CEO CFO

ImQuest BioSciences

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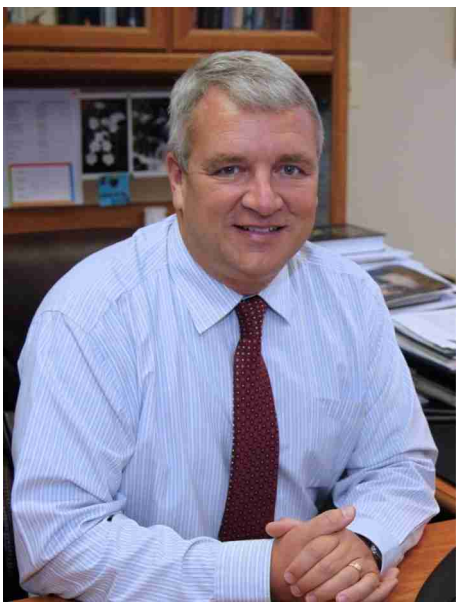
Providing a Highly Customized Professional and Consultative Approach to their Preclinical Research and Development Services, ImQuest BioSciences is Helping Clients Develop Small Molecule, Biologic and Vaccine Products for Infectious Disease and Cancer in an Expedited and Cost-Effective Manner

Healthcare
Preclinical Research
(Private)

ImQuest BioSciences

7340 Executive Way, Suite R
Frederick, Maryland 21704
Phone: 301-696-0274
www.imquestbio.com



Robert W. Buckheit, Jr., Ph.D.
Founder, President, CEO
and Director

BIO:
Dr. Buckheit is a well-respected and internationally recognized virologist with over 20 years of experience in the research and development of therapies for AIDS, infectious diseases, and cancer. His experiences include HIV drug development, immunology, retrovirology, molecular biology and antiviral and anti-cancer assay development. Educated and trained at Duke University and The University of North Carolina at Chapel Hill, Dr. Buckheit's career has focused on the development of anti-infective agents to prevent the transmission and spread of infectious disease, including evaluation of efficacy and toxicity, range and mechanism of anti-infective action, anti-infective resistance, anti-infective combination therapy and animal model development. Dr. Buckheit is well-versed in the use of both cell based and molecular/biochemical assays as components of drug development algorithms and has participated in the development of dozens of compounds which have progressed to IND submission and human clinical testing. Dr. Buckheit has developed and managed anti-infective and anti-cancer drug development programs in the CRO sector for the bulk of his career, including the development of drugs for the therapy of HIV, hepatitis B & C, herpes simplex virus, respiratory and enteric viruses, bacterial and fungal pathogens and bio-defense related organisms. At ImQuest, Dr. Buckheit has been awarded over $30 million in research grants from the National Institutes of Health, including a variety of Phase 1 and 2 Small Business Innovative Research Awards. Dr. Buckheit sits on the Editorial Boards of the journals Antiviral Research and Expert Opinion on Investigational Drugs and is an ad hoc reviewer for the Journal of Virology and Antimicrobial Agents and Chemotherapy as well as numerous other journals. Dr. Buckheit is also an active member of the International Society for Antiviral Research and was recently elected by the membership to the position of President-Elect after serving five years as Chair of the Program Committee for the annual conference of the Society (ICAR). Dr. Buckheit has authored over 150 papers in the peer reviewed literature and regularly presents laboratory data at a variety of international scientific meetings. Dr. Buckheit founded ImQuest BioSciences in 2004 and has acted as the Chief Scientific and Executive official of the company since its inception.

Company Profile:
ImQuest BioSciences aims to be the leading international provider of preclinical research and development services for small molecule, biologic, and vaccine products for the treatment and prevention of infectious disease and cancer.

Utilizing our expert and highly experienced technical and professional staff and service offerings, ImQuest develops viable solutions to our client's drug development problems, resulting in the expedited and cost-effective development of novel new agents for human disease.

ImQuest recognizes that every product and every client is unique. We are committed to providing responsive, professional, and collaborative services to our clients in a highly customized and consultative fashion. Our goal is to develop productive, long term relationships which result in the successful discovery and development of products which improve the lives of people throughout the world.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Buckheit, what is the vision for ImQuest Biosciences?

Dr. Buckheit: Primarily, ImQuest Biosciences is a highly successful and profitable contract research organization. We provide fee for services with a focus in the infectious disease and cancer areas. We provide all product development support to allow our clients, the pharmaceutical companies, biotechnology, academic labs or even NIH or federal labs, to complete their lead selection and advance their products to human clinical trials through submission of an IND to the FDA for clinical evaluation of a compound. In addition, we have formed our own pharmaceutical company to develop novel prevention and therapeutic products. Our pharmaceutical company originally started off as a value-added CRO service but has now become a significant part of what we do. We look at partnering with our clients or in-licensing compounds from our clients and working with them to develop highly novel and potent compounds for targets that we are interested in at ImQuest such as HIV, hepatitis, and respiratory viruses. So, we essentially have a mixed business model where we are using highly profitable service oriented operations to provide R&D level support to our clients, but at the same time, we are looking at products where we can also participate in the clinical development and essentially share in the rewards down stream of having a successful product be introduced to human use.

