

# OCULUS INNOVATIVE SCIENCES, INC.

## FORM 10-K (Annual Report)

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Address	1129 N MCDOWELL BLVD PETALUMA, CA 94954
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended March 31, 2011
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-33216

**OCULUS INNOVATIVE SCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**68-0423298**  
(I.R.S. Employer  
Identification No.)

**1129 N. McDowell Blvd.**  
**Petaluma, California 94954**  
(Address of principal executive offices) (Zip Code)

**(707) 782-0792**  
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.0001 par value	NASDAQ Capital Market

**Securities registered pursuant to Section 12(g) of the Act:**

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  
Yes  No

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant on September 30, 2010 was approximately \$34,538,723 based on a total of 22,140,207 shares of the registrant's common stock held by non-affiliates on September 30, 2010,

at the closing price of \$1.56 per share as reported on the NASDAQ Capital Market.

There were 26,686,302 shares of the registrant's common stock issued and outstanding on June 2, 2011.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2011 Annual Meeting of Stockholders.

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## PART I

*This report includes “forward-looking statements.” The words “may,” “will,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “aim,” “seek,” “should,” “is likely,” and similar expressions as they relate to us or our management are intended to identify these forward-looking statements. All statements by us regarding our expected financial position, revenues, cash flows and other operating results, business strategy, legal proceedings and similar matters are forward-looking statements. Our expectations expressed or implied in these forward-looking statements may not turn out to be correct. Our results could be materially different from our expectations because of various risks, including the risks discussed in this report under “Part I — Item 1A — Risk Factors.” Any forward-looking statement speaks only as of the date as of which such statement is made, and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances, including unanticipated events, after the date as of which such statement was made.*

### ITEM 1. *Business*

#### **Corporate Information**

We incorporated under the laws of the State of California in April 1999 as Micromed Laboratories, Inc. In August 2001, we changed our name to Oculus Innovative Sciences, Inc. In December 2006, we reincorporated under the laws of the State of Delaware. Our principal executive offices are located at 1129 N. McDowell Blvd., Petaluma, California, 94954, and our telephone number is (707) 782-0792. We have two principal subsidiaries: Oculus Technologies of Mexico, S.A. de C.V., organized in Mexico, and Oculus Innovative Sciences Netherlands, B.V., organized in the Netherlands. On January 20, 2009, we dissolved our subsidiary, Oculus Innovative Sciences Japan, KK., which was organized under Japanese law. Our fiscal year end is March 31. Our website is [www.oculusis.com](http://www.oculusis.com). We do not intend for information on our website to be incorporated into this 10-K.

#### **Our Business**

We develop, manufacture and market a family of tissue care products that cure infections and, through a separate mechanism of action, enhance healing while reducing the need for antibiotics. Infection is a serious potential complication in both chronic and acute wounds, and controlling infection is a critical step in wound healing. Our platform technology, called Microcyn®, is a proprietary solution of electrically charged oxychlorine small molecules designed to treat a wide range of organisms that cause disease (pathogens). These include viruses, fungi, spores and antibiotic-resistant strains of bacteria, such as methicillin-resistant *Staphylococcus aureus*, or MRSA, and vancomycin-resistant *Enterococcus*, or VRE, in wounds, as well as *Clostridium difficile*, or C. diff, a highly contagious bacteria spread by human contact.

We do not have the necessary regulatory approvals to market Microcyn in the United States as a drug. In the United States, our device product does, however, have seven clearances as a 510(k) medical device for the following summary indications:

- 1) Moistening and lubricating absorbent wound dressings for traumatic wounds requiring a prescription;
- 2) Moistening and debriding acute and chronic dermal lesions requiring a prescription;
- 3) Moistening absorbent wound dressings and cleaning minor cuts as an over-the-counter product;

- 4) Management of exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers and for the management of mechanical or surgical debridement of wounds in a gel form and required as a prescription;
- 5) Debridement of wounds, such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first- and second-degree burns, grafted and donor sites as a preservative, which can kill listed bacteria such as MRSA & VRE and required as a prescription;
- 6) As a hydrogel, for management of wounds including itch and pain relief associated with dermal irritation, sores, injuries and ulcers of dermal tissue as a prescription. As an over-the-counter product, the hydrogel is intended to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns. It is also indicated for management of irritation and pain from minor sunburn: and.
- 7) As a hydrogel, for management and relief of burning, itching and pain experienced with various types of dermatoses including atopic dermatitis and radiation dermatitis.

We do not have the necessary regulatory clearance or approval to market Microcyn in the U.S. as a medical device with an antimicrobial or wound healing indication. In the future we expect to apply with the FDA for clearance as an antimicrobial in a liquid and a hydrogel form and as conducive to wound healing..

Outside the United States, our product has a CE Mark device approval in Europe for debriding, irrigating and moistening acute and chronic wounds in comprehensive wound treatment by reducing microbial load and creating a moist environment. In Mexico, we are approved as a drug for antiseptic treatment of wounds and infected areas. In India, our technology has a drug license for cleaning and debriding in wound management. In China, we have obtained a medical device approval by the State Food and Drug Administration for reducing the propagation of microbes in wounds and creating a moist environment for wound healing.

While in the United States, we do not have the necessary regulatory clearance for an antimicrobial or wound healing indication, clinical and laboratory testing we conducted in connection with our submissions to the FDA, as well as physician clinical studies and scientific papers, suggest that our Microcyn Technology may help reduce a wide range of pathogens from acute and chronic wounds while curing or improving infection and concurrently enhancing wound healing through modes of action unrelated to the treatment of infection. These physician-led clinical studies suggest that our Microcyn is safe, easy to use and complementary to many existing treatment methods in wound care. Physician-led clinical studies and usage in the United States suggest that our 510(k)-cleared products may shorten hospital stays, lower aggregate patient care costs and, in certain cases, reduce the need for systemic antibiotics. We are also pursuing the use of our Microcyn platform technology in other markets outside of wound and skin care, including the respiratory, ophthalmology, dental, dermatology, animal healthcare and industrial markets.

In 2005, chronic and acute wound care represented an aggregate of \$9.6 billion in global product sales, of which \$3.3 billion was spent for the treatment of skin ulcers, \$1.6 billion to treat burns and \$4.7 billion for the treatment of surgical and trauma wounds, according to Kalorama Information, a life sciences market research firm. Based on the firm's research, we believe the markets most related to our product involve approximately \$1.3 billion for the treatment of skin ulcers, \$300 million for the treatment of burns and \$700 million for the treatment of surgical and trauma wounds. Common methods of controlling infection, including topical antiseptics and antibiotics, have proven to be only moderately effective in combating infection in the wound bed. However, topical antiseptics tend to inhibit the healing process due to their toxicity and may require specialized preparation or handling. Antibiotics can lead to the emergence of resistant bacteria, such as MRSA and VRE. Systemic antibiotics may be less effective in controlling infection in patients with disorders affecting circulation, such as diabetes, which are commonly associated with chronic wounds. As a result, no single treatment is used across all types of wounds and stages of healing.

We believe the Microcyn Technology is the only known stable, anti-infective therapeutic available in the world today that simultaneously cures or improves infection while also promoting wound healing through increased blood flow to the wound bed and reduction of chronic inflammation. Also, we believe Microcyn provides significant advantages over current methods of care in the treatment of a wide range of chronic and acute wounds throughout all stages of treatment. These stages include cleaning, debridement, prevention and treatment of infections and wound healing. We believe that unlike antibiotics, antiseptics, growth regulators and other advanced wound care products, Microcyn is the only stable wound care solution that is as safe as saline, and also cures infection while simultaneously accelerating wound healing. Also, unlike most antibiotics, we believe Microcyn does not target specific strains of bacteria, a practice which has been shown to promote the development of resistant bacteria. In addition, our products are shelf stable, non-toxic, require no special preparation and are easy to use.

Our goal is to become a worldwide leader as the standard of care in the treatment and irrigation of open wounds and skin care. We currently have, and intend to seek additional, regulatory clearances and approvals to market our Microcyn-based products worldwide. In July 2004, we began selling Microdacyn60™ in Mexico after receiving approval from the Mexican Ministry of Health, for the use as an antiseptic, disinfectant and sterilant. Since then, physicians in the United States, Europe, India, Pakistan, China and Mexico have conducted more than 32 physician clinical studies assessing Microcyn Technology's use in the treatment of infections in a variety of wound types, including hard-to-treat wounds such as diabetic ulcers and burns. Most of these studies were not intended to be rigorously designed or controlled clinical trials and, as such, did not have all of the controls required for clinical trials used to support a new drug application submission to the FDA. A number of these studies did not include blinding, randomization, predefined clinical end points, use of placebo and active control groups or U.S. good clinical practices requirements. We used the data generated from some of these studies to support our application for the CE Mark, or European Union certification, for wound cleaning and reduction of microbial load. We received the CE Mark in November 2004 and additional international approvals in China, Canada, Mexico and India. On May 27, 2009, we received a 510(k) clearance from the FDA to market our Microcyn Skin and Wound HydroGel™ as both a prescription and over-the-counter formulation. Additionally, on June 4, 2009, we received an expanded 510(k) label clearance from the FDA to market our Microcyn Skin and Wound Care with preservatives as both a prescription and over-the-counter formulation. The new prescription product is indicated for use by health care professionals to manage the debridement of wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first- and second-degree burns, grafted and donor sites. On March 8, 2010, we received a 510(k) clearance from the FDA to market our Microcyn Skin and Wound HydroGel for management of dermal irritation, sores, injuries and ulcers of dermal tissue including itch and pain relief as a prescription and as an over-the-counter product intended to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns. On February 8, 2011, we received 510(k) clearance from the FDA as a hydrogel to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis and radiation dermatitis. It may also be used to relieve the pain of first- and second-degree burns and can help to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. The Microcyn technology has received seven FDA 510(k) clearances in total. Many of these approvals are for use as a medical device in wound cleaning, or debridement, lubricating, moistening and dressing, including traumatic wounds and acute and chronic dermal lesions.

In the fourth quarter of 2007, we completed a Phase II randomized clinical trial, which was designed to evaluate the effectiveness of Microcyn in mildly infected diabetic foot ulcers with the primary endpoint of clinical cure or improvement in signs and symptoms of infection according to guidelines of Infectious Disease Society of America. We used 15 clinical sites and enrolled 48 evaluable patients in three arms, using Microcyn alone, Microcyn plus an oral antibiotic and saline plus an oral antibiotic. We announced the results of our Phase II trial in March 2008. In the clinically evaluable population of the study, the clinical success rate at visit four (test of cure) for patients treated with Microcyn alone was 93.3% compared to 56.3% for the Levofloxacin plus saline-treated patients. This study was not statistically powered, but the high clinical success rate (93.3%) and the p-value (0.033) would suggest the difference is meaningfully positive for the Microcyn-treated patients. Also, for this set of data, the 95.0% confidence interval for the Microcyn-only arm ranged from 80.7% to 100.0% while the 95.0% confidence interval for the Levofloxacin and saline arm ranged from 31.9% to 80.6%; the confidence intervals do not overlap, thus indicating a favorable clinical success for Microcyn compared to Levofloxacin. At visit three (end of treatment) the clinical success rate for patients treated with Microcyn alone was 77.8% compared to 61.1% for the Levofloxacin plus saline-treated patients.

We conducted a review meeting with the FDA in August 2008 to discuss the results of our Phase II trial and our future clinical program. Following a review of the Phase II data on Microcyn Technology for the treatment of mildly infected diabetic foot ulcers, the FDA agreed:

- We may move forward into the pivotal phase of our U.S. clinical program for Microcyn Technology.
- There were no safety issues relative to moving into this next clinical phase immediately, and carcinogenicity studies will not be required for product approval; and
- Clinical requirements for efficacy and safety for a new drug application will be appropriately accounted for within the agreed upon pivotal trial designs.

Two pivotal clinical trials must be completed for submission of a new drug application to the FDA for the treatment of mildly infected diabetic foot ulcers. Commencement of these trials will be dependent upon the support of a strategic partner. In the event that we successfully complete clinical trials and obtain drug approval from the FDA, we may seek clearance for treatment of other types of wounds. We are currently pursuing strategic partnerships to assess potential applications for Microcyn Technology in several other markets and therapeutic categories, including respiratory, ophthalmology, dermatology, dental and veterinary markets. FDA or other governmental approvals will be required for any potential new products or new indications.

The FDA requirements for device and drug approvals are discussed in greater detail under *Government Regulation*.

### ***Market Opportunity — Key Limitations of Existing Treatments***

Commonly used topical antiseptics and antibiotics have limitations and side effects that may constrain their usage. For example:

- antibiotics and antiseptics can kill bacteria and cure infection but do not independently accelerate wound healing;
- many antiseptics, including Betadine, hydrogen peroxide and Dakin's solution, are toxic, can destroy human cells and tissue, may cause allergic reactions and can impede the wound healing process;
- silver-based products are expensive and require precise dosage and close monitoring by trained medical staff to minimize the potential for tissue toxicity, allergic reactions and bacterial resistance;
- the increase in antibiotic-resistant bacterial strains, such as MRSA, VRE, and C. diff have compromised the effectiveness of some widely used topical and systemic antibiotics, including Neosporin and Bacitracin;
- oral and systemic antibiotics often are not effective in treating topical infections especially if the patient does not have adequate blood flow to the wound and they can also cause serious side effects; and
- growth regulators, skin substitutes and vacuum-assisted closure accelerate wound healing but do not cure infection.

## Our Solution

We believe the Microcyn has potential advantages over current methods of care in the treatment of chronic and acute wounds, including the following:

- *Cures Infection.* Our Phase II results and several physician-based studies suggest that Microcyn may be effective in curing and improving the signs and symptoms of infections.
- *Accelerates Wound Healing.* Based on numerous physician-based studies and usage feedback from doctors, we believe that Microcyn Technology may accelerate the wound healing process independently of the benefits of curing the infection.
- *Wound Care Solution.* Our FDA 510(k) approved products are cleared as a medical device for sale in the United States in wound cleaning, or debridement, lubricating, moistening and dressing. Laboratory testing and physician clinical studies further suggest that our 510(k) Microcyn products are effective against a wide range of bacteria that causes infection in a variety of acute and chronic wounds. In addition, because of its mechanism of action, we believe Microcyn does not target specific strains of bacteria, the practice of which has been shown to promote the development of resistant bacteria. In physician clinical studies, our 510(k)-cleared Microcyn has been used in conjunction with other wound care therapeutic products. Data from these studies suggest that patients generally experienced less pain, improved mobility and physical activity levels and better quality of life.
- *Non-irritating.* Our 510(k) product labels states that our 510(k) product, which is based on Microcyn, is non-irritating and non-sensitizing to the skin and eyes. Throughout all our clinical trials and physician clinical studies to date and since our first commercial sale of Microdacyn60 in Mexico in 2004, we have received no reports of serious adverse events related to the use of Microcyn products when used according to label instructions.
- *Ease of Use.* Our 510(k) product labels states that our 510(k) products require no special handling precautions. Our products require no preparation before use or at time of disposal, and caregivers can use our products without significant training. In addition, Microcyn can be stored at room temperature. Unlike other oxychlorine solutions, which are typically stable for not more than 48 hours, our laboratory tests show that Microcyn has a shelf life ranging from one to two years depending on the size and type of packaging. Our products are also designed to be complementary to most advanced technologies to treat serious wounds, such as negative-pressure wound therapy, jet lavage and tissue-engineered skin substitutes.
- *Cost-Effectiveness.* The treatment of many wounds requires extended hospitalization and care, including the use of expensive systemic antibiotics. Infection prolongs the healing time and necessitates increased use of systemic antibiotics. We believe that Microcyn has the potential to cure infection, accelerate healing time and, in certain cases, may help reduce the need for systemic antibiotics, reduce the need for amputation and lead to earlier hospital discharge, thereby lowering overall patient cost.

## Microcyn Platform Technology

### *Mechanism of Action*

We believe Microcyn's ability to reduce the use of antibiotics through prevention and treatment of infections while promoting wound healing is based on its uniquely engineered chemistry. As a result of our patented manufacturing process, Microcyn is a proprietary solution of oxychlorine compounds that, among other things, interact with and inactivate surface proteins on cell walls and membranes of microorganisms. The function of these proteins are varied and play significant roles in cell communication, nutrient and waste transport and other required functions for cell viability. Once Microcyn surrounds single cell microorganisms, it damages these proteins, causing the cell membrane to rupture, leading to cell death, which we believe is caused by increased membrane permeability and induced osmotic pressure imbalance. We continue to study the exact mechanisms by which protein and structural components of the bacterial cell walls and membranes, and the protein shell that surrounds a virus, are affected by Microcyn. This destruction of the cell appears to occur through a fundamentally different process than that which occurs as a result of contact with a bleach-based solution because experiments have demonstrated that Microcyn kills bleach-resistant bacteria. However, we believe the solution remains non-irritating to human tissues because human cells have unique protective mechanisms, are interlocked, and prevent Microcyn from targeting and surrounding single cells topically on the body. Laboratory tests suggest that our solution does not penetrate and kill multi-cellular organisms and does not damage or affect human DNA.

In laboratory tests, Microcyn has been shown to destroy certain biofilms. A biofilm is a complex cluster of microorganisms or bacteria marked by the formation of a protective shell, allowing the bacteria to collect and proliferate. It is estimated that over 65% of microbial infections in the body involve bacteria growing as a biofilm. Bacteria living in a biofilm typically have significantly different properties from free-floating bacteria of the same species. One result of this film environment is increased resistance to antibiotics and to the body's immune system. In chronic wounds, biofilms interfere with the normal healing process and halt or slow wound closure. Bacteria growing in biofilms can become up to 1000-fold more resistant to antibiotics and other biocides as compared to their planktonic counterparts. As a result, biofilm infections cannot be effectively treated with conventional antibiotic therapy. In our laboratory studies, Microcyn was shown to destroy two common biofilms after five minutes of exposure.

In recently published studies, Microcyn has been shown to significantly increase the dilation of capillaries in wounds as indicated by higher levels of oxygen at a wound site after the application of our product and also reduce inflammation by inhibiting certain inflammatory responses from allergy-producing mast cells. It is widely accepted that reducing chronic inflammation surrounding an injury or wound is beneficial to wound healing. Our laboratory research suggests that Microcyn's interference with these cells is selective to only the inflammatory response and does not interfere with other functions of these cells.

Microcyn Technology has demonstrated antimicrobial activity against numerous bacterial, viral and fungal pathogens, including antibiotic-resistant strains, as evidenced by passing results in numerous standardized laboratory microbiology tests conducted on our 510(k) approved technology by a variety of certified independent testing laboratories. Some of the pathogens against which Microcyn has demonstrated antimicrobial activity are listed below:

#### **Pathogen**

##### **Antibiotic-Resistant Bacteria**

Vancomycin Resistant *Enterococcus faecalis* (VRE)  
Methicillin Resistant *Staphylococcus aureus* (MRSA)  
*Clostridium difficile* (*C. diff*)

##### **Other Bacteria**

*Acinetobacter baumannii*  
*Aspergillus niger*  
*Escherichia coli*  
*Escherichia coli O157:H7*  
*Klebsiella pneumoniae*  
*Mycobacterium bovis*  
*Pseudomonas aeruginosa*  
*Salmonella typhi*

##### **Viruses**

Human Coronavirus  
Human Immunodeficiency Virus Type 1 — HIV

Influenza A  
 Influenza A Type H1N1  
 Rhinovirus Type 37  
**Fungi**  
*Candida albicans*  
*Trichophyton mentagrophytes*

In addition to the above mentioned independent laboratory microbiology tests, a study was completed and published in the *Journal of Hospital Infection* in 2005, that showed that Microcyn exerts a wide range of antimicrobial activity (Landa-Solis, González-Espinosa D, Guzman B, Snyder M, Reyes-Terán G, Torres K and Gutiérrez AA. Microcyn: a novel super-oxidized water with neutral pH and disinfectant activity. *J Hosp Infect* (UK) 61: 291-299).

### Current Regulatory Approvals and Clearances

All of our current products are based on our Microcyn Technology platform. We are able to modify the chemistry of Microcyn by changing the oxidation-reduction potential, pH level and concentrations of specific ions or chemicals, which allows us to manufacture a variety of solutions, each specifically designed for maximum efficacy and safety by indication. The indications for our products vary from country to country due to different regulatory requirements and standards from jurisdiction to jurisdiction. The indications below are summaries of the indications approved by the regulatory authority or authorities in the listed jurisdiction. The similarly named products have similar formulations; however, they may not have identical specifications due to varying requirements in different jurisdictions' regulatory agencies. The following is a list of the regulatory approvals and clearances that Microcyn-based products have received for our most significant or potentially significant markets:

<b>Region</b>	<b>Approval or Clearance Type</b>	<b>Year of Approval or Clearance</b>	<b>Summary Indication</b>
United States	510(k)	2005	Moistening and lubricating absorbent wound dressings for traumatic wounds.
	510(k)	2005	Moistening and debriding acute and chronic dermal lesions.
	510(k)	2006	Moistening absorbent wound dressings and cleaning minor cuts.
	510(k)	2009	Management of exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers and for the management of mechanically or surgically debridement of wounds.
	510(k)	2009	Debridement of wounds, such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second burns, grafted and donor sites.
	510(k)	2010	Management of dermal irritation, sores, injuries and ulcers of dermal tissue including itch and pain relief
	510(k)	2011	Management and relief of the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis and radiation dermatitis.

European Union	CE Mark	2004	Debriding, irrigating and moistening acute and chronic wounds in comprehensive wound treatment by reducing microbial load and creating moist environment.
Mexico	Product Registration	2003	Antiseptic disinfection solution for high level disinfection of medical instruments, and/or equipment and clean-rooms, areas of medical instruments, equipment and clean room areas.
	Product Registration	2004	Antiseptic treatment of wounds and infected areas.
Canada	Class II-Medical Device (Inactive)	2004	Moistening, irrigating, cleansing and debriding acute and chronic dermal lesions, diabetic ulcers and post-surgical wounds.
India(1)	Drug License	2006	Cleaning and debriding in wound management.
China	Medical Device	2008	Reduces the propagation of microbes in wounds and creates a moist environment for wound healing.

Notes

(1) Drug license held by Indian distributor as required by Indian law.

***Clinical Trials***

We have completed a proof-of-concept Phase II trial in the U.S., which demonstrated the effectiveness of Microcyn Technology in mildly infected diabetic foot ulcers with the primary endpoint of clinical cure and improvement of infection. We used 15 clinical sites and enrolled 48 evaluable patients in three arms, using Microcyn alone, Microcyn plus an oral antibiotic and saline plus an oral antibiotic. We announced the results of our Phase II trial in March 2008. In the clinically evaluable population of the study, the clinical success rate at visit four (test of cure) for Microcyn-alone-treated patients was 93.3% compared to 56.3% for the levofloxacin plus saline-treated patients. This study was not statistically powered, but the high clinical success rate (93.3%) and the p-value (0.033) suggests the difference is meaningfully positive for the Microcyn-treated patients. Also, for this set of data, the 95.0% confidence interval for the Microcyn only arm ranged from 80.7% to 100% while the 95.0% confidence interval for the levofloxacin and saline arm ranged from 31.9% to 80.6%; the confidence intervals do not overlap, indicating a favorable clinical success for Microcyn compared to levofloxacin. At visit 3 (end of treatment), the clinical success rate for patients treated with Microcyn-alone was 77.8% compared to 61.1% for the levofloxacin plus saline-treated patients.

### Physician Clinical Studies

In addition to the Phase II trial mentioned above, several physicians and scientists have completed more than 40 clinical and scientific studies of Microcyn generating data suggesting that the technology is non-irritating to healthy tissue, reduces microbial load, accelerates wound healing, reduces pain, shortens treatment time and may have the potential to reduce costs to healthcare providers and patients. We have sponsored many of the physicians performing these studies by supplying Microcyn-based products, unrestricted research grants, paying expenses or providing honoraria. In some cases, the physicians who performed these studies also hold equity in our Company. The studies were performed in the United States, Europe, India, Pakistan, China and Mexico, and used various endpoints, methods and controls (for example, saline, antiseptics and antibiotics). These studies were not intended to be rigorously designed or controlled clinical trials and, as such, did not have all of the controls required for clinical trials used to support a new drug application submission to the FDA in that they did not necessarily include blinding, randomization, predefined clinical endpoints, use of placebo and active control groups or U.S. good clinical practice requirements.

In many cases the physicians who led these studies have published articles on their studies and results. The following table lists publications and presentations at peer-reviewed meetings from physicians who have completed studies on the use of Microcyn Technology for wound care and wound irrigation.

<b>Physician</b>	<b>Country</b>	<b>Number of Patients</b>	<b>Publication</b>
David E. Allie, M.D.(1)	U.S.	40	Allie D. Super-Oxidized Dermacyn in Lower-Extremity Wounds. <i>Wounds</i> , 2006, 18 (Suppl), 3-6.
Tom Wolvos, M.D.(2)	U.S.	26	Wolvos TA. Advanced Wound Care with Stable, Super-Oxidized Water. A look at how combination therapy can optimize wound healing. <i>Wounds</i> , 2006, 18 (Suppl), 11-13.
Cheryl Bongiovanni, Ph.D.(3)	U.S.	8	Bongiovanni CM. Superoxidized Water Improves Wound Care Outcomes in Diabetic Patients. <i>Diabetic Microvascular Complications Today</i> , 2006, May-Jun: 11-14.
		3	Bongiovanni CM. Nonsurgical Management of Chronic Wounds in Patients with Diabetes. <i>Journal of Vascular Ultrasound</i> , 2006, 30: 215-218.
Luca Dalla Paola, M.D.(4)	Italy	218	Dalla Paola L, Brocco E, Senesi, A, Merico M, De Vido D, Assaloni R, DaRos R. Super-Oxidized Solution (SOS) Therapy for Infected Diabetic Foot Ulcers. <i>Wounds</i> , 2006, vol. 18: 262-270
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Fermin Martinez M.D.	Mexico	45	Martínez-De Jesús FR, Ramos-De la Medina A, Remes-Troche JM, Armstrong DG, Wu SC, Lázaro Martínez JL, Beneit-Montesinos JV. Efficacy and safety of neutral pH superoxidised solution in severe diabetic foot infections. <i>Int Wound J</i> . 2007, 4:353-362.
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Ning Fanggang MD(3)	China	20	Fanggang N, Guoan Z. The clinical efficacy of Dermacyn on deep partial thickness burn wounds.

