

A Drug Discovery Services Company, BioSeek Applies Human Primary Cell Assays and Predictive Disease Models to the Discovery and Development of Human Therapeutics and Safer Chemicals for Pharmaceutical Companies and Government

**Healthcare
High Throughput
Biological-Systems**

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**Dr. Ellen L. Berg
General Manager**

BIO: Ellen Berg was a cofounder of BioSeek and served as its Chief Scientific Officer. She is now General Manager and Scientific Director, BioSeek, a division of DiscoverX after the acquisition of BioSeek in 2012. Dr. Berg has more than 20 years of research experience in pathophysiologic mechanisms of inflammation and immunity. Her expertise in complex cell-based biological assays led to the development of the company's proprietary BioMAP® technology for drug characterization and chemical safety testing using primary human cell systems. Prior to founding BioSeek, Inc., Dr. Berg was at Protein Design Labs, Inc. where she was involved in the

discovery and development of therapeutic antibodies for treatment of inflammatory diseases. Dr. Berg holds a Ph.D. from Northwestern University and was a postdoctoral fellow at Stanford University where she was supported by fellowships from the American Cancer Society, the Stanford Cancer Biology Program, and the Leukemia Society of America. Dr. Berg holds a number of patents in the fields of inflammation biology and cell adhesion, and has over 70 publications in peer-reviewed journals.

About BioSeek, Inc.:

BioSeek is a drug discovery services company that applies human primary cell assays and predictive disease models to the discovery and development of human therapeutics and safer chemicals.

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

CEOCFO: Dr. Berg, what is the basic concept at BioSeek, Inc.?

Dr. Berg: At BioSeek, we offer a service to pharmaceutical companies, government, and people interested in chemical safety for testing their materials for likelihood to be active in people, whether it is for drug efficacy, chemical safety, or effects of nanomaterials. We have built, over the last 14 years, a suite of assays using primary human cells. These are the real deal and not artificial, and we have constructed them into models of disease and tissue biology. To cover an area of biology, we have particular systems and panels of systems that are designed to model that disease and tissue biology. By testing

compounds across the panel, one develops signatures that are more predictive of effects in people. It is very difficult when we have a compound, chemical, or drug from the get go to be able to predict that it is going to be active in people. That is what our platform does and we do services, work with biotech companies, pharmaceutical companies, small and large, startups, as well as the US government to do screening and testing for them. We are hopefully improving the drug approval process, the ability of a compound to become approved, reduce the risk, and make it a faster process.

CEOCFO: Why do these various entities want to use BioSeek and the BioSeek method as opposed to your competitors?

Dr. Berg: It is better, faster, and cheaper. What our customers and clients are looking for is more predictive methods that are faster and more economical. When one compares us to what our competitors offer, there are many profiling technologies. You can also use animal models to try to predict effects in people but we know how well that has been working and there are limitations. Animals do not get the same types of diseases that people get and live a much shorter life span. People come to us because we have the broadest panels of primary human cell-based assays and certainly the most predictive. We are a service company and our technology is available to any researcher.

CEOCFO: Why would anybody want to use an animal if they can have real human cells?

Dr. Berg: The reason for that is historical. Animal data is what people had access to before so they have a lot of legacy data. If that is all you have, that is what you use. Animal models have been around for many years and this is especially true in toxicology where the FDA requires certain animal tests to be done before going into people. They are trying to reduce the risk of harm to humans. Using animal models can reduce some of the risk but obviously not all of the risk or we would not have so many compounds failing in the clinic for toxicity.

CEO CFO: How do you reach prospective customers to help them understand what you have and why they should be paying attention?

Dr. Berg: In the early days, we certainly took a science first approach and did our own validation studies. We also worked with academic collaborators to really test our system, to work out the kinks, and to make sure that it was really useful. For a science first approach, you go to conferences to present your work and receive feedback and then you participate in face-to-face meetings to talk to people about what we do. People were interested in what we were doing because everyone had experienced the problems and difficulty in translational biology that is translating data from a test tube into people. They were looking for solutions so they were certainly very interested in hearing about something new and different. Our approach was a face-to-face discussion of the problem and then designing the right solution based on what we had. Today, people know about us more so word of mouth is hugely important for us. We have a lot of very happy customers who will tell their friends and their colleagues about us. We are working on making what we do more flexible and accessible to everyone, not just pharmaceutical companies and larger companies but also smaller groups and academics.

