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BIOTECHNOLOGY

Device expected to greatly widen Oculus' market

PETALUMA BIOTECH SEEKS PATENT FOR SYSTEM THAT MONITORS, CLEANS WOUNDS

Monday, June 9, 2008

BY LORALEE STEVENS
STAFF REPORTER

PETALUMA – Oculus Innovative Sciences plans to put its wound-cleaning Microcyn solution to work in a wide new market with a unique automated monitoring and cleaning system.

The company has filed for a patent on the system and intends to file for a 510k FDA clearance, which could be granted within a year, allowing Oculus entry to a \$9.6 billion market for chronic and acute wound care.

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"We're excited by what our R&D team has developed," said Oculus founder and CEO Hoji Alimi. "It's entirely new, and while the additional revenues will be valuable as we pursue our key U.S. clinical trails to establish Microcyn as a pharmaceutical drug, our near-term goal is to get Microcyn to the people who need it."

The shelf-stable oxychlorine compound is currently undergoing U.S. trials to show it can be used in addition to – or as a replacement for – antibiotics in the treatment of mildly infected diabetic ulcers.

It has already received approval outside the U.S. for use as an anti-infective. The FDA so far has cleared it to moisten and clean wounds.

"Under that FDA clearance we can market it in conjunction with this new wound-cleaning system," said Mr. Alimi. "It opens our immediate market to include C-sections and other surgical incisions, burns and any other open wounds."

The system delivers a Microcyn-based solution to a chronic or acute wound site and uses a vacuum process. But unlike other vacuum-process systems – and there are many on the market – the Oculus device doesn't cover the wound with sponge material.

"That sponge has to be changed every three days, damaging healthy tissue," said Mr. Alimi.

"The beauty of our system is that it removes load by constantly cleaning the wound, checking and automatically delivering just the needed amount of Microcyn to moisten the site, without the need to change dressings."

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Because the systems use is external, the FDA's clinical and data requirements for clearance are far less demanding and expensive.

"We'll be able to put Microcyn into much wider use in the U.S. in a relatively short time before our current clinical drug trials are completed," he said.

Those trials are proceeding well. In March, Microcyn completed the FDA's Phase II trials with flying colors, demonstrating that the technology is effective at curing or reducing mild infections in diabetic foot ulcers.

Recently, Mr. Alimi visited a wound-care clinic in Klamath Falls, Ore., that is using the Microcyn technology. There he met with several patients whose ulcers were not responding to antibiotics.

"I shook their hands. They were alive because of our products. It was enormously touching. That's why we want

to get our technology into the widest use as soon as possible: it saves lives," said Mr. Alimi.

Oculus employs 76 internationally, 40 at its Petaluma headquarters.

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