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Strategic Planning, Business and Drug Development Services for the Pharmaceutical Industry

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About Anixis Biomedical Consulting
ANIXIS Biomedical Consulting provides strategic planning, business and drug development services to the pharmaceutical industry by helping clients to put science on a regulatory track rapidly and optimizing product development in terms of time and cost in a flexible non-brick and mortar model environment.

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

CEOCFO: *Dr. Loullis, what is the concept for Anixis Biomedical Consulting?*
Dr. Loullis: In the big picture, Anixis wants to provide biotech companies primarily, but all companies and research institutions involved in drug development, help to generate scientifically reliable information and business information that can lead to business decisions, which will increase the value of their products. That is in fact what every company is looking for because the goal is to make decisions based on the best quality of the data and information in order to increase the probability of success. Sometimes we use that information for internal purposes to see how we might want to make a decision just for the company, or we may want to use it on the outside for regulatory purposes, business development purposes and so on. The other aspect of the organization which I think is one that is worth mentioning is that we, instead of having brick and mortar in terms of offices and all of the usual things that we see with consulting and CRO companies, we maintain a very flexible model. This is also our advice in fact to biotech companies for their organizations. We follow our own advice to them, and we bring together different experts and capabilities to the table depending on what the client needs. This provides flexibility both for the client and for us, and it allows for considerable savings as well as agility.

CEOCFO: *What types of companies tend to come to you for services?*
Dr. Loullis: Primarily the companies are biotech companies because that is where the need for the expertise is. Many of the large pharmaceutical companies will need help from time to time, but it is on a different basis and more rare at least for our work. Also, smaller clinical research organization where we have relationships and we help them do their protocols or oversee their clinical trials or even when they are involved in some product development to help them do that.

CEOCFO: *What is the current atmosphere?*
Dr. Loullis: There is a tremendous amount of confusion and apprehension. I think it is beginning to change a little bit, but we still have a long way to go. I am not even going to address the economic difficulties in the United States as a whole. I can talk a little bit about what I understand best and that is drug development. I think that what we have seen over the years and very few people will argue with this although there may be differences in where we are going and where we will end up, big pharmaceutical companies have seen a decrease in their returns from their R&D. As a result, they reacted initially through a cycle of mergers and acquisitions that resulted in synergies and cost cutting that lasted for quite a while. In terms of the bottom line, stock etc., it looked good but it was not productive in the sense that it did not really result in new drugs, which was the purpose in the first place. As a result, big Pharma has decreased their R&D capabilities and is increasingly relying on outside sources to feed their pipeline. There were a number of avenues that are now beginning to be exhausted to achieve this. The first one was to pick up an existing phase 2 drug – a drug that had at least some phase 2 data or preferably had a proof of principle trial that made it attractive; to pick it up and then put their engine to work, which is what they are good at; to run the program beyond that to phase three, approval and so on through the regulatory system. That has more or less dried up. There are some instances here and there, but there is not an awful lot of that available. Reformulations of existing products and clever repositioning of products has also helped, but it is just really not enough. What we are left with is then an increased dependence of the large pharmaceutical companies on biotechnology companies and on university and research institutions to be able to supply their pipelines. That is where we are right now. That is where the pharmaceutical companies are. They are trying to explore and generate models addressing how they

can support these processes, how they can nurture them and how they can create useful and productive relationships. I can give you more information and more examples, but that is where we are, and it is a very difficult time. In terms of the biotech companies, that certainly reflects on what we do. It means that biotech companies have to be more attractive in terms of how they develop their products. They have to be much focused and they have to use the expensive capital that they raise very wisely. I think our approach of wanting to make sure that products or inventions are put on the regulatory path very quickly, so their focus is on where these products are going to go and what the determinants and studies are that will make them move forward in the approval process. If they do not survive a next step stress test, the existing resources should go to something else. Traditionally, companies have been afraid to kill their products. We think that is a mistake because you are wasting money and effort that can be best utilized toward a more deserving product.

