

# Oculus Innovative Sciences Announces Fiscal Fourth Quarter and Full Year 2008 Financial Results and Corporate Update

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

Oculus Innovative Sciences, Inc. (NASDAQ:OCLS):

Recent Highlights

- -- Filed patent on advanced wound care device
- -- Announced market assessment of near-term commercialization opportunities for 510k cleared Dermacyn Wound Care in United States
- -- Presented positive Phase II Microcyn(R) data in mildly infected diabetic foot ulcers at DFCon 08
- -- Received Chinese SFDA regulatory approval of Microcyn in various acute and chronic wounds
- -- Announced initial Chinese commercialization plan for Microcyn Technology
- -- Appointed Michelle Carpenter, JD, RAC, as vice president of regulatory affairs and quality
- -- Raised \$13.9 million (gross) in registered direct offering of common stock and warrants to institutional investors
- -- Reduced international operating expenses by \$4 million
- -- Mexico operation reached breakeven for the month of March 2008

Oculus Innovative Sciences, Inc. (NASDAQ:OCLS) today announced quarterly results for its fiscal fourth quarter and full year ended March 31, 2008.

Hoji Alimi, CEO and founder, stated, "Our full-year financials reflect Oculus' strategic goal to focus primarily on the successful completion of our Phase II clinical trial in the U.S. while simultaneously reducing expenses outside-the-United States as part of our plan to fund this successful clinical program. The day-24 results of the Phase II trial demonstrated a 93% cure and improvement rate in the Microcyn-only arm in the treatment of mildly infected diabetic ulcers versus a 56% cure and improvement rate in the control group using saline and levofloxacin, an antibiotic with \$2.4 billion in annual sales last year. And looking forward, unlike a year ago, we now have an increased level of market awareness in the United States for Dermacyn(TM) Wound Care as well as clinical data demonstrating Dermacyn's pharmacoeconomic benefits versus saline in the treatment of wounds. As a result we feel we

may have an opportunity to establish an effective commercialization strategy within the existing regulatory label claims."

The first step in this process will be to confirm the company's assumptions through a market assessment initiative announced last week. This will provide the company with a better understanding of how to optimally discuss Dermacyn Wound Care with clinicians while remaining compliant with the regulatory limitations of the 510k-cleared label claims. In addition to the U.S. market assessment, the company also announced this past week that it had filed a patent with the U.S. Patent and Trademark office on an advanced wound treatment device that delivers a Microcyn-based solution to the wound and transports organic load away from it via a vacuum process. The device has the capability to monitor the wound environment and deliver additional Microcyn solution to the wound when required. The device's innovative sponge-free dressing avoids contact with the wound, thereby eliminating the common practice of repeatedly debriding otherwise healthy fibroblast as dressings are changed. Unnecessary trauma to the wound bed can hamper or delay wound healing.

Alimi continued, "With the highest level of confidence in the Microcyn Technology's efficacy and safety, we begin fiscal year 2009 by focusing on multiple opportunities. First and foremost, we recently requested an End-of-Phase II meeting with the FDA so as to continue to the next step in our U.S. clinical program and our efforts to secure a drug approval. Secondly, we are evaluating the U.S. market for near-term commercialization potential for our 510k-cleared product. This initiative is based on positive feedback over the past year from U.S. physicians and medical practitioners at many hospitals and clinics who have been treating wounds with the Microcyn Technology. As we have test marketed our technology in the U.S., we have received significant clinical data as well as encouraging pharmacoeconomic results related to the use of Microcyn Technology versus saline in managing multiple wound types. The subsequent plan following this U.S. market assessment will address differentiation of the 510k product and its branding while maintaining the integrity of the drug opportunity."

In addition to a steady stream of accomplishments related to Oculus' U.S. clinical development program and partnering, the Microcyn Technology also achieved positive gains abroad. In March, China's State Food and Drug Administration (SFDA) granted marketing authorization to Microcyn as a treatment for various acute and chronic wounds. For the first time in China, Microcyn-based products will be available and marketed by Oculus partner China Bao Tai and its various sub-distributors including Sinopharm, which is the largest pharmaceutical group in China, and Lianhua Supermarket Holdings Co., Ltd. In April, the Oculus development team visited Beijing and met with the Chinese partner where they reviewed their multi-tier strategy proposed for the launch of Microcyn in China. This will initially target key opinion leaders via trials at multiple medical centers for the purpose of securing both post-market clinical data and reimbursement.