Amar Pal Suri DPM(6)	India	100	Suri AP. The Effectiveness of Stable Neutral Super-oxidized Solution for the Treatment of Infected Diabetic Foot Wounds. Diabetic Foot Global Conference. Hollywood, CA. 13-15 March. 2008. Submitted for publication Jan, 2008.
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Dharap SB	India	30	Dharap SB, Ghag GS, Kulkarni KP, Venkatesh V. Efficacy and safety of Oxum in the treatment of the venous ulcer. <i>J Indian Med Assoc</i> 2008, 106:326-330.
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Christopher J. Gauland DPM (3)	U.S.	16	Comparison of Microcyn and Amerigel in the Podiatric Clinical Setting
Andres Tirado-Sanchez & RosaMaria Ponce-Olivera	Mexico	89	Efficacy and tolerance of superoxidized solution in the treatment of mild to moderate inflammatory acne. A double-blinded, placebo-controlled, parallel-group, randomized, clinical trial. <i>Journal of Dermatological Treatment</i> . 2009; 20:289–292

#### Notes

- (1) Indicates that the physician is a stockholder and was a member of our Medical and Business Advisory Board that we dissolved in April 2007, and was a paid consultant and received research grants, expense payments, honorarium and Microcyn to complete the study.
- (2) Indicates that the physician was a paid consultant, received expenses in connection with corporate development and licensing evaluations and is a warrant holder.
- (3) Indicates that the physician received Microcyn to complete the study.
- (4) Indicates that the physician is a paid consultant, was a member of our Medical and Business Advisory Board, which we dissolved in April 2007, and received expense payments and Microcyn to complete the study.
- (5) Indicates that the physician received payments, expense payments and Microcyn to complete the study.
- (6) Indicates that the physician received reimbursement of travel expenses and received Microcyn to complete the study.

In addition to the above articles and publications, several additional papers on the basic science of the technology have been published or have been submitted for peer review and publication, including:

<b>Researchers</b>	<b>Country</b>	<b>Publication</b>
Landa-Solis, González-Espinosa D., Guzman B, Snyder M, Reyes-Terán G., Torres K, and Gutiérrez AA(1)	Mexico	Microcyn™ a novel super-oxidized water with neutral pH and disinfectant activity. <i>J Hosp Infect</i> (UK) 2005, 61: 291-299.
Gutiérrez, AA(1)	U.S.	The science behind stable, super-oxidized water. Exploring the various applications of super-oxidized solutions. <i>Wounds</i> , 2006, 18 (Suppl), 7-10.
Dalla Paola L, Faglia E(2)	Italy	Treatment of diabetic foot ulcer: an overview. Strategies for clinical approach. <i>Current Diabetes Reviews</i> , 2006, 2, 431-447 431.
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Medina-Tamayo J, Balleza-Tapia H, López, X, Cid, ME, González-Espinosa, D, Gutiérrez AA, González-Espinosa C(1)	Mexico, U.S.	Super-oxidized water inhibits IgE-antigen- induced degranulation and cytokine release in mast cells. <i>International Immunopharmacology</i> 2007 2007, 7:1013-1024.
Le Duc Q	UK	Le Duc Q, Breetveld M, Middelkoop E, Scheper RJ, Ulrich MMW, Gibbs S. A cytotoxic analysis of antiseptic medication on skin substitutes and autograft. <i>Br J Dermatology</i> . 2007, 157:33-40.
McCurdy B	U.S.	McCurdy B. Emerging Innovations in Treatment . <i>Podiatry Today</i> 2006, 19: 40-48.
Zahumensky E	Czech Republic	Infections and diabetic foot syndrome in field practice. <i>Vnitr Lek</i> . 2006;52:411-416.
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Paul M., Setlow B. and Setlow P.(5)	U.S.	The killing of spores of <i>Bacillus subtilis</i> by Microcyn(TM), a stable superoxidized water. Submitted 2008.
Thatcher E(4), AA Gutierrez(1)	U.S.	The Anti-Bacterial Efficacy of a New Super-Oxidized Solution. 47(th) ICAAC Meeting. Chicago, IL. USA. Sept 17-20, 2007.

Michael Taketa-Graham(5), Gutierrez AA(1), Thatcher E(4)	U.S.	The Anti-Viral Efficacy of a New Super-Oxidized Solution.. 47th ICAAC Meeting. Poster L-1144. Chicago, IL. USA. Sept 17-20, 2007.
Dardine J, Martinez C, Thatcher E(4)	U.S.	Activity of a pH Neutral Super-Oxidized Solution Against Bacteria Selected for Sodium Hypochlorite Resistance. 47th ICAAC Meeting. Poster L-1144. Chicago, IL. USA. Sept 17-20, 2007.
Sauer K, Vazquez G, Thatcher E, Northey R & Gutierrez AA(1),(4),(5)	U.S.	Neutral super-oxidized solution is effective in killing <i>P. aeruginosa</i> biofilms. Biofouling, Vol 25, No. 1, January 2009, 45-54.

#### Notes

- (1) Dr. Gutierrez was our Director of Medical Affairs and conducted the study during his employment at our Company.
- (2) Dr. Dalla Paola was a member of our Medical and Business Advisory Board, which we dissolved in April 2007, and received expense payments and Microcyn to complete the study.
- (3) Indicates that investigator received Microcyn to complete the study.
- (4) Dr. Thatcher is a full-time consultant to us, is a stockholder, previously served on our board of directors, and received Microcyn to complete the study.
- (5) Dr. Northey is our Director of Research and Development and conducted the study during his employment at our Company.

#### Sales and Marketing

In the quarter ending December 31, 2008, our initial sales were in the podiatry market in the United States. In the second quarter of 2009, we expanded our sales effort to include wound care centers, hospitals, nursing homes, urgent care clinics and home healthcare, utilizing a contract sales organization. We continue to seek opportunities to expand the applicability of our products. Our products are purchased by, among others, hospitals, physicians, nurses, and other healthcare practitioners who are the primary caregivers to patients being treated for acute or chronic wounds or undergoing surgical procedures as well as to dermatologists for treatment of various skin afflictions.

We currently make Microcyn Technology-based human wound care products available, both as prescription and over-the-counter products, under our seven 510(k) clearances in the United States, primarily through a partnership with a combination of Advocos, a specialty U.S. contract sales organization, and with such partners as Amneal Enterprises and PreCision Dermatology, mentioned in greater detail below. Specifically, we have announced the commercialization of a Microcyn hydrogel for wound care sold through a combination of contract and commissioned sales forces, and the commercialization of a Microcyn hydrogel for dermatology through partnerships with Quinnova Pharmaceuticals and PreCision Dermatology. Our partner, Union Springs Pharmaceuticals, a subsidiary of the Drug Enhancement Company of America, has marketed MyClyns, an over-the-counter “first responder” pen application, with Microcyn as a component in the United States since January 2008.

Additionally, through our partner Innovacyn, we currently make available Microcyn Technology-based animal healthcare products branded as Vetericyn in the U.S. and Europe. We plan to introduce these products into Canada and have received approval from Health Canada to begin marketing our products in their country, and in the future, to expand to Asia.

We intend to pursue additional regulatory approvals in Europe, China, India and Mexico for our products and plan to initiate commercialization upon obtaining these approvals.

#### *Animal Healthcare*

On January 26, 2009, we announced a strategic revenue-sharing partnership with Vetericyn, Inc, now named Innovacyn, Inc. The agreement was amended on February 24, 2009, July 24, 2009, June 1, 2010 and September 1, 2010. At the time of each of the 2009 transactions, Vetericyn was wholly-owned by Robert Burlingame, who was also a director of our Company. Pursuant to this agreement, we granted Innovacyn exclusive rights to market the Microcyn Technology in the North American animal healthcare market. As part of this agreement, we will not incur marketing or sales expenses, but will share in all revenues. On May 13, 2010, Innovacyn received confirmation from Health Canada that it has approval to market these veterinary products in the Canadian market as well.

On September 15, 2009, we entered a commercial agreement with V&M Industries, Inc., a California corporation, to market and sell Microcyn over-the-counter liquid and gel products for animal healthcare. At the time of the 2009 transaction, V&M Industries, Inc. was wholly-owned by Robert Burlingame, who was also a director of our Company at the time of the transaction. V&M Industries, Inc. subsequently changed its name to Innovacyn, Inc. On June 1, 2010 and September 1, 2010, we entered into amendments to this agreement. Once certain milestones are met by Innovacyn, Inc., but no later than July 1, 2011, we will share profits generated by Innovacyn, Inc.

#### *Dental*

Our prescription dental partner, OroScience, Inc. has the exclusive right to sell prescription dental products in the United States and Europe subject to certain annual minimum payments and has filed applications for two 510(k) clearances to market Microcyn-based products for use as an oral rinse in liquid form and for oral mucositis in a gel form.

#### *Dermatology*

On November 8, 2010, we announced a definitive agreement with Onset Therapeutics, now called PreCision Dermatology, Inc. Under this agreement, PreCision Dermatology is combining the currently approved Microcyn hydrogel with their new skin barrier product into an prescription convenience kit, targeting sales to patients with atopic dermatitis and related conditions. PreCision Dermatology has about 35 salespeople along with a complete line of dermatology products sold throughout the U.S and launched the kit in the first quarter of 2011.

On February 14, 2011, we announced that we formed a broad multi-year collaboration with Amneal Enterprises to realize the development and commercial potential of Microcyn Technology. Amneal Enterprises is an affiliation of independent pharmaceutical marketing, discovery and development companies. As a part of this collaboration, Quinnova Pharmaceuticals, Inc. (“Quinnova”) an Amneal alliance member, has licensed, with a \$500,000 prepayment and ongoing double-digit royalties, the U.S. and Canadian rights to the Microcyn-based dermatology atopic dermatitis hydrogel that received FDA clearance. Future prescription dermatology products can also be licensed for undisclosed upfront payments. In addition, Quinnova will co-promote the current prescription Microcyn-based wound care products to podiatry professionals in the United States and Canada. Quinnova has a sales force of over 35 people, selling to dermatologists and podiatrists with a complete line of dermatology products.

Additionally, we sold the option to exclusively sell and distribute a prescription pharmaceutical product developed with Microcyn technology and designed for the treatment of acne to AmDerma Pharmaceuticals, LLC, an Amneal alliance member. We received a non-refundable initial payment of \$500,000 and the option will expire June 30, 2011. If this option is exercised, a separate license and supply agreement will be executed for the proposed acne drug, outlining AmDerma's U.S. and European rights to the product. We will retain rights to the "rest of world," including undisclosed upfront, milestone and royalty payments.

#### *Marketing Abroad*

We currently rely on exclusive agreements with country-specific distributors for the sale of Microcyn-based products in Europe, in Italy, the Netherlands, Germany, Czech Republic, Sweden, Finland and Denmark.

In Mexico, we market our products through our established distribution network and direct sales organization. We have a dedicated contract sales force, including salespeople, nurses and clinical support staff, responsible for selling Microcyn to private and public hospitals and to retail pharmacies. Our sales force is focused on the wound care and dermatology markets. We have also launched a dermatology product, designed to treat acne.

In India, we entered into an exclusive agreement with Alkem Laboratories, a large pharmaceutical company in India, for the sale of Microcyn-based products in India and Nepal.

On January 28, 2011, we entered into an agreement with Tianjin Ascent Import and Export Company, Ltd., a distributor in China, to sell certain of our products into the People's Republic of China. Pursuant to the agreement, we received a \$350,000 non-refundable upfront payment from the distributor in return for exclusivity to sell these products for the first contract year. In order to maintain exclusivity in subsequent years, the distributor will need to meet minimum purchase requirements each contract year. The initial term of the contract is for five years and cancellable if certain conditions are not met.

Throughout the rest of the world, we intend to use strategic partners and distributors who have a significant sales, marketing and distribution presence in their respective countries. We have established partners and distribution channels for our wound care products in Bangladesh, Pakistan, Singapore, United Arab Emirates and Saudi Arabia.

#### **Manufacturing**

We manufacture Microcyn through a proprietary electrolysis process within a multi-chamber system. We are able to control the passage of ions through proprietary membranes, yielding electrolyzed water with only trace amounts of chlorine. This process is fundamentally different from the processes for manufacturing hydrogen peroxide and bleach and, we believe, is the basis for our technology's effectiveness and safety. Our manufacturing process produces very little waste, which is disposed of as water after a simple non-toxic chemical treatment.

We manufacture our products at our facilities in Petaluma, California and Zapopan, Mexico. Additionally, in Rialto, California, Innovacyn manufactures Microcyn Technology products that support the animal health care market. We have developed an automated manufacturing process and conduct quality assurance testing on each production batch in accordance with current U.S. Current Good Manufacturing Practice. Our facilities are required to meet and maintain regulatory standards applicable to the manufacture of pharmaceutical and medical device products. Our United States facilities are certified and comply with U.S. Current Good Manufacturing Practice medical device Quality Systems Regulation, and International Organization for Standardization, or ISO, guidelines. Our Mexico facility has been approved by the Ministry of Health and is also ISO certified.

Our machines are subjected to a series of tests, which is part of a validation protocol mandated by U.S. Current Good Manufacturing Practice, Quality Systems Regulation, and ISO requirements. This validation is designed to ensure that the final product is consistently manufactured in accordance with product specifications at all manufacturing sites. Certain materials and components used in manufacturing our machines are proprietary to us.

We believe we have a sufficient number of machines to produce an adequate amount of Microcyn to meet anticipated future requirements for at least the next two years. As we expand into new geographic markets, we may establish additional manufacturing facilities to better serve those new markets.

## **Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our product technology and know-how, to operate without infringing proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing, when possible, U.S. and foreign patent applications relating to our technology, inventions and improvements that are important to our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

As of May 9, 2011, we own two issued U.S. patents, one issued and one allowed European patent, one allowed Canadian patent, one issued Japanese patent, 14 pending U.S. patent applications and 79 foreign pending patent applications generally relating to electrolyzed water. These applications include four international Patent Cooperation Treaty applications for which the time to file counterpart national phase applications has not yet expired. Our portfolio of issued and pending applications can be divided into two groups. The first group includes two issued U.S. patents, one issued and one allowed European patent, one allowed, Canadian patent, one issued Japanese patent, two pending U.S. patent applications, and three foreign patent applications that relate to early generation electrolyzed water product, methods of using electrolyzed water, and aspects of the method and apparatus for manufacturing electrolyzed water. The second group includes 12 pending U.S. patent applications (including provisional U.S. patent applications) and 76 foreign patent applications (including international Patent Cooperation Treaty applications) that relate to Microcyn, the method and apparatus for manufacturing Microcyn, and its uses. In addition to our own patents and applications, we have licensed technology developed in Japan relating to an electrolyzed water solution, methods of manufacture and electrolytic cell designs. This license includes eight issued Japanese patents.

Although we work to protect our technology, we cannot assure you that any patent will be issued from our currently pending patent applications or from future patent applications. We also cannot assure you that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of our patents will be held valid if subsequently challenged, or that others will not claim rights in or ownership of our patents and proprietary rights. Furthermore, we cannot assure you that others have not developed or will not develop similar products, will not duplicate any of our products or design around our patents.

We have also filed for trademark protection for marks used with our Microcyn products in each of the United States, Europe, Canada, certain countries in Central and South America, including Mexico and Brazil, and certain countries in Asia, including Japan, China, the Republic of Korea, India and Australia. In addition to patents and trademarks, we rely on trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our intellectual property rights. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationship with us. We also require our employees, consultants and advisors with whom we expect to work on our products to agree to disclose and assign to us all inventions made in the course of our working relationship with them, while using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to wrongfully obtain or use information that we regard as proprietary.

## Competition

The wound and skin care market is highly competitive. We compete with a number of large, well-established and well-funded companies that sell a broad range of wound care products, including topical anti-infectives and antibiotics, as well as some advanced wound technologies, such as skin substitutes, growth factors and sophisticated delayed release silver-based dressings. We believe the principal competitive factors in our target market include improved patient outcomes, such as time in the hospital, healing time, adverse events, safety of products, ease of use, stability, pathogen killing and cost effectiveness.

Our products compete with a variety of products used for wound cleaning, debriding and moistening, including sterile saline, and chlorhexadine-based products, and they also compete with a large number of prescription and over-the-counter products for the prevention and treatment of infections, including topical anti-infectives, such as Betadine, silver sulfadiazine, hydrogen peroxide, Dakin's solution and hypochlorous acid, and topical antibiotics, such as Neosporin, Mupirocin and Bacitracin. Currently, no single anti-infective product dominates the chronic or acute wound markets because many of the products have serious limitations or tend to inhibit the wound healing process.

Our products can replace the use of saline for debriding and moistening a dressing as well as for use as a complementary product with many advanced wound care technologies, such as the VAC Therapy System from Kinetic Concepts Inc., skin substitute products from Smith & Nephew, Advanced BioHealing, Integra Life Sciences, Life Cell, Organogenesis and Ortec International, and ultrasound from Celleration. We believe that Microcyn Technology can enhance the effectiveness of many of these advanced wound care technologies. Because Microcyn is competitive with some of the large wound care companies' products and complementary to others, we may compete with such companies in some product lines and complement such companies in other product lines.

While many companies are able to produce oxychlorine formulations, their products, unlike ours, typically become unstable after a relatively short period of time. One such company, PuriCore, sells electrolysis machines used to manufacture brine-based oxidized water primarily as a sterilant. Additionally, we believe that the Microcyn Technology is the only stable anti-infective therapeutic available in the world today that simultaneously cures or improves infection while also accelerating wound healing through increased blood flow to the wound bed and reduction of inflammation.

Some of our competitors enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relationships with healthcare professionals, patients and third-party payors;
- established distribution networks;
- additional product lines and the ability to offer rebates or bundle products to offer discounts or incentives;
- greater experience in conducting research and development, manufacturing, obtaining regulatory approval for products and marketing; and
- greater financial and human resources for product development, sales and marketing and patient support.

## Government Regulation

Government authorities in the United States at the federal, state and local levels and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, and import and export of pharmaceutical products, biologics and medical devices. All of our products in development will require regulatory approval or clearance by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. Various federal, state, local and foreign statutes and regulations also govern testing, manufacturing, safety, labeling, storage, distribution and record-keeping related to such products and their marketing. The process of obtaining these approvals and clearances, and the subsequent process of maintaining substantial compliance with appropriate federal, state, local, and foreign statutes and regulations, require the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations and policies may change and new legislation or regulations may be issued that could delay such approvals.

## ***Medical Device Regulation***

Microcyn has received seven 510(k) clearances for use as a medical device in wound care management (cleaning, debridement, lubricating, moistening and dressing) including for acute and chronic wounds as well as in dermatology applications. Any future product candidates or new applications using Microcyn that are classified as medical devices will need clearance by the FDA.

Medical devices, such as Microcyn Wound Care, are subject to FDA clearance and extensive regulation under the Federal Food Drug and Cosmetic Act. Under the Federal Food Drug and Cosmetic Act, medical devices are classified into one of three classes: Class I, Class II or Class III. The classification of a device into one of these three classes generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness. Devices may also be designated unclassified. Unclassified devices are legally marketed pre-amendment device for which a classification regulation has yet to be finalized and for which a pre-market approval is not required.

Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation, which sets forth good manufacturing practice requirements; facility registration, device listing and product reporting of adverse medical events; truthful and non-misleading labeling; and promotion of the device only for its cleared or approved intended uses. Class II devices are also subject to these general controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the 510(k) pre-market notification procedure. When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a legally marketed device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a pre-market approval.

Clinical trials are almost always required to support a pre-market approval application and are sometimes required for a 510(k) pre-market notification. These trials generally require submission of an application for an investigational device exemption. An investigational device exemption must be supported by pre-clinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. The investigational device exemption must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and is eligible for more abbreviated investigational device exemption requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with the Quality System Regulation, which sets forth the Current Good Manufacturing Practice requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation and distribution of all finished medical devices intended for human use.

FDA regulations prohibit the advertising and promotion of a medical device for any use outside the scope of a 510(k) clearance or pre-market approval or for unsupported safety or effectiveness claims. Although the FDA does not regulate physicians' practice of medicine, the FDA does regulate manufacturer communications with respect to off-label use.

If the FDA finds that a manufacturer has failed to comply with FDA laws and regulations or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions such as:

- fines, injunctions and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or pre-market approval of new products;
- withdrawing 510(k) clearance or pre-market approval approvals already granted; and
- criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device.

The FDA also administers certain controls over the export of medical devices from the United States, as international sales of medical devices that have not received FDA clearance are subject to FDA export requirements. Additionally, each foreign country subjects such medical devices to its own regulatory requirements. In the European Union, a single regulatory approval process has been created, and approval is represented by the CE Mark.

### ***Combination Products***

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. Because combination products involve components that would normally be regulated under different types of regulatory authorities, and frequently by different FDA Centers, they raise challenging regulatory, policy, and review management challenges. Differences in regulatory pathways for each component can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications

The FDA has established an Office of Combination Products to address the challenges associated with the review and regulation of combination products. The Office of Combination Products assists in determining strategies for the approval of drug/delivery combinations and assuring agreement within the FDA on review responsibilities. To the extent permitted under the Federal Food Drug and Cosmetic Act and current FDA policy, we may seek regulatory review for potential device/drug combination products under the medical device provisions, rather than under the new drug provisions, of the Federal Food Drug and Cosmetic Act. We intend to pursue such strategies as permitted by the law and as directed by the FDA either through guidance documents or discussions.

If the FDA concludes that any or all of our new combination products must be handled under the new drug provisions of the Federal Food Drug and Cosmetic Act, substantially greater regulatory requirements and approval times will be imposed. Use of a modified new product with a previously unapproved new drug likely will be handled as part of the new drug application for the new drug itself. Under these circumstances, the device component will be handled as a drug accessory and will be approved, if ever, only when the new drug application itself is approved. In general, the drug requirements under the Federal Food Drug and Cosmetic Act are more onerous than medical device requirements. These requirements could have a substantial adverse impact on our ability to commercialize our products and our operations.

## ***Pharmaceutical Product Regulation***

Any pharmaceutical product candidates that are regulated by the FDA will require approval before we can market or sell them as drugs. Any future product candidates or new applications using Microcyn that are classified as drugs will need approval by the FDA.

In the United States, the FDA regulates drugs under the Federal Food Drug and Cosmetic Act and implementing regulations that are adopted under the Act. In the case of biologics, the FDA regulates such products under the Public Health Service Act. If we fail to comply with the applicable requirements under these laws and regulations at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us. The FDA also administers certain controls over the export of drugs and biologics from the United States.

- *Pre-Clinical Phase.* The pre-clinical phase involves the discovery, characterization, product formulation and animal testing necessary to prepare an investigational new drug application for submission to the FDA. The investigational new drug application must be accepted by the FDA before the drug can be tested in humans.
- *Clinical Phase.* The clinical phase of development follows a successful investigational new drug submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the substance in humans, as well as the ability to produce the substance in accordance with U.S. Current Good Manufacturing Practice requirements. Data from these activities are compiled in a new drug application, or for biologic products a biologics license application, for submission to the FDA requesting approval to market the drug.
- *Post-Approval Phase.* The post-approval phase follows FDA approval of the new drug application or biologics license application, and involves the production and continued analytical and clinical monitoring of the product. The post-approval phase may also involve the development and regulatory approval of product modifications and line extensions, including improved dosage form, of the approved product, as well as for generic versions of the approved drug, as the product approaches expiration of patent or other exclusivity protection.

Each of these three phases is discussed further below.

*Pre-Clinical Phase.* The development of a new pharmaceutical agent begins with the discovery or synthesis of a new molecule. These agents are screened for pharmacological activity using various animal and tissue models, with the goal of selecting a lead agent for further development. Additional studies are conducted to confirm pharmacological activity, to generate safety data, and to evaluate prototype dosage forms for appropriate release and activity characteristics. Once the pharmaceutically active molecule is fully characterized, an initial purity profile of the agent is established. During this and subsequent stages of development, the agent is analyzed to confirm the integrity and quality of material produced. In addition, development and optimization of the initial dosage forms to be used in clinical trials are completed, together with analytical models to determine product stability and degradation. A bulk supply of the active ingredient to support the necessary dosing in initial clinical trials must be secured. Upon successful completion of pre-clinical safety and efficacy studies in animals, an investigational new drug application submission is prepared and provided to the FDA for review prior to commencement of human clinical trials. The investigational new drug application consists of the initial chemistry, analytical, formulation and animal testing data generated during the pre-clinical phase. The review period for an investigational new drug application submission is 30 days, after which, if no comments are made by the FDA, the product candidate can be studied in Phase I clinical trials.

