

## Oculus cuts costs in advance of U.S. launch of Microcyn

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**Oculus Innovative Sciences** (Petaluma, California) is cutting back on expenses – including shifting the cost of a planned \$30 million pivotal trial to a potential partner – while it prepares to launch its Microcyn Technology-based product in the U.S. as early as January. The company also let go of some employees, including COO Michael Wokasch.

The company is developing a gel-based version of its wound treatment product based on physician feedback of the liquid-based version of the technology, Hoji Alimi, CEO and founder of Oculus, told *Medical Device Daily*.

Oculus said it wants to achieve profitability by slashing its net loss by roughly \$1 million a quarter beginning in the third quarter, which starts Oct. 1, compared to recent quarters.

The company said it would focus on several revenue growth initiatives: launching its 510(k)-cleared Microcyn in the U.S., preceded by the expected completion in November of its ongoing U.S. marketing trials, including physician focus groups; supporting the launch of Dermacyn in China; expanding its existing distribution network in Europe; filing for approvals of the Microcyn Gel formulation in the U.S., China, India, Europe and Mexico and preparing for subsequent launch of gel-based products in these countries; and expanding Oculus' partnerships outside human wound care.

"Self-sustainability gained by growth of revenue and expense control remains an important objective," Alimi said. "We believe we are positioned to continue to grow revenue and accelerate new product research and development efforts, while expanding our portfolio of partners and reducing our cash burn."

Oculus makes a family of products based on its Microcyn Technology platform, which is intended to help prevent and treat infections in chronic and acute wounds.

"It will eradicate infection very, very quickly," Alimi told *MDD*. "In less than a minute it will kill MRSA, VRE, staph, viruses, spores. It's extremely antimicrobial."

The technology platform features a biocompatible, self-stable solution containing active oxychlorine compounds that is currently sold primarily in Europe, India, China and Mexico for the treatment of infected wounds.

The solutions derived from this platform have demonstrated, according to the company, the ability to treat a wide range of pathogens, including antibiotic-resistant strains of bacteria, viruses, fungi and spores. Oculus also makes a number of devices and products under 510(k) regulatory approvals to professionals and consumers.

In 2005 Oculus received its first 510(k) clearance from FDA to market Dermacyn Wound Care, formulated with Microcyn Technology, as a medical device for moistening, lubricating and debriding acute and traumatic wounds and

burns Oculus described Microcyn as a super-oxidized, pH-neutral solution ready for use without requiring dilution or mixing, and needing no special handling or disposal. It is manufactured using a multi-chamber electrolysis process in which ionic species are selectively produced and isolated. This process allows for the production of a pH-neutral solution while minimizing the level of chlorine in the final product, the company said (*Medical Device Daily*, May 13, 2005).

### Today's MDD food for med-tech thought

*"We know we have the tiger by the tail and now there is a significant amount of demand for this product. We think this is very good, positive data from Phase II."*

— Hoji Alimi, CEO and founder of Oculus Innovative Sciences, discussing the company's development of a gel-based version of its wound treatment product based on Microcyn Technology, "Oculus cuts costs in advance of U.S. launch of Microcyn," pp. 2, 10.

Oculus completed a Phase II study of its technology as a topical antimicrobial treatment for mildly infected diabetic foot ulcers in December 2007. According to the company, 93.3% of patients treated with Microcyn alone, compared with only 56.3% of patients treated with Levofloxacin plus saline, showed infection improvement after 10 days of treatment. The company said it wanted to compare its product to Levoflaccacin because it is one of the more potent, broad-spectrum oral antibiotics indicated for the treatment of complicated skin and skin structure infections.

"We know we have the tiger by the tail and now there is a significant amount of demand for this product," Alimi told *MDD*. "We think this is very good, positive data from Phase II, which was followed by a very successful end-of-Phase II meeting with FDA."

Alimi said he expects the data to bolster Oculus' position to look at partnerships and have a larger drug company partner with it on the drug development.

"Our team delivered two key items: positive clinical data and a successful end-of-Phase II meeting with the FDA that allows us to move the U.S. clinical program forward into pivotal trials," he said. "Now we are targeting our resources on the commercialization effort to provide millions of patients across the globe with access to our patented Microcyn Technology, while pursuing discussions with prospective partners that can move the Microcyn Technology towards drug approval in the U.S."

Alimi said he would provide more information about Oculus' commercialization efforts during the company's next earnings call in November.

"What really excites me about our technology — and the company actually — is when you look at young pharmaceutical companies what sets us apart is that we already have regulatory approvals worldwide, and we have already established distribution channels and direct sales force..." Alimi said. ■