

A Clinical Trials Partner for Central and Eastern Europe, August Research is a Regional CRO Designed to Meet the Needs of Small and Medium Sized Biopharmaceutical Companies with a Focus on High Quality and Cost Efficiencies

Healthcare CRO

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Dana Leff Niedzielska
CEO

BIO: From 2000-2009, she served as Chief Executive Officer for AbCRO, Inc., a niche contract research organization she co-founded which operated in Bulgaria, Romania, Croatia, Serbia, Poland, Russia and Ukraine before it was purchased by PPD in 2009. At the time of acquisition, AbCRO had over 230 employees. From 2009-2011, Dana served as an Executive Director, Clinical Operations at PPD. Dana also founded Sofia Bio (www.sofiabio.com), a customized tissue procurement company which operates in Bulgaria and Poland.

Dana has a B.S. from Cornell University and an MBA from The Darden School at the University of Virginia.

About August Research:

August Research is your clinical trials partner for Central and Eastern Europe. August Research is a regional CRO designed to meet the needs of small and medium sized biopharmaceutical companies. We are operationally oriented on providing all in-country clinical trial services with a focus on high quality and cost efficiencies.

August Research is an American-owned CRO with operations in Bulgaria, Romania, Poland and Croatia, and plans for further expansion in the CEE region. The company was founded by Dana Leff Niedzielska and Lukasz Niedzielski who previously owned/managed AbCRO, Inc., a CRO which was acquired by a global CRO in April 2009.

Interview conducted by: Lynn Fosse, Senior Editor

CEOCFO: Ms. Niedzielska, you have a long history in the industry. Why are you doing August Research now?

Ms. Niedzielska: I previously ran a CRO in the same region and a small company. I ran that company for nine years. It was acquired by a large global CRO and I worked for that company for a few years. I realized that there is really still a demand for services and for service providers who can be small, flexible and very responsive to clients' needs, and that is why I decided to start a new company in the same area.

CEOCFO: What is an example of what you might be able to? because of that personal touch which other companies of your size do not provide?

Ms. Niedzielska: We are a bit unique in that we are an American owned company. I am the CEO and one of the owners but all of our operations are in central and eastern Europe. We really combine what we think is the best combination of western style American understanding of customer service and customers' expectations, with the local expertise needed to run clinical trials well in central and eastern Europe. English is not necessarily widely spoken in this region and you need to have local connections and knowledge to work efficiently.

CEOCFO: Why are eastern and central Europe good places to run trials?

Ms. Niedzielska: In our opinion it is the most efficient region in the world for running clinical trials. The basis for that is the historical nature of the region, in that it was all part of the soviet system previously. What you have left from that, despite the countries are pretty much all democratic now, is you have a leftover medical system which is a very centralized healthcare system. So unlike in the US where every city may have a hospital where patients with cancer are being treated, in our region we have much larger treatment centers that are regionally divided. Patients are routed into these larger treatment centers. From a clinical trial perspective it is much easier and faster to identify sights and patients

who might be eligible for a trial. The patient enrollment is much faster and in general the biggest cause of delays and additional costs with clinical trials is that you cannot get the enrollment done on time. For us, eastern and central Europe gives you the best chance to enroll the trials on time. We have healthcare systems which are inferior to US or western European standard of care so clinical trials in many cases are offering the best treatment options for patients. From a patient perspective going into a clinical trial is quite attractive. The public sector in our region generally is not wealthy. These are countries which are on average 20% to 50% poorer than Western Europe, so doctors are not well paid and for them clinical trials is a really great way to supplement their income while participating in cutting-edge research. We have a great deal of motivation from the investigator side as well. In some cases, that is missing in other parts of Europe than Western Europe. You have less investigative motivation to participate in trials in general. A combination of being able to identify patients, having factors which motivate patients to join clinical trials and having doctors who are motivated to participate in trials, really combine to give you a good base for running efficient in trials.

CEOFCO: Is there a risk they will not be as objective?

Ms. Niedzielska: Our job is to ensure the quality, and while we have investigators who are interested in trials, they are interested in repeat work as well. They know they need to perform properly in the clinical trials. Investigators are not paid by their results, rather they are paid for clean data. Interfering or engaging in any type of fraud really with proper monitoring becomes evident quite quickly and it disqualifies investigators from future research. Giving the results that people want is not actually helping the client or helping the investigator long-term.

CEOFCO: Do the cultural differences other than language matter?

Ms. Niedzielska: For us, our staff is very important because they are the bridge. They all work in the country where they are from so they all speak the local language. We have been working in these countries for a long time so we have a reputation and we have connections. We know who has the right hospitals and doctors to work with. At the same time our staff is fluent in English and they are all speaking directly with our clients. They are able to meet the demands on both sides. They are able to work within their own culture and they are still understanding what kind of questions and answers our clients are expecting. That is important because going back to what I said earlier about what makes us unique, is there are

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- Dana Leff Niedzielska

many companies that know how to run trials in their country but because they cannot relate to what the Americans are thinking about, what is going on in their country, they end up with miscommunications. For example, in Europe oftentimes people have long holidays in the summer and in many cases in America we are not used to that, so the expectation is that there is work that should be continuing. When things slow down, our job is to inform clients ahead of time and let them know a few months ahead that the summer is coming and enrollment might slow down. Or, summer is coming and we will not be able to get the approval in July or August and we cannot assume that the clients know that because they are not from that country. Many times there is miscommunication and people say

well of course we cannot do this it is the summer and that is not what an American client wants to hear. We need to anticipate what the expectations and the cultural differences are between the countries so that nobody has unpleasant surprises.

CEOFCO: Your website mentions office space staff. Will you explain the importance there?