*Clinical Phase.* Following successful submission of an investigational new drug application, the sponsor is permitted to conduct clinical trials involving the administration of the investigational product candidate to human subjects under the supervision of qualified investigators in accordance with good clinical practice. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the efficacy of the drug. Each protocol must be submitted to the FDA as part of the investigational new drug application prior to beginning the trial. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board, and each trial, with limited exceptions, must include the patient's informed consent. Typically, clinical evaluation involves the following time-consuming and costly three-phase sequential process:

- *Phase I.* Phase I human clinical trials are conducted on a limited number of healthy individuals to determine the drug's safety and tolerability and include biological analyses to determine the availability and metabolization of the active ingredient following administration. The total number of subjects and patients included in Phase I clinical trials varies, but is generally in the range of 20 to 80 people.
- *Phase II.* Phase II clinical trials involve administering the drug to individuals who suffer from the target disease or condition to determine the drug's potential efficacy and ideal dose. These clinical trials are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. These trials require scale up for manufacture of increasingly larger batches of bulk chemical. These batches require validation analysis to confirm the consistent composition of the product.
- *Phase III.* Phase III clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained and safety (toxicity), tolerability, and an ideal dosing regimen have been established. Phase III clinical trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to complete the information needed to provide adequate instructions for the use of the drug. Phase III trials usually include from several hundred to several thousand subjects.

Throughout the clinical phase, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed. Phase I, II, and III testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an investigational new drug application and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. Clinical investigators and companies may be subject to pre-approval, routine, or "for cause" inspections by the FDA for compliance with Good Clinical Practice, and FDA regulations governing clinical investigations. The FDA may suspend or terminate clinical trials, or a clinical investigator's participation in a clinical trial, at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition of product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, institutional review boards, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

*Post-Approval Phase.* After approval, we are still subject to continuing regulation by the FDA, including, but not limited to, record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product, and complying with drug sampling and distribution requirements. In addition, we are required to maintain and provide updated safety and efficacy information to the FDA. We are also required to comply with requirements concerning advertising and promotional labeling. In that regard, our advertising and promotional materials must be truthful and not misleading. We are also prohibited from promoting any non-FDA approved or “off-label” indications of products. Failure to comply with those requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials, and substantial fines. Also, quality control and manufacturing procedures must continue to conform to U.S. Current Good Manufacturing Practice after approval.

Drug and biologics manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic routine and unannounced inspections by the FDA to assess compliance with U.S. Current Good Manufacturing Practice regulations. Facilities may also be subject to inspections by other federal, foreign, state, or local agencies. In addition, approved biological drug products may be subject to lot-by-lot release testing by the FDA before these products can be commercially distributed. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with U.S. Current Good Manufacturing Practice and other aspects of regulatory compliance. Future FDA inspections may identify compliance issues at our facilities or at other facilities that may disrupt production or distribution, or require substantial resources to correct.

In addition, following FDA approval of a product, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications. Also, the FDA may require post-market testing and surveillance to monitor the product’s safety or efficacy, including additional clinical studies, known as Phase IV trials, to evaluate long-term effects.

### ***Other Regulation in the United States***

#### ***Health Care Coverage and Reimbursement by Third-Party Payors***

Commercial success in marketing and selling our products depends, in part, on the availability of adequate coverage and reimbursement from third-party health care payors, such as government and private health insurers and managed care organizations. Third-party payors are increasingly challenging the pricing of medical products and services. Government and private sector initiatives to limit the growth of health care costs, including price regulation, competitive pricing, and managed-care arrangements, are continuing in many countries where we do business, including the United States. These changes are causing the marketplace to be more cost-conscious and focused on the delivery of more cost-effective medical products. Government programs, including Medicare and Medicaid, private health care insurance companies, and managed-care plans control costs by limiting coverage and the amount of reimbursement for particular procedures or treatments. This has created an increasing level of price sensitivity among customers for our products. Some third-party payors also require that a favorable coverage determination be made for new or innovative medical devices or therapies before they will provide reimbursement of those medical devices or therapies. Even though a new medical product may have been cleared or approved for commercial distribution, we may find limited demand for the product until adequate coverage and reimbursement have been obtained from governmental and other third-party payors.

In the United States, we are subject to various federal and state laws pertaining to healthcare fraud and abuse, which, among other things, prohibit the offer or acceptance of remuneration intended to induce or in exchange for the purchase of products or services reimbursed under a federal healthcare program and the submission of false or fraudulent claims with the government. These laws include the federal Anti-Kickback Statute, the False Claim Act and comparable state laws. These laws regulate the activities of entities involved in the healthcare industry, such as us, by limiting the kinds of financial arrangements such entities may have with healthcare providers who use or recommend the use of medical products (including for example, sales and marketing programs, advisory boards and research and educational grants). In addition, in order to ensure that healthcare entities comply with healthcare laws, the Office of Inspector General of the U.S. Department of Health and Human Services recommends that healthcare entities institute effective compliance programs. To assist in the development of effective compliance programs, the Office of Inspector General has issued model Compliance Program Guidance, materials for a variety of healthcare entities which, among other things, identify practices to avoid that may implicate the federal Anti-Kickback Statute and other relevant laws and describes elements of an effective compliance program. While compliance with the Compliance Program Guidance materials is voluntary, a recent California law requires pharmaceutical and devices manufacturers to initiate compliance programs that incorporate the Compliance Program Guidance and the July 2002 Pharmaceuticals Research and Manufacturers of America Code on Interactions with Healthcare Professionals.

Due to the scope and breadth of the provisions of some of these laws, it is possible that some of our practices might be challenged by the government under one or more of these laws in the future. Violations of these laws, which are discussed more fully below, can lead to civil and criminal penalties, damages, imprisonment, fines, exclusion from participation in Medicare, Medicaid and other federal health care programs, and the curtailment or restructuring of our operations. Any such violations could have a material adverse effect on our business, financial condition, results of operations or cash flows.

*Anti-Kickback Laws.* Our operations are subject to federal and state anti-kickback laws. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual for a good or service reimbursed under a federal healthcare program, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The definition of “remuneration” has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, waiver of co-payments, and providing anything at less than its fair market value. Because the Anti-Kickback Statute makes illegal a wide variety of common (even beneficial) business arrangements, the Office of Inspector General was tasked with issuing regulations, commonly known as “safe harbors,” that describe arrangements where the risk of illegal remuneration is minimal. As long as all of the requirements of a particular safe harbor are strictly met, the entity engaging in that activity will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the Office of Inspector General. Our agreements to pay compensation to our advisory board members and physicians who conduct clinical trials or provide other services for us may be subject to challenge to the extent they do not fall within relevant safe harbors under state and federal anti-kickback laws. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute which apply to the referral of patients for healthcare services reimbursed by Medicaid, and some have adopted such laws with respect to private insurance. Violations of the Anti-Kickback Statute are subject to significant fines and penalties and may lead to a company being excluded from participating in federal health care programs.

*False Claims Laws.* The federal False Claims Act prohibits knowingly filing a false claim, knowingly causing the filing of a false claim, or knowingly using false statements to obtain payment from the federal government. Under the False Claims Act, such suits are known as “qui tam” actions. Individuals may file suit on behalf of the government and share in any amounts received by the government pursuant to a settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act under the Deficit Reduction Act of 2005, where the federal government created financial incentives for states to enact false claims laws consistent with the federal False Claims Act. As more states enact such laws, we expect the number of qui tam lawsuits to increase. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claims action, pay fines or be excluded from Medicare, Medicaid or other federal or state government healthcare programs as a result of investigations arising out of such actions.

**HIPAA.** Two federal crimes were created under the Health Insurance Portability and Accountability Act of 1996, or HIPAA: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

### *Health Information Privacy and Security*

Individually identifiable health information is subject to an array of federal and state regulation. Federal rules promulgated pursuant to HIPAA regulate the use and disclosure of health information by “covered entities.” Covered entities include individual and institutional health care providers from which we may receive individually identifiable health information. These regulations govern, among other things, the use and disclosure of health information for research purposes, and require the covered entity to obtain the written authorization of the individual before using or disclosing health information for research. Failure of the covered entity to obtain such authorization could subject the covered entity to civil and criminal penalties. We may experience delays and complex negotiations as we deal with each entity’s differing interpretation of the regulations and what is required for compliance. Also, where our customers or contractors are covered entities, including hospitals, universities, physicians or clinics, we may be required by the HIPAA regulations to enter into “business associate” agreements that subject us to certain privacy and security requirements. In addition, many states have laws that apply to the use and disclosure of health information, and these laws could also affect the manner in which we conduct our research and other aspects of our business. Such state laws are not preempted by the federal privacy law where they afford greater privacy protection to the individual. While activities to assure compliance with health information privacy laws are a routine business practice, we are unable to predict the extent to which our resources may be diverted in the event of an investigation or enforcement action with respect to such laws.

### ***Foreign Regulation***

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the applicable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered under a three-phase sequential process similar to that discussed above for pharmaceutical products.

### *European Union Regulation*

**Medical Device Regulation.** Our Dermacyn products are classified as medical devices in the European Union. In order to sell our medical device products within the European Union, we are required to comply with the requirements of the Medical Devices Directive, and its national implementations, including affixing CE Marks on our products. In order to comply with the Medical Devices Directive, we must meet certain requirements relating to the safety and performance of our products and, prior to marketing our products, we must successfully undergo verification of our product’s regulatory compliance, or conformity assessment.

Medical devices are divided into three regulatory classes: Class I, Class IIB and Class III. The nature of the conformity assessment procedures depends on the regulatory class of the product. In order to comply with the examination, we completed, among other things, a risk analysis and presented clinical data, which demonstrated that our products met the performance specifications claimed by us, provided sufficient evidence of adequate assessment of unwanted side effects and demonstrated that the benefits to the patient outweigh the risks associated with the device. We will be subject to continued supervision and will be required to report any serious adverse incidents to the appropriate authorities. We will also be required to comply with additional national requirements that are beyond the scope of the Medical Devices Directive.

We received our CE certificate for Dermacyn Wound Care as a Class IIB medical device in February 2005. We may not be able to maintain the requirements established for CE Marks for any or all of our products or be able to produce these products in a timely and profitable manner while complying with the requirements of the Medical Devices Directive and other regulatory requirements. The classification of Dermacyn as a Class IIB medical device is under evaluation with the Notified Body. The classification may be elevated to Class III as a result of post-market scientific information and clinical observation.

*Marketing Authorizations for Drugs.* In order to obtain marketing approval of any of our drug products in Europe, we must submit for review an application similar to a U.S. new drug application to the relevant authority. In contrast to the United States, where the FDA is the only authority that administers and approves new drug applications, in Europe there are multiple authorities that administer and approve these applications. Marketing Authorizations in Europe expire after five years but may be renewed.

We believe that any drug candidate will be reviewed by the Committee for Medicinal Products for Human Use, on behalf of the European Medicines Agency. Based upon the review of the Committee for Medicinal Products for Human Use, the European Medicines Agency provides an opinion to the European Commission on the safety, quality and efficacy of the drug. The decision to grant or refuse an authorization is made by the European Commission.

Approval of Marketing Applications can take several months to several years, or may be denied. This approval process can be affected by many of the same factors relating to safety, quality and efficacy as in the approval process for new drug applications in the United States. As in the United States, European drug regulatory authorities can require us to perform additional non-clinical studies and clinical trials. The need for such studies or trials, if imposed, may delay marketing approval and involve unanticipated costs. Inspection of clinical investigation sites by a competent authority may also be required as part of the regulatory approval procedure. In addition, as a condition of marketing approval, regulatory agencies in Europe may require post-marketing surveillance to monitor for adverse effects, or other additional studies may be required as deemed appropriate. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product. In addition, after approval for the initial indication, further clinical studies are usually necessary to gain approval for any additional indications.

*European Good Manufacturing Process.* In the European Union, the manufacture of pharmaceutical products and clinical trial supplies is subject to good manufacturing practice as set forth in the relevant laws and guidelines. Compliance with good manufacturing practice is generally assessed by the competent regulatory authorities. They may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further inspections may occur over the life of the product.

#### *Mexican Regulation*

The Ministry of Health is the authority in charge of sanitary controls in Mexico. Sanitary controls are a group of practices related to the orientation, education, testing, verification and application of security measures and sanctions exercised by the Ministry of Health. The Ministry of Health acts by virtue of the Federal Commission for the Protection against Sanitary Risks, or COFEPRIS, a decentralized entity of the Ministry of Health whose mission is to protect the population against sanitary risks, by means of centralized sanitary regulations, controls and by raising public awareness.

The Ministry of Health is responsible for the issuance of Official Mexican Standards and specifications for drugs subject to the provisions of the General Health Law, which govern the process and specifications of drugs, including the obtaining, preparing, manufacturing, maintaining, mixing, conditioning, packaging, handling, transporting, distributing, storing and supplying of products to the public at large. In addition, a medical device is defined as a device that may contain antiseptics or germicides used in surgical practice or in the treatment of continuity solutions, skin injuries or its attachments.

Regulations applicable to medical devices and drugs are divided into two sections: the business that manufactures the medical device or drug and the product itself.

*Manufacturing a Medical Device or Drug.* Under the General Health Law, a business that manufactures drugs is either required to obtain a Sanitary Authorization or to file an Operating Notice. Our Mexico subsidiary, Oculus Technologies of Mexico, S.A. de C.V. is considered a business that manufactures medical devices and therefore is not subject to a Sanitary Authorization, but rather only an Operating Notice.

In addition to its Operating Notice, our Mexico subsidiary has obtained a “Good Processing Practices Certificate” issued by Mexican Federal Commission for the Protection against Sanitary Risks, which demonstrates that the manufacturing of Microcyn at the facility located in Zapopan, Mexico, operates in accordance with the applicable official standards.

*Commercialization of Drugs and Medical Devices.* Drugs and medical devices should be commercialized in appropriate packaging containing labels printed in accordance with specific official standards. For medical devices, there are no specific standards or regulations related to the labeling of the product, but rather only a general standard related to the labeling for all types of products to be commercialized in Mexico. Advertising of medical devices is regulated in the General Health Law and in the specific regulations of the General Health Law related to advertising. Generally, the advertising of medical devices is subject to a permit only in the case that such advertising is directed to the general public.

*Medical Devices and Drugs as a Product.* To produce, sell or distribute medical devices, a Sanitary Registry is required in accordance with the General Health Law and the Regulation for Drugs. Such registry is granted for a term of five years, and this term may be extended. The Sanitary Registry may be revoked if the interested party does not request the extension in the term or the product or the manufacturer or the raw material is changed without the permission of the Ministry of Health.

The Ministry of Health classifies the medical devices in three classes:

- *Class I.* Devices for which safety and effectiveness have been duly proved and are generally not used inside the body;
- *Class II.* Devices that may vary with respect to the material used for its fabrication or in its concentration and generally used in the inside of the body for a period no greater than 30 days; and
- *Class III.* New devices or recently approved devices in the medical practice or those used inside the body and which shall remain inside the body for a period greater than 30 days.

Violation of these regulations may result in the revocation of the registrations or approvals, and, in addition, economic fines. In some cases, such violations may constitute criminal actions.

In addition, regulatory approval of prices is required in most countries other than the United States, which could result in lengthy negotiations delaying our ability to commercialize our products. We face the risk that the prices which result from the regulatory approval process would be insufficient to generate an acceptable return.

## **Research and Development**

Research and development expense consists primarily of personnel expenses, clinical and regulatory services and supplies. For the years ended March 31, 2011 and 2010, research and development expense amounted to \$2,046,000 and \$1,996,000, respectively. None of this expense was borne by our customers.

## **Our Employees**

As of May 26, 2011, we had 31 full-time employees and 1 part-time employee. We are not a party to any collective bargaining agreements. We believe our relations with our employees are good.

## **Available Information**

Our website is located at [www.oculusis.com](http://www.oculusis.com). We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

## **ITEM 1A: Risk Factors**

### **Risks Related to Our Business**

*We have a history of losses, we expect to continue to incur losses and we may never achieve profitability.*

We incurred net losses of \$7,948,000 and \$8,232,000 for the years ended March 31, 2011 and 2010, respectively. At March 31, 2011, our accumulated deficit amounted to \$124,985,000. During the year ended March 31, 2011, net cash used in operating activities amounted to \$4,429,000. At March 31, 2011, our working capital amounted to \$3,394,000. We expect to continue incurring losses for the foreseeable future and may raise additional capital to pursue product development initiatives and penetrate markets for the sale of our products. We believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means. If the economic climate in the U.S. does not improve or deteriorates, our ability to raise additional capital could be negatively impacted. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to commercialize our products in the U.S., which is critical to the realization of our business plan and to future operations.

*Declining general economic or business conditions may have a negative impact on our business.*

Concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining real estate market in the U.S. have contributed to increased volatility and diminished expectations for the global economy and expectations of slower global economic growth going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated a global economic slowdown. If the economic climate in the U.S. does not improve or deteriorates, our business, including our patient population, our suppliers and our third-party payors, could be negatively affected, resulting in a negative impact on our business.

*Our inability to raise additional capital on acceptable terms in the future may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain the business, and would have a material adverse effect on our business and financial condition.*

We expect capital outlays and operating expenditures to increase over the next several years as we work to conduct regulatory trials, commercialize our products and expand our infrastructure. We may need to raise additional capital to, among other things:

- fund our clinical trials and preclinical studies;
- sustain commercialization of our current products or new products;
- expand our manufacturing capabilities;
- increase our sales and marketing efforts to drive market adoption and address competitive developments;
- acquire or license technologies; and
- finance capital expenditures and our general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the progress and timing of our clinical trials;
- the level of research and development investment required to maintain and improve our technology position;
- cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our efforts to acquire or license complementary technologies or acquire complementary businesses;
- changes in product development plans needed to address any difficulties in commercialization;
- competing technological and market developments; and
- changes in regulatory policies or laws that affect our operations.

If we raise additional funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. A failure to obtain adequate funds may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain the business, and would have a material adverse effect on our business and financial condition.

***We do not have the necessary regulatory approvals to market Microcyn as a drug in the United States.***

We have obtained seven 510(k) clearances in the United States that permit us to sell Microcyn-based products as medical devices. Before we are permitted to sell Microcyn as a drug in the United States, we must, among other things, successfully complete additional preclinical studies and well-controlled clinical trials, submit a new drug application to the FDA and obtain FDA approval.

The FDA approval process is expensive and uncertain, requires detailed and comprehensive scientific and other data and generally takes several years. Despite the time and expense exerted, approval is never guaranteed. Even if we obtain FDA approval to sell Microcyn as a drug, we may not be able to successfully commercialize Microcyn as a drug in the United States and may never recover the substantial costs we have invested in the development of our Microcyn-based products.

***Delays or adverse results in clinical trials could result in increased costs to us and delay our ability to generate revenue.***

Clinical trials can be long and expensive, and the outcome of clinical trials is uncertain and subject to delays. It may take several years to complete clinical trials, if at all, and a product candidate may fail at any stage of the clinical trial process. The length of time required varies substantially according to the type, complexity, novelty and intended use of the product candidate. Interim results of a preclinical study or clinical trial do not necessarily predict final results, and acceptable results in preclinical studies or early clinical trials may not be repeatable in later subsequent clinical trials. The commencement or completion of any of our clinical trials may be delayed or halted for a variety of reasons, including the following:

- insufficient funds to continue our clinical trials;
- changes in the FDA requirements for approval, including requirements for testing efficacy and safety;
- the FDA or other regulatory authority approval of a clinical trial protocol;
- patients do not enrolling in clinical trials at the rate we expect;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites;
- delays in obtaining institutional review board approval to conduct a study at a prospective site;
- third party clinical investigators not performing our clinical trials on our anticipated schedule or performance is not consistent with the clinical trial protocol and good clinical practices, or the third party organizations do not performing data collection and analysis in a timely or accurate manner; and
- changes in governmental regulations or administrative actions.

We do not know whether future clinical trials will demonstrate safety and efficacy sufficiently to result in additional FDA approvals. While a number of physicians have conducted clinical studies assessing the safety and efficacy of Microcyn for various indications, the data from these studies is not sufficient to support approval of Microcyn as a drug in the United States.

The FDA and other regulatory bodies may also change standards and acceptable trial procedures required for a showing of safety and efficacy. For example, until recently, the FDA accepted non-inferiority clinical trials, or clinical trials that show that a new treatment is equivalent to standard treatment, as the standard for anti-infective drug approvals. On October 12, 2007, the FDA released draft guidance entitled Antibacterial Drug Products: Use of Non-inferiority Studies to Support Approval. This new agency guidance requires either placebo-controlled or superiority trial designs, which are designed to test whether, and to what extent, a new treatment is better than the placebo. The uncertainty of clinical trial protocols and changes within FDA guidelines could have a negative impact on the timelines and milestones for our clinical program.

***If we fail to obtain, or experience significant delays in obtaining, additional regulatory clearances or approvals to market our current or future products, we may be unable to commercialize these products.***

The developing, testing, manufacturing, marketing and selling of medical technology products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. The process of obtaining regulatory clearance and approval of medical technology products is costly and time consuming. Even though the underlying product formulation may be the same or similar, our products are subject to different regulations and approval processes depending upon their intended use.

To obtain regulatory approval of our products as drugs in the United States, we must first show that our products are safe and effective for target indications through preclinical studies (laboratory and animal testing) and clinical trials (human testing). The FDA generally clears marketing of a medical device through the 510(k) pre-market clearance process if it is demonstrated that the new product has the same intended use and the same or similar technological characteristics as another legally marketed Class II device, such as a device already cleared by the FDA through the 510(k) premarket notification process, and otherwise meets the FDA's requirements. Product modifications, including labeling the product for a new intended use, may require the submission of a new 510(k) clearance and FDA approval before the modified product can be marketed.

The outcomes of clinical trials are inherently uncertain. In addition, we do not know whether the necessary approvals or clearances will be granted or delayed for future products. The FDA could request additional information, changes to formulation or clinical testing that could adversely affect the time to market and sale of products as drugs. If we do not obtain the requisite regulatory clearances and approvals, we will be unable to commercialize our products as drugs or devices and may never recover any of the substantial costs we have invested in the development of Microcyn.

Distribution of our products outside the United States is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary from country to country. We do not know whether we will obtain regulatory approvals in such countries or that we will not be required to incur significant costs in obtaining or maintaining these regulatory approvals. In addition, the export by us of certain of our products that have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements would have a material adverse effect on our future business, financial condition, and results of operations.

***If our products do not gain market acceptance, our business will suffer because we might not be able to fund future operations.***

A number of factors may affect the market acceptance of our products or any other products we develop or acquire, including, among others:

- the price of our products relative to other treatments for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our products for their indicated applications and treatments;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

If our products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new product candidates and expanding our sales and marketing efforts for our approved products, which would cause our business to suffer.

***If our competitors develop products similar to Microcyn, we may need to modify or alter our business strategy, which may delay the achievement of our goals.***

Competitors may develop products with similar characteristics to Microcyn. Such similar products marketed by larger competitors can hinder our efforts to penetrate the market. As a result, we may be forced to modify or alter our business and regulatory strategy and sales and marketing plans, as a response to changes in the market, competition and technology limitations, among others. Such modifications may pose additional delays in achieving our goals .

***We intend to license or collaborate with third parties in various potential markets, and events involving these strategic partners or any future collaboration could delay or prevent us from developing or commercializing products.***

Our business strategy and our short- and long-term operating results will depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. We believe collaborations allow us to leverage our resources and technologies and to access markets that are compatible with our own core areas of expertise while avoiding the cost of establishing or maintaining a direct sales force in each market. We may incur significant costs in the use of third parties to identify and assist in establishing relationships with potential collaborators.

To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of products. For example, depending upon our analysis of the time and expense involved in obtaining FDA approval to sell a product to treat open wounds, we may choose to license our technology to a third party as opposed to pursuing commercialization ourselves. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property filings and next generation formations. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborations or potential products. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. By entering into collaboration, we may preclude opportunities to collaborate with other third parties who do not wish to associate with our existing third party strategic partners. Moreover, in the event of termination of a collaboration agreement, termination negotiations may result in less favorable terms.

***Our dependence on a commission-based sales force and distributors for sales could limit or prevent us from selling our products and from realizing long-term revenue growth.***

We currently depend on a commission-based sales force and distributors to sell Microcyn in the United States, Europe and other countries and intend to continue to sell our products primarily through a commission-based sales force and distributors in Europe and the United States for the foreseeable future. If we are unable to expand our direct sales force, we will continue to rely on a commission-based sales force and distributors to sell Microcyn. Our existing commission-based sales force and distribution agreements are generally short-term in duration, and we may need to pursue alternate partners if the other parties to these agreements terminate or elect not to renew their agreements. If we are unable to retain our current commission-based sales force and distributors for any reason, we must replace them with alternate salespeople and distributors experienced in supplying the wound care market, which could be time-consuming and divert management's attention from other operational matters. In addition, we will need to attract additional distributors to expand the geographic areas in which we sell Microcyn. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations, which could harm our ability to generate revenues. In addition, some of our distributors may also sell products that compete with ours. In some countries, regulatory licenses must be held by residents of the country. For example, the regulatory approval for one product in India is owned and held by our Indian distributor. If the licenses are not in our name or under our control, we might not have the power to ensure their ongoing effectiveness and use by us. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term revenue growth.