"We are delighted to have secured a foothold in Asia's fastest growing territory to deliver an effective topical wound care treatment through China's largest pharmaceutical group," said Alimi. "We look forward to an eventful fiscal year 2009 and thank all of our shareholders for their continuing support as we continue to move forward in our U.S. clinical program, further examine U.S. 510k commercialization opportunities and continue our business development initiatives worldwide."

Fiscal Fourth Quarter and Full Year 2008 Results (Period ended March 31, 2008)

Last year, the company made a strategic decision to focus its resources on the clinical drug development process in the United States since it is the largest addressable market in the world for Microcyn, and to dramatically reduce international expenses.

The primary objectives for the fiscal year 2008 in Mexico were to reduce operating expenses and break even by the end of the year. Both objectives were achieved. Mexico broke even in the last month of the year and reduced operating expenses by \$2.6 million for the year. As a result of reducing the Mexican sales force from over 70 to approximately 30, the company decided to focus its sales efforts on growing the more profitable pharmacy sector and demphasizing sales coverage in the less-profitable public hospital sector. To provide a sense of the relative profitability, the revenue per liter in the pharmacy sector is about seven times that of the public hospitals in Mexico. As a result of this shift in focus and a smaller sales force, the company had lower sales in Mexico for the quarter and the year due to lower sales to the hospital sector.

But overall, the Mexican operation improved its cash flow, the primary objective for Mexico in fiscal year 2008, enabling it to break even by the end of the year. The sales to the pharmacies grew 37% for the full fiscal year compared to last year and 29% for the fourth quarter. With 6% of the pharmacy topical antiseptic market share in Mexico, selling on average 25,000 240ml units per month in the fourth quarter, Oculus will use this distribution channel, which includes Wal-Mart, Grupo Casa Saba, S.A. de C.V. and NADRO, S.A. de C.V., as the platform for growth in Mexico.

As a result of Oculus' experience internationally, the strategy for expanding is that of affiliation with strong partners, as the company has done in India and China. This allows revenues to be grown without investing internal resources in the marketing and sales effort. As a part of this strategy Oculus' partners control the specific marketing and sales tactics customized for their particular market. The sales to India were down for the full fiscal year compared to last year's large initial stocking orders of \$606,000, which was used to broadly distribute samples during the product launch in fiscal year 2007, and for sales of the product from Alkem to their customers in fiscal year 2008.

Actual sales of Microcyn-based product by Alkem Laboratories to their customers have continued to show steady unit growth since the product launch in September 2007 to monthly sales of 33,000 100 ml units during the fourth quarter. Oculus expects continued growth in units delivered to the India market by Alkem.

Additionally, clinical results of Microcyn use in India and Mexico continue to demonstrate consistent safety, potency in curing infection and efficacy in wound healing. For example, a randomized Indian trial involving the Microcyn Technology in 100 patients was presented at DFCon 08 in Hollywood this March. The trial data demonstrated faster wound healing and increased reduction of bioburden in the Microcyn arm, consistent with the results in more than 25 other clinical trials on Microcyn.

Total revenues for the fiscal year ended March 31, 2008 were \$3.8 million, compared to \$4.5 million in the prior year primarily due to lower bulk sales to Oculus' India-based distribution partner, Alkem Laboratories Limited, as previously explained. This 2008 revenue does not include \$615,000 of deferred revenue related to upfront cash payments from the

partnership transactions with China Bao Tai and Union Springs Pharmaceuticals. Service revenues for the full fiscal year were up 10% due to a higher volume of testing.

Total revenues for the fiscal fourth quarter of 2008 were \$926,000, compared to \$1.2 million in the fiscal fourth quarter 2007, mainly due to international sales force reductions and cost cutting aimed at achieving breakeven in Mexico as mentioned above. Service revenues were down 16% in the quarter due to lower testing volumes. Gross product margins in the fourth fiscal quarter of 2008 were 34%, compared to 45% in the year-ago period, caused primarily by lower sales in Mexico.

Operating expenses for the fiscal year 2008 were \$23.5 million, up from \$21.0 million during the fiscal year 2007, primarily as a result of higher research and development expenses. The increase in research and development expenses were caused by clinical costs, which rose by \$3.1 over the prior year period mostly associated with the U.S. Phase II clinical trial, as well as the build up of research and regulatory teams in preparation for Oculus' continuing U.S. clinical program and additional research activities.