CEOCFO: ***What is the key to working with a company where you are working with the person who has developed the drug. How do you break it to them gently that it is not going to work?***
Dr. Loullis: It is very difficult. I think there are a couple ways. I think this is not something you can really walk in and do. If you provide that information abruptly, then all the communication channels will shut down. It is something that you build with a relationship that has trust and understanding that the data and information that you have will drive the decisions. It is extremely important to have that relationship and in many cases, one just will not be successful without it. All one can do and say is: this is why we think you are better off going to another invention that you have or another product. In many cases, I think that it works. It really in the end is a matter of trusting that somebody is giving you reliable information. The best way that I know how to do this is to convince people that we are working on a model where the data are going to drive their decisions. There is of course business considerations that must drive decisions on pursuing something or not, but at the very base of it, you have to have reliable information about the science first.

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CEOCFO: ***When making an assessment, how do you balance the data and the gut feeling that may tell you something different?***
Dr. Loullis: I look at it a little differently. I look at it in terms of a focused effort to get a product through the regulatory system in the United States and/or in another country. Largely, the regulatory system is what we are all working with. We need to plan execute and provide the required data, and negotiate the process with the regulatory agencies. That is certainly part of what we offer, satisfying those requirements. Keeping that in mind is the key to being able to progress in a focused way. When companies try to pursue a number of different directions for a product, most of the time, it ends up in failure because there are not enough resources, particularly in small companies, to be able to pursue all of those.

CEOCFO: ***Are there particular projects you like to work on or particular areas?***
Dr. Loullis: I can give you some examples. That is the fun of doing consulting. You can be involved in a client wanting to get a clinical protocol written and perhaps oversee the clinical trial or getting involved in providing a business plan and strategy for a particular venture. I will give you an exciting example of that. A while back a colleague and I were invited by an Alaskan company to put together for them a strategy, a program and to execute some initial steps as a proof of principle for a project. The premise was, given the severe and extreme climatic conditions in Alaska, could we find in the vegetation and in some of the animal life there compounds that would be unique in addressing a number of different disease states with unmet needs. The assumption was because of the extreme pressure on these organisms, it would be entirely possible that something like that would occur and that some compounds that we had not seen before would have been generated. We started with this premise and we spend a good two years carrying out both the strategy as well as the execution of collecting specimens, talking to indigenous people and looking at how they use plants in their traditional medicine. It was really quite a wonderful experience and in the end we actually ended up not only with a business plan for them but also a proof of principle that gave us some further directions in what some of these extracted compounds could potentially do in biological systems. This process represents the first step in drug development parenthetically and demonstrates that novelty is very much treasured in the pharmaceutical industry.

CEOCFO: ***How is business currently?***
Dr. Loullis: It is not bad now. The whole area went through a difficult time over the last few of years, as you can imagine. A situation where the small biotech companies suffered from lack of capital as investors were sitting on the sidelines and trying to figure out what would happen with the economy. Things have picked up and I think it is very helpful for all the participants in the drug development process. I hope we are slowly getting out of the woods. I do not think we are there yet, but I think we are heading in the right direction.

CEOCFO: ***How do potential clients reach you? Do you do outreach as well?***
Dr. Loullis: I have a website of course but word of mouth is one of the major ways that we meet clients. Usually somebody will recommend our work from somebody who has had experience with it and we go from there. We do get projects from the various listings of companies on biotech directories etc.

CEOCFO: ***Put it together for our readers. Why pay attention to Anixis Biomedical Consulting?***
Dr. Loullis: I think the model that we have is a very attractive one and a timely one. I think that apart from the skills that we bring to the table both in terms of drug development, the breadth of that, and the understanding of the regulatory system and so on, this particular model is very useful, although I do not see many doing that. I see a great deal of brick and mortar and one could argue waste. I hate to say that, because maybe it is not for those organizations, but when I see it from my perspective and my clients' perspective, I want to provide them with what they need. Some companies have no staff at all and therefore they would need a tremendous amount of support. Some of them have quite a number of people and anywhere in between. My purpose is to try to provide them with only what they need and allow them to develop more products for the same money.

BIO: Dr. Loullis after baptism by fire in several large pharmaceutical and biotechnology settings is now the founder and CEO of Anixis Biomedical Consulting. He firmly believes that putting promising science on a regulatory track as quickly as possible and streamlining drug development in terms of time and cost holds the best promise for badly needed new and game changing medical treatments. He has served as a company officer and a key member of a number of executive management teams, where he headed R&D and was fully engaged in strategic planning, operations, fund raising and business development as well as budget generation and oversight.

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