***If we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.***

Regulatory approvals or clearances that we currently have and that we may receive in the future are subject to limitations on the indicated uses for which the products may be marketed, and any future approvals could contain requirements for potentially costly post-marketing follow-up studies. If the FDA determines that our promotional materials or activities constitute promotion of an unapproved use or we otherwise fail to comply with FDA regulations, we may be subject to regulatory enforcement actions, including a warning letter, injunction, seizure, civil fine or criminal penalties. In addition, the manufacturing, labeling, packaging, adverse event reporting, storing, advertising, promoting, distributing and record-keeping for approved products are subject to extensive regulation. Our manufacturing facilities, processes and specifications are subject to periodic inspection by the FDA, European and other regulatory authorities and from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our failure to continue to meet regulatory standards or to remedy any deficiencies could result in restrictions being imposed on products or manufacturing processes, fines, suspension or loss of regulatory approvals or clearances, product recalls, termination of distribution, product seizures or the need to invest substantial resources to comply with various existing and new requirements. In the more egregious cases, criminal sanctions, civil penalties, disgorgement of profits or closure of our manufacturing facilities are possible. The subsequent discovery of previously unknown problems with Microcyn, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of our products, and could include voluntary or mandatory recall or withdrawal of products from the market.

New government regulations may be enacted and changes in FDA policies and regulations and, their interpretation and enforcement, could prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Therefore, we do not know whether we will be able to continue to comply with any regulations or that the costs of such compliance will not have a material adverse effect on our future business, financial condition, and results of operations. If we are not able to maintain regulatory compliance, we will not be permitted to market our products and our business would suffer.

***We may experience difficulties in manufacturing Microcyn, which could prevent us from commercializing one or more of our products.***

The machines used to manufacture our Microcyn-based products are complex, use complicated software and must be monitored by highly trained engineers. Slight deviations anywhere in our manufacturing process, including quality control, labeling and packaging, could lead to a failure to meet the specifications required by the FDA, the Environmental Protection Agency, European notified bodies, Mexican regulatory agencies and other foreign regulatory bodies, which may result in lot failures or product recalls. If we are unable to obtain quality internal and external components, mechanical and electrical parts, if our software contains defects or is corrupted, or if we are unable to attract and retain qualified technicians to manufacture our products, our manufacturing output of Microcyn, or any other product candidate based on our platform that we may develop, could fail to meet required standards, our regulatory approvals could be delayed, denied or revoked, and commercialization of one or more of our Microcyn-based products may be delayed or foregone. Manufacturing processes that are used to produce the smaller quantities of Microcyn needed for clinical tests and current commercial sales may not be successfully scaled up to allow production of significant commercial quantities. Any failure to manufacture our products to required standards on a commercial scale could result in reduced revenues, delays in generating revenue and increased costs.

***Our competitive position depends on our ability to protect our intellectual property and our proprietary technologies.***

Our ability to compete and to achieve and maintain profitability depends on our ability to protect our intellectual property and proprietary technologies. We currently rely on a combination of patents, patent applications, trademarks, trade secret laws, confidentiality agreements, license agreements and invention assignment agreements to protect our intellectual property rights. We also rely upon unpatented know-how and continuing technological innovation to develop and maintain our competitive position. These measures may not be adequate to safeguard our Microcyn Technology. In addition, we granted a security interest in our assets, excluding our intellectual property under certain circumstances, under a loan and security agreement. If we do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced.

Although we have filed U.S. and foreign patent applications related to our Microcyn-based products, the manufacturing technology for making the products, and their uses, only two U.S. patents have been issued from these applications to date.

Our pending patent applications and any patent applications we may file in the future may not result in issued patents, and we do not know whether any of our in-licensed patents or any additional patents that might ultimately be issued by the U.S. Patent and Trademark Office or foreign regulatory body will protect our Microcyn technology. Any claims that are issued may not be sufficiently broad to prevent third parties from producing competing substitutes and may be infringed, designed around, or invalidated by third parties. Even issued patents may later be found to be invalid, or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our European patent that was issued on May 30, 2007, was revoked by the Opposition Division of the European Patent Office in December, 2009 following opposition proceedings instituted by a competitor.

The degree of future protection for our proprietary rights is more uncertain in part because legal means afford only limited protection and may not adequately protect our rights, and we will not be able to ensure that:

- we were the first to invent the inventions described in patent applications;
- we were the first to file patent applications for inventions;
- others will not independently develop similar or alternative technologies or duplicate our products without infringing our intellectual property rights;
- any patents licensed or issued to us will provide us with any competitive advantages;
- we will develop proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our ability to do business.

The policies we use to protect our trade secrets may not be effective in preventing misappropriation of our trade secrets by others. In addition, confidentiality and invention assignment agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosures. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property in the United States, or in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

***We may face intellectual property infringement claims that could be time-consuming, costly to defend and could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages.***

On occasion, we may receive notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. We may have disputes regarding intellectual property rights with the parties that have licensed those rights to us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of its outcome, is expensive and time-consuming, could divert management's attention from our business and could have a material negative effect on our business, operating results or financial condition. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re-approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

***Our ability to generate revenue will be diminished if we are unable to obtain acceptable prices or an adequate level of reimbursement from third-party payors of healthcare costs.***

The continuing efforts of governmental and other third-party payors, including managed care organizations such as health maintenance organizations, or HMOs, to contain or reduce costs of health care may affect our future revenue and profitability, and the future revenue and profitability of our potential customers, suppliers and collaborative or license partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, governmental and private payors have limited the growth of health care costs through price regulation or controls, competitive pricing programs and drug rebate programs. Our ability to commercialize our products successfully will depend in part on the extent to which appropriate coverage and reimbursement levels for the cost of our Microcyn products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as HMOs.

There is significant uncertainty concerning third-party coverage and reimbursement of newly approved medical products and drugs. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed healthcare in the United States and the concurrent growth of organizations such as HMOs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may result in lower prices for or rejection of our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our ability to generate revenues.

In addition, given ongoing federal and state government initiatives directed at lowering the total cost of health care, the United States Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and the reform of the Medicare and Medicaid payment systems. While we cannot predict whether any proposed cost-containment measures will be adopted, the announcement or adoption of these proposals could reduce the price that we receive for our Microcyn products in the future.

*We could be required to indemnify third parties for alleged infringement, which could cause us to incur significant costs.*

Some of our distribution agreements contain commitments to indemnify our distributors against liability arising from infringement of third party intellectual property such as patents. We may be required to indemnify our customers for claims made against them or contribute to license fees they are required to pay. If we are forced to indemnify for claims or to pay license fees, our business and financial condition could be substantially harmed.

*A significant part of our business is conducted outside of the United States, exposing us to additional risks that may not exist in the United States, which in turn could cause our business and operating results to suffer.*

We have international operations in Mexico and Europe. During the years ended March 31, 2011 and 2010, approximately 62% and 69% of our total revenues were generated from sales outside of the United States. Our business is highly regulated for the use, marketing and manufacturing of our Microcyn-based products both domestically and internationally. Our international operations are subject to risks, including:

- local political or economic instability;
- changes in governmental regulation;
- changes in import/export duties;
- trade restrictions;
- lack of experience in foreign markets;
- difficulties and costs of staffing and managing operations in certain foreign countries;
- work stoppages or other changes in labor conditions;
- difficulties in collecting accounts receivables on a timely basis or at all; and
- adverse tax consequences or overlapping tax structures.

We plan to continue to market and sell our products internationally to respond to customer requirements and market opportunities. We currently have international manufacturing facilities in Mexico and the United States. Establishing operations in any foreign country or region presents risks such as those described above as well as risks specific to the particular country or region. In addition, until a payment history is established over time with customers in a new geography or region, the likelihood of collecting receivables generated by such operations could be less than our expectations. As a result, there is a greater risk that reserves set with respect to the collection of such receivables may be inadequate. If our operations in any foreign country are unsuccessful, we could incur significant losses and we may not achieve profitability.

In addition, changes in policies or laws of the United States or foreign governments resulting in, among other things, changes in regulations and the approval process, higher taxation, currency conversion limitations, restrictions on fund transfers or the expropriation of private enterprises, could reduce the anticipated benefits of our international expansion. If we fail to realize the anticipated revenue growth of our future international operations, our business and operating results could suffer.

***Our sales in international markets subject us to foreign currency exchange and other risks and costs which could harm our business.***

A substantial portion of our revenues are derived from outside the United States; primarily from Mexico. We anticipate that revenues from international customers will continue to represent a substantial portion of our revenues for the foreseeable future. Because we generate revenues in foreign currencies, we are subject to the effects of exchange rate fluctuations. The functional currency of our Mexican subsidiary is the Mexican Peso and the functional currency of our Netherlands subsidiary is the Euro. For the preparation of our consolidated financial statements, the financial results of our foreign subsidiaries are translated into U.S. dollars on average exchange rates during the applicable period. If the U.S. dollar appreciates against the Mexican Peso or the Euro, as applicable, the revenues we recognize from sales by our subsidiaries will be adversely impacted. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our revenues. Additionally, if the effective price of our products were to increase as a result of fluctuations in foreign currency exchange rates, demand for our products could decline and adversely affect our results of operations and financial condition.

***We rely on a number of key customers who may not consistently purchase our products in the future and if we lose any one of these customers, our revenues may decline.***

Although we have a significant number of customers in each of the geographic markets that we operate in, we rely on certain key customers for a significant portion of our sales. During the year ended March 31, 2011, one customer represented 17%, one customer represented 5%, and one customer represented 4% of our sales. During the year ended March 31, 2010, one customer represented 9% and two customers each represented 7% of our sales. In the future, a small number of customers may continue to represent a significant portion of our total revenues in any given period. These customers may not consistently purchase our products at a particular rate over any subsequent period. A loss of any of these customers could adversely affect our revenues.

***Negative economic conditions increase the risk that we could suffer unrecoverable losses on our customers' accounts receivable which would adversely affect our financial results.***

We grant credit to our business customers, which are primarily located in Mexico, Europe and the United States. Collateral is generally not required for trade receivables. We maintain allowances for potential credit losses. At March 31, 2011, one customer represented 11%, one customer represented 9%, and one customer represented 7% of our net accounts receivable balance. At March 31, 2010, one customer represented 24% and two customers each represented 9% of our net accounts receivable balance. While we believe we have a varied customer base and have experienced strong collections in the past, if current economic conditions disproportionately impact any one of our key customers, including reductions in their purchasing commitments to us or their ability to pay their obligations, it could have a material adverse effect on our revenues and liquidity. We have not purchased insurance on our accounts receivable balances.

***The loss of key members of our senior management team, one of our directors or our inability to retain highly skilled scientists, technicians and salespeople could adversely affect our business.***

Our success depends largely on the skills, experience and performance of key members of our executive management team, including Hojabr Alimi, our Chief Executive Officer, and Robert Northey, our Director of Research and Development. The efforts of these people will be critical to us as we continue to develop our products and attempt to commercialize products in the wound and skin care markets. If we were to lose one or more of these individuals, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among medical technology businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in wound care and close relationships with the medical community, including physicians and other medical staff. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our products. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our research, development and sales programs.

We maintain key-person life insurance only on Mr. Alimi. We may discontinue this insurance in the future, it may not continue to be available on commercially reasonable terms or, if continued, it may prove inadequate to compensate us for the loss of Mr. Alimi's services.

***The wound care industry is highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are less expensive or more effective than any products that we may develop, our commercial opportunity will be reduced or eliminated.***

Our success depends, in part, upon our ability to stay at the forefront of technological change and maintain a competitive position. We compete with large healthcare, pharmaceutical and biotechnology companies, along with smaller or early-stage companies that have collaborative arrangements with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our competitors may:

- develop and patent processes or products earlier than we will;
- develop and commercialize products that are less expensive or more efficient than any products that we may develop;
- obtain regulatory approvals for competing products more rapidly than we will; and
- improve upon existing technological approaches or develop new or different approaches that render our technology or products obsolete or non-competitive.

As a result, we may not be able to successfully commercialize any future products.

***The success of our research and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful, our research and development efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.***

An important element of our business strategy will be to enter into collaborative or license arrangements under which we license our Microcyn Technology to other parties for development and commercialization. We expect to seek collaborators for our drug candidates and for a number of our potential products because of the expense, effort and expertise required to conduct additional clinical trials and further develop those potential product candidates. Because collaboration arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. If we need third party assistance in identifying and negotiating one or more acceptable arrangements, it might be costly. Also, we may not have products that are desirable to other parties, or we may be unwilling to license a potential product because the party interested in it is a competitor. The terms of any arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaborative agreements, we may not be able to develop and commercialize new products, which would adversely affect our business and our revenues.

In order for any of these collaboration or license arrangements to be successful, we must first identify potential collaborators or licensees whose capabilities complement and integrate well with ours. We may rely on these arrangements for not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licenses to technology rights. However, it is likely that we will not be able to control the amount and timing or resources that our collaborators or licensees devote to our programs or potential products. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, or do not devote adequate resources to the program, the relationship will not be successful. If a business combination involving a collaborator or licensee and a third party were to occur, the effect could be to diminish, terminate or cause delays in development of a potential product.

***If we are unable to comply with broad and complex federal and state fraud and abuse laws, including state and federal anti-kickback laws, we could face substantial penalties and our products could be excluded from government healthcare programs.***

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, which include, among other things, “anti-kickback” laws that prohibit payments to induce the referral of products and services, and “false claims” statutes that prohibit the fraudulent billing of federal healthcare programs. Our operations are subject to the Federal Anti-Kickback Statute, a criminal statute that, subject to certain statutory exceptions, prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward a person either (i) for referring an individual for the furnishing of items or services for which payment may be made in whole or in part by a government healthcare program such as Medicare or Medicaid, or (ii) for purchasing, leasing, ordering or arranging for or recommending the purchasing, leasing or ordering of an item or service for which payment may be made under a government healthcare program. Because of the breadth of the federal anti-kickback statute, the Office of Inspector General of the U.S. Department of Health and Human Services, was authorized to adopt regulations setting forth additional exceptions to the prohibitions of the statute commonly known as “safe harbors.” If all of the elements of an applicable safe harbor are fully satisfied, an arrangement will not be subject to prosecution under the federal anti-kickback statute.

In addition, if there is a change in law, regulation or administrative or judicial interpretations of these laws, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a negative effect on our business, financial condition and results of operations.

Healthcare fraud and abuse laws are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a statute or regulation has been violated. The frequency of suits to enforce these laws has increased significantly in recent years and has increased the risk that a healthcare company will have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action. We cannot assure you that we will not become subject to such litigation. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could harm our reputation, be costly to defend and divert management’s attention from other aspects of our business. Similarly, if the physicians or other providers or entities with which we do business are found to have violated abuse laws, they may be subject to sanctions, which could also have a negative impact on us.

***Our efforts to discover and develop potential products may not lead to the discovery, development, commercialization or marketing of actual drug products.***

We are currently engaged in a number of different approaches to discover and develop new product applications and product candidates. We also have a non-Microcyn-based compound in the research and development phase. We believe this compound has potential applications in oncology. Discovery and development of potential drug candidates are expensive and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. If our efforts do not lead to the discovery of a suitable drug candidate, we may be unable to grow our clinical pipeline or we may be unable to enter into agreements with collaborators who are willing to develop our drug candidates.

***We must maintain expensive finance and accounting systems, procedures and controls to accommodate growth of our business and organization and to satisfy public company reporting requirements, which will increase our costs and require additional management resources.***

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission. Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires our management to perform an annual assessment of our internal control over financial reporting. Compliance with Section 404 and other requirements of doing business as a public company have and will continue to increase our costs and require additional management resources to implement an ongoing program to perform system and process evaluation and testing of our internal controls. In the past, we entered into transactions that resulted in accounting consequences that we did not identify at the time of the transactions. As a result, our prior independent auditors informed us that we did not have the appropriate financial management and reporting structure in place to meet the demands of a public company and that our accounting and financial personnel lacked the appropriate level of accounting knowledge, experience and training. In calendar year 2006, our current independent auditors recommended certain changes which, in addition to other changes in our financial reporting and management structure, have been implemented at additional cost. We have upgraded our accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization, enter into complex business transactions and take actions designed to satisfy reporting requirements. Our management has concluded that our internal controls were adequate to meet the required Section 404 assessment. If we are unable to complete the required Section 404 assessment as to adequacy of our internal control over financial reporting in future Form 10-K filings, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Securities Exchange Act of 1934. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

***We may not be able to maintain sufficient product liability insurance to cover claims against us.***

Product liability insurance for the healthcare industry is generally expensive to the extent it is available at all. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage and not subject to any indemnification or contribution could have a material adverse effect on our future business, financial condition, and results of operations.

#### **Risks Related to Our Common Stock**

***Our operating results may fluctuate, which could cause our stock price to decrease.***

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by physicians, other medical staff and patients for our Microcyn-based products;
- reimbursement decisions by third-party payors and announcements of those decisions;
- clinical trial results and publication of results in peer-reviewed journals or the presentation at medical conferences;
- the inclusion or exclusion of our Microcyn-based products in large clinical trials conducted by others;

- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- issues in manufacturing our product candidates or products;
- new or less expensive products and services or new technology introduced or offered by our competitors or us;
- the development and commercialization of product enhancements;
- changes in the regulatory environment;
- delays in establishing new strategic relationships;
- costs associated with collaborations and new product candidates;
- introduction of technological innovations or new commercial products by us or our competitors;
- litigation or public concern about the safety of our product candidates or products;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel; and
- general market conditions.

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, the NASDAQ Capital Market, in general, and the market for life sciences companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

***If an active, liquid trading market for our common stock does not develop, you may not be able to sell your shares quickly or at or above the price you paid for it.***

Although our common stock is listed on the NASDAQ Capital Market, an active and liquid trading market for our common stock has not yet and may not ever develop or be sustained. You may not be able to sell your shares quickly or at or above the price you paid for our stock if trading in our stock is not active.

***Anti-takeover provisions in our charter and by-laws and under Delaware law may make it more difficult for stockholders to change our management and may also make a takeover difficult.***

Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include:

- the ability of our board of directors to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of convertible preferred stock, which rights could be senior to those of common stock;

- limitations on persons authorized to call a special meeting of stockholders; and
- advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before meetings of stockholders.

These provisions might discourage, delay or prevent a change of control in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our board of directors.

***Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock or other securities convertible into common stock.***

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of convertible preferred stock. In the event we issue additional shares of our capital stock, dilution to our stockholders could result. In addition, if we issue and designate a class of convertible preferred stock, these securities may provide for rights, preferences or privileges senior to those of holders of our common stock.

## **ITEM 2. *Properties***

We currently lease 13,840 square feet of office, research and manufacturing space in Petaluma, California, which serves as our principal executive offices. The lease was set to expire on September 30, 2011. On May 31, 2011, we entered into Amendment No. 6 to our property lease agreement, extending the lease expiration to September 30, 2014.

We currently lease approximately 12,000 square feet of office and manufacturing space and approximately 5,000 square feet of warehouse space in Zapopan, Mexico, under leases that are set to expire on April 30, 2013 and June 14, 2011, respectively.

We currently rent approximately 800 square feet of sales office space in Herten, the Netherlands. The office space is rented on a month to month basis requiring a sixty day notice for cancellation.

As we expand, we may need to establish manufacturing facilities in other countries.

We believe that our properties will be adequate to meet our needs through March 31, 2012.

## **ITEM 3. *Legal Proceedings***

In June 2006, we received a written communication from the grantor of a license to an earlier version of its technology indicating that such license was terminated due to an alleged breach of the license agreement by us. The license agreement extends to our use of the technology in Japan only. While we do not believe that the grantor's revocation is valid under the terms of the license agreement and no legal claim has been threatened to date, we cannot provide any assurance that the grantor will not take legal action to restrict our use of the technology in the licensed territory. While our management does not anticipate that the outcome of this matter is likely to result in a material loss, there can be no assurance that if the grantor pursues legal action, such legal action would not have a material adverse effect on our financial position or results of operations.

From time to time, we are involved in legal matters arising in the ordinary course of business including matters involving proprietary technology. While we believe that such matters are currently not material, there can be no assurance that matters arising in the ordinary course of business for which we are or could become involved in litigation, will not have a material adverse effect on our business, financial condition or results of operations.

**ITEM 4. (Removed and Reserved)**

**PART II**

**ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

**Market Information**

Our common stock is traded on the NASDAQ Capital Market under the symbol "OCLS" and has been trading since our initial public offering on January 25, 2007. The following table sets forth the range of high and low sales prices for our common stock, based on the last daily sale, in each of the quarters since our stock began trading:

	<b>Year Ended March 31, 2011</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Stock price-high	\$ 2.38	\$ 2.03	\$ 1.89	\$ 2.25
Stock price-low	\$ 1.82	\$ 1.43	\$ 1.44	\$ 1.74

  

	<b>Year Ended March 31, 2010</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Stock price-high	\$ 4.91	\$ 3.45	\$ 2.33	\$ 2.69
Stock price-low	\$ 1.01	\$ 3.02	\$ 1.39	\$ 1.75

**Holdings**

As of May 27, 2011, we had approximately 583 holders of record of our common stock. Holders of record include nominees who may hold shares on behalf of multiple owners.

**Dividends**

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future.

**Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities**

On March 24, 2011, we issued 23,316 shares of common stock to Windsor Corporation, as compensation for financial advisory services in connection with an agreement between us and Windsor Corporation.

With respect to the issuance of our common stock described above, we relied on the Section 4(2) exemption from securities registration under the federal securities laws for transactions not involving any public offering. No advertising or general solicitation was employed in offering the shares. The shares were issued to an accredited investor.

## **ITEM 6. Selected Financial Data**

As a Smaller Reporting Company, as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this Item.

## **ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **Business Overview**

We are a commercial, health care company that develops, manufactures and markets a family of tissue care products, based on our platform called Microcyn Technology, intended to prevent and treat infections in open wounds and in skin care and through a unique and separate mechanism of action, enhance healing while reducing the need for antibiotics. Microcyn Technology is a non-irritating oxychlorine compound designed to treat a wide range of pathogens, including antibiotic-resistant strains of bacteria, viruses, fungi and spores.

### **Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to exercise its judgment. We exercise considerable judgment with respect to establishing sound accounting policies and in making estimates and assumptions that affect the reported amounts of our assets and liabilities, our recognition of revenues and expenses, and disclosure of commitments and contingencies at the date of the consolidated financial statements.

On an ongoing basis, we evaluate our estimates and judgments. Areas in which we exercise significant judgment include, but are not necessarily limited to, our valuation of accounts receivable, inventory, income taxes, equity transactions (compensatory and financing) and contingencies. We have also adopted certain policies with respect to our recognition of revenue that we believe are consistent with the guidance provided under Securities and Exchange Commission Staff Accounting Bulletin No. 104.

We base our estimates and judgments on a variety of factors including our historical experience, knowledge of our business and industry, current and expected economic conditions, the attributes of our products, regulatory environment, and in certain cases, the results of outside appraisals. We periodically re-evaluate our estimates and assumptions with respect to these judgments and modify our approach when circumstances indicate that modifications are necessary.

While we believe that the factors we evaluate provide us with a meaningful basis for establishing and applying sound accounting policies, we cannot guarantee that the results will always be accurate. Since the determination of these estimates requires the exercise of judgment, actual results could differ from such estimates.

A description of significant accounting policies that require us to make estimates and assumptions in the preparation of our consolidated financial statements is as follows:

### **Stock-based Compensation**

We account for share-based awards exchanged for employee services at the estimated grant date fair value of the award. We estimate the fair value of employee stock awards using the Black-Scholes option pricing model. We amortize the fair value of employee stock options on a straight-line basis over the requisite service period of the awards. Compensation expense includes the impact of an estimate for forfeitures for all stock options.

We account for equity instruments issued to non-employees at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests or becomes non-forfeitable. Non-employee stock-based compensation charges are amortized over the vesting period or as earned.

### ***Revenue Recognition and Accounts Receivable***

We generate product revenues from sales of our products to hospitals, medical centers, doctors, pharmacies, distributors and strategic partners. We sell our products directly to third parties and to distributors through various cancelable distribution agreements. We have also entered into an agreement to license our products.

We record revenues when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed or determinable, and collectability of the sale is reasonably assured.

We require all of our product sales to be supported by evidence of a sale transaction that clearly indicates the selling price to the customer, shipping terms and payment terms. Evidence of an arrangement generally consists of a contract or purchase order approved by the customer. We have ongoing relationships with certain customers from which we customarily accept orders by telephone in lieu of a purchase order.

We recognize revenues at the time in which we receive a confirmation that the goods were either tendered at their destination when shipped "FOB destination," or transferred to a shipping agent when shipped "FOB shipping point." Delivery to the customer is deemed to have occurred when the customer takes title to the product. Generally, title passes to the customer upon shipment, but could occur when the customer receives the product based on the terms of the agreement with the customer.

While we have a policy of investigating the creditworthiness of our customers, we have, under certain circumstances, shipped goods in the past and deferred the recognition of revenues when available information indicates that collection is in doubt. We establish allowances for doubtful accounts when available information causes us to believe that a credit loss is probable.

Our treatment for recognizing revenue related to distributors that have the inability to provide inventory or product sell-through reports on a timely basis, is to defer and recognize revenue when payment is received. We believe the receipt of payment is the best indication of product sell-through. We have entered into distribution agreements in Europe. Recognition of revenue and related cost of revenue from product sales is deferred until the product is sold from the distributors to their customers.

Service revenues are recorded upon performance of the service contracts. Revenues generated from testing contracts are recorded when the test is completed and the final report is sent to the customer.

### ***Inventory***

Inventories are stated at the lower of cost, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis), or market. Due to changing market conditions, estimated future requirements, age of the inventories on hand and production of new products, we regularly review inventory quantities on hand and records a provision to write down excess and obsolete inventory to its estimated net realizable value.