The increase in clinical expenses was partially offset by a 17%, or \$2.8 million, decrease in selling, general and administrative expenses to \$13.7 million for the fiscal year ended March 31, 2008 from \$16.5 million for the fiscal year ended March 31, 2007. This is consistent with Oculus' strategy to reduce international costs and to focus the company's resources on U.S. clinical trials. Selling, general and administrative expenses declined by \$4 million year-over-year in Mexico and Europe, which were partially offset by the higher accounting, legal and insurance costs associated with being a public company.

Operating expenses for the fiscal fourth quarter ended March 31, 2008 were \$6.0 million, down from \$6.2 million in the prior year period. The decline in operating expenses was attributable to significant reductions in Mexico and Europe, partially offset by the building of our research and development teams and related costs and higher selling, general, and administrative costs associated with being a public company.

Net loss for the fiscal year ended March 31, 2008 was \$20.3 million, or \$1.60 per basic and diluted share, compared to a net loss of \$20.2 million, or \$3.71 per basic and diluted share in the fiscal year ended March 31, 2007. Full year 2008 net loss included \$1.3 million of non-cash stock-based compensation expenses, compared to \$1.6 million in the year ago period.

Net loss for the fourth fiscal quarter of 2008 was \$4.5 million compared to a net loss of \$6.3 million in the fiscal fourth quarter of 2007. Net loss for the fiscal fourth quarter included \$422,000 of non-cash stock-based compensation expenses, compared to \$522,000 in the fiscal fourth quarter of 2007.

Cash and cash equivalents, at March 31, 2008, was \$18.8 million, compared to \$19.1 million at March 31, 2007 and \$10.4 million on December 31, 2007. For the year ended March 31, 2008, the company raised a net \$21.7 million through a net \$9.1 million private placement in August 2007 and a net \$12.9 million registered direct offering in March 2008. During fiscal year 2008, Oculus reduced its net debt by \$5.9 million to \$2.2 million, down from \$8.1 million at March 31, 2007.

Corporate Highlights:

Announced market assessment of near-term commercialization opportunities in the United States for Dermacyn Wound Care

Company initiated a market analysis to study near-term commercialization opportunities for Dermacyn(TM) Wound Care in the United States. Dermacyn Wound Care received three FDA 510k clearances in May of 2005 for use in moistening, lubricating, cleaning and debriding wounds. While exploring these near-term opportunities, the company continues to advance its U.S. clinical program for drug approval of the Microcyn Technology, having recently requested an End-of-Phase II meeting with the FDA.

Files for patent protection with U.S. Patent and Trademark Office on advanced wound care device

Company filed a patent application with the U.S. Patent and Trademark Office in which it seeks patent protection for an advanced wound care device. The device delivers a Microcyn-based solution to the wound and transports organic load away from it via a vacuum process. The device automatically monitors the wound environment and delivers additional Microcyn solution to the wound when required. The device's innovative sponge-free dressing does not come in contact with the wound, thereby eliminating the common practice of repeatedly debriding otherwise healthy fibroblast as dressings are changed.

### U.S. Clinical Achievements

Presented Phase II Microcyn data in mildly infected diabetic foot ulcers at DFCon 08

Three peer-reviewed abstracts on the safety and efficacy of Microcyn were presented at one of the world's premier diabetic foot conferences, DFCon 08. The company also provided expanded Phase II results in patients with mild diabetic foot infections. Key data on the clinically evaluable population at the test-of-cure visit (day 24) showed a clinical success rate of 93% in the Microcyn monotherapy arm versus 56% in the arm that received levofloxacin, an antibiotic, in combination with saline. Oculus recently requested an End-of-Phase II meeting with the FDA to discuss the trial data and potential design of the next stage of the U.S. clinical program.

Microcyn Advancements in China

Received Chinese SFDA approval of Microcyn in various acute and chronic wounds

Microcyn received marketing authorization in China from the State Drug and Food Administration for treatment of various acute and chronic wounds including ulcers, cuts, contusions and burns. Chinese partner China Bao Tai, and its various sub-distributors, including Sinopharm and Lianhua Supermarket Holdings Co., Ltd., will commercialize Microcyn as a technology that provides a moist environment for wounds and accelerates wound healing through the reduction of microorganisms in wounds.