CEOCFO: When you are evaluating a project to take on where you are going to be partnering, how much is the science and how much is gut instinct?

Dr. Buckheit: We have a development platform, which we refer to as the ImQuestSUCCESS platform, and there are three components to it. One includes evaluation of the efficacy of potential molecules. Second is their safety and we examine both in vitro and ex vivo toxicity. Then there is the third important area of pharmaceutical properties where our main interest is actually in the ability of the compound to be formulated and delivered. Specifically, we are looking at preformulation and formulation characteristics of the potential drug candidate and trying to define if this product could actually be delivered at an effective concentration in humans. When we look at the data from those three areas, we believe that we can at least predict compounds which may fail during their clinical development. There are certain safety or efficacy signals that we look at. If the compound passes all those hurdles, and we believe it has an excellent chance of success in the clinic, the next thing we would look at is novelty. For example, we are not in business to develop another HIV protease inhibitor or an integrase inhibitor. We are looking for novel targets that would expand the therapeutic choices for infected patients. After we get through the ImQuestSUCCESS platform, we believe we have reduced the risk that a compound is going to fail during clinical trials. At the final step, we would look for novelty and that would be how we would choose our products moving forward.

We want to provide a highly customized professional and consultative approach to our services that will distinguish us from our competitors and will essentially make us a member of our clients' product development team. We strive hard with communication and the building of relationships. Our clients believe that we know what we are doing, we have the necessary expertise, and they want to work with us. We have a tremendous number of clients that are repeat customers which we have been working with in some cases for over a decade. - Robert W. Buckheit, Jr., Ph.D.

CEOCFO: Your website mentions unique molecules and unique clients, what is unique about who you are working with and what you are doing?

Dr. Buckheit: The point we are trying to get across as a contract research service provider is that clients and projects are not identical so we do not employ a cookie-cutter approach to our services. We will engage a new client in a conversation so that we understand what their product does, what problems they have been facing, and what hurdles they have left to jump, to provide a view of the successful possibilities for the compound. We will fine-tune our proposals to them to specifically address what they hope their compound will do. Essentially every client brings us a product to test and each one of those products is unique. We never have a project which follows the exact same development pathway, it is all very customizable, flexible and fine-tuned both to clients and their needs as well as the product that we are trying to evaluate.

CEOFO: CRO is certainly a crowded field; why are your clients coming to you and how do you reach more potential clients?

Dr. Buckheit: We strongly believe and specifically discuss the concept in all of our strategic planning, that expertise is the critical issue. Anyone that wants to use a service provider is going to want to make sure that the service provider has the capability and the expertise to get the job done quickly and efficiently, which I believe is somewhat different from other contract research service providers. Many of our clients are essentially looking for an extension of their own R&D laboratories and capabilities. They are looking for someone that can fill the role of a CSO and a group that can add to their R&D capabilities as an extension of their laboratories. When I say we are not a cookie-cutter approach company, we are also not a cafeteria plan where we just throw a bunch of choices at our clients and tell them to choose what they want to do and we will just write them a quote. We like to work with our clients to understand what they are doing and to provide them with a consultative and professional approach for how we think their development program should be developed and run. On the back end, we are not going to just give them data and tell them good luck, we prefer to be engaged in a relationship where

we can explain what the data mean and offer suggestions on what to do next, and inform them of what the FDA will be looking at when they evaluate the data. At ImQuest, we want to provide a highly customized professional and consultative approach to our services that will distinguish us from our competitors and will essentially make us a member of our clients' product development team. We strive hard with communication and the building of relationships. Our clients believe that we know what we are doing, we have the necessary expertise, and they want to work with us. We have a tremendous number of clients that are repeat customers which we have been working with in some cases for over a decade.

CEOCFO: How do you get around the fact that many creators of drugs have a different idea going forward than what your expertise brings to the table?

Dr. Buckheit: We deal with that all the time. These companies have raised money and invested a great deal in their product. I look at it as my job to essentially kill their compounds as fast as I can - if the product is not going to make it why spend all their money on it - they should be out looking for other alternative compounds or other ways of developing this particular molecule. And if I can't kill it through evaluation in our ImQuestSUCCESS platform, then the compound has a real chance of being successfully developed through human trials. We sometimes have very frank discussions with our clients who sometimes do not agree with us and want to continue down the development path. I believe it is important to be honest with them and tell them where the problems are so they can be dealt with. Sometimes the problems are not insurmountable. It is just a matter of perhaps changing the formulation or changing the targets. We would work together with them to help them realize their dream. We are always going to point out that these are issues that need to be dealt with and engage them in a good honest discussion. Obviously most of the time they know a little bit more than we know about what their products are, so we learn plenty from this relationship also. We just give our best consultative, scientific, and professional advice. Some have problems with it, we have had clients at times that have decided to move their business elsewhere but that is very rare and few and far between.