## ***Income Taxes***

We are required to determine the aggregate amount of income tax expense or loss based upon tax statutes in jurisdictions in which we conduct business. In making these estimates, we adjust our results determined in accordance with generally accepted accounting principles for items that are treated differently by the applicable taxing authorities. Deferred tax assets and liabilities resulting from these differences are reflected on our balance sheet for temporary differences in loss and credit carryforwards that will reverse in subsequent years. We also establish a valuation allowance against deferred tax assets when it is more likely than not that some or all of the deferred tax assets will not be realized. Valuation allowances are based, in part, on predictions that management must make as to our results in future periods. The outcome of events could differ over time which would require that we make changes in our valuation allowance.

## ***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. These estimates and assumptions include reserves and write-downs related to receivables and inventories, the recoverability of long-lived assets, deferred taxes and related valuation allowances, and valuation of equity and derivative instruments and debt discounts.

## ***Recent Accounting Pronouncements***

In March 2010, the FASB issued ASU No. 2010-17, "Revenue Recognition— Milestone Method (Topic 605): Milestone Method of Revenue Recognition." This standard provides that the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestones will be achieved. Determining whether a milestone is substantive requires judgment that should be made at the inception of the arrangement. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance, and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. The new standard is effective for interim and annual periods beginning on or after June 15, 2010. The adoption of this standard did not have any impact on our consolidated financial position and results of operations.

Other accounting standards that have been issued or proposed by the FASB, the EITF, the SEC and or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

## **Comparison of Fiscal Years Ended March 31, 2011 and 2010**

### ***Revenues***

Total revenues were \$9,754,000 during the year ended March 31, 2011 compared to \$7,364,000 in the prior year period. Product revenues increased \$2,528,000, or 40%, with increases in the U.S., Mexico, Europe, Middle East and China.

Product revenue in the United States increased \$1,588,000, or 133% from the prior year period. Most of the growth in our U.S. revenues resulted from a \$1,291,000 increase in animal wound care which was primarily related to television advertising and sales initiatives sponsored by Innovacyn, Inc. We also had increases in human wound care. In the United States, increases in revenues resulted from increases in the number of units sold.

Revenue in Mexico increased 11% from the prior year period. We believe during the fiscal year ended March 31, 2010, the swine flu epidemic in Mexico resulted in \$300,000 to \$400,000 of higher than normal sales. Total sales of our 120 and 240-milliliter presentation, which is primarily sold to pharmacies in Mexico, increased 9% from the prior year period. The average prices increased while the number of units sold was up 2%. Sales to hospitals increased 13% with a combination of both price and unit increases.

Europe and “Rest of World” revenue increased \$513,000, up 42% over the prior year period, due to higher sales in Europe, Middle East and China slightly offset by a small decline in sales in India. During the year ended March 31, 2011, we recorded product revenue of \$210,000 related to China which was the result of the conversion of our exclusive relationship with China Bao Tai to a non-exclusive relationship and recognition of deferred revenue related to an upfront payment from China Bao Tai.

The following table shows our product revenues by geographic region (in thousands):

	Year Ended March 31,		Increase	Increase
	2011	2010		
U.S.	\$ 2,784	\$ 1,196	\$ 1,588	133%
Europe and Rest of World	1,735	1,222	513	42%
Mexico	4,307	3,880	427	11%
Total	<u>\$ 8,826</u>	<u>\$ 6,298</u>	<u>\$ 2,528</u>	40%

Service revenue decreased \$138,000 when compared to the prior year period due to a decrease in the number of tests provided by our services business.

### ***Gross Profit***

During the year ended March 31, 2011, we reported a gross profit of \$5,950,000 from our Microcyn products business, or 67% of product revenues, compared to a gross profit of \$3,665,000, or 58% of product revenues, in the prior year period. We experienced higher margins in U.S. and Europe and Rest of World, offset by lower gross margins in Mexico. The higher margins in the U.S. are due to improved product mix for certain U.S. sales. Mexico’s margins were 72% during the year ended March 31, 2011, compared to 79% in the prior year period due to the high volume in the year ended March 31, 2010 caused by the swine flu epidemic and the lower margins on exported product produced by Mexico. We expect our gross margins to improve as our unit volume increases.

### ***Research and Development Expense***

Research and development expense increased \$50,000, or 3%, to \$2,046,000 for the year ended March 31, 2011, compared to \$1,996,000 in the prior year period. Most of the increase was attributable a the non-cash write off of research equipment and studies related to new products, partially offset by a reduction in personnel and related expenses, as we converted our research and development facility and the related people to operational manufacturing, supporting U.S. and European sales.

We expect that our research and development expense will slightly increase over the next few quarters as we incur additional expenses related to laboratory tests, clinical trials and the development and approval of new products.

### ***Selling, General and Administrative Expense***

Selling, general and administrative expense increased \$1,702,000, or 17%, to \$11,600,000 during the year ended March 31, 2011, from \$9,898,000 during the year ended March 31, 2010. Primarily, this increase was due to higher sales and marketing costs in Mexico and U.S., greater stock compensation costs, up by \$791,000 and higher salary and bonus costs in the U.S. Bonuses consisting of stock options and cash were recorded and paid during the first quarter of the fiscal year. These increases were partially offset by lower sales and marketing costs in Europe.

We expect selling, general and administrative expenses to grow slightly in future periods as we incur additional expenses to expand our sales efforts in the U.S., Europe and Mexico markets.

### ***Interest income and expense***

Interest expense increased by \$397,000 to \$406,000 during the year ended March 31, 2011 from \$9,000 during the year ended March 31, 2010. Primarily this increase was due to \$247,000 of cash interest incurred and \$159,000 of non-cash interest incurred during the year ended March 31, 2011. The non-cash interest is related to the \$2,000,000 borrowed on May 3, 2010 and the \$1,000,000 borrowed on November 17, 2010. Interest income showed no material change from the same period last year.

### ***Other income and expense, net***

Other income and expense, net increased \$115,000 to net other expense of \$175,000 for the year ended March 31, 2011, from net other expense of \$60,000 for the same period last year. The change in other income and expense, net was primarily related to the quarterly unrealized foreign exchange gains and losses on intercompany transactions and taxes paid in Mexico.

### ***Derivative liability***

During the year ended March 31, 2011 we recorded a gain on the fair value of our derivative liability of \$135,000 and as a result we recorded this amount as income. For the year ended March 31, 2010, we recorded a loss of \$149,000. The change in the fair value of our derivative liability was primarily the result of the exercise of warrants and decreases in our stock price.

### ***Net Loss***

Net loss for the year ended March 31, 2011 was \$7,948,000, down \$284,000 from \$8,232,000 for the same period in the prior year. The non-cash stock compensation charges were \$2,366,000 and \$1,432,000 for the year ended in March 31, 2011 and 2010, respectively.

### **Liquidity and Capital Resources**

We incurred a net loss of \$7,948,000 for the year ended March 31, 2011. At March 31, 2011, our accumulated deficit amounted to \$124,985,000. We had working capital of \$3,394,000 as of March 31, 2011. In the future, we may raise additional capital from external sources in order to continue the longer term efforts contemplated under our business plan. We expect to continue incurring losses for the foreseeable future and may raise additional capital to pursue our product development initiatives, penetrate markets for the sale of our products and continue as a going concern. We cannot provide any assurance that we will raise additional capital. Our management believes that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, we have not secured any commitment for new financing at this time.

### **Sources of Liquidity**

As of March 31, 2011, we had cash and cash equivalents of \$4,371,000. Since our inception, substantially all of our operations have been financed through sales of equity securities. Other sources of financing that we have used to date include our revenues, as well as various loans.

Since our inception, substantially all of our operations have been financed through the sale of \$114,534,000 (net proceeds) of our common and convertible preferred stock. This includes:

- net proceeds \$21,936,000 raised in our initial public offering on January 30, 2007;
- net proceeds of \$9,124,000 raised in a private placement of common shares on August 13, 2007;
- net proceeds of \$12,613,000 raised through a registered direct placement from March 31, 2008 to April 1, 2008;
- net proceeds of \$1,514,000 raised through a private placement on February 6, 2009;
- net proceeds of \$948,000 from a private placement on February 24, 2009;
- net proceeds of \$2,000,000 from a private placement on June 1, 2009;
- net proceeds of \$5,411,000 from a registered direct offering on July 30, 2009; and
- \$4,317,000 received from the exercise of common stock purchase warrants and options during the years ended March 31, 2011 and 2010.

On May 1, 2010, we entered into a Loan and Security Agreement and a Supplement to the Loan and Security Agreement with Venture Lending & Leasing V, Inc. to borrow up to an aggregate of \$3,000,000 (collectively, the “Agreements”). The Agreements provide for our borrowing a first tranche of \$2 million and, upon meeting certain milestones, a second tranche of \$1 million. The loan is secured by the assets of our company. On May 3, 2010, we borrowed \$2 million on the first tranche. The cash interest or “streaming” rate on the loan is 10%. For the first eight payments, we make monthly interest only payments set at \$16,660 through December 2010. Thereafter, we make interest and principal payments of \$75,000 per month through June 1, 2013. Additionally, we will make a final balloon payment of \$132,340 on June 1, 2013, resulting in an effective interest rate of 13%.

We became eligible to borrow \$1 million under the second tranche and made the determination to borrow. We are making interest-only payments for 6 months following the commencement of the second tranche. Following the interest only period, the second tranche will be amortized over 30 months, with a final payment due equal to 6.617% of the original principal balance.

In connection with the Agreements, we issued a warrant to Venture Lending & Leasing V, Inc. for the purchase of 166,667 shares of our common stock. When we became eligible to draw the second tranche of the loan, we became obliged to issue a second warrant for the purchase of an additional 83,333 shares of our common stock. The warrants may be exercised for a cash payment of \$2.00 per share of common stock, subject to adjustment. The warrants also have a cashless exercise feature. The warrants expire on November 30, 2017.

The warrants may be put back to us for \$500,000 cash initially, plus an additional \$250,000 when we became eligible to draw the second tranche of the loan. The put feature is available to the holder for 60 days after the first of the following to occur: i) a change of control of our Company, ii) the closing of at least \$15 million of additional equity financing, or iii) March 31, 2014.

## **Cash Flows**

As of March 31, 2011, we had unrestricted cash and cash equivalents of \$4,371,000 compared to \$6,258,000 at March 31, 2010.

Net cash used in operating activities during the year ended March 31, 2011 was \$4,429,000, primarily due to the \$7,948,000 net loss for the period along with increases in accounts receivables of \$626,000 and increases in inventory of \$245,000. These increases were offset in part by \$1,350,000 received in upfront payments from commercial partners and non-cash charges including \$2,366,000 of stock-based compensation and \$395,000 related to depreciation.

Net cash used in operating activities during the year ended March 31, 2010 was \$6,639,000, primarily due to the \$8,232,000 net loss for the period along with increases in accounts receivables and inventory, offset in part by non-cash charges, including \$149,000 loss on the fair value of derivative instruments, \$1,432,000 of stock-based compensation, and \$433,000 of depreciation.

Net cash used in investing activities was \$164,000 and \$184,000 for the year ended March 31, 2011 and 2010, respectively, primarily for the purchase of equipment.

Net cash provided by financing activities was \$2,684,000 for the year ended March 31, 2011. We received net proceeds from the issuance or debt during this period of \$3,000,000 offset by principal payments on debt in the amount of \$410,000. Additionally, we received proceeds of \$94,000 related to the exercise of common stock options. Net cash provided by financing activities was \$11,084,000 for the year ended March 31, 2010. We received net proceeds from the sale of common stock during this period of \$7,155,000. Additionally, we received proceeds of \$4,223,000 related to the exercise of common stock purchase warrants and stock options.

### Contractual Obligations

As of March 31, 2011, we had contractual obligations as follows (long-term debt amounts include principal payments only) (in thousands):

	Payments Due by Period			
	Total	Less Than 1 Year	1-3 Years	After 3 Years
Long-term debt	\$ 3,136	\$ 1,144	\$ 1,983	\$ 9
Operating leases	229	221	8	—
<b>Total</b>	<b>\$ 3,365</b>	<b>\$ 1,365</b>	<b>\$ 1,991</b>	<b>\$ 9</b>

We currently lease 13,840 square feet of office, research and manufacturing space in Petaluma, California, which serves as our principal executive offices. The lease is set to expire on September 30, 2011. On May 31, 2011, we entered into Amendment No. 6 to our property lease agreement, extending the lease expiration to September 30, 2014. In connection with the lease extension, we will incur additional payments of \$311,000, of which \$62,000 will be paid in less than one year and \$249,000 will be paid in years one to three.

Fiscal Year ended	Lease Payment
3/31/2012	62,000
3/31/2013	125,000
3/31/2014	125,000
3/31/2015	62,000
	<b>374,000</b>

### Operating Capital and Capital Expenditure Requirements

We incurred a net loss of \$7,948,000 for the year ended March 31, 2011. At March 31, 2011 and 2010, our accumulated deficit amounted to \$124,985,000 and \$117,037,000, respectively. At March 31, 2011, our working capital amounted to \$3,394,000.

We may raise additional capital from external sources in order to continue the longer term efforts contemplated under our business plan. We expect to continue incurring losses for the foreseeable future and may raise additional capital to pursue our product development initiatives, to penetrate markets for the sale of our products.

We have undertaken initiatives to reduce costs in an effort to conserve liquidity. Future pivotal trials will require the selection of a partner and must also be completed in order for us to commercialize Microcyn as a drug product in the United States. Commencement of the pivotal clinical trials will be delayed until we find a strategic partner to fund these trials. Without a strategic partner or additional capital, our pivotal clinical trials will be delayed for a period of time that is currently indeterminate.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

- the extent to which we acquire or invest in businesses, products and technologies.

### **Off-Balance Sheet Transactions**

We currently have no off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **ITEM 7A. *Quantitative and Qualitative Disclosures About Market Risk***

As a Smaller Reporting Company as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this Item.

### **ITEM 8. *Financial Statements and Supplementary Data***

#### **Oculus Innovative Sciences, Inc.**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of the Board of Directors and Shareholders  
of Oculus Innovative Sciences, Inc.

We have audited the accompanying consolidated balance sheets of Oculus Innovative Sciences, Inc. and Subsidiaries (the "Company") as of March 31, 2011 and 2010, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oculus Innovative Sciences, Inc. and Subsidiaries, as of March 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP

New York, NY  
June 3, 2011

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,371	\$ 6,258
Accounts receivable, net	2,094	1,416
Inventory, net	733	565
Prepaid expenses and other current assets	611	811
Total current assets	7,809	9,050
Property and equipment, net	802	1,108
Other assets	53	60
Total assets	\$ 8,664	\$ 10,218
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 669	\$ 981
Accrued expenses and other current liabilities	694	760
Deferred revenue	1,808	318
Current portion of long-term debt, net of debt discount of \$237	907	204
Derivative liability	337	472
Total current liabilities	4,415	2,735
Deferred revenue	160	328
Long-term debt, less current portion, net of debt discount of \$591	1,638	110
Put warrant liability	750	—
Total liabilities	6,963	3,173
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Convertible preferred stock, \$0.0001 par value; 5,000,000 shares authorized, none issued and outstanding at March 31, 2011 and 2010	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 26,576,302 and 26,161,428 shares issued and outstanding at March 31, 2011 and 2010, respectively	3	3
Additional paid-in capital	129,584	127,067
Accumulated other comprehensive loss	(2,901)	(2,988)
Accumulated deficit	(124,985)	(117,037)
Total stockholders' equity	1,701	7,045
Total liabilities and stockholders' equity	\$ 8,664	\$ 10,218

The accompanying footnotes are an integral part of these consolidated financial statements.

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	Year Ended March 31,	
	2011	2010
	(In thousands, except per share amounts)	
<b>Revenues</b>		
Product	\$ 8,826	\$ 6,298
Service	928	1,066
Total revenues	<u>9,754</u>	<u>7,364</u>
<b>Cost of revenues</b>		
Product	2,876	2,633
Service	737	853
Total cost of revenues	<u>3,613</u>	<u>3,486</u>
<b>Gross profit</b>	6,141	3,878
<b>Operating expenses</b>		
Research and development	2,046	1,996
Selling, general and administrative	11,600	9,898
Total operating expenses	<u>13,646</u>	<u>11,894</u>
<b>Loss from operations</b>	(7,505)	(8,016)
<b>Interest expense</b>	(406)	(9)
<b>Interest income</b>	3	2
<b>Gain (loss) due to change in fair value of derivative instruments</b>	135	(149)
<b>Other expense, net</b>	(175)	(60)
<b>Net loss</b>	<u>\$ (7,948)</u>	<u>\$ (8,232)</u>
<b>Net loss per common share: basic and diluted</b>	<u>\$ (0.30)</u>	<u>\$ (0.36)</u>
<b>Weighted-average number of shares used in per common share calculations:</b>		
Basic and diluted	<u>26,374</u>	<u>22,993</u>
<b>Other comprehensive loss</b>		
Net loss	\$ (7,948)	\$ (8,232)
Foreign currency translation adjustments	87	66
Comprehensive loss	<u>\$ (7,861)</u>	<u>\$ (8,166)</u>

The accompanying footnotes are an integral part of these consolidated financial statements.

**OCULUS INNOVATIVE SCIENCES, INC**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

	Common Stock (\$0.0001 par Value)		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
	(In thousands, except share and per share amounts)					
Balance, March 31, 2009	18,402,820	\$ 2	\$ 113,803	\$ (3,054)	\$ (108,482)	\$ 2,269
Issuance of common stock in connection with June 1, 2009 closing of offering, net of commissions, expenses and other offering costs	1,709,402	—	2,000	—	—	2,000
Issuance of common stock in connection with July 30, 2009 offering, net of commissions, expenses and other offering costs	2,454,000	1	5,154	—	—	5,155
Issuance of common stock in connection with exercise of stock purchase warrants	2,193,959	—	3,975	—	—	3,975
Issuance of common stock in connection with exercise of stock options	663,592	—	248	—	—	248
Issuance of common stock for accounts payable obligations	230,602	—	455	—	—	455
Issuance of common stock for services	491,096	—	567	—	—	567
Issuance of restricted stock units from the 2006 Stock Incentive Plan	15,957	—	29	—	—	29
Employee stock-based compensation expense, net of forfeitures	—	—	836	—	—	836
Foreign currency translation adjustment	—	—	—	66	—	66
Cumulative effect adjustment to retained earnings related to derivative liabilities	—	—	—	—	(323)	(323)
Net loss	—	—	—	—	(8,232)	(8,232)
Balance, March 31, 2010	26,161,428	\$ 3	\$ 127,067	\$ (2,988)	\$ (117,037)	\$ 7,045
Issuance of common stock in connection with exercise of stock options	126,120	—	94	—	—	94
Issuance of common stock for accounts payable obligations	35,000	—	57	—	—	57
Issuance of common stock for services	253,754	—	482	—	—	482
Employee stock-based compensation expense, net of forfeitures	—	—	1,884	—	—	1,884
Foreign currency translation adjustment	—	—	—	87	—	87
Net loss	—	—	—	—	(7,948)	(7,948)
Balance, March 31, 2011	<u>26,576,302</u>	<u>\$ 3</u>	<u>\$ 129,584</u>	<u>\$ (2,901)</u>	<u>\$ (124,985)</u>	<u>\$ 1,701</u>

The accompanying footnotes are an integral part of these consolidated financial statements.

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In thousands)</b>	
<b>Cash flows from operating activities</b>		
Net loss	\$ (7,948)	\$ (8,232)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	395	433
Provision for doubtful accounts	17	61
Provision for obsolete inventory	98	184
Stock-based compensation	2,366	1,432
Change in fair value of derivative liability	(135)	149
Non-cash interest expense	159	—
Foreign currency transaction (gains) losses	(2)	(97)
Loss on disposal of assets	157	169
Changes in operating assets and liabilities:		
Accounts receivable	(626)	(453)
Inventories	(245)	(388)
Prepaid expenses and other current assets	375	190
Accounts payable	(266)	(163)
Accrued expenses and other liabilities	1,226	76
Net cash used in operating activities	<u>(4,429)</u>	<u>(6,639)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(174)	(141)
Long-term deposits	10	(43)
Net cash used in investing activities	<u>(164)</u>	<u>(184)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net of offering costs	—	7,155
Proceeds from issuance of common stock upon exercise of stock options and warrants	94	4,223
Proceeds from issuance of long-term debt	3,000	—
Principal payments on long-term debt	(410)	(288)
Payments on capital lease obligations	—	(6)
Net cash provided by financing activities	<u>2,684</u>	<u>11,084</u>
Effect of exchange rate on cash and cash equivalents	22	76
Net (decrease) increase in cash and cash equivalents	(1,887)	4,337
Cash and cash equivalents, beginning of year	6,258	1,921
Cash and cash equivalents, end of year	<u>\$ 4,371</u>	<u>\$ 6,258</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 247</u>	<u>\$ 9</u>
Issuance of common stock for accounts payable obligations	<u>\$ 57</u>	<u>\$ 455</u>
<b>Non-cash operating and financing activities:</b>		
Insurance premiums financed	<u>\$ 165</u>	<u>\$ 184</u>
<b>Non-cash investing and financing activities:</b>		
Equipment financed	<u>\$ 68</u>	<u>\$ 157</u>
Debt discount in connection with long-term debt	<u>\$ 750,000</u>	<u>\$ —</u>

The accompanying footnotes are an integral part of these consolidated financial statements

**OCULUS INNOVATIVE SCIENCES, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 — The Company**

*Organization*

Oculus Innovative Sciences, Inc. (the “Company”) was incorporated under the laws of the State of California in April 1999 and was reincorporated under the laws of the State of Delaware in December 2006. The Company’s principal office is located in Petaluma, California. The Company develops, manufactures and markets a family of tissue care products to treat infections and, through a separate mechanism of action, enhance healing while reducing the need for antibiotics. The Company’s platform technology, called Microcyn® , is a proprietary solution of electrically charged oxochlorine small molecules designed to treat a wide range of organisms that cause disease (pathogens).

**NOTE 2 — Liquidity and Financial Condition**

The Company incurred a net loss of \$7,948,000 for the year ended March 31, 2011. At March 31, 2011, the Company’s accumulated deficit amounted to \$124,985,000. The Company had working capital of \$3,394,000 as of March 31, 2011. The Company may raise additional capital from external sources in order to continue the longer term efforts contemplated under its business plan. The Company expects to continue incurring losses for the foreseeable future and may raise additional capital to pursue its product development initiatives, penetrate markets for the sale of its products and continue as a going concern.

On May 1, 2010, the Company entered into a Loan and Security Agreement and a Supplement to the Loan and Security Agreement with Venture Lending & Leasing, Inc. (as discussed in Note 9) to borrow up to an aggregate of \$3,000,000. On May 3, 2010, the Company borrowed \$2,000,000 and on November 17, 2010 the Company borrowed the remaining \$1,000,000. The effective interest rate on the loan is 13.3%.

During the year ended March 31, 2011, the Company received \$94,000 in connection with the exercise of 126,120 employee stock options.

The Company currently anticipates that its cash and cash equivalents will be sufficient to meet its working capital requirements to continue its sales and marketing and research and development through at least April 1, 2012. However, in order to execute the Company’s long-term Microcyn product development strategy and to penetrate new and existing markets, the Company may need to raise additional funds, through public or private equity offerings, debt financings, corporate collaborations or other means. The Company may raise additional capital to pursue its product development initiatives and penetrate markets for the sale of its products.

Management believes that the Company has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, the Company has not secured any commitment for new financing at this time, nor can it provide any assurance that new financing will be available on commercially acceptable terms, if needed. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash.

**NOTE 3 — Summary of Significant Accounting Policies**

*Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Aquamed Technologies, Inc., Oculus Technologies of Mexico S.A. de C.V. (“OTM”) and Oculus Innovative Sciences Netherlands, B.V. (“OIS Europe”). All significant intercompany accounts and transactions have been eliminated in consolidation.

### *Use of Estimates*

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include reserves and write-downs related to receivables and inventories, the recoverability of long-lived assets, deferred taxes and related valuation allowances, valuation of equity and derivative instruments, and debt discounts.

### *Revenue Recognition*

The Company generates revenue from sales of its products to hospitals, medical centers, doctors, pharmacies, and distributors. The Company sells its products directly to third parties and to distributors through various cancelable distribution agreements. The Company has also entered into agreements to license its technology.

The Company also provides regulatory compliance testing and quality assurance services to medical device and pharmaceutical companies.

The Company records revenue when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred, (iii) the fee is fixed or determinable, and (iv) collectability of the sale is reasonably assured.

The Company requires all of its product sales to be supported by evidence of a sale transaction that clearly indicates the selling price to the customer, shipping terms and payment terms. Evidence of an arrangement generally consists of a contract or purchase order approved by the customer. The Company has ongoing relationships with certain customers from which it customarily accepts orders by telephone in lieu of purchase orders.

The Company recognizes revenue at the time in which it receives a confirmation that the goods were either tendered at their destination when shipped "FOB destination," or transferred to a shipping agent when shipped "FOB shipping point." Delivery to the customer is deemed to have occurred when the customer takes title to the product. Generally, title passes to the customer upon shipment, but could occur when the customer receives the product based on the terms of the agreement with the customer.

The selling prices of all goods that the Company sells are fixed, and agreed to with the customer, prior to shipment. Selling prices are generally based on established list prices. The Company does not customarily permit its customers to return any of its products for monetary refunds or credit against completed or future sales. The Company, from time to time, may replace expired goods on a discretionary basis. The Company records these types of adjustments, when made, as a reduction of revenue. Sales adjustments were insignificant during the years ended March 31, 2011 and 2010.

