CEO CFO

Harbor BioSciences

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The Most Powerful Name In Corporate News and Information

With a Partner in China to Help Bring their Drugs for Obesity Diabetes and Cancer Through Clinical Trials and into Commercialization, Leaving the Rest of the World Open for More Partnerships, Harbor BioSciences, Inc. is Well Positioned for Future Growth

Healthcare
Bioscience
(HRBR-OTC: BB)

Harbor BioSciences, Inc.

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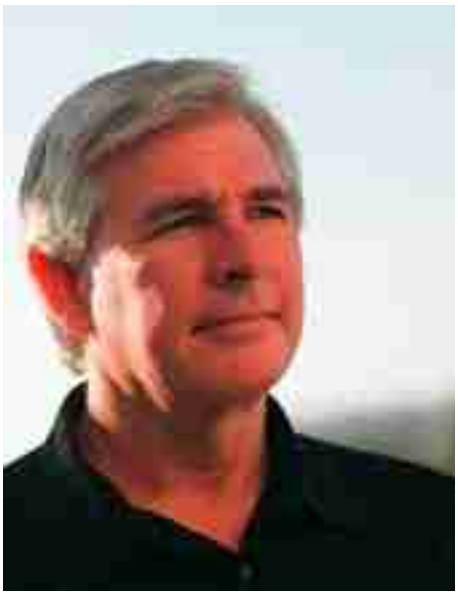

Dr. James M. Frincke Ph.D.
President, CEO and
Board of Directors

BIO:
James M. Frincke, Ph.D., was appointed President and Chief Executive Officer and elected to the company's board of directors in June 2009. He joined Harbor BioSciences as Vice President, Research and Development in 1997, was promoted to Executive Vice President in 1999, to Chief Scientific Officer in 2001, Chief Operating Officer in 2007 and was named Interim Chief Executive Officer in March 2009. Dr. Frincke joined Harbor BioSciences from Prolinx, Inc., where he served as Vice President, Therapeutics Research and Development from 1995 to 1997. During his 30 years in the biotechnology industry, Dr. Frincke has managed major development programs including drugs, biologicals, and cellular and gene therapy products aimed at the treatment of cancer, infectious diseases, autoimmune diseases, metabolic disease and organ transplantation. Since joining the biotechnology industry, Dr. Frincke has held vice president, research and development positions in top tier biotechnology companies including Hybritech/Eli Lilly and SyStemix Inc. (acquired by Novartis). In various capacities, he has been responsible for all aspects of pharmaceutical development including early stage research programs, product evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters for lead product opportunities. Dr. Frincke has authored or co-authored more than 100 scientific articles, abstracts and regulatory filings. Dr. Frincke received his B.S. in Chemistry and his Ph.D. in Chemistry from the University of California, Davis. Dr. Frincke completed his postdoctoral work at the University of California, San Diego in pharmacognosy.

Company Profile:
Harbor BioSciences is a development-stage company with two product candidates, which recently completed Phase I/IIa clinical trials: Apoptone® (HE3235) in patients with late-stage prostate cancer, and Triolex® (HE3286) in obese type 2 diabetes mellitus patients. Apoptone and Triolex represent two of the lead candidates from Harbor BioSciences' small molecule platform based on metabolites or synthetic analogs of endogenous human steroids.

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

CEOCFO: Dr. James M. Frincke, Ph.D , how has Harbor advanced under your leadership?
Dr. Frincke: I have been in this position for two years. We have pulled forward two key pharmaceutical entities directly from our platform and have demonstrated their initial safety and the initial indication of activity in two very diverse areas of clinical interest. One is actually in type II diabetes where the compound, which acts as an anti-inflammatory, is able to treat a subset of diabetics, namely the inflamed obese diabetic. The second compound is an anti-cancer agent; we have been prosecuting it in prostate cancer where we first identified its activity. It is active in hormonally driven prostate cancer. It has been in clinical trials now for about two years and we just finished the Phase IIA pieces where we expanded certain groups to understand the activity at that dose and have demonstrated its activity. The uniqueness of this compound is the mechanism of action, which is different than any other that

has been studied in prostate cancer today.

CEOCFO: How have you chosen these two areas?

Dr. Frincke: That comes from the history of the company. The company is centered on a platform which is comprised of C-19 steroids, which were overlooked when steroids were being investigated strongly in the 1960's, 1970's and in the early 1980's. We started the company based on the activity of one of these compounds in what is called host targeting. Based on early indications of activity there we were able to expand our assets by both in-licensing and patent programs. Through the years, we have gone in and what we call "mined the platform" for some of the pharmaceutical activities, which the literature indicated we should be able to retrieve based on those studies.

CEOCFO: Would you give us more detail on the prostate cancer item and what makes your approach unique?

Mr. Francke: This particular compound acts through a new cell surface receptor that then triggers a pathway that leads to apoptosis. The uniqueness here is that it does not involve either the androgen receptor or ligand binding that antagonizes androgen receptor. Prostate cancer for decades now has been treated through the androgen receptor ligand interaction pathway, which is of course the major growth-promoting pathway for prostate cancer. Our compound, which was found in a screen of a cell line called the LNCaP cell line, was extremely potent. We isolated it and found that the material through investigations here at the company actually had a mechanism that is independent of this androgen receptor cognate ligand binding pathway that everybody else has been exploiting for years.

