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Imalux shifts focus to putting its product into practice

Imaging company works to build demand for early-stage cancer detecting device

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Imalux Corp. of Cleveland is facing the last, and one of the biggest, hurdles in the long journey to become a successful medical device company – trying to convince people to use its product.

After working for 10 years and raising more than \$10 million in venture capital to develop an imaging device that uses light waves to detect early-stage cancer, 12-person Imalux is finding out whether doctors will buy into the fruit of its labor

Peddling the \$65,000 product during the past 18 months has been a challenge because there is no existing market for what Imalux is selling, said CEO Lloyd Breedlove, who will step down at the end of the year to take a job closer to his family in North Carolina. The company is searching for a replacement.

Since winning Food and Drug Administration clearance for its device in March 2004, Imalux has 12 units in use; three of those are at the Cleveland Clinic, and one is at University Hospitals of Cleveland. The company would not disclose how many of those were sold and how many are loaned to doctors to entice them to try the device.

Imalux's device functions much like an ultrasound, but with light waves rather than sound. The image the infrared light waves produce detects tissue changes at the cellular level that could be an early sign of cancer.

The challenge for the company is selling the device to doctors who are not accustomed to buying imaging equipment and convincing them to incorporate a new procedure into their routine that will be better than the current methods.

"We are not altering an existing technology," Mr. Breedlove said. "It is not like we have a new knife that will replace an existing knife. We have to create demand."

A new image

Most medical imaging is done by large, expensive equipment purchased and operated by radiologists. By contrast, Imalux's device fits on a tablet and is used by a physician.

Imalux is relying on its current users to create demand by publishing research papers in medical journals, giving scientific presentations on the device at conferences and recommending it to other doctors.

“They just have to tell a lot of people to use it,” Mr. Breedlove said.

The company also has a small sales force in the United States and distributors in Australia and Hong Kong trying to drum up market demand for the product.

“The end goal for Imalux investors is to get a return on their investment by selling the company or putting it up for an initial public offering. To reach that point, Imalux must have ‘some groundswell of support’ from doctors to convince serious buyers that Imalux has big potential,” Mr. Breedlove said.

Jonathan Murray, a partner at Early Stage Partners LP and one of the first Imalux investor, agrees.

“Adoption of imaging technology takes a long time,’ Mr. Murray said. ‘You have to educate an entire market.”

‘Like the Holy Grail’

While the road Imalux is traveling may seem long, it parallels the one many health care startups must take.

“The time it takes to get these technologies adopted is stunning,” said Baiju Shah, president of economic development nonprofit BioEnterprise Corp. ““Medical professionals are conservative by nature. The credo is first do no harm, so it takes them awhile.”

Imalux began in 1996 when two Hahn Loeser Parks LLP attorneys found a technology being developed at the Institute of Applied Physics in Russia that they thought could change the way doctors diagnose cancer.

The attorneys, Warren Goldenberg and Leon Polott, couldn’t find anyone in Cleveland to commercialize the technology, so the pair took matters into their own hands.

“Imalux became like the Holy Grail,” Mr. Goldenberg said. “We could not get anyone in Cleveland or anywhere to invest money or manage it, so Leon and I decided we would do it ourselves.”

After four years of product development, Imalux received a \$3.5 million investment from a group of four local investors.

Enduring the long path

Mr. Goldenberg said Mr. Murray was the first venture capitalist to give the technology a chance, and other local investors soon followed.

“That was the beginning of the buy-in from the establishment in Cleveland,” Mr. Goldenberg said. “At the time people thought the idea was off the wall.”

The company’s current investors are Cleveland medical device company Biomec, nc.; real estate developer RMS Investment Corp. of Cleveland; BioInfo Accelerator Ltd., a group of local individual investors; Columbus venture capital firm Reservoir Venture Partners; and Symark LLC, an investment firm whose chairman, Bill Sanford, was CEO of medical sterilization company Steris Corp. of Mentor when Mr. Breedlove worked there as senior vice president.

In 2003, Imalux hired Mr. Breedlove, who helped give the company credibility with investors because of his experience as a vice president of Steris during the 1990s when the company experienced tremendous growth.

Steris was founded in 1988 with \$1.2 million in venture capital to sell a device that sterilized endoscopic

equipment. The sterilizer caught on, and in 1992 the company went public. When Mr. Breedlove left Steris in 1999, it was approaching \$800 million in annual revenue. In the company's last fiscal year, which ended March 31, 2005, it had \$1.1 billion in revenue.

After leaving Steris Mr. Breedlove was enjoying retirement in North Carolina and working with some startup companies there when Mr. Sanford, the chairman of Imalux's board, asked him to run the imaging company.

Based on his experience at Steris, Mr. Breedlove knows patience is a virtue.

"This is the path any medical device company will have to endure," Mr. Breedlove said.