The Company evaluates the creditworthiness of new customers and monitors the creditworthiness of its existing customers to determine whether events or changes in their financial circumstances would raise doubt as to the collectability of a sale at the time in which a sale is made. Payment terms on sales made in the United States are generally 30 days and internationally, generally range from 30 days to 90 days.

In the event a sale is made to a customer under circumstances in which collectability is not reasonably assured, the Company either requires the customer to remit payment prior to shipment or defers recognition of the revenue until payment is received. The Company maintains a reserve for amounts which may not be collectible due to risk of credit losses.

Additionally, the Company's treatment for recognizing revenue related to distributors' that have the inability to provide inventory or product sell-through reports on a timely basis, is to defer and recognize revenue when payment is received. The Company believes the receipt of payment is the best indication of product sell-through.

The Company has entered into distribution agreements in Europe. Recognition of revenue and related cost of revenue from product sales is deferred until the product is sold from the distributors to their customers.

When the Company receives letters of credit and the terms of the sale provide for no right of return except to replace defective product, revenue is recognized when the letter of credit becomes effective and the product is shipped.

License revenue is generated through agreements with strategic partners for the commercialization of Microcyn products. The terms of the agreements sometimes include non-refundable upfront fees. The Company analyzes multiple element arrangements to determine whether the elements can be separated. Analysis is performed at the inception of the arrangement and as each product is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance obligation period.

Assuming the elements meet the criteria for separation and all other revenue requirements for recognition, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

When appropriate, the Company defers recognition of non-refundable upfront fees. If it has continuing performance obligations then such upfront fees are deferred and recognized over the period of continuing involvement.

The Company recognizes royalty revenues from licensed products upon the sale of the related products.

Revenue from consulting contracts is recognized as services are provided. Revenue from testing contracts is recognized as tests are completed and a final report is sent to the customer.

#### ***Sales Tax and Value Added Taxes***

The Company accounts for sales taxes and value added taxes imposed on its goods and services on a net basis.

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents may be invested in money market funds, commercial paper, variable rate demand instruments, and certificates of deposits.

#### ***Concentration of Credit Risk and Major Customers***

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents and accounts receivable. Cash and cash equivalents are maintained in financial institutions in the United States, Mexico and the Netherlands. The Company is exposed to credit risk in the event of default by these financial institutions for amounts in excess of the Federal Deposit Insurance Corporation insured limits. Cash and cash equivalents held in foreign banks are intentionally kept at minimal levels, and therefore have minimal credit risk associated with them.

The Company grants credit to its business customers, which are primarily located in Mexico, Europe and the United States. Collateral is generally not required for trade receivables. The Company maintains allowances for potential credit losses. At March 31, 2011, one customer represented 11%, one customer represented 9%, and one customer represented 7% of the net accounts receivable balance. At March 31, 2010, one customer represented 24% and two customers each represented 9% of the net accounts receivable balance. During the year ended March 31, 2011, one customer represented 17%, one customer represented 5% and one customer represented 4% of sales. During the year ended March 31, 2010, one customer represented 9% and two customers each represented 7% of sales.

### ***Accounts Receivable***

Trade accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, and sales returns. Estimates for cash discounts and sales returns are based on analysis of contractual terms and historical trends.

The Company's policy is to reserve for uncollectible accounts based on its best estimate of the amount of probable credit losses in its existing accounts receivable. The Company periodically reviews its accounts receivable to determine whether an allowance for doubtful accounts is necessary based on an analysis of past due accounts and other factors that may indicate that the realization of an account may be in doubt. Other factors that the Company considers include its existing contractual obligations, historical payment patterns of its customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region, and a review of the local economic environment and its potential impact on government funding and reimbursement practices. Account balances deemed to be uncollectible are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The allowance for doubtful accounts at March 31, 2011 and 2010 represents probable credit losses in the amounts of \$62,000 and \$96,000, respectively.

### ***Inventories***

Inventories are stated at the lower of cost, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis), or market.

Due to changing market conditions, estimated future requirements, age of the inventories on hand and production of new products, the Company regularly reviews inventory quantities on hand and records a provision to write down excess and obsolete inventory to its estimated net realizable value. The Company recorded reserves to reduce the carrying amounts of inventories to their net realizable value in the amounts of \$158,000 and \$143,000 at March 31, 2011 and 2010, respectively.

### ***Fair Value of Financial Assets and Liabilities***

Financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of capital lease obligations and equipment loans approximates their carrying amounts as a market rate of interest is attached to their repayment.

The Company measures the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. The Company uses three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 — inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

Financial liabilities measured at fair value on a recurring basis are summarized below:

	<b>Fair Value Measurements at March 31, 2011 Using</b>			
	<b>Total March 31, 2011</b>	<b>Quoted prices in active markets for identical assets (Level 1)</b>	<b>Significant other observable inputs (Level 2)</b>	<b>Significant other unobservable inputs (Level 3)</b>
<b>Liabilities:</b>				
Derivative liability - warrants	\$ 337	\$ —	\$ —	\$ 337

	<b>Fair Value Measurements at March 31, 2010 Using</b>			
	<b>Total March 31, 2010</b>	<b>Quoted prices in active markets for identical assets (Level 1)</b>	<b>Significant other observable inputs (Level 2)</b>	<b>Significant other unobservable inputs (Level 3)</b>
<b>Liabilities:</b>				
Derivative liability - warrants	\$ 472	\$ —	\$ —	\$ 472

### ***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation of leasehold improvements is computed using the straight-line method over the lesser of the estimated useful life of the improvement or the remaining term of the lease. Estimated useful asset life by classification is as follows:

	<b>Years</b>
Office equipment	3
Manufacturing, lab and other equipment	5
Furniture and fixtures	7

Upon retirement or sale, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

### ***Impairment of Long-Lived Assets***

The Company periodically reviews the carrying values of its long-lived assets in accordance when events or changes in circumstances would indicate that it is more likely than not that their carrying values may exceed their realizable values, and records impairment charges when considered necessary. Specific potential indicators of impairment include, but are not necessarily limited to:

- a significant decrease in the fair value of an asset;
- a significant change in the extent or manner in which an asset is used or a significant physical change in an asset;
- a significant adverse change in legal factors or in the business climate that affects the value of an asset;
- an adverse action or assessment by the U.S. Food and Drug Administration or another regulator;
- an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset; and operating or cash flow losses combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an income-producing asset.

When circumstances indicate that an impairment may have occurred, the Company tests such assets for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of such assets and their eventual disposition to their carrying amounts. In estimating these future cash flows, assets and liabilities are grouped at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other such groups. If the undiscounted future cash flows are less than the carrying amount of the asset, an impairment loss, measured as the excess of the carrying value of the asset over its estimated fair value, will be recognized. The cash flow estimates used in such calculations are based on estimates and assumptions, using all available information that management believes is reasonable. During the years ended March 31, 2011 and 2010, the Company had noted no indicators of impairment.

### ***Research and Development***

Research and development expense is charged to operations as incurred and consists primarily of personnel expenses, clinical and regulatory services and supplies. For the years ended March 31, 2011 and 2010, research and development expense amounted to \$2,046,000 and \$1,996,000, respectively.

### ***Advertising Costs***

Advertising costs are expensed as incurred. Advertising costs amounted to \$304,000 and \$246,000, for the years ended March 31, 2011 and 2010, respectively. Advertising costs are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

### ***Shipping and Handling Costs***

The Company classifies amounts billed to customers related to shipping and handling in sale transactions as revenue. Shipping and handling costs incurred are recorded in cost of product revenues. For the years ended March 31, 2011 and 2010, the Company recorded revenue related to shipping and handling costs of \$63,000 and \$47,000, respectively.

### ***Foreign Currency Reporting***

The Company's subsidiary, OTM uses the local currency (Mexican Pesos) as its functional currency and OIS Europe uses the local currency (Euro) as its functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date, and revenue and expense accounts are translated at average exchange rates during the period. Resulting translation adjustments were recorded in accumulated other comprehensive loss in the accompanying consolidated balance sheets at March 31, 2011 and March 31, 2010.

Foreign currency transaction gains (losses) relate primarily to trade payables and receivables between subsidiaries OTM and OIS Europe. These transactions are expected to be settled in the foreseeable future. The Company recorded foreign currency transaction losses of \$2,000 and \$97,000 for the years ended March 31, 2011 and 2010, respectively. The related losses were recorded in other income and expense, net, in the accompanying consolidated statements of operations.

### ***Stock-Based Compensation***

The Company accounts for share-based awards exchanged for employee services at the estimated grant date fair value of the award. The Company estimates the fair value of employee stock awards using the Black-Scholes option pricing model. The Company amortizes the fair value of employee stock options on a straight-line basis over the requisite service period of the awards. Compensation expense includes the impact of an estimate for forfeitures for all stock options.

The Company accounts for equity instruments issued to non-employees at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests or becomes non-forfeitable. Non-employee stock-based compensation charges are amortized over the vesting period or as earned.

For the years ended March 31, 2011 and 2010, the Company recognized stock-based compensation expense in the accompanying consolidated statements of operations of \$2,366,000 and \$1,432,000, respectively.

### ***Income Taxes***

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Tax benefits claimed or expected to be claimed on a tax return are recorded in the Company's consolidated financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Uncertain tax positions have had no impact on the Company's consolidated financial condition, results of operations or cash flows.

### ***Comprehensive Loss***

Other comprehensive loss includes all changes in stockholders' equity during a period from non-owner sources and is reported in the consolidated statement of stockholders' equity. To date, other comprehensive loss consists of changes in accumulated foreign currency translation adjustments. Accumulated other comprehensive losses at March 31, 2011 and 2010 were \$2,901,000 and \$2,988,000, respectively.

### *Net Loss Per Share*

The Company computes basic net loss per share by dividing net loss per share available to common stockholders by the weighted average number of common shares outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the “treasury stock” and/or “if converted” methods as applicable. The computation of basic loss per share for the years ended March 31, 2011 and 2010, excludes potentially dilutive securities because their inclusion would be anti-dilutive.

	<b>Year Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In thousands)</b>	
<b>Anti-dilutive securities excluded from the computation of basic and diluted net loss per share are as follows:</b>		
Options to purchase common stock	4,396	3,987
Warrants to purchase common stock	9,366	9,144
	<u>13,762</u>	<u>13,131</u>

### *Common Stock Purchase Warrants and Other Derivative Financial Instruments*

The Company classifies common stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contracts that contain reset provisions as either an asset or a liability. The Company assesses classification of its freestanding derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required. The Company determined that its freestanding derivatives, which principally consist of warrants to purchase common stock, satisfied the criteria for classification as equity instruments at March 31, 2011, other than certain warrants that contain reset provisions that the Company classified as derivative liabilities as more fully described in Note 11.

### *Subsequent Events*

Management has evaluated subsequent events or transactions occurring through the date these consolidated financial statements were issued.

### *Recent Accounting Pronouncements*

In March 2010, the FASB issued ASU No. 2010-17, “Revenue Recognition— Milestone Method (Topic 605): Milestone Method of Revenue Recognition”. This standard provides that the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestones will be achieved. Determining whether a milestone is substantive requires judgment that should be made at the inception of the arrangement. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance, and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. The new standard is effective for interim and annual periods beginning on or after June 15, 2010. The adoption of this standard did not have any impact on the Company’s consolidated financial position and results of operations.

Other accounting standards that have been issued or proposed by the FASB, the EITF, the SEC and or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements upon adoption.

**NOTE 4 — Accounts Receivable**

Accounts receivable consists of the following (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
Accounts receivable	\$ 2,156	\$ 1,512
Less: allowance for doubtful accounts	(62)	(96)
	<u>\$ 2,094</u>	<u>\$ 1,416</u>

Allowance for doubtful accounts activities are as follows (in thousands):

<b>Year Ended March 31</b>	<b>Balance at Beginning of Year</b>	<b>Additions Charged to Operations</b>	<b>Deductions Write-Offs</b>	<b>Balance at End of Year</b>
2010	\$ 51	\$ 61	\$ (16)	\$ 96
2011	\$ 96	\$ 17	\$ (51)	\$ 62

**NOTE 5 — Inventories**

Inventories consist of the following (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
Raw materials	\$ 482	\$ 406
Finished goods	409	302
	891	708
Less: inventory allowances	(158)	(143)
	<u>\$ 733</u>	<u>\$ 565</u>

Reserve for obsolete inventories activities are as follows (in thousands):

<b>Year Ended March 31</b>	<b>Balance at Beginning of Year</b>	<b>Additions Charged to Cost of Product Revenues</b>	<b>Deductions Write-Offs</b>	<b>Balance at End of Year</b>
2010	\$ 71	\$ 184	\$ (112)	\$ 143
2011	\$ 143	\$ 98	\$ (83)	\$ 158

**NOTE 6 — Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
Prepaid expenses	\$ 403	\$ 590
Value Added Tax receivable	24	31
Other current assets	184	190
	<u>\$ 611</u>	<u>\$ 811</u>

**NOTE 7 — Property and Equipment**

Property and equipment consists of the following (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
Manufacturing, lab, and other equipment	\$ 2,375	\$ 2,470
Office equipment	333	388
Furniture and fixtures	53	52
Leasehold improvements	284	275
	<u>3,045</u>	<u>3,185</u>
Less: accumulated depreciation and amortization	<u>(2,243)</u>	<u>(2,077)</u>
	<u>\$ 802</u>	<u>\$ 1,108</u>

Depreciation and amortization expense amounted to \$395,000 and \$433,000 for the years ended March 31, 2011 and 2010, respectively.

During the years ended March 31, 2011 and 2010, the Company incurred losses on the disposal of assets in the amount of \$157,000 and \$169,000, respectively. These amounts are recorded as operating expenses in the accompanying consolidated statements of operations.

**NOTE 8 — Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consist of the following (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
Salaries and related costs	\$ 472	\$ 467
Professional fees	36	143
Value Added Tax payable	143	140
Other	43	10
	<u>\$ 694</u>	<u>\$ 760</u>

## NOTE 9 — Long-Term Debt

From February 2005 to March 2006, the Company issued various notes for aggregate principal amounting to \$182,000 with interest rates ranging from 6.25% to 14.44% per annum. The proceeds of these notes were used to purchase automobiles and software. The Company made principal payments on these notes of \$10,000 and \$28,000, during the years ended March 31, 2011 and 2010, respectively. Aggregate interest expense under these obligations amounted to \$400 and \$2,000 for the years ended March 31, 2011 and 2010, respectively. These notes were payable in aggregate monthly installments of \$1,000 including interest with a final payment on March 14, 2011.

On August 29, 2009, the Company entered into a note agreement for principal amounting to \$100,000 with an interest rate of 2.90% per annum. This instrument was issued in connection with financing an automobile. The note is payable in monthly installments of \$1,800 through August 29, 2014. During the year ended March 31, 2011 and 2010, the Company made principal payments on this note in the amount of \$19,000 and \$11,000, respectively. During the year ended March 31, 2011 and 2010, the Company made interest payments related to this note in the amounts of \$2,000. The remaining balance of this note amounted to \$70,000 at March 31, 2011 of which \$20,000 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

On October 7, 2009, the Company entered into a note agreement for principal amounting to \$57,000 with an interest rate of 1.0% per annum. This instrument was issued in connection with financing an automobile. The note is payable in monthly installments of \$900 through October 26, 2014. During the year ended March 31, 2011 and 2010, the Company made principal payments on this note in the amount of \$11,000 and \$4,000, respectively. During the year ended March 31, 2011 and 2010, the Company made interest payments related to this note in the amounts of \$400 and \$100, respectively. The remaining balance of this note amounted to \$39,000 at March 31, 2011 of which \$11,000 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

On March 16, 2010, the Company entered into a note agreement for \$184,000 with an interest rate of 4.0% per annum. This instrument was issued in connection with financing insurance premiums. The note was payable in monthly installments of \$20,800 with the final payment on November 16, 2010. During the year ended March 31, 2011 and 2010, the Company made principal payments of \$164,000 and \$20,000, respectively. During the year ended March 31, 2011 and 2010, the Company made interest payments of \$2,500 and \$1,000, respectively.

On May 1, 2010, the Company entered into a Loan and Security Agreement and a Supplement to the Loan and Security Agreement with Venture Lending & Leasing V, Inc. to borrow up to an aggregate of \$3,000,000 (collectively, the "Agreements"). The Agreements provide for a first tranche of \$2,000,000 and, upon meeting certain financial milestones, a second tranche of \$1,000,000. On May 3, 2010, the Company borrowed \$2,000,000 on the first tranche and on November 17, 2010 the Company borrowed \$1,000,000 on the second tranche. The loan is secured by the assets of the Company excluding intellectual property under certain circumstances. Related to the first tranche, the Company made eight monthly interest only payments set at \$16,660 through December 1, 2010. Thereafter, the Company will make interest and principal payments of \$75,000 per month through June 1, 2013. Related to the second tranche, the Company pays monthly interest only payments set at \$8,330 through May 1, 2011. Thereafter, the Company will make interest and principal payments of \$37,500 per month through November 1, 2013. Additionally, the Company will make a final balloon payment related to the first tranche of \$132,000 on June 1, 2013 and will make a final balloon payment related to the second tranche of \$66,000 on November 1, 2013. The effective interest rate on the first and second tranche is 13.3%. During the year ended March 31, 2011, the Company made principal and interest payments of \$160,000 and \$236,000, respectively.

Additionally, in connection with the Agreements, the Company issued warrants to Venture Lending & Leasing, Inc. for the purchase of 250,000 shares of the Company's common stock (the "Warrants"). The Warrants may be exercised for a cash payment of \$2.00 per share of common stock. The Warrants are subject to adjustment for stock splits, dividends, a change in control or similar transactions. The Warrants also have a cashless exercise feature. The Warrants expire on November 30, 2017. The Warrants may be put back to the Company for \$750,000 in cash. The put feature is available to the holder for 60 days after the first of the following to occur: i) a change of control of the Company, ii) the closing of at least \$15,000,000 of additional equity financing, or iii) March 31, 2014. The \$750,000 cash value of the warrant was recorded as a put warrant liability and a corresponding amount of \$750,000 was recorded as a discount on the note payable. The discount will be accreted to non-cash interest expense over the term of the loan using the effective interest method. During the year ended March 31, 2011, the Company recorded \$159,000 of non-cash interest expense related to this to this note. The remaining balance of the notes amounted to \$2,840,000, and the carrying value, net of \$591,000 discount, amounted to \$2,249,000, at March 31, 2011, of which \$737,000, net of \$237,000 discount, is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

On August 12, 2010, the Company entered into a note agreement for principal amounting to \$40,000 with an interest rate of 11.99% per year. This instrument was issued in connection with the financing of an automobile. During the three months ended March 31, 2011, the Company made principal and interest payments related to this note in the amounts of \$8,000 and \$3,000, respectively. The remaining balance of this note amounted to \$32,000 at March 31, 2011 of which \$5,400 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

On November 30, 2010, the Company entered into a note agreement for principal amounting to \$27,000 with an interest rate of 8.90% per year. This instrument was issued in connection with the financing of an automobile. During the year ended March 31, 2011, the Company made principal and interest payments related to this note in the amount of \$1,000 and \$700, respectively. The remaining balance of this note amounted to \$26,000 at March 31, 2011 of which \$4,600 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

On February 25, 2011, the Company entered into a note agreement for \$165,000 with an interest rate of 4.24% per annum. This instrument was issued in connection with financing insurance premiums. The note is payable in monthly installments of \$18,700 with the final payment on October 25, 2011. During the year ended March 31, 2011, the Company made principal and interest payments of \$36,000 and \$2,000, respectively. The remaining balance of this note amounted to \$129,000 at March 31, 2011 and is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

A summary of principal payments due in years subsequent to March 31, 2011 is as follows (in thousands):

**For Years Ending March 31,**

2012	\$	1,144
2013		1,214
2014		739
2015		30
2016		9
Total principal payments		<u>3,136</u>
Less: current portion		<u>(1,144)</u>
Long-term portion	\$	<u><u>1,992</u></u>

**NOTE 10 — Capital Lease Obligations**

On November 10, 2004, the Company entered into a capital lease under which the present value of the minimum lease payments amounted to \$37,000. The present value of the minimum lease payments was calculated using a discount rate of 10%. Lease payments, including amounts representing interest, amounted to \$6,000 for the year ended March 31, 2010. The capital lease was paid in full during the year ended March 31, 2010.

## NOTE 11 — Derivative Liability

The Company deems financial instruments which do not have fixed settlement provisions to be derivative instruments. The common stock purchase warrants issued with the Company's August 13, 2007 private placement, and the common stock purchase warrants issued to the placement agent in the transaction, do not have fixed settlement provisions because their exercise prices may be lowered if the Company issues securities at lower prices in the future. The Company was required to include the reset provisions in order to protect the warrant holders from the potential dilution associated with future financings. At issuance, the warrants were recognized as equity instruments and have since been re-characterized as derivative liabilities. Accordingly, the warrant obligations are adjusted to fair value at the end of each reporting period with the change in value reported in the statement of operations. Such fair values were estimated using the Black-Scholes valuation model. Although the Company determined the common stock warrants include an implied down-side protection feature, it performed a Monte-Carlo simulation and concluded that the value of the feature is de minimis and the use of the Black-Scholes valuation model is considered to be a reasonable method to value the warrants. The Company will continue to adjust the warrant liability for changes in fair value until the earlier of the exercise, at which time the liability will be reclassified to stockholders' equity, or expiration of the warrants.

The derivative liabilities were valued using the Black-Scholes option valuation model and the following assumptions on the following dates:

	<u>March 31,</u> <u>2011</u>	<u>March 31,</u> <u>2010</u>
Expected Term	1.87 yrs	2.37 yrs
Risk-free interest rate	0.61%	1.02%
Dividend yield	0.00%	0.00%
Volatility	83.0%	84.0%
Warrants outstanding	725,866	724,188
Fair value of warrants	\$ 337,000	\$ 472,000

The fair value of the derivative liability decreased to \$337,000 at March 31, 2011 from \$472,000 at March 31, 2010. Accordingly, the Company decreased the derivative liability by \$135,000 to reflect the change in fair value at March 31, 2011. This amount is included as a change in the fair value of derivative instruments in the accompanying consolidated statement of operations for the year ended March 31, 2011. The following table sets forth a summary of the changes in the fair value of our Level 3 financial liabilities that are measured at fair value on a recurring basis:

	<u>Years Ended March 31,</u>	
	<u>2011</u>	<u>2010</u>
Beginning balance	\$ (472)	\$ (323)
Net unrealized gain (loss)	135	(149)
Ending balance	<u>\$ (337)</u>	<u>\$ (472)</u>

## NOTE 12 — Commitments and Contingencies

### *Lease Commitments*

The Company has entered into various non-cancelable operating leases, primarily for office facility space, that expire at various times through April 30, 2012.

On September 13, 2007, the Company entered into Amendment No. 4 to the property lease agreement for its facility in Petaluma, California. The amendment extended the lease expiration date to September 30, 2010. On May 1, 2009, the Company entered into Amendment No. 5 to the property lease agreement which resulted in a reduction of the Company's monthly lease payment. Pursuant to the amendment, the Company agreed to surrender 8,534 square feet of office space, extended the lease expiration on the remaining lease to September 30, 2011, provided the property owner with a \$50,000 cash payment, and on August 28, 2009 issued the property owner 53,847 shares of the Company's common stock with a fair value of \$70,000 (Note 13). On May 31, 2011, the Company entered into Amendment No. 6 to its property lease agreement, extending the lease expiration to September 30, 2014 (Note 18).

Minimum lease payments for non-cancelable operating leases are as follows (in thousands):

**For Years Ending March 31,**

2012	\$	221
2013		8
Total minimum lease payments	\$	<u>229</u>

Rent expense amounted to \$486,000 and \$499,000 for the years ended March 31, 2011 and 2010, respectively.

***Legal Matters***

In June 2006, the Company received a written communication from the grantor of a license to an earlier version of its technology indicating that such license was terminated due to an alleged breach of the license agreement by the Company. The license agreement extends to the Company's use of the technology in Japan only. While the Company does not believe that the grantor's revocation is valid under the terms of the license agreement and no legal claim has been threatened to date, the Company cannot provide any assurance that the grantor will not take legal action to restrict the Company's use of the technology in the licensed territory. While the Company's management does not anticipate that the outcome of this matter is likely to result in a material loss, there can be no assurance that if the grantor pursues legal action, such legal action would not have a material adverse effect on the Company's financial position or results of operations.

The Company, from time to time, is involved in legal matters arising in the ordinary course of its business including matters involving proprietary technology. While management believes that such matters are currently not material, there can be no assurance that matters arising in the ordinary course of business for which the Company is or could become involved in litigation, will not have a material adverse effect on its business, financial condition or results of operations.

***Other Matters***

On September 16, 2005, the Company entered into a series of agreements with Quimica Pasteur S.A. de C.V. ("QP"), a Mexico-based company engaged in the business of distributing pharmaceutical products to hospitals and health care entities owned or operated by the Mexican Ministry of Health. Among other things, these agreements provided for QP to act as the Company's exclusive distributor of Microcyn to the Mexican Ministry of Health for a period of three years. In connection with these agreements, the Company was concurrently granted an option to acquire all except a minority share of the equity of QP directly from its principals in exchange for 150,000 shares of common stock, contingent upon QP's attainment of certain financial milestones. The Company's distribution and related agreements were cancelable by the Company on thirty days' notice without cause and included certain provisions to hold the Company harmless from debts incurred by QP outside the scope of the distribution and related agreements. The Company terminated these agreements on March 26, 2006 without having exercised the option.

