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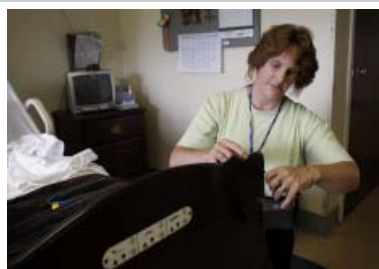
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Two Roanoke medical companies on the cutting edge

Breakthroughs by Wireless Medicare and OcuCure Therapeutics could put Roanoke on the medical map.

By Sarah Bruyn Jones
981-3264



Eric Brady | The Roanoke Times

Rhonda Workman of Wireless Medicare installs a radio frequency identification tag reader as part of the company's sensor equipment, which monitors a patient's movement. Raleigh Court Healthcare Center in Roanoke is being used as a test facility.

There isn't a receptionist. Or a flashy sign.

Cubicles are surrounded by a conference room, kitchenette and a couple of offices. There is a warehouse room in the back.

But this space on the second floor of 15 East Salem Ave. in downtown Roanoke is home to two companies each on the verge of taking a significant step into the health care industry.

Wireless Medicare LLC and OcuCure Therapeutics Inc. have shared the office space since April 2007. It's a home base as they dream of bringing their respective products to market in the Roanoke region and ultimately to the national and global communities.

While the two small start-ups have mostly kept to themselves -- sharing details on occasion -- recent breakthroughs in research have led both to speak more publicly as they look for more investors.

Wireless Medicare is now working toward getting approval from the Food and Drug Administration to begin selling a sensor system that can detect movement in hospital and nursing home beds.

The device is designed to help prevent bedsores on patients who must be rotated on a regular basis. It also could help prevent falls by alerting nursing staff when a patient tries to get out of the bed unassisted.

Recent research results from OcuCure indicate that the company is getting closer to developing a prescription eyedrop that could help treat, and maybe even reverse, age-related macular degeneration.

Testing OcuCure

Everywhere Sunder Malkani goes, he carries a small eyedrop bottle with a milky white solution.

"This has been my life for six years," said Malkani, president and CEO of OcuCure, shaking the bottle.

Eventually, Malkani and his co-workers hope the bottle will make waves in the \$1 billion industry of treatment for age-related macular degeneration. And they believe they are getting closer to that goal.

While in the infancy stages of new drug development, OcuCure has seen some promising results come out of its early research.

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The research results have been so positive that the company is now seeking to raise about \$20 million so it can start down the road to getting approval for human testing from the federal Food and Drug Administration and begin the testing. That money, however, will take the company only through the early human testing trials.

"We are having very productive talks with potential investors," Malkani said.

He would not specify how much money has been invested in the company to date, only saying it is "millions."

Macular degeneration occurs when the membrane in the eye ruptures, allowing blood vessels to grow into the retina. This causes blurred vision and can lead to loss of vision. It is a leading cause of blindness in Americans 60 and older, according to the National Institutes of Health.

The goal of the drug being developed by OcuCure is to stop the growth of new blood vessels into the retina, and to cause existing abnormal vessels to regress.

In 2008, the primary product on the market for treating macular degeneration saw \$1 billion in sales. The product, Lucentis, is given by injection.

Malkani and his partners hope that by developing an eyedrop treatment they can capture some of the market from Lucentis.

"We really believe we have the ability to charge into the market," Malkani said.

Much of that confidence stems from the research results OcuCure has seen in testing the eyedrop in animals. Using rats and primates, the data showed the eyedrop was effective in inhibiting the growth of blood vessels, said Patricia Williams, the chief scientific officer for OcuCure.

Williams conducted the studies at the Eastern Virginia Medical School's T.R. Lee Center for Ocular Pharmacology in Norfolk.

Researchers also found that the drug didn't have adverse side effects on the animals, specifically concluding that during a six- to nine-month time span there was no evidence of major organ dysfunction. A six-month study in rats corresponds to what the drug will do if used on a long-term basis in humans, Malkani said.

"Also the results in primates is a good predictor of what can be expected in human trials," he said. "That's why we did the primate studies. That's important."