CEOCFO: Has the medical community started to pay attention?

Dr. Frincke: They have. It has gotten the attention of the Prostate Cancer Clinical Trials Consortium, which actually participated and helped to design the initial clinical trials that helped us demonstrate the activity. Therefore, we had three notable clinical sites that participated here in identification of initial activity and safety. Those were the Memorial Sloan Kettering, which is where the PCCTC is headed up, the University of California San Francisco, and the University of Washington where the principal investigator Bruce Montgomery resides.

CEOCFO: What happens next with your technology for obese diabetes?

Dr. Frincke: There are a couple of directions. You contacted me based on our press release as it relates to our development partnership in China. The next clinical step of course is to drive the Phase II trials, which are dose selection trials. So the optimum dose found there would be taken on into a Phase III trial. It is a perfect linear process as development goes as it is currently viewed for this compound. Now having said that, the development partner is actually preparing materials for us that will be used in most trials. They are preparing it centric for their territory although we will end up with a low cost supply arrangement that will allow us then to study it in Phase II trials, for instance in this country. Therefore, we are continuing to look for development partners here in the US, Europe and other regions that are interested in these therapies, to run Phase II trials in their specific genetic populations that exist in these other areas.

Nobody has ever set up a biotechnology business that functions like this, where a development partner comes in and makes a huge investment in one region in the world, leaving the rest of the world to us enabling us to pursue our business in this fashion.

- Dr. James M. Frincke Ph.D.

CEOCFO: Many companies who enter the Chinese market find unexpected challenges; does this hold true in the medical arena?

Dr. Frincke: I have heard a number of horror stories and a number of concerns as we entered into this particular relationship. We are very excited about our relationship and I will tell you why. This particular group is actually the group that has been formed in China in order to bring generics in and develop them, then subsequently license them to businesses in China that grew their generic pharmaceutical industry, which is very robust today. This is a group that has extensive resources at their disposal and they have been at this for a long period of time. One of the reasons we were selected was not only based on our platform but this is the first foray for the Chinese government into new chemical entity development. We have extensive experience, the folks that work here and I, in new chemical entity development. As a matter of fact, that is all we have ever done our entire careers. One aspect of the relationship is that they wish to learn from us in terms of how to develop a new chemical entity. It really makes for a very nice partnership because we know how to go about developing these compounds. We have de-risked them by showing that they are both safe and have activity and now they wish to develop them for their country. I do not think we are going to run into some of the difficulties that others have described in the major industries where China is limiting their participation in ways they would otherwise wish.

CEOCFO: Why do we need something new for diabetes; there are many drugs now?

Dr. Frincke: The particular area that we are working in is insulin sensitization. I will give some background to put it into perspective for you. The metabolic syndrome that is epidemic in this country is driving an epidemic in type II diabetes. This is a new phenomena that has been described by thought leaders now for about a decade and that is that obesity actually causes insulin resistance, which if it goes unchecked ultimately leads to diabetes. So we got into this area, with the assistance of a man here at the University of California, San Diego, named Jerry Olefsky, which is an area he is particularly interested in. This insulin resistance phenomenon is actually driven by inflammation that can arise from obesity. That is to say,

when individuals generate inflammation as a result of obesity, that causes the insulin signaling pathway to become less sensitive to insulin. The end result is that you will end up with hyperglycemia that ultimately turns into the disease we call type II diabetes.

What is going on in the market revolves around a class of drugs we call the thiaglitazones, which is a class of compounds that came under study back in the 1990's that are PPAR agonists. They are anti-inflammatory in nature and they cause the reversal of the insulin resistance phenomenon that is generated in this manner. The problem with them that has been in the news now is that there is a safety issue, with Actos and Avandia. Therefore, the FDA has given them what is called a "black box warning", and one of them was actually taken off the market.

What has happened is that there is a big hole in the market place, so the community doesn't have any approved safe insulin sensitizers to fill that void. It is actually an important contribution that our compound can make to this area of type II diabetes. The biggest issue that the sponsors are facing are the regulatory barriers. At issue are the time and the dollars that it will take to satisfy the new regulations that are going into place in order to show that new compounds with new pathways do not have the same safety issues as the thiaglitazones.

