Tampa Bay Business Journal - November 27, 2006
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TAMPA BAY Business Journal

Friday, November 24, 2006

Claro 'changes the game' of blood analysis

Biomedical firm develops new technology

Tampa Bay Business Journal - by Margie Manning Senior staff writer

St. Petersburg -- From labs in St. Petersburg and in France, researchers for **Claro Scientific** are working to fine-tune technology that could help reduce the incidence of killers such as malaria and sepsis.

Kathleen Cabble

Above, Claro Scientific's Dr. Luis Garcia-Rubio, president and chief scientific officer, and Dr. Debra Huffman, senior scientist, evaluate blood cultures for sepsis in their lab on the Florida Blood Services campus in St. Petersburg.

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Claro, a startup biomedical firm, has developed a process for analyzing blood for pathogens such as bacteria, fungi, viruses and parasites that company officials say is quicker and cheaper than existing methods, allowing doctors to treat patients at earlier stages of their illness and more effectively.

Instead of relying on microbiology or molecular biology, Claro takes a physics approach, using light to detect the optical properties of pathogens in blood and other bodily fluids.

"Claro's technology will allow what was possible only in centralized labs with a PhD to move out of the lab to the patient's bedside," said Matt Eyring, CEO. "There's an opportunity to create a large market for testing that didn't exist before."

Eyring is a founder of **Innosight LLC** and **Innosight Ventures**, a Boston-based firm that has provided initial financial backing for Claro.

"The chance to change the game in diagnostics is what was so exciting about partnering with Claro," Eyring said.

Claro was founded by Luis Garcia-Rubio and Dr. German Leparc. Garcia-Rubio is a University of South Florida professor who earlier founded **Ocean Optics** in Dunedin, which sells products for optical sensing, or methods for measuring and interpreting the interaction of light with matter. Leparc is chief medical officer of **Florida Blood Services**, home to Claro's headquarters and a laboratory. A lab in France is working on detecting pathogens in urine.

Current detection lengthy

The company's first target is sepsis, a serious medical condition resulting from the immune

response to a severe infection, typically an infection in the bloodstream.

There are about 5 million sepsis tests conducted annually, with 750,000 positive results, according to Claro presentations. With 200,000 deaths, sepsis is the 10th leading cause of death in the United States. The cost of treatment is $20,000 a patient, or $17 billion a year.

"Overall sepsis has a mortality rate that ranges from 20 percent to 60 percent," Dr. Todd Wills, an infectious disease specialist at **USF**, said. "The number of people that die from sepsis is about the same as die from heart attacks."

The most common method of detection now is microbiology, taking samples of blood or urine and trying to grow bacteria from those samples. The method is reliable but it takes a day or two before results can be obtained.

Quicker diagnosis would allow doctors to give more appropriate antibiotic therapy earlier in the course of an infection and perhaps save lives, Wills said.

Wills also has heard a lot of talk about molecular techniques amplifying genetic material to detect the presence or absence of pathogens, but he said that method is not very frequently used right now. Andrew Malcolmson, Claro's VP for business development, said molecular methods are accurate but expensive and it's challenging to get a sample.

Saving health care costs

Claro has developed a small portable unit that attaches to a catheter to continuously monitor for infections. The technology looks for the unique optical properties of pathogens as well as that of blood whose normal signature has been changed by the presence of pathogens. Results are generated in seconds, not hours or days.

Leparc said the technology represents a paradigm shift in blood analysis. Instead of requiring a large lab, the equipment is portable and testing is "point of care," done at the patient's bedside. Novices can operate the equipment, and the costs are low. The blood analysis units can be made for $10,000 or less, Eyring said.

"If you made testing cheap and easy and move it out of the lab, you can test all the time and save health care costs," he said.

Malcolmson said he knows the company is likely to get pushback from microbiologists and others in what is now a $30 billion a year testing industry.

"This is in left field. It's completely different. It's not just a better way of doing the same thing," he said.

Business model

Eyring said there is a potential $4 billion market opportunity from sepsis testing alone. The number of additional applications for Claro's technology is very large, he said.

"Bedside sepsis analysis is the first focus to achieve business success," Eyring said. "I'd love to see it detecting illness in developing nations. We just have to figure out a business model to get

it there."

Claro has received about $900,000 in seed capital, and the company plans to raise about $10 million over the next 24 months in two offerings. Within those two years, it anticipates completing clinical trials, receiving **Food and Drug Administration** approval for its device, and starting commercial sales.

Eventually the company might have an initial public offering, but a corporate buy-out is a more probable exit strategy, according to investor presentation materials.

Florida Blood Services, which President Dan Doddridge said has been working to diversify its business plan, also will get a percentage from the royalties generated from Claro's patents, Leparc said.

The Tampa Bay area has been long known as a leader in medical devices, but increasingly that segment is merging with other segments of the biosciences, said Russell Allen, president of **BioFlorida**, a West Palm Beach-based trade association.

Claro is an example of that convergence, Allen said.

"It plays to the strengths that exist in the state but it is technology that is valuable everywhere," he said. "A two-to-five person company developing technology like this is just as important as what Scripps is doing."

The **Scripps Research Institute** received hefty economic incentives from the state to locate a facility on the east coast of Florida in 2003. Allen said it's important to ensure biotech companies have a good home in Florida.

"We may overemphasize the economic benefits, and I don't want to downplay them because they bring in high wage jobs," he said. "But more importantly, this is part of a health care industry that looks to cure disease and save lives. That's what makes it exciting and important to support."

mmmanning@bizjournals.com | 813.342.2473