disease.

CEOCFO: *A company or researcher would come to you and say this is what they need and then you would find it?*
Mr. Shumbera: Yes, we would develop X-Aptamers to that target.

CEOCFO: ***What are the limitations to what you can develop or is it case-by-case?***
Mr. Shumbera: It is case-by-case. There are certain targets that are resistant to developing X-Aptamers as there are targets that are resistant to developing monoclonal antibodies. There are no set rules to determine beforehand which target would be resistant.

CEOCFO: ***How do you help people along so that they know to come to you?***
Mr. Shumbera: We advertise. We use Google Adwords and also send out press releases to periodicals that we think are being read by our target life science customers. We also are publishing papers in scientific journals to show that X-Aptamers perform very well.

CEOCFO: ***What are you finding is the resistance area or is it just lack of awareness?***
Mr. Shumbera: It is a combination. It is resistance to change because antibodies are widely used and people are comfortable using them. However, many people have not heard of X-Aptamers, so they do not know that the technology exists. To some extent, we need to increase the number of published peer reviewed scientific papers that focus on X-Aptamers. Those carry a lot of weight with our target customers who are primarily scientists.

CEOCFO: ***What are your plans to get more attention?***
Mr. Shumbera: We have to have more scientific performance data. The data that we are generating then has to be published in peer-reviewed journals. We also need for more of our customers to report that they have had good results with their X-Aptamers so we work with them when appropriate to publish their results.

"Cost definitely plays a role but performance is the key." - Mark Shumbera

CEOCFO: ***Do you have a method to get both of those in place?***
Mr. Shumbera: Certainly. We have several ongoing projects that are being funded by various federal granting agencies. We have received grants for developing X-Aptamers from the Bill & Melinda Gates Foundation, the National Institutes of Health, NASA, and DARPA. All of those entities see the value in having synthetic affinity reagents, like X-Aptamers to compliment and maybe replace antibodies. They understand that the scientific data is what proves that they work well.

CEOCFO: ***Are you under regulatory scrutiny?***
Mr. Shumbera: No, because the markets that we are targeting are non-regulated; they are research markets.

CEOCFO: ***What is the competitive landscape?***
Mr. Shumbera: There is competition from companies that develop conventional aptamers. The largest and most notable is SomaLogic. They are based in Colorado and are one of the original aptamer-focused companies. There are maybe fifteen to twenty small companies worldwide that develop aptamers but all of our competitors use a technology that is less capable of producing the types of chemically enhanced X-Aptamer molecules that we develop at AM Biotech. They use an older technology that is not able to incorporate as many of the chemical modifications that we are able to with our X-Aptamer technology.

CEOCFO: ***Are you able to patent your technology?***
Mr. Shumbera: We have several patents as well as a few patent applications pending worldwide. We also have trade secrets that have been developed over the years of working with our process for selecting X-Aptamers.

CEOCFO: ***Do potential customers care about the process or is it the results they want?***
Mr. Shumbera: Results matter, of course, but I think that our customers care about both. Many of our customers want to do the selection process themselves. They want to experiment with unique targets or with using their own conditions that match their intended application. Our technology enables us to package our process into a kit that enables our customers to select their own X-Aptamers. The X-Aptamers Selection Kit is a brand-new product on the market. Feedback from our initial customers is that they like the simplicity of our selection process; it is very easy to complete, which is a huge competitive advantage for us. The process our competitors use for selecting conventional aptamers is not very user-friendly at all. Our process is much more predictable, takes less time and the research community readily embraces the kit format.

CEOCFO: ***Is cost a big factor?***
Mr. Shumbera: It can be. Our X-Aptamers selection kit is by far the most economical way to select a synthetic affinity reagent. The total cost of our kit including all the processing is a little less than six thousand dollars, and that includes

developing X-Aptamers for up to three targets in parallel. That is less than two thousand dollars per target. For a frame of reference, many of our competitors are charging between $15 thousand and $25 thousand to perform a turnkey selection of an aptamer for just one customer target.

CEOCFO: ***Is it significant enough to the people using it to get a foot in the door or do all the other factors overshadow the cost?***
Mr. Shumbera: We think cost definitely plays a role but performance is the key. The performance of X-Aptamers really shines because X-Aptamers demonstrate much higher affinity to their targets and can have better specificity than regular aptamers. The cost for developing an X-Aptamer is also much less than having a monoclonal antibody developed while delivering comparable performance.

CEOCFO: ***You mentioned you had funding from a variety of places. Are you looking for partnerships and investment or are you able to use what you are receiving now to get you further along?***
Mr. Shumbera: We are still looking for investment. We have had two rounds already from the same investor, MEI Technologies, Inc. We are currently seeking more investment in order to build our infrastructure so that we can produce more kits and support their processing. We also need to ramp up our marketing efforts and speed up the development of products that are based on some of the X-Aptamers that we have already selected internally.

CEOCFO: ***How did the process develop, was it a conscious effort?***
Mr. Shumbera: It was a conscious effort to try to find a way to incorporate chemical modifications into aptamers to improve their performance. The X-Aptamer selection process was developed by Dr. David Gorenstein along with Dr. Xianbin Yang and others. Dr. Yang is our Director of Research and Development at AM Biotech and Dr. Gorenstein is currently the Deputy Director of the Institute of Molecular Medicine at the University of Texas Health Science Center in Houston. He is also our founder. .

CEOCFO: ***Why does AM Biotech standout?***
Mr. Shumbera: We offer a very unique and flexible technology that we believe makes synthetic affinity reagents a credible and compelling alternative to monoclonal antibodies.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

AM Biotechnologies, LLC

For more information visit:
www.am-biotech.com

Contact:
Mark Shumbera
832-295-1483
mark.shumbera@am-biotech.com