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Vision for the future

Cleveland's Imalux develops medical imaging system

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Jerry Cirino is trying to launch his company's product the right way.

The product, Niris, uses near-infrared light to create images of tissue in the human body. Its cross-sectional images are up to 100 times more resolute than those produced by ultrasound, which uses sound waves instead of light waves.

Niris can reliably detect abnormal tissue, such as tumors in the bladder. The system also can tell whether the tumors have invaded the bladder wall without cutting away a piece of the bladder for analysis.

Niris can "see" the neurovascular bundle near the prostate during surgery -- a bundle urologists know is there but can't detect with their eyes or instruments. Preserving the neurovascular bundle preserves erectile function for the patient.

The system also is less expensive than many high-tech medical imagers -- it costs less than \$80,000. It is relatively inexpensive to operate and requires no shielding, like other imagers do. Doctors can learn to read its images in half an hour. The Food and Drug Administration has approved Niris for sale in the United States.

But because Niris is based on a new imaging technology -- optical coherence tomography, or OCT -- most doctors are waiting for medical opinion leaders to adopt and test the technology first.

"It takes time and patience to sire a new product into the medical community and get the right opinion leaders to see it, touch it, feel it, use it, feel good about it before they can start buying it," Cirino said.

So the chief executive of Imalux Corp., the Cleveland company that is developing Niris, and his colleagues are helping early adopters use their system. They're also looking for more investor money and corporate partnerships to launch Niris commercially, possibly next year.

"It's tempting for a company with a new product to do a full market launch before it should," Cirino said. "Maybe investors want to start seeing [sales], or you're anxious to get the product out there."

But it's best to develop the clinical basis for the product, build clinical evidence of its uses and effectiveness, report that evidence, then do a "proper market launch," he said.

"There's no substitute for developing clinical momentum that eventually will stoke demand for the product," said Cirino, who joined Imalux a year ago after helping to sell SourceOne Healthcare Technologies Inc. in Mentor to an out-of-town competitor.

Optical coherence tomography has been used for more than a decade by ophthalmologists. But Imalux is furthest along at developing the imaging technology for other medical uses.

"The good news is, we don't have competition," Cirino said. That's also the bad news.

"When you have multiple players, it raises the visibility of your technology. It's always fun to rise up and meet the competition."

Niris, which can image large cells, is used most often to look at layers of tissue, said Dr. Nancy Tresser, medical director for Imalux.

Doctors, such as urologists, use Niris to take images inside the body through endoscopes, she said.

Why target urologists? "Urologists are early adopters of technology," Tresser said. Urologists already use fiber-optic devices to see inside the body. For them, OCT could be the next step.

Dr. Michael Manyak, a urologist who teaches at George Washington University in Washington, has been working with Imalux for about three years. Manyak did the first U.S. study of how well Niris detects bladder cancer.

Now also vice president of medical affairs at Cytogen Corp. in Princeton, Manyak found that Niris reliably detected normal and abnormal tissue in the bladder.

The device easily picked out tumors and whether the tumors had invaded the bladder wall, without taking a biopsy, Manyak said.

"There's nothing else that competes with this right now," Manyak said. "The only way you can tell tissue invasion is to take biopsies."

Manyak's results were published in the August 2006 edition of the Journal of Endourology.

Manyak also said Niris is the only device on the market that can detect the neurovascular bundle during prostate surgery.

"There is no competing technology," he said. "Nothing images tissue to the extent that Niris does."

While Imalux supports clinical trials of Niris in the next 18 months, the company also is looking to raise more money from investors, Cirino said. As of January 2005, Imalux had raised \$10.4 million of capital.

Cirino tried getting some of that money from venture capital firms in Boston and New York last summer. But the venture capitalists wanted to see more clinical development of the system.

Even though the private equity world is awash in money, "the criteria for investments are still very tough," Cirino said. "Capital has to be earned. You have to convince [the investors] that your initiative will be a payback for them."

Until Niris has the clinical depth that venture capitalists require, Cirino is looking for wealthy individuals, often called angel investors, who could invest smaller amounts of money in Imalux.

This week, he and Imalux investor Trevor Jones presented the company at a BioEnterprise event for angel investors in Naples, Fla.

Jones is chairman and founder of Biomec Inc., a multifaceted company that invests in young medical device makers, develops and commercializes devices of its own, and makes devices for customers. Jones also has been a member of the National Academy of Engineering.

Biomec makes the computer console for Niris. That company also is landlord for Imalux and its 10 employees.

"My job in a company like this is to continually foster and develop potential investors, because the need for capital is ongoing," Cirino said.

While Imalux looks for more investor money, it also is looking for "strategic partnerships" that could provide distribution channels for its system, said Baiju Shah, president of BioEnterprise, the Northeast Ohio health care company developer.

Medical device makers could incorporate the Niris probe in their devices, Cirino said. Big imaging companies also are interested in OCT, he said.

"We're working several angles at the same time," Cirino said. "You have to. You can't focus on one thing because what if that one thing doesn't work out?"

Whatever happens, Cirino would like to keep Imalux close to imaging researchers at the Cleveland Clinic, University Hospitals Case Medical Center and Case Western Reserve University.

A majority of Imalux investors also are in Northeast Ohio.

"We're all hoping that this will be a big win for all of us and for Cleveland," he said.

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