Ms. Niedzielska: For us we want to provide the best services we can for our clients. One of the ways that we do that is by having motivated staff that are committed to the company and by providing real career and development potential for the staff. For us it is important that we work together and see people and people have managers and mentors that can develop their skills. Having a home-based work force is like having freelancers. People work independently and do not necessarily feel like they are part of a team and they do not really have a lot of loyalty to their company. One of the big problems in CROs is a very high rate of turnover of staff. In some large companies it is just considered the cost of doing business. As a smaller company, we do not want to bear that cost

and we would prefer to invest in our staff and keep them happy and motivated and understanding what the company is doing rather than just churn through people and spend a great deal of time and money on recruitment. For us it is important that we work together as a team. While things are growing, because clinical research has been done in Eastern Europe for almost twenty years now, we are still in the general lower level of experience within the clinical research industry compared to Western Europe or the US. Where you might have people who have been monitoring trials for twenty years in the US, and they can do the job completely on their own, generally that is not the case for us.

CEO CFO: How do you attract business?

Ms. Niedzielska: We rely on repeat business. This goes back to our aims in terms of quality and customer service that we provide. We participate in a number of industry conferences where we have a chance to meet new clients and meet up with our existing clients. We also have dedicated business resources in the US who follow-up on leads and people that we meet at different conferences. So, it is a combination of direct targeting of people and companies in our industry as well as trying to have some profile and participation in some of the main industry events.

CEO CFO: Are there any particular types of trials or diseases that you prefer to work on or does it matter?

Ms. Niedzielska: We consider ourselves to be regionally specialized and because of the centralized nature of the healthcare system which I described earlier it is pretty easy for us to identify patients in any indication that is viable for our region. For instance, tropical diseases, we do not have sites for that. In general we can pretty much cover anything that is available within the region. However, in terms of experience, we do have the most experience in four areas. Oncology, cardiovascular diseases, respiratory, pulmonary diseases and diabetes. I think that in some way matches the areas which are being researched the most. Those are the kinds of trials that lend themselves well to our region. We have higher rates of smoking which leads to many cancers and obviously a lot of respiratory diseases so many things are related to lifestyle factors.

CEO CFO: How is business these days?

Ms. Niedzielska: Good. We launched the company last April and we now have around twenty employees. We have offices in five countries such as Bulgaria, Romania, Poland, Croatia, Czech Republic and Serbia. We are looking to expand within our region into new countries. We are building our client base. Things are going quite well.

CEO CFO: Is the culture generally the same throughout the countries or are there substantial differences?

Ms. Niedzielska: I would say there are more similarities than differences. One of the reasons why we stay in the region of eastern and central Europe is because of the similarities in the healthcare system and lifestyle. Generally it is a highly educated population so there are a lot of similarities. For instance sometimes people ask us why we do not work in Greece or Turkey because they are neighboring countries of Bulgaria. For us, those countries are organized completely differently, so we do not feel like the advantages that we have in our region translate to those other countries. For us, certainly the languages are different and many of the countries have Slavic languages so even that is similar. There are slight differences but in general they are more the same than different. From a regulatory perspective as well most of the countries are part of the European Union, they are following the European Union clinical trial directive. Some small local additions or subtractions but in general 80% of the regulatory procedures are the same throughout the region.

CEO CFO: What surprised you most as the company has developed?

Ms. Niedzielska: Good question. We ran a company in the same region for nine years and one of the things that has been a pleasant surprise is how many of our former employees are interested to work with us again. It was my hope that we could attract some of the people back and once we started working and opening positions, we had a great amount of interest. We have many people who have come back and remember how much they liked working in AbCRO and remember it as a good place. That has been gratifying and has helped us build the company.

CEO CFO: What have you learned to possibly avoid from your earlier experiences or something in your background that has helped you in this venture?

Ms. Niedzielska: One thing is the importance of marketing and business

development. When we started the first company we did not invest a ton in that in the beginning, and without that like with in every other industry, you can have the best product but if you are not telling anyone to buy it you are not getting anywhere. We need to be out there and that is one reason we are at a lot of tradeshows this year. We need to get our name out and we want to remind people who we are and that we are existing in the marketplace. I think I knew it when I started the first company, is that our business is a people business and a reputational business and all we are selling at the end of the day are people and the skills that they have. We have to invest in our staff and keep them happy and keep them motivated because if they are all those things it will bring us business and success as well as grow the company. It builds on itself that way. That is our focus in many ways. We spend a lot of time looking for business and clients, but keeping our employees motivated, interested, growing and happy also helps bring business and helps us grow in that way. It is the most important thing for our success.

CEO CFO: Why did you choose the name August Research?

Ms. Niedzielska: Our previous company was called AbCRO. In an industry like ours, people actually do look at alphabetical lists quite often, and every show has a directory with an alphabetical list of companies. We wanted to be an A. I went through the dictionary a few times looking for words with positive connotations that began with A and August met our requirements. It has two meanings. There is the month which everyone likes and then there is the second meaning which is we want to be distinguished, we want to be at a high level. We want to meet both ends of the word. Regarding cultural differences one thing that is nice about having the name August is that it is a word that means the same thing in all countries that we work with and it is something that makes sense. The name of our last company was AbCRO, but we had many clients that called us AbCRO or Ab or just did not

know how to say it. When you translate that into languages with other alphabets and things it gets very complicated. It was nice for us to come up with something that meant the same in ten different languages.

CEOCFO: Why should the business and investment community pay attention to August Research?

Ms. Niedzielska: We offer an excellent value for our customers. We have been working in eastern and central Europe for over thirteen years now so we have a very deep experience in running trials in the countries there. At the same time because we only focus on that region, we are not trying to do so many different things around the world. We

are focused on operational excellence and value for money in the services that we provide. We try to keep things as simple as we can so that we are not charging our clients for a ton of bureaucracy.

