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Inside The Diagnostics Industry

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Rheonix Sees Automation as Key to Expanding Molecular Testing

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The molecular firm Rheonix (Ithaca, N.Y.) developed a microfluidic platform capable of fully automating multiplex molecular testing—from raw sample to result—at a lower cost. One novel feature of the platform is the Rheonix CARD (Chemistry And Reagent Device) that fully automates sample preparation for molecular testing for a wide array of diagnostic applications including next-generation sequencing (NGS).

Rheonix believes the platform's small size, affordability, and flexibility will enable the expansion of molecular testing applications both in the clinical realm, as well as in the food and beverage industry. *DTET* recently spoke to Gregory Galvin, Ph.D., Rheonix's CEO, as well as Richard Montagna, Ph.D., senior vice president of scientific and clinical affairs, regarding the company's technology and its commercial launch.

How can Rheonix's platform expand the applications and settings for molecular diagnostics (MDx)?

Galvin: Historically the issue with MDx assays is that they are complicated and require highly skilled labor and a room full of different instruments. That complexity and high labor requirement have impeded the rollout of molecular assays for a really broad spectrum of applications, for which they are ideally suited. Rheonix is focusing on creating a completely automated platform that allows, from the user's perspective, to take the complexity out. The complexity is there in what actually transpires, but users are not involved in it, so you can disperse MDx into a much broader arena, more economically, than has been possible.

At the 40,000-foot level, Rheonix is not primarily in the business of creating biochemistry or genetics or science. We provide the platform that allows a very wide variety of genetic-based science to be delivered in an economic manner.

In what areas is Rheonix planning on applying its technology?

Montagna: We think there is potential in a lot of different areas. Obviously there is the clinical diagnostics market. In addition, there are food and beverage applications. If you

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Automated Sample
The Encompass Optimum workstation can take up to 24 samples of blood, saliva, urine, or formalin-fixed, paraffin-embedded tissue and automatically lyse, extract, and purify DNA and RNA for analysis. Total sample preparation and load in requires less than five minutes.

look at the food and beverage market, up until recently, and even now, most testing is relying on 200-year-old methods. Sub-cultures take a long time and do not deliver the most sensitive results. Now with molecular opportunities you can get answers much more quickly and with much greater accuracy.

A third arena would be NGS, which yields a tremendous amount of data, but the issue is again, complexity. The actual sequencing is very automated, but on either side of it you still have complexity—the upfront sample preparation, to prepare the DNA to analyze it and the backend, bioinformatics analysis of the data. Rheonix is not tackling the backend, but upfront we know we can use the automated capabilities of our system to prepare the DNA libraries for NGS.

We are in the middle of a project right now with New York Center of Excellence at University of Buffalo. Their library preparation methods typically take, using multiple pieces of equipment, about a day and a half. Once they get the raw sample it takes a day and a half to get everything ready before they can begin the sequencing. We have been able to reduce that day and a half to 146 minutes. It is truly automated. You put the sample in and hit a button. The sophistication is still there, but it is handled by an instrument. The user can basically go get a cup of coffee while this is happening. That allows laboratories to decrease the cost of the labor. Highly skilled people are not needed because the instrument is capable of taking complex steps and automating it without intervention on the part of the user.

With personalized medicine there are a number of gene sequences known to predict whether an individual will respond to a particular therapy. Rheonix plays a role by providing the opportunity to reduce the cost and the labor to generate the sample.

Rheonix is simultaneously pursuing the clinical MDx market, as well as the food and beverage market. Can you explain the strategy?

Galvin: My experience with technology companies is that companies want to pursue as many different things as the technology allows them. For the business to be successful, you have to contain that spread because you cannot do everything. The Rheonix platform is extremely flexible. So one of our business challenges is to focus on those areas we know we can rapidly deploy a solution, since we can't do them all simultaneously. We evolved to the three-pronged product/market strategy.

First is the clinical in vitro diagnostics (IVD), which ultimately is the largest value and largest dollar market, but it is also the longest to market. Second, is the laboratory developed test (LDT) market, which is still a clinical market, but somewhat of a lower barrier to entry. Third is the applied markets, the non-clinical markets. We were surprised by the inbound interest for customers in this space. There is a lot of interest in the food and beverage world in molecular testing because of the sensitivity and specificity of the tests. But, the industry historically could not afford the labor, nor did they have access to the highly skilled staff and complex laboratories needed for molecular testing. For us

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this is an opportunistic, underserved market that allows us to get product into nonregulated market very quickly. Our solution is extremely simple to use and addresses the key pain points in this market. So, our strategy is partially technology driven and partially financially driven—to generate revenue sooner rather than later.

The LDT market is one of the core areas the company is pursuing. Can you talk about how Rheonix is preparing for the possibility of the U.S. Food and Drug Administration's (FDA's) expanded regulation of LDTs?

Montagna: Our philosophy is to be very open with the FDA. We have purposely engaged FDA early and have shown the agency our intended approach. If the guidance documents are finalized in their current format, the FDA does not want to see companies working with CLIA laboratories to help them develop tests, which due to our DNA capture probe technology we would have to do. If you want to target ABCD, you get a specific probe and you would have to contract with us to put that probe on the array. We have come up with a novel approach that we call the universal CARD that allows the end-user to modify and functionalize the array for their own purposes. We have proven we can do this in a lot of different arenas and showed that to the FDA. As part of a presubmission meeting, we essentially reached an agreement with them for how we could proceed to get the platform approved for our own products and for laboratories that develop their own LDTs, which we call user-defined assays, to stay away from the hot button of LDT.

Galvin: Because the platform is so simple to use the food and beverage sector also can develop their own assay. It is very easy to functionalize the CARD automatically. The beauty of the system is that if you put a raw sample in and think about what has to happen, the cells have to be lysed, the DNA or RNA extracted, purified, amplified, and detected. While that is happening, simultaneously the CARD is automatically functionalized. The user doesn't lose any time. They can amplify the targets of interest and when they want to detect them, by the time the amplicons make their way to the array the probes will already be there.

Rheonix By-the-Numbers

- 7 publications in scientific journals
- 24 samples processed simultaneous with the automated Encompass workstations and CARD technology
- 51 U.S. issued patents, plus 16 pending U.S. patent applications
- 70 employees
- 2008 year founded

Can you speak of the current development status along your product lines?

Galvin: In food and beverage the first assay to be commercially released is a beer spoilage organism assay that will be introduced this August. The LDT or user defined assay is presently in beta testing at a couple of different sites, so that will be the next to roll out. And in the traditional clinical IVD segment, products in sexually transmitted infections are entering clinical trials and will need to be submitted for 510k approval. So, that is furthest away, but they are all moving forward in parallel.

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In addition to STI, you are also working on HIV and Zika testing. How does the company evaluate which assays to pursue?

Galvin: It is very much a subject of internal discussion with some guidance from outside consultants. It really is the intersection of the business opportunity and the technology. Some of the questions we ask are can we do it? Will it be near or far to enter the market? Is the market sufficient? Is it a fit with the volume and throughput of our platform? Is reimbursement appropriate? Who is competing in the space?

As an industry, how will molecular testing evolve in the next several years?

Galvin: We are excited about where molecular testing is going. Fundamentally, from a scientific basis, the idea that you can look at a gene sequence and know very accurately the diagnosis of a pathogen or the susceptibility to a disease or medical condition or which medicines will be effective is all good for patient care. We are just at the tip of the iceberg of the science and are bringing the business and the economics of it in line with the technical opportunities. The changes in economics will drive new markets.

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