CEOCFO: You commented earlier about hepatitis and HIV, why are those areas a focus?

Dr. Buckheit: The entire company evolved out of my HIV training and background through the last twenty years. I was trained as an HIV virologist at the time that HIV was rising to the forefront as an issue. Historically, many HIV research projects have been done here. We have about one hundred and fifty papers on my curriculum vitae that are related to HIV drug development. As the antiviral field has evolved, many investigators that were initially working in the HIV area shifted from HIV to HCV as the HIV field became crowded and more and more compounds were approved for use. Now there are many compounds that are in the clinic for HCV and we are seeing many of those same clients that are now looking at hepatitis B virus or influenza virus. As the clinical development accelerates and many compounds get into development, academic investigators in biotech start looking for the initiatives that they can work in which will get them bigger and better opportunities. We have followed that same progression from a preclinical perspective. HIV and HCV were untreatable diseases at first and now they are highly treatable, many compounds are available for therapy, and attention focuses elsewhere as money becomes available from the NIH and from venture capital and other sources. Our program is very diverse. We have programs involving HIV and retroviruses, hepatitis C and hepatitis B, and other flaviviruses like Dengue virus and Yellow fever. We also have programs involving respiratory viruses like influenza A and B, as well as Respiratory Syncytial Virus. We have a very large program looking at the prevention of sexually transmitted infections involving HIV, herpes, sexually transmitted bacteria and fungi. Our capabilities span a diverse set of capabilities. We find our clients are interested in an HIV program but also interested in influenza or herpes viruses so we can work with our clients in multiple areas.

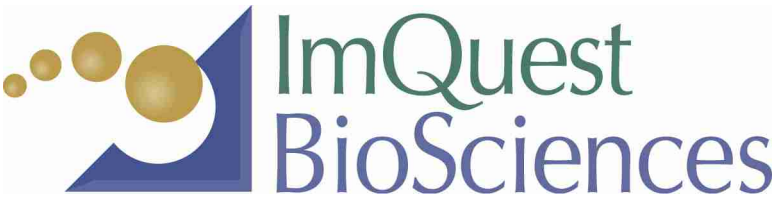
CEOCFO: How is business these days?

Dr. Buckheit: Our business is booming. The company formed in 2004 and with the economic meltdown that occurred in 2008, we were a little frightened by the whole possibility of being in business for ourselves. We found that outsourcing has picked up quite a bit as the economy has struggled. We have been very stable thanks to a large part of our success in generating funding from the NIH through small business grants and other larger program project grants. We have been growing. For the last three or four years, we have gone from twelve people to eighteen - soon to be twenty - staff members. We have gone from a 4000 square foot facility to a nearly 12000 square foot facility. Business has been good in our particular area.

CEOCFO: Why should investors pay attention to ImQuest?

Dr. Buckheit: I think they should be paying attention to us because we have some very unique molecules that are getting ready to enter human clinical trials. Our funding is from angel investors and from profits from our CRO operations and we have been able to parlay those dollars into topical microbicide products for HIV that will be entering clinical trials next year. We are well along the way of looking at the development of a transdermal patch for HIV therapeutic drug delivery that, if successful, will tend to revolutionize therapeutic drug delivery. This is because rather than taking a pill daily, we can load a patch with enough drug that we could essentially have a once per week dosing schedule, which would make it much more convenient for the individuals infected with different viruses. The patch is very discreet, you can put it under your clothing and no one knows that you are on an anti-retroviral or anti-herpes drug. We have many other products that are at an earlier stage of development and we are looking at opportunities where we can spin off other companies from ImQuest or maintain some of the intel-

lectual property in-house to develop a new product. We have been very successful in the NIH grant world with the acquisition of small business grants and other grants surrounding these products, which we believe gives us a vote of confidence from review groups regarding the potential of these products to be successfully developed. The fact that we have a profitable CRO that is generating a good return on investment and we have the opportunity of selling products or spinning off other companies over the next several years, we believe it would be a great investment opportunity for individuals that are interested in companies that have more than one chance of success. Many biotech companies are really investing in one product, and if that product fails, they are kind of lost. In our hands, we are looking at only developing up to the IND or the Phase I studies and then selling the product, we do not want to pursue this into very expensive Phase III studies. That is not where our expertise is. An investor will have multiple chances of success, so the return on investment may be smaller for each product, but if we can do it three, four, up to ten or twenty times, over time investors in our company would actually have a great opportunity to see return on a multitude of products. That is what distinguishes us from your typical biotech company.



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