Interview



Roger Deutsch

EDITORS' NOTE Roger Deutsch is one of the pioneers of food and chemical sensitivities testing with involvement in this field since 1986. He has been responsible for the commercialization of the Alcat Test® throughout the world. He is the co-author of Your Hidden Food Allergies Are Making You Fat. He is also the CEO of Cell Science Systems, GmbH, Potsdam, Germany.

COMPANY BRIEF Cell Science Systems (cellsciencesystems.com) is a specialty clinical laboratory that develops and performs laboratory testing in immunology, cell biology, molecular diagnostics, and other specialties, supporting the personalized treatment and prevention of chronic disease. Cell Science Systems, Corp. operates a CLIA certified laboratory and is an FDA inspected registered, cGMP medical device manufacturer meeting ISO EN13485 standards. Cell Science Systems is best known for pioneering the Alcat Test for food and chemical sensitivities. Cell Science Systems is the recipient of the 2016 North American Food Intolerance Testing Company of the Year Award. The company operates a wholly owned subsidiary in Europe.

Will you talk about the vison and mission around the creation of Cell Science Systems and provide an overview of the core focus of the business?

The mission and overarching aim of the business is to help people live healthier lives, but it's also to improve healthcare and reduce its cost, to improve communication between patients and physicians, and to get people more attuned to prevention by providing tools so they can actively and constructively participate in their personal healthcare.

What does the company do to accomplish this?

We provide information based on a scientific analytical process, which is unique to the individual. In its simplest form, it gives them advice regarding what they can safely eat, what they should not eat if they want to optimize

Living a Healthier Life

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their health and abate symptoms. This can help resolve complicated medical health problems that have been unresponsive to conventional approaches.

On top of that, through our sister company, we provide counseling. When a patient has a test, they are entitled to a free follow-up consultation with a dietitian. For a period of time, they will also have access to unlimited personal one-on-one consultations with a lifestyle counselor. Our aim is to give them useful information and to help them take action on that information.

This is based on the premise that food can be very healing and health-promoting. Under certain circumstances, it can also detract from health

Will you touch on the Alcat Test and what has made it a differentiator for the company?

The core of the business is the Alcat Test. What makes it different is that the approach we take is to identify how the immune system responds to different foods, chemicals, food additives, and a variety of other substances including things like functional foods and medicinal herbs that people are exposed to. We're all unique and each of us has our own genetic and biochemical makeup, and we all respond to these things differently.

Generally, most foods are safe for most people, but in modern times, we're exposed to foods that are not indigenous to our culture or to our current climate. They may naturally contain substances, or have had substances added to them, that will activate the innate immune system and trigger a state of chronic inflammation.

The most accurate way to identify how one responds to these foods is not to look for one single chemical in the blood or one single antibody or factor, but to try to replicate as closely as possible in the laboratory how the whole immune system responds under natural exposure.

In order to be accurate, the test is, by necessity, very complex. We address those complexities by designing and building instrumentation, especially for the measurements of the cellular responses, by controlling the manufacture of the substances that are used in the testing process. This requires that we register with the FDA and comply with FDA current good manufacturing procedures. This is unusual for

a laboratory because laboratories usually purchase their instrumentation from third parties who deal with just that. But we have that vertical integration, which makes us unique.

It has to be integrated because we need to have control over the substances that go into the test to control their potency and ensure that they are in the right range. We have to make the instrumentation because no one else makes an instrument that could do this test.

There is also an education component around it – creating the awareness within the public at large and the professional community that many complicated health issues can be addressed through dietary manipulation. Physicians do not learn this in medical school, so they need to be educated about it.

How critical are metrics in the process and are they the key competitive advantage for the Alcat Test?

Accuracy and precision are fundamental for any assay, but we have to have the right analyte, that is, measure the right marker. If one is measuring the wrong thing accurately, it's garbage in and garbage out.

Quality of the laboratory and quality of the manufacturing processes are foundational; that's a given. But at day's end, we have to be looking in the right direction, too. Conventional medicine today has been slow to adapt to new paradigms. We have to be able to identify the elements of key relevance to identify these reactions and the triggers. This is where the Alcat Test is most differentiated from technologies that other companies have to offer.

This would seem to be a test that almost anyone is a candidate for. Is the market that broad?

The test is designed for anyone who has a health issue that is in some way related to the inflammatory process where the trigger is unknown. Our job is to figure out what the triggers are. It's also addressed towards anyone who wants to live a better, healthier life. This even includes people who are already relatively free from symptoms and relatively high performing, but who want to enhance their performance. They can derive benefit from optimizing their diet based on a scientific process.

How much growth do you anticipate and how large can this company get?

Our limiting factor is how quickly we can scale up. Based on instances in the past where there has been a scientific report delivered to the public where there is a huge demand, I can easily envision the day when most Americans want to have this test done on a routine basis as part of their annual check-up.

Will you talk about PreviMedica and what it adds to the company?

PreviMedica is our sister company and it plays a supporting role. Utilizing our own proprietary softare tools, PreviMedica provides the services of our own in-house registered dietitians and dietetic counselors. Our network of dietitians has been trained by us and can provide one-on-one counseling to patients who want to find ways to integrate the Alcat test-driven dietary modifications into their lives.

