

# Oculus Innovative Sciences Provides 2010 U.S. Milestones Update

# Microcyn(R)-Based Product Introductions:

- -- Orthopedic and Surgical Microcyn Technology Product Introduction into Orthopedic and Surgical Markets (Jan. 2010)
- -- Negative-Pressure Wound Therapy Microcyn Technology Product Introduction as Accessory for Negative-Pressure Wound Therapy Devices (Feb. 2010)
- -- Microcyn Skin and Wound HydroGel Dermatology Indications Microcyn Technology HydroGel Product Introduction into Dermatology Market (Q2 2010)

## Microcyn-Based Products FDA Clearances:

- -- Upper Respiratory Expecting FDA Clearance for Allergy Block HydroGel (Q3 2010)
- -- Second Dermatology Product Expecting FDA Clearance for Atopic Dermatitis HydroGel (Q3 2010)

#### **Oculus Partner Updates:**

- -- Animal Health Vetericyn(TM) Animal Products Introduced into Canine Market through Dog Whisperer, Cesar Millan (Current)
- -- Professional Oral Care Microcyn Technology Products FDA Cleared and Introduced into Oral Biofilm and Mucoprotectant Market (Q2/Q3 2010)

PETALUMA, Calif.--(BUSINESS WIRE)-- Oculus Innovative Sciences, Inc. (Nasdaq: OCLS), a biopharmaceutical company that develops, manufactures and markets a family of products based upon the Microcyn<sup>(R)</sup> Technology platform, initially intended to treat chronic and acute wounds, today unveiled an expanded regulatory/commercial pipeline for its Microcyn-based products as preparation for the company's CEO and founder, Hoji Alimi, to provide even greater detail at the OneMedForum on January 12, 2010 in San Francisco.

"We see 2010 as being a breakout year in terms of U.S. product regulatory clearances, new product introductions, revenue growth and partner activities. While we're unable to control the timing of the FDA review process, we believe these anticipated marketing clearances will be transformative, creating added revenue streams that will help get us to revenues of greater than \$45 million to \$60 million with operating profitability of 20% by 2013," said Hoji Alimi, Oculus CEO and founder. "Based upon shareholder feedback, we have decided to provide greater transparency in terms of identifying the 2010 milestones by which we will measure our success over the coming year. I think it important that investors be able to see the extensive efforts being put forth by Oculus' R&D and marketing teams, as well as our

U.S. partners, to move beyond the existing product portfolio and generate new Microcynbased products for applications including orthopedic and surgical irrigation, an advanced solution that is complementary to negative-pressure wound therapy devices, oral care, dermatology treatments and allergy relief."

United States Product Introductions:

Orthopedic and Surgical Irrigation - (Introduction: Jan. 2010)

Packaged in a sterile, spikeable bottle that is ideal for use in orthopedic and surgical applications, Oculus will introduce Microcyn OSID in January of 2010. Oculus will leverage its 30-second kill times in solution against dangerous pathogens such as MRSA and VRE. Unlike current standards of care, Microcyn OSID is non-foaming, non-sensitizing, and based upon evidence, does not appear to facilitate resistant strains of bacteria.

Adam Landsman, DPM, Ph.D. and assistant professor of surgery at Harvard Medical School in Boston, who was lead investigator in a Phase II trial in which the Microcyn Technology was used to treat mildly infected diabetic foot ulcers in 2007, stated: "The current standard for surgical wound cleansing and irrigation involves the use of products that do not kill the MRSA infection in-vitro. This is important in light of the skyrocketing proliferation of these dangerous bacteria as well as the evolving 'super bug' mutations. Microcyn is also highly attractive since it does not produce foam, which hampers visualization of the wound. And finally, with the health community so vitally focused on cost savings, the Microcyn OSID will actually cost less than the current combination of saline and bacitracin."

For years, the standard of care for surgical irrigation was saline infused with bacitracin, an antibiotic first discovered in 1945. According to the journal Orthopedics (2008; 31:37), due to resulting resistance, bacitracin is no longer considered effective for MRSA decolonization. Surgical irrigation and debridement remains the standard of care for removal of necrotic tissue and is used when the tissue removal needs are extensive, or when the patient has a serious infection associated with the surgical wound site.

