

February 27, 2008



# Oculus Innovative Sciences Announces Positive Top-Line Phase II Data with Microcyn(R) Technology in Mildly Infected Diabetic Foot Ulcers

## Met Primary Endpoint of Clinical Cure or Improvement of Infection

PETALUMA, Calif.--(BUSINESS WIRE)--

Oculus Innovative Sciences, Inc. (Nasdaq:OCLS) today announced positive top-line results from its U.S. Phase II clinical trial evaluating Microcyn(R) Technology as a topical antimicrobial treatment for mildly infected diabetic foot ulcers. Microcyn demonstrated a positive clinical response, defined as the clinical cure or improvement of infection, as a monotherapy and in combination with levofloxacin, a systemic antibiotic. The company plans to request an end-of-Phase II meeting with the FDA to discuss Phase II results and define the scope and parameters for advancing the clinical program.

Top-line results are as follows:

Clinical Cure or Improvement of Infection at Days 10 and 24 (ITT)

|                                        | Microcyn<br>(Monotherapy) |         | Saline +<br>Levofloxacin |         | Microcyn +<br>Levofloxacin |         |
|----------------------------------------|---------------------------|---------|--------------------------|---------|----------------------------|---------|
|                                        | # Patients                | Percent | # Patients               | Percent | # Patients                 | Percent |
| Day 10                                 |                           |         |                          |         |                            |         |
| Clinical Success<br>(Primary Endpoint) | 15                        | 75%     | 12                       | 57%     | 16                         | 64%     |
| Cure                                   | 6                         | 30%     | 7                        | 33%     | 9                          | 36%     |
| Improvement                            | 9                         | 45%     | 5                        | 24%     | 7                          | 28%     |

|                                       |    |     |    |     |    |     |
|---------------------------------------|----|-----|----|-----|----|-----|
| Day 24                                |    |     |    |     |    |     |
| Clinical Success<br>(Follow-Up Visit) | 15 | 75% | 11 | 52% | 18 | 72% |
| Cure                                  | 11 | 55% | 6  | 29% | 11 | 44% |
| Improvement                           | 4  | 20% | 5  | 24% | 7  | 28% |

Intent to  
Treat (ITT)  
Population

(a) Intent-to Treat (ITT) Sample: All randomized subjects having taken at least one dose of study drug and having provided any on-treatment data. Percentages are based on the number of ITT patients in each treatment group.

Hoji Alimi, CEO and founder of Oculus Innovative Sciences, said, "We believe that Microcyn has the potential to be the first topical drug to provide patients with a favorable safety profile and effective antimicrobial properties. The top-line results of the study are a major milestone for Oculus. Microcyn demonstrated a positive clinical success rate by meeting the primary endpoint of clinical cure or improvement of infection. We are extremely encouraged by the preliminary Phase II data available today and are pleased to announce an initial analysis of the primary endpoint ahead of schedule. We are now focusing on further analysis of the complete trial data to prepare for our end-of-Phase II meeting with the FDA."

Andres A. Gutierrez, M.D., Ph.D., director of medical affairs for Oculus Innovative Sciences, stated, "We look forward to continuing our evaluation and presenting expanded results on March 14, 2008 at DF Con, which is one of the premier international diabetic foot conferences held annually."

The primary Phase II endpoint was clinical cure or improvement of infection at the end of therapy (day 10). Clinical cure of infection is defined as the elimination of all five of the Infectious Diseases Society of America (IDSA) visual symptoms that characterize mildly infected diabetic foot ulcers, including: 1) presence of erythema less than two centimeters around the ulcer, 2) detectable increase in temperature of the wound or periwound area, 3) culturable exudate and/or extension of redness is present, 4) localized swelling or induration, and 5) localized tenderness or pain. Clinical improvement of infection is defined as the elimination of at least two of the five IDSA symptomatic visual indications.

Levofloxacin was chosen for the control group because it is one of the more potent, broad-spectrum oral antibiotics indicated for the treatment of complicated skin and skin structure infections (CSSSIs). IDSA guidelines also recognize Levofloxacin as an appropriate treatment for the treatment of diabetic foot infections. According to the Datamonitor Pharmaceutical Report, Levofloxacin generated \$2.4 billion in global sales in 2005.

#### Preliminary Phase II Data Analysis

No serious drug-related adverse events were reported in any of the three treatment arms. In the Microcyn-Levofloxacin combination arm, two patients experienced stomach discomfort and amnesia, respectively, both related to levofloxacin while one patient experienced a burning sensation attributed to Microcyn, which is consistent with observations in prior Microcyn studies.

Although microbiological data does not impact the clinical success achieved in meeting our primary endpoint, we continue to clean and analyze this raw data. A preliminary review of the raw data suggests that there were fewer eradications of bacterial strains in the Microcyn monotherapy arm. Our initial impression is that it would appear the population of bacteria was lowered sufficiently to induce a clinical response rate of 75%.