Due to its liquidity circumstances, QP was unable to sustain operations without the Company's subordinated financial and management support. Accordingly, QP was deemed to be a variable interest entity and its results were consolidated with the Company's consolidated financial statements for the period of September 16, 2005 through March 26, 2006, the effective termination date of the distribution and related agreement, without such option having been exercised.

Subsequent to having entered into the agreements with QP, the Company became aware of an alleged tax avoidance scheme involving the principals of QP. The audit committee of the Company's board of directors engaged an independent counsel, as well as tax counsel in Mexico to investigate this matter. The audit committee of the board of directors was advised that QP's principals could be liable for up to \$7,000,000 of unpaid taxes. The Company is unlikely to have any loss exposure with respect to this matter because the alleged tax omission occurred prior to the Company's involvement with QP. The Company has not received any communications to date from Mexican tax authorities with respect to this matter. Based on an opinion of Mexico counsel, the Company's management and the audit committee of the board of directors do not believe that the Company is likely to experience any loss with respect to this matter. However, there can be no assurance that the Mexican tax authorities will not pursue this matter and, if pursued, that it would not result in a material loss to the Company.

### ***Employment Agreements***

As of March 31, 2011, the Company had employment agreements in place with five of its key executives. The agreements provide, among other things, for the payment of nine to twenty-four months of severance compensation for terminations under certain circumstances. With respect to these agreements, at March 31, 2011, potential severance amounted to \$1,913,000 and aggregated annual salaries amounted to \$1,350,000.

### ***Related Party Agreements***

On February 24, 2009, the Company entered into a Purchase Agreement with Seamus Burlingame and Robert Burlingame. Robert Burlingame was a Director at the time of the transaction but subsequently resigned from the Board on February 10, 2010. Seamus Burlingame is Robert Burlingame's son. Pursuant to the terms of the Purchase Agreement, the investors agreed to make a \$3,000,000 investment in the Company. The investors paid \$1,000,000 (net proceeds of \$948,000 after deducting offering expenses) for 854,701 shares of common stock on February 24, 2009 and paid \$2,000,000 for 1,709,402 shares of common stock on June 1, 2009. In addition, the Company issued to the investors Series A Warrants to purchase a total of 1,500,000 shares of common stock pro rata to the number of shares of common stock issued on each closing date at an exercise price of \$1.87 per share. The Series A Warrants became exercisable after nine months and have a five year term. The Company also issued to the investors Series B Warrants to purchase a total of 2,000,000 shares of common stock pro rata to the number of shares of common stock issued on each closing date at an exercise price of \$1.13 per share. The Series B Warrants became exercisable after nine months and have a three year term. In addition, for every two shares of common stock the investor purchases upon exercise of a Series B Warrant, the investor will receive an additional Series C Warrant to purchase one share of common stock. The Series C Warrant shall be exercisable after nine months and will have an exercise price of \$1.94 per share and a five year term. The Company will only be obligated to issue Series C Warrants to purchase up to 1,000,000 shares of common stock.

On September 15, 2009, the Company entered a commercial agreement with V&M Industries, Inc., a California corporation, to market and sell Microcyn over-the-counter liquid and gel products on a non-exclusive basis. At the time of the 2009 transaction, V&M Industries, Inc. was wholly-owned by Robert Burlingame, who was also a Director at the time of the transaction. V&M Industries, Inc. subsequently changed its name to Innovacyn, Inc ("Innovacyn"). On June 1, 2010, and September 1, 2010, Innovacyn and the Company amended this agreement granting Innovacyn the exclusive right to sell certain over-the-counter products. Additionally, once certain milestones are met, but no later than July 1, 2011, the Company will share profits related to Vetericyn and Microcyn over-the-counter sales. During the years ended March 31, 2011 and 2010, the Company recorded revenue related to these agreements in the amounts of \$1,810,000 and \$519,000, respectively. The revenue is recorded in product revenues in the accompanying consolidated statements of operations. At March 31, 2011 and 2010, the Company had outstanding accounts receivable of \$118,000 and \$105,000, respectively, related to Innovacyn.

On April 1, 2009, the Company entered into a six month agreement with Mr. Robert Burlingame, who at the time was a member of its Board of Directors. Pursuant to the agreement, Mr. Burlingame agreed to provide the Company with sales and marketing expertise and services as part of another revenue sharing agreement. In consideration for his services, the Company issued Mr. Burlingame 435,897 unregistered shares of its common stock. The Company issued the shares on June 12, 2009. The shares were fully vested and non-forfeitable at the time of issuance. The fair value of the common stock was more readily determinable than the fair value of the services rendered. The Company amortized the fair value of the warrants over the six month term of the consulting agreement which is consistent with its treatment of similar cash transactions. Accordingly, the Company recorded \$476,000 of stock compensation expense related to this agreement which was recognized on a straight-line basis over the six month term of the agreement from April 1, 2009 to October 1, 2009. The expense was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations for the year ended March 31, 2010.

### ***Commercial Agreements***

On May 8, 2007, and June 11, 2007, the Company entered into separate commercial agreements with two unrelated customers granting such customers the exclusive right to sell the Company's products in specified territories or for specified uses. Both customers are required to maintain certain minimum levels of purchases of the Company's products in order to maintain the exclusive right to sell the Company's products. Non-refundable up-front payments amounting to \$625,000 were paid under these agreements and were recorded as deferred revenue. On April 16, 2010, the Company terminated the exclusive agreement with one of the customers. Accordingly, during the year ended March 31, 2011, the Company recorded as revenue the remaining balance of the unamortized upfront fees which amounted to \$210,000. For the year ended March 31, 2011 and 2010, the Company recorded revenues of \$238,000 and \$97,000, respectively, related to the non-refundable upfront payments. These amounts were included in product revenue in the accompanying consolidated statements of operations. At March 31, 2011, deferred revenue related to the remaining agreement amounted to \$160,000 of which \$28,000 was short-term and is included in deferred revenue in the accompanying consolidated balance sheet. The remaining up-front fee will be amortized on a straight-line basis over the term of the underlying agreement.

On January 28, 2011, the Company entered into an agreement with a distributor in China to sell specific Company products into the People's Republic of China. Pursuant to the agreement, the distributor paid a \$350,000 non-refundable upfront payment for which they were given exclusivity to sell these products for the first contract year. The upfront fee will be amortized on a straight line basis over the first contract year. During the year ended March 31, 2011 the Company recorded revenue of \$59,000 related to the upfront fee which is included in product revenue in the accompanying consolidated statement of operations. In order to maintain exclusivity in subsequent years, the distributor will need to meet minimum purchase requirements each contract year. The initial term of the contract is for five years cancellable if certain conditions are not met.

On February 14, 2011, the Company entered into an Exclusive Sales and Distribution Agreement with Quinnova Pharmaceuticals, Inc., pursuant to which the Company granted Quinnova the right to act as an exclusive sales, marketing, and distribution agent in the United States, its territories and possessions, and Canada for certain liquid and gel products in the prescription dermatology market. Under the Agreement, the Company will manufacture products and samples. Quinnova will be responsible for all sales, marketing and clinical activity associated with the current products and any future products later approved by the FDA. We retained final approval on any and all new promotional materials or portions of materials specific to the products developed by Quinnova. The Agreement is for a term of five years and will automatically renew for successive one-year terms. Additionally, Quinnova made a payment of \$500,000 as an advance for the first \$500,000 of product purchases. This amount is recorded in deferred revenue in the March 31, 2011 accompanying consolidated balance sheet.

On February 14, 2011, the Company entered into a Product Option Agreement with an Amneal affiliate, AmDerma Pharmaceuticals, LLC. The Company plans to use its proprietary Microcyn technology to develop a prescription pharmaceutical product for the treatment of acne (the "Future Acne Product"). Pursuant to the Agreement, the Company sold the option to exclusively sell and distribute the Future Acne Product to AmDerma for a one-time non-refundable payment of \$500,000. Upon execution of a separate license and supply agreement for the Future Acne Product, the option payment of \$500,000 will be credited against the upfront payment expected in the transaction. This amount is recorded in deferred revenue in the March 31, 2011 accompanying consolidated balance sheet.

## **NOTE 13 — Stockholders' Equity**

### ***Authorized Capital***

The Company is authorized to issue up to 100,000,000 shares of common stock with a par value of \$0.0001 per share and 5,000,000 shares of convertible preferred stock with a par value of \$0.0001 per share.

### ***Description of Common Stock***

Each share of common stock has the right to one vote. The holders of common stock are entitled to dividends when funds are legally available and when declared by the board of directors.

### ***Common Stock Issued in Private Placement to a Related Party***

On February 24, 2009, the Company entered into a Purchase Agreement with Robert Burlingame, a director of the Company at the time of the transaction, and an accredited investor. Pursuant to the terms of the Purchase Agreement, the investors agreed to make a \$3,000,000 investment in the Company. The investors paid \$1,000,000 (net proceeds of \$948,000 after deducting offering expenses) for 854,701 shares of common stock on February 24, 2009 and paid \$2,000,000 for 1,709,402 shares of common stock on June 1, 2009. In addition, the Company issued to the investors Series A Warrants to purchase a total of 1,500,000 shares of common stock pro rata to the number of shares of common stock issued on each closing date at an exercise price of \$1.87 per share. The Series A Warrants became exercisable after six months and have a five year term. The Company also issued to the investors Series B Warrants to purchase a total of 2,000,000 shares of common stock pro rata to the number of shares of common stock issued on each closing date at an exercise price of \$1.13 per share. The Series B Warrants became exercisable after six months and have a three year term. In addition, for every two shares of common stock the investor purchases upon exercise of a Series B Warrant, the investor will receive an additional Series C Warrant to purchase one share of common stock. The Series C Warrant shall be exercisable after six months and will have an exercise price of \$1.94 per share and a five year term. The Company will only be obligated to issue Series C Warrants to purchase up to 1,000,000 shares of common stock.

### ***Registered Direct Offering***

On July 30, 2009, the Company closed a registered direct placement of Units of its common stock to certain accredited investors. For each Unit purchased in this offering, the investors received one share of the Company's common stock and a warrant to purchase one half of one share of common stock. The offering price of each Unit was \$2.45 per Unit. The Company sold 2,454,000 units consisting of 2,454,000 shares of common stock and 1,226,991 warrants to purchase common stock. The exercise price of each warrant is \$3.3875 per share, the warrants become exercisable six months following the close of the offering and expire five years following the close of the offering. The Company received gross proceeds of \$6,012,000 (net proceeds of \$5,155,000 after deducting the placement agent's commissions and other offering costs) from this offering. Additionally, the Company issued warrants to purchase 245,400 shares of common to the placement agents involved in this transaction. The placement agent warrants have similar terms to the investor warrants.

### *Common Stock Issued to Non-Employees For Services*

On April 1, 2009, the Company entered into a six month agreement with Mr. Bob Burlingame, who was then a member of its Board of Directors. Pursuant to the agreement, Mr. Burlingame provided the Company with sales and marketing expertise and services as part of another revenue sharing agreement. In consideration of his services, on June 12, 2009, the Company issued Mr. Burlingame 435,897 unregistered shares of its common stock. The Company issued the shares on June 12, 2009. The shares were fully vested and non-forfeitable at the time of issuance. The fair value of the common stock was more readily determinable than the fair value of the services rendered. The Company has amortized the fair value of the warrants over the six month term of the consulting agreement which is consistent with its treatment of similar cash transactions. Accordingly, the Company recorded \$476,000 of stock compensation expense related to this agreement which was recognized on a straight-line basis over the six month term of the agreement (April 1, 2009 to October 1, 2009). The expense was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations for the year ended March 31, 2010.

On April 24, 2009, the Company entered into an agreement with Advocos LLC, a contract sales organization that serves as part of the Company's sales force for the sale of wound care products in the United States. Pursuant to the agreement, the Company agreed to pay the contract sales organization a monthly fee and potential bonuses that will be based on achievement of certain levels of sales. The Company agreed to issue the contract sales organization shares of common stock each month as compensation for its services. During the year ended March 31, 2011 and 2010, the Company issued 44,400 and 50,654 shares of common stock, respectively, in connection with this agreement. The Company has determined that the fair value of the common stock, which was calculated as shares were issued, was more readily determinable than the fair value of the services rendered. Accordingly, the Company recorded the fair market value of the stock as compensation expense. During the year ended March 31, 2011 and 2010, the Company recorded \$82,000 and \$81,000 of stock compensation expense related to this agreement, respectively. The expense was recorded as selling, general and administrative expense in the accompanying consolidated statements of operations.

On October 27, 2009, the Company entered into an agreement with a consultant that provides services relating to assisting the Company with raising capital. Pursuant to the agreement, the Company agreed to pay the consultant a cash fee of \$41,000 and 4,545 shares of common stock with a fair value of \$10,000. On October 7, 2009, the Company issued the shares of common stock. The Company determined that the fair value of the common stock was more readily determinable than the fair value of the services rendered. Accordingly, the Company recorded the fair market value of the stock as compensation expense. The Company recorded \$51,000 of expense related to this agreement which was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations for the year ended March 31, 2010.

On December 17, 2009, the Company entered into an agreement with Windsor Corporation. Windsor Corporation provides financial advisory services to the Company. Pursuant to the agreement, the Company agreed to pay Windsor Corporation, on a quarterly basis, common stock as compensation for services provided. The Company determined that the fair value of the common stock was more readily determinable than the fair value of the services rendered. Accordingly, the Company recorded the fair market value of the stock as compensation expense. During the year ended March 31, 2011, the Company issued 84,354 shares of common stock. During the year ended March 31, 2011, the Company recorded \$156,000 of expense related to this agreement which was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations.

On May 19, 2010, the Company issued common stock to Life Tech Capital, a Division of Aurora Capital, LLC, for providing financial advisory services. The Company agreed to pay Life Tech Capital, a Division of Aurora Capital, LLC, 20,000 shares of common stock for the services provided. The Company determined the fair value of the common stock was more readily determinable than the fair value of the services rendered. The aggregate fair value of the common stock amounted to \$44,000. Accordingly, during the year ended March 31, 2011, the Company recorded \$44,000 of expense related to this agreement which was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations.

On May 19, 2010, the Company issued common stock to Acute Care Partners, Inc., for providing recruiting and other management services. The Company agreed to pay Acute Care Partners, Inc. 50,000 shares of common stock for the services provided. The Company determined that the fair value of the common stock was more readily determinable than the fair value of the services rendered. The aggregate fair value of common stock amounted to \$111,000. Accordingly, during the year ended March 31, 2011, the Company recorded \$111,000 of expense related to this agreement which was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations.

On September 9, 2010, the Company issued common stock to Vista Partners, for providing financial advisory services. The Company agreed to pay Vista Partners 55,000 shares of common stock for the services provided. The Company determined that the fair value of the common stock was more readily determinable than the fair value of the services rendered. The aggregate fair value of common stock amounted to \$90,000. Accordingly, during the year ended March 31, 2011, the Company recorded \$90,000 of expense related to this agreement which was recorded as selling, general and administrative expense in the accompanying consolidated statement of operations.

#### ***Common Stock Issued to Settle Obligations***

During the year ended March 31, 2010, the Company issued shares of common stock to various vendors to settle outstanding accounts payable. The Company entered into settlement agreements with these vendors and issued a total of 176,755 shares with a fair value equal to the outstanding payables or \$385,000. Additionally, the Company issued the property owner of its Petaluma, CA facility 53,847 shares with a fair value of \$70,000. These shares were issued as partial settlement in connection with the renegotiation of the lease (Note 12). The fair value of the shares will be amortized on a straight-line basis over the remaining term of the lease which expires on September 30, 2011.

During the year ended March 31, 2011, the Company issued shares of common stock to a vendor to settle outstanding accounts payable. The Company entered into a settlement agreement with this vendor and issued a total of 35,000 shares with a fair value equal to the outstanding payable, or \$57,000.

#### ***Anti-dilution Adjustments***

Pursuant to an anti-dilution provision contained in the August 13, 2007 private placement investor and a placement agent warrant agreement, for various financing transactions and common stock issuances during the years ended March 31, 2010 and 2009, the Company was required to adjust the exercise price and the number of warrants held by each warrant holder under these agreements. The exercise price for the warrants has been adjusted from \$9.50 to \$4.34. At March 31, 2011, there were 725,866 warrants outstanding that contain this anti-dilution provision. The warrants were classified as derivative liabilities in the March 31, 2011 consolidated balance sheet (Note 11).

#### ***Modification of Common Stock Purchase Warrants***

During the year ended March 31, 2010, the Company extended two separate offers to certain warrant holders by which the exercise price of the warrants was reduced in return for immediate exercise of the warrants. On December 9, 2009, the Company made an offer to reduce the exercise price of certain warrants from \$4.34 per share to \$1.70 per share. Related to this offer, 295,692 warrants were exercised resulting in \$504,000 in proceeds to the Company. On March 10, 2010, the Company made a second offer to reduce the exercise price of certain warrants to \$2.40 per share. Related to this offer, the exercise price of 85,622 warrants was reduced from \$4.34 per share to \$2.40 per share and the exercise price of 993,709 warrants was reduced from \$6.85 per share to \$2.40 per share. The second offer resulted in \$2,590,000 of proceeds to the Company. The modification of the warrants did not result in incremental fair value or an additional charge to Company's consolidated statement of operations for the year ended March 31, 2010 as the reduction in exercise price offer was available for only one day.

#### ***Cashless Common Stock Purchase Warrant Exercise***

On March 15, 2010, the Company issued 38,936 shares of common stock in connection with a net-share exercise of 104,958 common stock purchase warrants. The warrant holder did not pay an exercise price for the shares in exchange for receiving a lower number of shares of common stock in the transaction. The warrant holder surrendered 66,022 warrants in connection with this transaction.

## **NOTE 14 — Stock-Based Compensation**

### ***1999, 2000, 2003 and 2004 Stock Option Plans***

The 1999, 2000, 2003 and 2004 Stock Option Plans became effective May 1999, June 2000, July 2003 and July 2004, respectively. The Plans provide for grants of both incentive stock options (ISOs) and non-qualified stock options (NSOs) to employees, consultants and directors.

In accordance with the Plans, the stated exercise price may not be less than 100% and 85% of the estimated fair market value of the Company's common stock on the date of grant for ISOs and NSOs, respectively, as determined by the board of directors at the date of grant. With respect to any 10% shareholder, the exercise price of an ISO or NSO was not to exceed 110% of the estimated fair market value per share on the date of grant.

Options issued under the Plans generally have a ten-year term and generally became exercisable over a five-year period.

On June 29, 2006, the compensation committee of the Company's board of directors resolved that it would not approve any further grants under its 1999, 2000 and 2003 Plans. Additionally, in connection with the Delaware reincorporation on December 15, 2006, no future options will be granted under the 2004 Plan.

### ***2006 Stock Plan***

On November 7, 2006, the board authorized and reserved 1,250,000 shares for issuance under the Company's 2006 Stock Incentive Plan, as amended (the "2006 Plan"), which was previously adopted by the board of directors in August 2006. On December 14, 2006, the stockholders approved the Company's 2006 Plan which became effective at the close of the Company's initial public offering. The 2006 Plan was amended by resolution of the board on April 26, 2007, and the amendments were subsequently approved by the stockholders. On September 10, 2009, the Company's shareholders approved another amendment of the 2006 Plan. This amendment authorized and reserved an additional 1,000,000 shares for issuance under the 2006 Plan.

The 2006 Plan provides for the granting of incentive stock options to employees and the granting of nonstatutory stock options to employees, non-employee directors, advisors and consultants. The 2006 Plan also provides for grants of restricted stock, stock appreciation rights and stock unit awards to employees, non-employee directors, advisors and consultants.

In accordance with the 2006 Plan, the stated exercise price may not be less than 100% and 85% of the estimated fair market value of common stock on the date of grant for ISOs and NSOs, respectively, as determined by the board of directors at the date of grant. With respect to any 10% stockholder, the exercise price of an ISO or NSO shall not be less than 110% of the estimated fair market value per share on the date of grant.

Options issued under the 2006 Plan generally have a ten-year term and generally become exercisable over a five-year period.

Shares subject to awards that expire unexercised or are forfeited or terminated will again become available for issuance under the 2006 Plan. No participant in the 2006 Plan can receive option grants, restricted shares, stock appreciation rights or stock units for more than 187,500 shares in the aggregate in any calendar year.

As provided under the 2006 Plan, the aggregate number of shares authorized for issuance as awards under the 2006 Plan automatically increases on April 1 of each year by 5% of the number of shares outstanding on March 31. On April 1, 2010, the aggregate number of shares authorized for issuance as awards under the 2006 Plan automatically increased by 1,308,071 shares. The number of shares authorized for issuance will be subject to adjustment on April 1, 2011 (Note 18).

Options and restricted stock units outstanding at March 31, 2011 under the various plans is as follows (in thousands):

Plan	Total Number of Options and Restricted Stock Units Outstanding in Plan
1999 Plan	4
2000 Plan	—
2003 Plan	162
2004 Plan	536
2006 Plan	3,694
	4,396

A summary of activity under all option Plans for the years ended March 31, 2011 and 2010 is presented below (in thousands, except per share data):

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term	Aggregate Intrinsic Value
Outstanding at March 31, 2009	3,964	\$ 3.28		
Options granted	1,140	1.89		
Options exercised	(664)	0.37		
Options forfeited or expired	(453)	6.93		
Outstanding at March 31, 2010	3,987	2.96		
Options granted	750	1.95		
Options exercised	(126)	0.74		
Options forfeited or expired	(215)	4.79		
Outstanding at March 31, 2011	4,396	\$ 2.76	7.41	\$ 1,903
Exercisable at March 31, 2011	2,947	\$ 3.25	6.87	\$ 1,200
Options available for grant as of March 31, 2011	1,805			

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock (\$2.01) for stock options.

#### ***Stock-Based Compensation***

The Company accounts for share-based awards exchanged for employee services at the estimated grant date fair value of the award. The Company amortizes the fair value of employee stock options on a straight-line basis over the requisite service period of the awards. Compensation expense includes the impact of an estimate for forfeitures for all stock options.

Employee stock-based compensation expense is as follows (in thousands, except per share amounts):

	<b>Employee Stock-based Compensation for the Year Ended March 31, 2011</b>	<b>Employee Stock-based Compensation for the Year Ended March 31, 2010</b>
Cost of revenues service	\$ 58	\$ 22
Research and development	206	97
Selling, general and administrative	1,620	746
Total stock-based compensation	<u>\$ 1,884</u>	<u>\$ 865</u>

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options.

The Company estimated the fair value of employee stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service periods of the respective awards. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	<b>Year Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Fair value of common stock	\$ 1.95	\$ 1.89
Expected Term	5.60 yrs	5.90 yrs
Risk-free interest rate	2.03%	2.45%
Dividend yield	0.00%	0.00%
Volatility	83.5%	84.2%

The weighted-average fair values of options granted during the years ended March 31, 2011 and 2010 were \$1.35 per share..

The expected term of stock options represents the average period the stock options are expected to remain outstanding and is based on the expected term calculated using the approach prescribed by SAB 107 for “plain vanilla” options. The expected stock price volatility for the Company’s stock options was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of the Company’s industry peers as well as the trading history for the Company’s common stock. The Company will continue to analyze the stock price volatility and expected term assumptions as more data for the Company’s common stock and exercise patterns becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company’s stock options. The expected dividend assumption is based on the Company’s history and expectation of dividend payouts.

The Company estimates forfeitures based on historical experience and reduces compensation expense accordingly. The estimated forfeiture rates used during the year ended March 31, 2011 ranged from 7.60% to 0.53%.

At March 31, 2011, there were unrecognized compensation costs of \$1,641,000 related to stock options which is expected to be recognized over a weighted-average amortization period of 1.69 years.

In addition to the above option activity, on April 26, 2007, an award of 60,000 stock units was issued to an officer of the Company. Each stock unit represents the right to receive a share of the Company's common stock, in consideration of past services rendered and the payment by the officer of \$3.00 per share, upon the settlement of the stock unit on a fixed date in the future. One half of the stock units, representing 30,000 shares, was forfeited on January 15, 2009 and the remaining 30,000 were forfeited on January 15, 2010. Additionally, on March 30, 2010, the Company issued 15,957 stock units to an outside consultant. The stock units were fully vested and non-forfeitable on the date of issuance and resulted in compensation expense of \$29,000 which is included in selling, general and administrative expenses in the accompanying consolidated statement of operations for the year ended March 31, 2010.

The Company did not capitalize any cost associated with stock-based compensation.

The Company issues new shares of common stock upon exercise of stock options.