CEO CFO: BioSeek works in several different areas. Do people in the drug sector care that you are not primarily a drug company?

Dr. Berg: I think it encourages them- especially for our pharmaceutical clients- because usually in a pharmaceutical company we are working with project teams who are experts in their particular area of disease biology or target. They know everything about that disease area and target but it is what they do not know that they realize they need to bring in from the outside. Our clients might have an idea that their compound is very important for immunology or inflammation but they would not know where to look to determine that their compound is going to cause a skin rash or some other side effect or actually might be useful in another therapeutic area. They are looking for help in broadly

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characterizing their compounds in areas where they do not have expertise, and so like the idea that we have built up a broad expertise in many areas that actually helps them. Our clients do not want to spend the money to try and become an expert in things that they are not really focused on.

CEO CFO: How is business these days?

Dr. Berg: Business is going very well. We have certainly increased the number of customers that we are working with and we are very excited about the future. We are now a division of DiscoverX; we were acquired last year and it has gone really well.

CEO CFO: Now that the company have been acquired what has changed?

Dr. Berg: It has helped quite a bit. Our parent company is also a service company in drug discovery so they have a lot of additional contacts for us. The platforms that DiscoverX built

the company on are target based whereas we are a phenotypic platform. There is a difference between a target-based drug discovery, where we really know the mechanism that the drug is against, and phenotypic drug discovery, that has biology endpoints. These are very compatible approaches and they are best when they are used together. It has been very good for us to be a part of a larger team, although we still have the same group of people at the same location and we are still working as we did before but there is the extra benefit of a bigger sales team and a group of scientists who are experts in target biology.

CEO CFO: What is your geographic range?

Dr. Berg: We work coast to coast Asia to Europe. It is global.

CEO CFO: Do you see any differences in some of the regulatory issues and some of the changes in government? Does it affect what you do or is it too far at the other end to make a difference?

Dr. Berg: I think it does. What is interesting is that it takes a long time for those regulatory changes to percolate down to the level that we are within the drug discovery process. I have seen a huge impact on early toxicity testing. There is a very big push for trying to understand potential side effects of drugs and lead candidates at the very early stage. It just gets too expensive to do triaging in animal testing and in Phase 1, 2 or 3 clinical trials after millions of dollars have been spent. Our customers are very interested, and have put into place processes to bring in in vitro screens earlier into the discovery process. There are two drivers: there are regulatory guidelines from the government and in pharmaceutical companies, there is the cost. Anything to bring down the cost of drug failures is going to be impactful.

CEO CFO: As cofounder of BioSeek, what has surprised you as the company has grown and developed?

Dr. Berg: How hard it is to start a company and to build it on a technology. I wish I could have spent

more time on the science and less on all of the other activities. You really need a team and knew that at the beginning. I really loved the startup team that we began with at BioSeek and that is critical. Even if you think that your platform works and it is commercially successful, the challenge is never over. There is always another challenge.

CEOCFO: Why should people in the business and investment community pay attention to BioSeek, Inc.?

Dr. Berg: I think that there are many companies who have the same intention that we have but we are

trying to revolutionize how the process of drug discovery works. In the future, we will see much more in vitro data and much more data-driven decision making in early discovery on very large data sets. We have seen this already with the “omics” data sets that people are familiar with in academics mostly and we will see the use of very smart assays and in vitro data driving drug discovery in the future. We are also seeing less and less reliance on and limitations to animal studies before clinical studies.

CEOCFO: Do you have any final thoughts?

Dr. Berg: One thing that has been happening in the pharmaceutical industry over the last ten years has been a big push to turn drug discovery into a lean six sigma driven cookiecutter process. People believed that if they could just get the process right we could automate the entire thing. The reality is that most drugs are discovered serendipitously and they get to the clinic because there is one person or a small team behind the drug and they do not give up. Our current atmosphere of funding does not find and support those small teams. You really do not need a billion dollars to find a drug.

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