According to Medtech Insight, a Division of Windhover Information, in 2004 there were approximately 36 million surgical wounds and nine million open trauma wounds in the United States. Initially, Microcyn OSID(TM) will be marketed by the Advocos sales team that is currently selling the professional formulations of the Microcyn-based wound care products.

Accessory for Negative-Pressure Wound Therapy (NPWT) Devices - (Introduction: Jan. 2010)

According to U.S. Markets for Current and Emerging Wound Closure Technologies, a report published in April 2009 by Medtech Insight, 2009 sales of negative-pressure wound therapy products will total approximately \$1.1 billion. Oculus' new Microcyn NPWT solution can be used in conjunction with the NPWT devices from Kinetic Concepts Inc., Smith and Nephew, ConvaTec, Innovative Therapies, Medela, NovaSpine and Boehringer Wound Systems.

Microcyn Skin and Wound HydroGel - Dermatology Indications - (FDA Regulatory Clearance and Introduction: Q2 2010)

Oculus has filed a 510(k) application with the FDA to secure marketing clearances of the

Microcyn HydroGel product for dermatological uses. This clearance is expected in the first half of 2010. The indication under review proposes that the HydroGel, under the supervision of a medical professional, be used for treatment of first- and second-degree burns (including sunburns), radiation dermatitis, itching, skin conditions associated with periostomy care, skin irritation associated with tattooing procedures, irritation and pain following skin laser resurfacing treatment, dermabrasion therapy and chemical peels.

**United States Regulatory Clearances:** 

Allergy Block HydroGel OTC - (FDA Regulatory Clearance: Q3 2010)

Microcyn Allergy Block HydroGel(TM) is designed as a self-contained package of disposable applicators and an anti-allergy formulation of Microcyn HydroGel to be applied to the interior of the nasal cavities for relief from allergy symptoms including allergic rhinitis.

An allergy is an overreaction of the immune system to a substance that's harmless to most people. But in someone with an allergy, the body's immune system treats the substance (called an allergen) as an invader and reacts inappropriately, resulting in symptoms that can be anywhere from annoying to possibly harmful to the person. In an attempt to protect the body, the immune system of the allergic person produces antibodies called immunoglobulin E (IgE). Those antibodies then cause mast cells to release chemicals, including histamine, into the bloodstream to defend against the allergen.

There were more than 12 million physician office visits because of allergic rhinitis in 2006, affecting between 10% and 30% of all adults and as many as 40% of children. From 2000 to 2005, the cost of treating allergic rhinitis almost doubled from \$6.1 billion (in 2005 dollars) to \$11.2 billion. More than half of that was spent on prescription medications.

Atopic Dermatitis HydroGel Rx - (FDA Regulatory Clearance: Q3 2010)

An FDA clearance for a prescription Microcyn AD HydroGel(TM) specially formulated for the treatment of atopic dermatitis is expected in Q3 2010, after which time it will be marketed to the nearly 16,000 U.S. dermatologists.

Atopic dermatitis is a common and chronic inflammatory skin disease marked by red, itchy rashes. It has been increasing in prevalence over the past two decades and affects a disproportionate number of children. According to current estimates, approximately 15 percent to 20 percent of children in the United States and other industrialized countries around the world develop atopic dermatitis in the first few years of life. By comparison, only an estimated three percent to five percent of adults have an active form of the condition.

The <u>skin</u> of a patient with atopic dermatitis reacts abnormally and easily to irritants, food, and environmental <u>allergens</u> and becomes red, flaky and very itchy. It also becomes vulnerable to surface infections caused by bacteria. The skin on the flexural surfaces of the joints (for example inner sides of elbows and knees) are the most commonly affected regions in people. Although there is no cure for atopic <u>eczema</u>, and its cause is not well understood, it can be treated in the short term through a combination of prevention (learning what triggers the allergic reactions) and drug therapy.