The data will be used as the company now takes the next step to get approval to begin testing the product in humans.

Once money is raised to proceed with the FDA approval process, research will take several more years before the product can enter the market. There are three phases to the FDA process. Malkani said the first phase will likely take 18 months, the second phase up to two years. If the drug reaches the third and final phase, Malkani said the company would look to partner with another established pharmaceutical company or go public with an initial public offering.

Sensing movement

The vision for Wireless Medicare began in 2001 when Dr. Andre Muelenaer, a pediatrician at Carilion Clinic, wanted a way to monitor a patient in bed using fiber optics.

The idea dates back to a specific teenage patient who was comatose and on a ventilator. The doctors needed an MRI of her brain, but didn't want to disconnect her from all the monitoring devices she was hooked up to.

"I realized we needed to have a better monitoring device for critical patients when they need an MRI," Muelenaer said. "So I went to Virginia Tech and talked to some people who work in fiber optics."

As they looked into developing a product that could monitor a patient's heartbeat, breathing and movement, Muelenaer and his partners began looking beyond solving the initial situation of giving a comatose teenager an MRI.

They turned to bedsores, or pressure ulcers, which are caused when an area of skin breaks down because the person has stayed in one position for too long. The constant pressure reduces the blood supply to the skin in that area and the affected tissue dies, according to the National Institutes of Health.

"In 2002, it was a \$10 billion market," said Muelenaer, who serves as the medical director for Wireless Medicare. "There was about \$5 billion in lawyers and legal fees and another \$5 billion in treating

pressure ulcers."

By 2007, Muelenaer had teamed up with Dan Wrappe, and the company developed a prototype for its bed sensor, naming it Vivatrak. Wrappe is the company's CEO and president.

By December 2008, the company began talks with area nursing homes about the sensor. Feedback from nurses and certified nursing assistants helped to improve the device, Wrappe said.

Working with Raleigh Court Healthcare Center in Roanoke, Wrappe said, they have been able to demonstrate how the data can be used to help the nursing home better monitor its patients. In June, eight beds had the device. That number will increase to 50 once the company has FDA approval.

Raleigh Court is helping to test and refine the product as the company goes through the FDA application, which Wrappe said is likely to be submitted in early September.

The hope is to bring the product to market and begin generating revenue by the fourth quarter of 2009.

The business plan is to sell subscriptions for the service. Wireless Medicare plans to install the device for the nursing home and then distill the data obtained into usable information about the patient.

The company is billing itself as a way for nursing homes to save money by taking better care of patients and avoiding lawsuits.

There are about 200,000 nursing beds in Virginia, North Carolina, South Carolina, Georgia and Tennessee, Wrappe said. For that same region, there are about 19,000 complaints of pressure ulcers a year to the Centers for Medicare & Medicaid Services.

"This is a big and a growing market," Wrappe said. "There is a specific need that we can meet."

Within a year Wrappe would like his device to be installed in 5,000 nursing home beds. He's planning on focusing the initial market penetration in the region surrounding Roanoke and Southwest Virginia. He estimates that means being in about 50 nursing homes.

"If we are at the 5,000 level in a year, we will be profitable in the second year of operation," he said.

From there, he plans to take the business to Texas, Florida and other areas where there are high concentrations of malpractice lawsuits and nursing homes.

'Homegrown,' future growth

Both Malkani and Wrappe are proud that their companies are products of Roanoke, and they want to provide jobs to the Roanoke Valley in the future.

"We are a Roanoke homegrown story, and we are doing work at the cutting edge of science," Malkani said.

Each company started out with support from the Carilion Biomedical Institute.

As his business grows, Wrappe said, he hopes to bring 100 jobs to Roanoke.

Both also have plans for developing products beyond the initial products they have decided to focus on. Wireless Medicare sees potential for using computer technology to continue to invent devices that monitor patients and help providers more easily do their jobs. And OcuCure has access to other intellectual property that could lead to the development of drugs to treat other eye diseases beyond macular degeneration.

"We're not a one-trick pony," Wrappe said. "What we really want to do is build a culture of health care innovation here. ... We're going to build what we believe can be a very big company starting with the Vivatrak and getting it to market."

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