CEOCFO: Where are you in that process and what is next?
Dr. Frincke: We have finished our Phase IIA studies and we have just buttoned them up. That particular program has also gone overseas to the group in China, specifically because they have an obesity-driven diabetes problem that is becoming epidemic. They are very interested in the compound and they are moving it forward in their environment where they don't have the regulatory barriers that exist here. They will be demonstrating the activity and the safety profile of the compound in diabetes. So we are staged here again to line up with a partner that would become interested in pursuing this particular pathway with a novel mechanism of action once again for purposes of satisfying the diabetes market. Having said that, as we started off, this is actually an anti-inflammatory agent and we all appreciate that anti-inflammatory agents have the potential to treat a wide variety of diseases. Here in the United States we are looking at partners to actually repurpose it and move it into areas of unmet medical need where the anti-inflammatory can be used in conditions of chronic inflammation when needed. For instance, the Michael J. Fox Foundation for Parkinson's disease has identified the compound and they were looking precisely for an anti-inflammatory to treat neural-inflammation, so we entered into an arrangement with them to explore Parkinson's disease. It gives you a sense of how and where a new anti-inflammatory can go. The pharmaceutical community has a very great need for an anti-inflammatory to be used chronically without the associated safety issues. This is one such possibility and we are very excited about it.

CEOCFO: With so many drugs being removed after some years in the market; what can Harbor do to ensure long-term safety
Dr. Frincke: When you begin one of these projects, you do not know. That is the reason for having very careful surveillance on your early safety trials. With this particular compound we have gone as far as long-term toxicology and found no safety issues at all associated with the compound. If we take in contrast the class we were just speaking to, there were safety issues that were observed and known when they were taken into the clinic. Those issues actually represent themselves as side-effects in patients with early disease. The compounds we were talking about were really never prosecuted clinically with any purpose in late-stage disease or macro-vascular disease and that is where they ran into a problem. At this stage we are bullish because we have seen no such side-effects that are associated with our compound. We have since discovered the target, although we have not publically disclosed the target, the target for this compound is unique and it has been unique and it has been of pharmaceutical interest for at least fifteen years. Now with the knowledge of what the target is, one can much more clearly understand whether there may be long-term side effects associated with chronic use.

CEOCFO: What is the timetable for the next year or so?
Dr. Frincke: The next year this company is turning into a business development company. We have secured our development partner and as we mentioned they have substantial capacity and substantial assets. One of the beauties of the agreement that we have entered into is that we have the rights to the rest of the world. We have the rights to all the data that are being produced, and we have a low cost supply arrangement that has come from them. So this group can now begin to search for its partners with the program de-risked because we don't have to raise the hundreds of millions of dollars to continue to drive it. We can go and secure individuals and regions all around the world that will be potentially interested in moving these pharmaceuticals into their populations once the approvals are found in China. That is going to be a very large project for us and we have reorganized our business plan accordingly. Therefore, we are no longer "at this stage a development" company, although we have schemes or designs to continue to access our platform technology, which is comprised of a very large number of molecules, in order to secure additional pharmaceutical activities that would be useful in other diseases. This next year we will be a business development company trying to monetize the assets that we have been working on this last decade.

CEOCFO: What is it in the background of you and your management team that will allow you to handle the commercialization?
Dr. Frincke: A number of us, I in particular, have been in the major pharmaceutical entities and participated in these teams. It is more the interface into the teams for the commercialization, so at this juncture we don't see ourselves actually being the marketers of products as they are delivered.

We see ourselves marketing the opportunity to groups that have the distribution capabilities and the capacity to commercialize these compounds in the future.

CEOCFO: What challenges do you have to be on the lookout for assuming the trials work well?
Dr. Frincke: The biggest challenge for us right now is getting information out there, although the interest is very high and it is growing rapidly. We wish to optimize the return on investment for the investor base of which some have been with us for a very long period of time, so some of the challenges are choosing your partners correctly. If we jump too fast in the wrong direction we may actually make mistakes in that regard. It is a very delicate process that you enter into at this stage of the development of the business.

CEOCFO: What is the financial picture like for Harbor BioSciences today?
Dr. Frincke: Our financial picture will take us to the later part of the year. What we will be doing is coming up with scenarios which we are working on very actively, to improve that, based on the concept that the Chinese have validated us as well as they have removed all the risk associated with investing hundreds of millions of dollars. Therefore, it turns into a very attractive business scenario. Coming back to one of the challenges; nobody has ever set up a biotechnology business that functions like this, where a development partner comes in and makes a huge investment in one region in the world, leaving the rest of the world to us enabling us to pursue our business in this fashion.

CEOCFO: Why should potential investors pick Harbor out of the crowd?
Dr. Frincke: Harbor has very unique situations in front of it right now. With our stock price where it is, it essentially is being viewed as a call option that does not expire. Right now by anyone's measure we are extremely undervalued. What we have in front of us is simply to execute as a business and given that the compounds are successful, then we are an unparalleled investment.

CEOCFO: Final thoughts, what should people remember most about Harbor BioSciences?
Dr. Frincke: There is another aspect that makes us extremely unique right now. That is, because we have really developed no relationships outside of our relationship with China, therefore, both our intellectual property and our business are completely unencumbered, and it makes us a pure play for China. So as you indicated at the beginning of our interview that groups are trying to find ways to get in and work in a productive way with the Chinese and in the world of healthcare, we are that pure play. We speak of this group, CIPI (China State Institute of Pharmaceutical Industry), which has become the research and development component of Sinopharm, which is the largest pharmaceutical entity in China, so it comes with a potentially substantial influence as we begin to develop our relationship with them and we move into the actual operation and development phases of our project.

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