#### About the Phase II Trial

The Phase II randomized, open-label study enrolled a total of 66 patients with mildly infected diabetic foot ulcers at 15 U.S. sites. Three treatment arms were evaluated: 1) 20 patients received topical Microcyn alone; 2) 25 patients received topical Microcyn in combination with oral levofloxacin; and 3) 21 patients received topical saline in combination with oral levofloxacin.

Patient enrollment criteria in all three treatment arms of the study included appropriate blood perfusion and mildly infected ulcers defined by IDSA classification of "mild" and University of Texas wound classification of "1B." Patients were randomized and treated for a total of 10 days. Designed into the trial were three assessment time points: day three, day 10, and day 24. The design provided flexibility for an optimal design of a Phase III trial based on a number of potential positive signals at various time points.

### Diabetes and Diabetic Foot Ulcers

According to the American Diabetes Association, 20.8 million children and adults in the United States, or 7% of the population, are afflicted with diabetes. If present trends continue, one in three Americans that were born in 2000 will develop diabetes during their lifetime. Each day, approximately 4,110 people are diagnosed with diabetes. The average cost of treatment is \$8,000 for a single ulcer, \$17,000 for an infected ulcer, and \$45,000 for an ulcer requiring major amputation. More than 80,000 amputations are performed each year on diabetic patients in the United States. 50% of patients who have undergone amputations will develop ulcerations and infections in the contralateral limb within 18 months, while 58% will have a contralateral amputation three to five years after the first amputation. In addition, the estimated three-year mortality rate is as high as 20%-50% after a first amputation. These figures have not changed much in the past 30 years, despite huge advances in the medical and surgical treatment of patients with diabetes.

A 2006 study published in *Clinical Diabetes* by Ingrid Kruse, DPM, and Steven Edelman, MD, indicated that diabetic foot problems, such as ulcerations, infections, and gangrene, are the most common causes of hospitalization among diabetic patients. Routine ulcer care, treatment of infections, amputations, and hospitalizations cost billions of dollars every year and place a tremendous burden on the health care system.

### Conference Call Information

Oculus Innovative Sciences, Inc. will host a teleconference at 9 a.m. EST (6 a.m. PST) today (February 27, 2008) to discuss the top-line Phase II results.

A live webcast over the Internet will be available at <http://ir.oculusis.com/events.cfm> and will be archived for one year.

To listen over the phone, please call 1-877-407-4021 (domestic/toll-free) or 1-201-689-8472 (international). A telephone replay will be available for 30 days after the call at 1-877-660-6853 (domestic/toll-free), or 1-201-612-7415 (international). Please enter account number 3055 and conference identification number 271899.

### About Oculus

Oculus Innovative Sciences is a biopharmaceutical company that develops, manufactures

and markets a family of products based upon the Microcyn(R) Technology platform, which is intended to help prevent and treat infections in chronic and acute wounds. The Microcyn Technology platform is a biocompatible solution containing active oxychlorine compounds. The solutions derived from the Microcyn Technology platform have demonstrated, in a variety of research and investigational studies, the ability to treat a wide range of pathogens, including antibiotic-resistant strains of bacteria (including MRSA and VRE), viruses, fungi and spores. The technology has also demonstrated wound healing in chronic and acute wounds in clinical investigational studies. It has been commercialized outside of the United States for the treatment of infected wounds.

Oculus' principal operations are in Petaluma, California, and it conducts operations in Europe, Latin America and Japan through its wholly owned subsidiaries, Oculus Innovative Sciences Netherlands B.V., Oculus Technologies of Mexico, S.A. de C.V. and Oculus Japan K.K. Oculus' website is [www.oculusis.com](http://www.oculusis.com).

#### Forward-Looking Statements

Except for historical information herein, some matters set forth in this press release are forward-looking within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements about our plans to request a meeting with the FDA, our belief that the design of our Phase II trial should provide important information for our planned Phase III trial, our ability to provide expanded analysis, or that our Phase II trials will be sufficient to allow the Company to move forward in its clinical program. These forward-looking statements are identified by the use of words such as "believe," "expect," "plan," and "should," among others. Forward-looking statements in this press release are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including risks inherent in the development and commercialization of potential products, the risk that regulatory clinical and guideline developments may change, the risk that scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, the risk that clinical results may not be replicated in actual patient settings, the risk that protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, the risk that present trends will continue and that the available market for our products will not be as large as expected, the risk that our products will not be able to penetrate one or more targeted markets, the risk that revenues will not be sufficient to fund further development and clinical studies, the Company's future capital needs, and its ability to obtain additional funding and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including the quarterly report on Form 10-Q for the quarter ended December 31, 2007. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements.

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Source: Oculus Innovative Sciences, Inc.