Announced initial commercialization plan for launching Microcyn Technology in China

Oculus' management team visited Beijing and met with Chinese partner China Bao Tai and sub-distributor Sinopharm to discuss commercialization strategy for Microcyn Technology in China. The first phase of the Chinese commercialization plan includes sampling of Chinese wound care professionals with the Microcyn-based Dermacyn product. This will initially

target key opinion leaders via trials at multiple medical centers for the purpose of securing both post-market clinical data and reimbursement.

# **Financing Activities**

Raised \$13.9 million in registered direct offering of common stock and warrants to institutional investors

The company offered approximately 2.65 million shares of Oculus common stock and warrants to purchase approximately 1.33 million shares of Oculus common stock. Rodman & Renshaw, LLC, a subsidiary of Rodman & Renshaw Capital Group, Inc., acted as exclusive placement agent for the offering.

# **Management Appointments**

Appointed Michelle Carpenter, JD, RAC, as vice president of regulatory affairs and quality

Ms. Carpenter joined Oculus' management team with 15 years experience in regulatory affairs. She was appointed to lead and manage regulatory and quality personnel and activities, including key negotiations with the FDA regarding clinical development initiatives.

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Oculus Innovative Sciences, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

		Three Months Ended March 31,				Year Ended March 31,			
		2008 2007		2007	2008		2007		
REVENUE	_	=0.6	_		_		_	0 650	
Product Service	Ş					2,881 954			
Service									
Total revenues		926		1,162		3,835		4,543	
COST OF REVENUES									
Product						1,774			
Service		216				977			
Total cost of revenues		703				2,751			
Gross profit		223		388		1,084		1,544	
OPERATING EXPENSES									
Research and development Selling, general and		2,708		2,118		9,778		4,508	
administrative		3 <b>,</b> 291				13,271		16,520	
Total operating expenses		5 <b>,</b> 999		6,158		23,509		21,028	
Loss from operations	(	5,776)	(	5,770)	(	22,425)		(19,484)	
Interest expense		(172)		(391)		(1,016)		(956)	
Interest income						630			
Other income (expense), net		1,399 		(312)		2,472		345	
Net loss	(	4,475)	(	6,291)	(	20,339)		(19,783)	

Preferred stock dividends	-	(41)	_	(404)
Net loss available to common stockholders	\$(4,475) ======	\$(6,332) ======	\$(20,339) ======	\$(20,187) ======
Net loss per common share: basic and diluted	\$ (0.34) ======	\$ (0.69)	\$ (1.60) ======	\$ (3.71) ======
Weighted-average number of shares used in per common share calculations: Basic and	12 271	0 100	10 707	E 440
diluted	13,271	9 <b>,</b> 192	12,/3/	5,448 =======

#### Conference Call

Oculus management will host an investment community conference call and webcast to discuss these topics on June 11, 2008, at 4:45 p.m. ET (1:45 p.m. PT). A live broadcast over the Internet will be available at <a href="http://ir.oculusis.com/events.cfm">http://ir.oculusis.com/events.cfm</a> and will be archived for one year. To listen over the phone, please call 1-877-407-4018 (domestic/toll-free) or 1-201-689-8471 (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 270645.

### **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, shelf-stable solution containing active oxychlorine compounds that is currently commercialized outside the United States (Europe, Mexico, India) for the treatment of infected wounds. 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.

A recently completed U.S. Phase II clinical trial of Microcyn Technology met the primary endpoints of safety and efficacy for the treatment of mildly infected diabetic foot ulcers.

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 <a href="https://www.oculusis.com">www.oculusis.com</a>.

## 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. These forward-looking statements are identified by the use of words such as "support," "suggest," "plan," "intend," "strategy," "focus," "confident," "may," and "prepare," among others, and include statements relating to our ability to identify and address a particular market, our ability to commercialize our products utilizing our existing or additional clearances, the ability of our market assessment, clinical data or

phamacoeconomic results to accurately predict successful markets, the likelihood that our new patent application will be issued and, if issued, our ability to commercialize breakthrough technology through practice of the patent, the ability of new technology to function as expected or intended, the size of any market and our ability, or the ability of any partner, to address all or any part of any market, our ability to obtain or to maintain any partner relationship whether with or without expenditure of internal resources, our ability to obtain drug approval or other clearances for our technology, our ability to maintain or grow our business and sales in any market, the ability to reproduce test data in FDA testing to establish safety and efficacy, our ability to proceed to Phase III trials, and our ability to further reduce expenses or to break even for any specified period. 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 guarter ended December 31, 2007. These forward-looking statements speak only as of the date hereof. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements.

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Source: Oculus Innovative Sciences, Inc.