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MicroPhage to tap European market

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LONGMONT — MicroPhage today announced it has received clearance to sell its medical diagnostic products in Europe.

This, and potential approval in the United States coming in the next several months, could mean the company will triple the size of its Longmont work force in the next couple of years.

MicroPhage's technology, first developed at the Colorado School of Mines, is an instrument-free method of identifying bacterial pathogens in blood. Its first products focus on detecting methicillin resistance (MRSA) and susceptibility (MSSA), infections that can be serious and resistant to most antibiotics.

The testing is done with two small tubes and a dipstick-like detector, similar to a home pregnancy test. The tests can be done in five hours, compared with traditional testing methods that can take up to three days.

With its European rollout, MicroPhage will first focus on the United Kingdom and France, CEO Steve Lundy said.

"Our initial market is 100 percent hospitals," he said, followed by clinics and doctor's offices.

An expansion this year that added 2,000 square feet and a clean room to the company's facility at 2400 Trade Centre Ave. was instrumental in getting approval in Europe and, Lundy hopes, soon in the U.S.

Both Europe and the U.S. Food and Drug Administration require the company have a facility that produces products under "good manufacturing practices," and an independent audit this fall showed MicroPhage meets that criteria.

MicroPhage moved to Longmont in November 2004, where it has focused on developing and testing its products.

To date, the company has raised \$13.5 million, all from private investors and \$4 million of which came in the past year. With approval to sell its products in Europe, and possibly soon in the U.S., raising more money to ramp up production remains "a big issue" for MicroPhage, Lundy said.

His goal is to raise \$10 million to \$15 million by the end of the first quarter of 2010, Lundy said. The company is targeting venture capitalists and institutional investors, which could include other medical companies in the diagnostic field.

Aside from ramping up production, which will increase "tenfold," Lundy said, the company also needs to raise money to hire more people. As it rolls out new products over the next three years, the company will need more people in its research and development department.

"For us to develop our new tests, that's going to take Ph.D.-level folks," Lundy said.

The company currently has 16 employees.

"In the next couple of years, that number's probably going to go to around 50, 50-plus," Lundy said.

He said the company plans to remain in Longmont and has room to expand in its current facility. He credited Circle Capital, his landlord, with going out of its way to address some air-quality issues that came up when the clean room was being built.

To gain FDA approval, the company has been conducting trials in the microbiology labs of four U.S. hospitals: Denver Health Medical Center, the hospitals at Duke University and Northwestern, and Robert Woods Johnson Hospital in New Jersey.



Research associates Michele Zediker, left, and Maria Izzo demonstrate on Friday how portions of MicroPhage's infection-detecting kit is produced at its facility in Longmont. The product allows detection of infections in hours. **Lewis Geyer/Times-Call**

The hospitals conduct blood tests using both the MicroPhage method and the traditional method, the an independent auditor compares the results. So far, there have been no variances between results of the two methods, Lundy said.

MicroPhage will submit its application to the FDA in January, and approval could be come within 120 days after that, he said.

The “in vitro” diagnostic market, which is MicroPhage’s focus, is a \$35 billion market worldwide, Lundy said, so he sees a lot of potential for growth.

One country he has his eye on in particular is China, which represents about a fourth of the worldwide market.

“We’re very bullish on China,” Lundy said.

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