PreviMedica also offers other lifestyle counseling regarding areas like exercise.

There is much discussion around food allergies but less so around food sensitivity. Is it important for you to build awareness about how critical that segment is?

Absolutely. A number of people are out there promoting awareness about food and one of the main focal points has been gluten.

In 2014, approximately 100 million people, at one point or another, experimented with a gluten-free diet, so there is a growing awareness that gluten is a potential trigger for not only celiac, but also non-celiac gluten sensitivity.

On the back of that, maybe there are other foods that can play a role in pathology. I cannot give a number on this, but I don't think a day goes by that I don't have a conversation with someone about what I do and they mention someone they know who has an allergy or sensitivity. There is a growing awareness that foods can trigger health issues.

What I see as a task for the growth of this company and for the achievement of the company's mission is building the awareness that we can accurately test for food sensitivity through scientific methods and get reliable and actionable information.

Does there need to be more of a focus on prevention instead of treating disease or illness after it has happened?

Absolutely. The escalating cost of healthcare is bankrupting the country. Yet, approximately 70 percent of diseases can be avoided by lifestyle changes. Knowing this, it does concern me that people don't pay more attention to

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prevention. It comes down to the challenges people face in terms of changing their lifestyle. Unless they have some condition or some factor that provides an impetus for them to do so, they don't think about making those changes.

We need to not only encourage people to change; we have to provide the tools and support to make it happen. Most people eat the same foods day in and day out. They don't vary things that much, so it takes a certain amount of effort. People are not, by nature, particularly adventurous when it comes to living habits so it really takes a helping hand.

If people have a health issue that is unresponsive to whatever it is they're doing and the proposition is presented to them that there is a way to identify foods that are relevant to their health condition through a simple Alcat test, many people will go for that proposition.

One of the limiting factors is the doctors. We have thousands of doctors who have used our tests and thousands that use them on an ongoing basis. However, there are approximately 800,000 medical doctors in this country and this testing is not a part of their training. One of the reasons for this is that their training curricula is indirectly funded by companies that don't have a vested interest in promoting prevention. There have been such stunning technological advances and success in diagnosing and treating medical conditions that the focus on prevention has been overshadowed. There is a different model that could be applied.

The conventional approach to health has been when we have an issue, we try to understand the biochemical underpinnings of that health issue and intervene at some step during that molecular process through an artificial substance. With the current model, why would drug companies want to encourage medical schools to teach about avoiding the things that cause the inflammation and symptoms that are treated with the drugs manufactured by these drug companies?

There needs to be an education effort to create awareness that lifestyle modification is not really a threat to the existing paradigm. It is a valuable adjunct that will improve outcomes. We can create much better outcomes if we integrate lifestyle factors into whatever kind of therapy regimen the doctor thinks is appropriate.

Does the company have a global focus or is it more directed at the U.S.?

We have a subsidiary in Germany and we have customers in Europe, South America, and Australia, as well as a few in Asia that buy our instrumentation and test reagents. Germany is the location we chose for our headquarters in Europe because of its central location and its high science standards. As we achieve more acceptance of the technology here, we hope that will translate internationally.

Does the Affordable Care Act (ACA) affect your business in any way?

Under ACA, payment models will shift from fee-for-service to incentivizing better outcomes. Also, ACA has some provisions that mandate payment for certain preventive services. The United States Preventive Services Task Force (USPSTF) reviews and makes recommendations for procedures or services in the area of prevention that they determine will have a positive impact on prevention.

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If they make an A or B recommendation, then the health insurance companies are required to pay for that service dollar one, meaning that there is no deductible applied. There is no copayment that has to be made before coverage kicks in.

A year ago, the USPSTF recommended that dietary counseling for the prevention of diabetes be given to people who are diagnosed with pre-diabetes. The insurance companies should cover services to address their metabolic health and we're targeting that. In conjunction with PreviMedica, we're building a network of physicians who offer services to patients who have GI issues. We are approaching GI issues in a formal manner, first, because the Alcat research that has been conducted at Yale School of Medicine deals primarily with patients with IBS, which means that we have validation of the efficacy of the program for treating patients with IBS.

However, patients with IBS oftentimes have elevated inflammatory markers that are risk factors for metabolic disorders, including diabetes. Many of those people might be considered pre-diabetic.

Through our network, we will be collecting data from patients at the baseline and at various intervals down the line, which track not only their improvement in symptoms of IBS, which might be their primary concern, but also track their risk factors for diabetes.

We're confident that we'll accumulate enough documentation that the evidence will be sufficient to encourage insurance companies to pay for Alcat testing services as well as PreviMedica consulting services for patients who fit the criteria. It won't be long before the cost savings are recognized and coverage becomes universal.

We have a roughly 1.5- to 2.5-year time horizon before we have accumulated sufficient data and have had the conversations with the insurance companies. At that stage, if things go according to our expectations, insurance companies will pay for Alcat testing for this category of people from dollar one. The demand is there; it is just up to us to educate the public at large as well as the scientific community about the existence of this program. We would then expect to be routinely testing approximately 3 to 5 percent of the U.S. population yearly. •