According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, in a

recent analysis of the costs associated with atopic dermatitis in the United States, researchers reviewed studies evaluating both direct costs (doctor visits, hospitalizations, and medicine) and indirect costs (over-the-counter remedies, lubricants, and days lost from work). They found that direct costs totaled about 25 percent, and indirect costs totaled about 75 percent of costs. Per patient, the costs averaged about \$600 per year. On the whole, direct costs alone may exceed \$3 billion per year.

Oculus Partner Updates:

Vetericyn(TM) Animal Healthcare Products - (Current)

Following the successful introduction via a national advertising campaign of the Vetericyn products into the equine market by Oculus' partner, Innovacyn, Vetericyn products for the canine market are now being promoted via the world-famous Cesar Millan and his Dog Whisperer(R) franchise.

Oral Antibiofilm and Mucoprotectant - (FDA Regulatory Clearance and Introduction: Q2/Q3 2010)

As announced in July 2009, Oculus licensed the Microcyn Technology to OroScience, Inc. for the professional oral care markets in the United States, Canada and Europe. OroScience anticipates initially introducing two Microcyn-based products, namely Periocyn(TM) Antitbiofilm Rinse for the treatment of gingivitis and Periocyn(TM) Mucoprotectant for the treatment of oral mucositis. OroScience believes FDA clearances to market these products are expected by early second guarter 2010.

Gingivitis is an inflammation of the gingival (gums) characterized by a change in color from normal pink to red, with swelling, bleeding, and often sensitivity and tenderness. Gingivitis is caused by bacteria in the biofilm or dental plaque that forms on oral surfaces. If left untreated, gingivitis can progress to more severe forms of periodontal disease and result in deep pockets between the teeth and gums and loss of <a href="bone">bone</a> around teeth and eventual loss of teeth as well as halitosis (bad breath). In a 1999 study reported by the Centers for Disease Control and Prevention, 50.3% of the U.S. population aged 30 years or older were afflicted with gingivitis. Early and sustained treatment of gingivitis is an important factor in preventing the progression of gingivitis to more severe forms of periodontal disease.

Oral mucositis (OM) is a common, painful, and often debilitating side effect of cancer therapy such as chemotherapy and radiotherapy. OM is estimated to affect more than 800,000 cancer patients each year in the EU and United States. OM affects approximately 40% of cancer patients who receive chemotherapy, more than 70% of those undergoing conditioning therapy for bone marrow transplantation, and patients receiving radiation therapy for head and neck cancer. The economic impact of mucositis can be significant, as the need for prolonged hospital stays, nutritional therapy and treatments for pain and infection can drive up the costs of therapy.

These professional Microcyn-based oral care products, along with future applications, will be distributed by OroScience beginning in mid-2010 via a large global dental distributor. Oculus retains the right to either market or license the over-the-counter formulations globally.

OneMedForum 2010 Update:

Hoji Alimi, Oculus CEO and founder, will provide a regulatory and commercialization update relative to the U.S. pipeline as well as advances being realized in the international markets during his 10:45 am, January 12, 2010 OneMedForum presentation at the Sir Francis Drake Hotel in San Francisco.

#### About Oculus Innovative Sciences

Oculus Innovative Sciences develops, manufactures and markets a family of products based upon the Microcyn<sup>(R)</sup> Technology platform, which includes new formulations designed to significantly reduce the need for antibiotics as it reduces infections. The Microcyn Technology platform features a biocompatible, shelf-stable solution that is currently commercialized in the United States, Europe, India, China and Mexico and select Middle East countries under various country specific regulatory clearances and approvals. Several solutions derived from this 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, increase blood flow to the wound site, reduce both inflammation and pain while assisting in faster wound closure. The company's headquarters are in Petaluma, California, with operations in Latin America. More information can be found at www.oculusis.com.

### Forward-Looking Statements

Except for historical information herein, matters set forth in this press release are forwardlooking within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements about the Company's commercial and technology progress and future financial performance. These forward-looking statements are identified by the use of words such as "introduced," "expecting," "will," and "generate," 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 such risks that regulatory clinical and guideline developments may change, scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, the Company may not meet its future capital needs, and its ability to obtain additional funding, as well as uncertainties relative to varying product formulations and a multitude of diverse regulatory and marketing requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including the annual report on Form 10-K for the year ended March 31, 2009. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements except as required by law.

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