#### NOTE 15 — Income Taxes

The Company has the following net deferred tax assets (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 34,532	\$ 33,477
Research and development tax credit carryforwards	1,187	1,335
Stock-based compensation	2,451	2,713
Reserves and accruals	2,044	2,267
Other deferred tax assets	23	19
Total deferred tax assets	<u>\$ 40,237</u>	<u>\$ 39,811</u>
Deferred tax liabilities:		
Basis difference in assets	(19)	(35)
Net deferred tax asset	40,218	39,776
Valuation allowance	(40,218)	(39,776)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

The Company's recorded income tax benefit, net of the change in the valuation allowance, for each of the periods presented is as follows:

	<b>Years Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Income tax benefit	\$ (442)	\$ (3,345)
Change in valuation allowance	442	3,345
Net income tax benefit	<u>\$ —</u>	<u>\$ —</u>

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	<b>Years Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Expected federal statutory rate	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(2.8)%	(5.8)%
Research and development credit	(1.1)%	(0.8) %
Foreign earnings taxed at different rates	1.7%	0.9%
Recognition of change in estimate of state and foreign NOL carryforward benefits	%	(2.5) %
Effect of permanent differences	13.2%	1.5%
Impact of change in foreign rate on deferred and true-ups	9.0%	
Cancellation of stock options	8.4%	
	(5.6)%	(40.7) %
Change in valuation allowance	5.6%	40.7%
<b>Totals</b>	<b>0.0%</b>	<b>0.0%</b>

At March 31, 2011, the Company had net operating loss carryforwards for federal, state and foreign income tax purposes of approximately \$76,760,000, \$62,509,000 and \$17,611,000, respectively. The carryforwards expire at various times beginning March 31, 2012. The Company also had, at March 31, 2011, federal and state research and development credit carryforwards of approximately \$721,000 and \$705,000, respectively. The federal credits expire beginning March 31, 2024 and the state credits do not expire.

In the year ended March 31, 2010, the Company completed a study to assess whether a change in control has occurred that would affect the ability to monetize tax attributes in future periods. The Company determined, based on the results of the study, that no change in control occurred for purposes of Internal Revenue Code section 382. The Company, after considering all available evidence, fully reserved its deferred tax assets since it is more likely than not that such benefits will not be realized in future periods. The Company has incurred losses for both financial reporting and income tax purposes for the year ended March 31, 2011. Accordingly, the Company is continuing to fully reserve for its deferred tax assets. The Company will continue to evaluate its deferred tax assets to determine whether any changes in circumstances could affect the realization of their future benefit. If it is determined in future periods that portions of the Company's deferred income tax assets satisfy the realization standards, the valuation allowance will be reduced accordingly.

As a result of certain realization requirements of ASC Topic 718, the table of deferred tax assets and liabilities shown above does not include certain deferred tax assets at March 31, 2011 that arose directly from tax deductions related to equity compensation in excess of compensation recognized for financial reporting purposes. Equity will be increased by approximately \$428,000 if and when such deferred tax assets are ultimately realized.

The Company only recognizes tax benefits from an uncertain tax position if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. To date, the Company has not recognized unrecognized tax benefits in its financial statements.

The Company files a consolidated U.S. federal income tax return and in the state of California. The Company is also subject to filing requirements in Mexico and The Netherlands. The Company's evaluation of uncertain tax matters was performed for tax years ended through March 31, 2011. Generally, the Company is subject to audit for the years ended March 31, 2010, 2009 and 2008 and may be subject to audit for amounts relating to net operating loss and other attribute carryforwards generated in periods prior to March 31, 2008. The Company has elected to retain its existing accounting policy with respect to the treatment of interest and penalties attributable to income taxes, and continues to reflect interest and penalties attributable to income taxes, to the extent they arise, as a component of its income tax expense. The Company believes that its income tax positions and deductions would be sustained on audit and does not anticipate any adjustments, other than those identified above that would result in a material change to its financial position. The Company does not have any tax positions for which it is reasonably possible the total amount of gross unrecognized tax benefits will increase or decrease within twelve months of March 31, 2011.

**NOTE 16 — Employee Benefit Plan**

The Company had a program to contribute and administer individual Simple IRA accounts for regular full time employees. Under the plan, the Company matched employee contributions to the plan up to 3% of the employee's salary. On December 31, 2010, the Company terminated the Simple IRA plan and established a qualified 401K plan. Under the 401K plan, the Company matches employee contributions to the plan up to 4% of the employee's salary. Aggregated Company contributions to the plans amounted to \$81,000 and \$67,000 for the years ended March 31, 2011 and 2010, respectively.

**NOTE 17 — Segment and Geographic Information**

The Company generates revenues from wound care products which are sold into the human and animal health care markets and the Company generates revenues from laboratory testing services which are provided to medical device manufacturers. The Company operates a single segment business which consists of three geographical sales territories as follows (in thousands):

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
U.S.	\$ 2,784	\$ 1,196
Mexico	4,307	3,880
Europe and other	1,735	1,222
	<u>\$ 8,826</u>	<u>\$ 6,298</u>

The Company's service revenues amounted to \$928,000 and \$1,066,000 for the years ended March 31, 2011 and 2010.

**NOTE 18 — Subsequent Events**

***Increase in Number of Shares Authorized in the 2006 Plan***

As provided under the 2006 Plan, the aggregate number of shares authorized for issuance as awards under the 2006 Plan automatically increased on April 1, 2011 by 1,328,815 shares (which number constitutes 5% of the outstanding shares on the last day of the year ended March 31, 2011). Total shares authorized for issuance subsequent to the increase is 3,133,595.

### ***Non-Executive Employee Option Grants***

On May 17, 2011, the Company granted stock options to its non-executive employees. In connection with the grants, the Company issued a total of 730,000 options with an exercise price of \$1.89 per share and a ten year term. The options vest monthly in equal amounts over thirty-six months following the grant date. The fair value of the options will be recognized on a straight-line basis over the vesting term of the options, or three years.

### ***Common Stock Issued to Company Service Providers***

On May 25, 2011, the Company issued 25,000 shares to Advocos LLC, issued 55,000 shares to Vista Partners LLC, and issued 30,000 shares to NetGain Financial, Inc. for services. The fair value of the shares amounted to \$173,000 which will be recognized as selling, general and administrative expense in the three months ended June 30, 2011.

### ***Lease Extension***

On May 31, 2011, the Company entered into Amendment No. 6 to its property lease agreement, extending its lease on its Petaluma, California facility to September 30, 2014. In connection with the lease extension, future minimum lease payments are as follows:

<b><u>For the year ending March 31,</u></b>	
2012	\$ 62,000
2013	125,000
2014	125,000
2015	62,000
<b>Total minimum payments</b>	<b>\$ 374,000</b>

### ***ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures***

None.

### ***ITEM 9A. Controls and Procedures***

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of our most recent fiscal year. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2011.

#### **Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of March 31, 2011. This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to the temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report on Form 10-K.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. Other Information**

None.

**PART III**

**ITEM 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2011 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended March 31, 2011 (the "2011 Proxy Statement").

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by 16(a) of the Exchange Act. This disclosure is contained in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement.

We have adopted a Code of Business Conduct that applies to all of our officers and employees, including our chief executive officer, president, chief operating officer, chief financial officer and other employees who perform financial or accounting functions. The Code of Business Conduct sets forth the basic principles that guide the business conduct of our employees. We have also adopted a Senior Financial Officers' Code of Ethics that specifically applies to our chief executive officer, president and chief operating officer, chief financial officer, and key management employees. Stockholders may request a free copy of our Code of Business Conduct and Ethics and our Senior Financial Officers' Code of Ethics by contacting Oculus Innovative Sciences, Inc., Attention: Chief Financial Officer, 1129 N. McDowell Blvd., Petaluma, California 94954.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Senior Financial Officers' Code of Ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Senior Officers' Code of Ethics or any waivers, if and when granted, of our Code of Business Conduct and Ethics or Senior Officers' Code of Ethics on our website at <http://www.oculusis.com> within four business days following the date of such amendment or waiver.

Our board of directors has appointed an audit committee, comprised of Mr. Richard Conley, as chairman, Mr. Jay Birnbaum and Mr. Gregg Alton. The board of directors has determined that Mr. Conley qualifies as an audit committee financial expert under the definition outlined by the Securities and Exchange Commission. In addition, Mr. Conley, Mr. Birnbaum and Mr. Alton each qualify as "independent directors" under the current NASDAQ Marketplace rules and Securities and Exchange Commission rules and regulations.

**ITEM 11. Executive Compensation**

The information required by this Item is incorporated by reference to the 2011 Proxy Statement.

**ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this Item is incorporated by reference to the 2011 Proxy Statement.

Information about securities authorized for issuance under our equity compensation plans appears under the caption "Equity Compensation Plan Information" in the Proxy Statement. That portion of the Proxy Statement is incorporated by reference into this report.

**ITEM 13. *Certain Relationships, Related Transactions, and Director Independence***

The information required by this Item is incorporated by reference to the 2011 Proxy Statement.

**ITEM 14. *Principal Accounting Fees and Services***

The information required by this Item is incorporated by reference to the 2011 Proxy Statement.

## PART IV

### ITEM 15. Exhibits, Financial Statement Schedules

#### (a) Documents filed as part of this report

##### (1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Oculus Innovative Sciences, Inc. under Item 8 of Part II hereof.

##### (2) Financial Statement Schedules

Financial statement schedules have been omitted that are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

#### (b) Exhibits

##### Exhibit Index

<b>Exhibit Number</b>	<b>Description</b>
3.1(i)	Restated Certificate of Incorporation of Registrant (incorporated by reference to the exhibit of the same number filed with the Company's Annual Report on Form 10-K for the year ended March 31, 2007).
3.1(ii)	Amended and Restated Bylaws of Registrant, as amended effective on June 11, 2008 (incorporated by reference to the exhibit of the same number filed with the Company's Annual Report on Form 10-K for the year ended March 31, 2008).
4.1	Specimen Common Stock Certificate (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
4.2	Warrant to Purchase Series A Preferred Stock of Registrant by and between Registrant and Venture Lending & Leasing III, Inc., dated April 21, 2004 (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
4.3	Warrant to Purchase Series B Preferred Stock of Registrant by and between Registrant and Venture Lending & Leasing IV, Inc., dated June 14, 2006 (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
4.4	Form of Warrant to Purchase Common Stock of Registrant (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
4.5	Form of Warrant to Purchase Common Stock of Registrant (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).

- 4.6 Amended and Restated Investors Rights Agreement, effective as of September 14, 2006 (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.7 Form of Promissory Note issued to Venture Lending & Leasing III, Inc. (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.8 Form of Promissory Note (Equipment and Soft Cost Loans) issued to Venture Lending & Leasing IV, Inc. (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.9 Form of Promissory Note (Growth Capital Loans) issued to Venture Lending & Leasing IV, Inc. (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.10 Form of Promissory Note (Working Capital Loans) issued to Venture Lending & Leasing IV, Inc. (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.11 Form of Warrant to Purchase Common Stock of Registrant (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.12 Form of Warrant to Purchase Common Stock of Registrant (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007).
- 4.13 Form of Warrant to Purchase Common Stock of Registrant (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 13, 2007).
- 4.14 Form of Warrant to Purchase Common Stock of Registrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed March 28, 2008).
- 4.15 Form of Common Stock Purchase Warrant for April 2009 offering (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-1 (File No. 333-158539) declared effective on July 24, 2009, and incorporated herein by reference).
- 4.16 Warrant issued to Dayl Crow, dated March 4, 2009 (included as Exhibit 4.16 to the Company's Annual Report on Form 10-K filed June 11, 2009 and incorporated herein by reference).
- 4.17 Form of Common Stock Purchase Warrant for July 2009 offering, (included as Exhibit 4.15 to the Registration Statement on Form S-1 (File No. 333-158539), as amended, declared effective on July 24, 2009)
- 10.1 Form of Indemnification Agreement between Registrant and its officers and directors (included as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.2 Form of 2006 Stock Incentive Plan and related form stock option plan agreements (included as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).

- 10.3 Amended and Restated Investors Rights Agreement, effective as of September 14, 2006 (included as Exhibit 4.6 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.4 Form of Promissory Note issued to Venture Lending & Leasing III, Inc. (included as Exhibit 4.7 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.5 Form of Promissory Note (Equipment and Soft Cost Loans) issued to Venture Lending & Leasing IV, Inc. (included as Exhibit 4.8 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.6 Form of Promissory Note (Growth Capital Loans) issued to Venture Lending & Leasing IV, Inc. (included as Exhibit 4.9 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.7 Form of Promissory Note (Working Capital Loans) issued to Venture Lending & Leasing IV, Inc. (included as Exhibit 4.10 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.8 Office Lease Agreement, dated October 26, 1999, between Registrant and RNM Lakeville, L.P. (included as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.9 Amendment to Office Lease No. 1, dated September 15, 2000, between Registrant and RNM Lakeville L.P. (included as Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.10 Amendment to Office Lease No. 2, dated July 29, 2005, between Registrant and RNM Lakeville L.P. (included as Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.11 Amendment No. 3 to Lease, dated August 23, 2006, between Registrant and RNM Lakeville L.P. (included as Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.12 Amendment No. 4 to Lease, dated September 13, 2007, by and between Registrant and RNM Lakeville L.P. (included as Exhibit 10.43 to the Company's Annual Report on Form 10-K filed June 13, 2008, and incorporated herein by reference).
- 10.13 Office Lease Agreement, dated May 15, 2005, between Oculus Technologies of Mexico, S.A. de C.V. and Antonio Sergio Arturo Fernandez Valenzuela (translated from Spanish) (included as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.14 Office Lease Agreement, dated July 2003, between Oculus Innovative Sciences, B.V. and Artikona Holding B.V. (translated from Dutch) (included as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.15 Amendment to Office Lease Agreement, effective February 15, 2008, by and between Oculus Innovative Sciences Netherlands B.V. and Artikona Holding B.V. (translated from Dutch) (included as Exhibit 10.44 to the Company's Annual Report on Form 10-K filed June 13, 2008, and incorporated herein by reference).

- 10.16 Form of Director Agreement (included as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.17 Leasing Agreement, dated May 5, 2006, by and between Mr. Jose Alfonzo I. Orozco Perez and Oculus Technologies of Mexico, S.A. de C.V. (included as Exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.18 Stock Purchase Agreement, dated June 16, 2005, by and between Registrant, Quimica Pasteur, S de R.L., Francisco Javier Orozco Gutierrez and Jorge Paulino Hermosillo Martin (included as Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.19 Framework Agreement, dated June 16, 2005, by and among Javier Orozco Gutierrez, Quimica Pasteur, S de R.L., Jorge Paulino Hermosillo Martin, Registrant and Oculus Technologies de Mexico, S.A. de C.V. (included as Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.20 Mercantile Consignment Agreement, dated June 16, 2005, between Oculus Technologies de Mexico, S.A. de C.V., Quimica Pasteur, S de R.L. and Francisco Javier Orozco Gutierrez (included as Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.21 Partnership Interest Purchase Option Agreement, dated June 16, 2005, by and between Registrant and Javier Orozco Gutierrez (included as Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.22 Termination of Registrant and Oculus Technologies de Mexico, S.A. de C.V. Agreements with Quimica Pasteur, S de R.L. by Jorge Paulino Hermosillo Martin (translated from Spanish) (included as Exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.23 Termination of Registrant and Oculus Technologies de Mexico, S.A. de C.V. Agreements with Quimica Pasteur, S de R.L. by Francisco Javier Orozco Gutierrez (translated from Spanish) (included as Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.24 Director Agreement, dated November 8, 2006, by and between Registrant and Robert Burlingame (included as Exhibit 10.34 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.25† Exclusive Marketing Agreement, dated December 5, 2005, by and between Registrant and Alkem Laboratories Ltd (included as Exhibit 10.35 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.26 Securities Purchase Agreement, dated August 7, 2007, by and between Registrant and certain purchasers identified on the signatures pages thereto (originally filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 13, 2007, and refiled as Exhibit 10.26 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010 to add signature pages of investors).

- 10.27 Registration Rights Agreement, dated August 7, 2007, by and between Registrant and certain purchasers identified on signatures pages thereto (originally filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 13, 2007, and refiled as Exhibit 10.27 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010 to add signature pages of investors).
- 10.28 Form of Securities Purchase Agreement, dated March 27, 2008, by and between Registrant and each investor signatory thereto (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 28, 2008, and incorporated herein by reference).
- 10.29 Purchase Agreement by and between Registrant and Robert Burlingame, dated January 26, 2009 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 29, 2009 and incorporated herein by reference).
- 10.30 Purchase Agreement by and between Registrant and Non-Affiliated Investors, dated January 26, 2009 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 29, 2009 and incorporated herein by reference).
- 10.31 Revenue Sharing Distribution Agreement by and between Registrant and VetCure, Inc., dated January 26, 2009 (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 29, 2009 and incorporated herein by reference).
- 10.32 Purchase Agreement by and between Registrant and certain accredited investors, dated February 6, 2009 (originally filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 9, 2009, and refiled as Exhibit 10.32 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010 to add investor lists and signature pages of investors).
- 10.33 Purchase Agreement by and between Registrant, Robert Burlingame and Seamus Burlingame, dated February 24, 2009 (included as Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 27, 2009 and incorporated herein by reference).
- 10.34 Amendment to Revenue Sharing Distribution Agreement by and between Registrant and Vetericyn, Inc., dated February 24, 2009 (included as Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 27, 2009 and incorporated herein by reference).
- 10.35 Agreement by and between Registrant and Robert C. Burlingame, dated April 1, 2009 (included as Exhibit 10.52 to the Company's Annual Report on Form 10-K filed June 11, 2009 and incorporated herein by reference).
- 10.36 Microcyn U.S. Commercial Launch Agreement, by and between Registrant and Advocos, dated April 24, 2009 (included as Exhibit 10.53 to the Company's Current Report on Form 10-K filed June 11, 2009 and incorporated herein by reference).
- 10.37 Amendment No. 5 to Lease by and between Registrant and RNM Lakeville, LLC, dated May 18, 2009 (included as Exhibit 10.54 to the Company's Current Report on Form 10-K filed June 11, 2009 and incorporated herein by reference).
- 10.38 Engagement Agreement by and between Registrant and Dawson James Securities, Inc., dated April 10, 2009, (included as Exhibit 10.55 to the Company's Registration Statement on Form S-1 (File No. 333-158539), as amended, declared effective on July 24, 2009, and incorporated herein by reference).
- 10.39 Letter Agreement by and between Registrant and Dawson James Securities, Inc., dated July 2, 2009, (included as Exhibit 10.56 to the Company's Registration Statement on Form S-1 (File No. 333-158539), as amended, declared effective on July 24, 2009, and incorporated herein by reference).

- 10.40 Letter Agreement by and between Registrant and Dawson James Securities, Inc., dated July 10, 2009, (included as Exhibit 10.57 to the Company's Registration Statement on Form S-1 (File No. 333-158539), as amended, declared effective on July 24, 2009, and incorporated herein by reference).
- 10.41 Warrant Purchase Agreement by and between Registrant and Dawson James Securities, Inc., dated July 13, 2009, (included as Exhibit 10.58 to the Company's Registration Statement on Form S-1 (File No. 333-158539), as amended, declared effective on July 24, 2009, and incorporated herein by reference).
- 10.42 Loan and Security Agreement, dated May 1, 2010 between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing V., Inc., (Included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 6, 2010, and incorporated herein by reference).
- 10.43 Supplement to the Loan and Security Agreement, dated as of May 1, 2010 between Oculus Innovative Sciences, Inc., and Venture Lending & Leasing V, Inc., (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 6, 2010, and incorporated herein by reference).
- 10.44† Amendment No. 2 to Revenue Sharing, Partnership and Distribution Agreement between the Registrant and Vetericyn, Inc., dated July 24, 2009 (refiled as Exhibit 10.44 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2010 filed April 29, 2011, and incorporated herein by reference).
- 10.45† Amendment No. 3 to Revenue Sharing, Partnership and Distribution Agreement between the Registrant and Vetericyn, Inc. dated June 1, 2010 (refiled as Exhibit 10.44 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended June 30, 2010 filed April 29, 2011 and incorporated herein by reference).
- 10.46† Amendment No. 1 to Exhibit A to the Revenue Sharing Distribution Agreement and to the Revenue Sharing, Partnership and Distribution Agreement as Revised and Amended, June 1, 2010, dated September 1, 2010 (included as Exhibit 10.46 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010 and incorporated herein by reference).
- 10.47 Continuous Offering Program Agreement, dated September 3, 2010 between Oculus Innovative Sciences, Inc. and Rodman & Renshaw, LLC (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 17, 2010, and incorporated herein by reference).
- 10.48† Distribution Agreement between Oculus Innovative Sciences, Inc. and Tianjian Ascent Import and Export Company, Ltd dated January 28, 2011 (included as Exhibit 10.47 to the Company's Quarterly Report on Form 10-Q filed February 4, 2011, and incorporated herein by reference).
- 10.49† Exclusive Sales and Distribution Agreement between Oculus Innovative Sciences, Inc. and Quinnova Pharmaceuticals, Inc., dated February 14, 2011 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 18, 2011, and incorporated herein by reference).
- 10.50† Exclusive Co-Promotion Agreement between Oculus Innovative Sciences, Inc. and Quinnova Pharmaceuticals, Inc., dated February 14, 2011 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 18, 2011, and incorporated herein by reference).
- 10.51 Product Option Agreement between Oculus Innovative Sciences, Inc. and AmDerma Pharmaceuticals, LLC, dated February 14, 2011 (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed February 18, 2011, and incorporated herein by reference).
- 10.52\* Amendment No. 6 to Lease by and between Registrant and RNM Lakeville, L.P., dated May 31, 2011.
- 21.1 List of Subsidiaries (included as Exhibit 21.1 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010, and incorporated herein by reference).

- 23.1\* Consent of Marcum LLP, independent registered public accounting firm.
- 31.1\* Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a — 14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a — 14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification of Officers pursuant to 18 U.S.C. Section 1250, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith

\*\* In accordance with Item 60(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management’s Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed “filed” for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

† Confidential treatment has been granted with respect to certain portions of this agreement.

Copies of above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Oculus Innovative Sciences, Inc., 1129 N. McDowell Blvd., Petaluma, California 94954.

**(c) Financial Statements and Schedules**

Reference is made to Item 15(a)(2) above.



**AMENDMENT NO. 6  
TO LEASE**

**THIS AMENDMENT NO. 6 TO LEASE** (“*Amendment*”) is made and entered into as of April 26, 2011, by and between **RNM LAKEVILLE, L.P.**, a California limited partnership (“*Landlord*”), and **OCULUS INNOVATIVE SCIENCES, INC.** (f/k/a MicroMed Laboratories, Inc.), a Delaware corporation (“*Tenant*”).

**RECITALS**

**A.** Landlord and Tenant are parties to that certain Lease dated as of October 26, 1999, as amended by Amendment No. 1 to Lease dated as of September 15, 2000, Amendment No. 2 to Lease dated as of July 29, 2005, Amendment No. 3 to Lease dated as of August 23, 2006, Amendment No 4 to Lease dated as of September 13, 2007 and Amendment No. 5 to Lease dated as of May 18, 2009 (collectively the “*Lease*”), pursuant to which Landlord leases to Tenant, and Tenant leases from Landlord, approximately 13,840 square feet at 1129 North McDowell Boulevard in Petaluma, California shown as **Exhibit A** to this Amendment. Unless otherwise defined herein, all capitalized terms shall have the meanings assigned to them in the Lease.

**B.** The Lease Term expires on September 30, 2011.

**C.** The parties wish to amend the Lease to extend the Lease Term and otherwise amend the Lease as provided herein.

**THEREFORE**, for consideration, the adequacy and receipt of which are hereby acknowledged, the parties agree as follows:

**1. Term.** The Termination Date is hereby extended to September 30, 2014. The period commencing on October 1, 2011 and ending on September 30, 2014 may be referred to herein as the “Extended Term.”

**2. Base Rent.** Base Rent for the Premises during the Extended Term shall be \$10,380 per month without further increase.

**3. Confirmation of Lease.** Tenant hereby represents and warrants to Landlord that, as of the date hereof, (a) the Lease is in full force and effect and has not been modified except pursuant to this Amendment; (b) Tenant has not subleased or assigned any of its right, title and interest in and to the Lease and has full power and authority to enter into and perform its obligations hereunder, (c) Tenant is not in default under the Lease, and to the best of Tenant's knowledge, there are no defaults on the part of Landlord existing under the Lease; (d) to the best of Tenant's knowledge, there exists no valid abatements, causes of action, counterclaims, disputes, defenses, offsets, credits, deductions, or claims against the enforcement of any of the terms and conditions of the Lease; (e) this Amendment has been duly authorized, executed and delivered by Tenant and constitutes the legal, valid and binding obligation of Tenant; and (f) there are no actions, whether voluntary or otherwise, pending against Tenant under the bankruptcy or insolvency laws of the United States or any state thereof.

**4. Brokers** . Each of Landlord and Tenant warrants to the other that it has had no dealing with any finder, broker or agent in connection with this Amendment. Each party shall indemnify, defend and hold harmless the other party from and against any and all costs, expenses or liability for commissions or other compensation or charges claimed by any finder, broker or agent based on dealings with the indemnifying party with respect to this Amendment.

**5. Attorneys' Fees** . Should any dispute arise between the parties hereto or their legal representatives, successors and assigns concerning any provision of this Amendment or the rights and duties of any person in relation thereto, the party prevailing in such dispute shall be entitled, in addition to such other relief that may be granted, to recover reasonable attorneys' fees and legal costs in connection with such dispute. Each party shall pay its own legal fees and costs incurred in connection with the negotiation and preparation of this Amendment.

**6. Warehouse Portion** . The warehouse portion shall be included in the terms of this Amendment and Landlord shall not have the right to terminate the lease as to the warehouse portion of the Premises.

**7. Governing Law** . This Amendment shall be governed and construed under the laws of the State of California.

**8. Counterparts** . This Amendment may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same Amendment. This Amendment may be executed by a party's signature transmitted by facsimile ("fax") or by electronic mail in portable document format ("pdf"), and copies of this Amendment executed and delivered by means of faxed or pdf signatures shall have the same force and effect as copies hereof executed and delivered with original signatures. Signatures sent by fax or pdf may be relied upon as if such signatures were originals. A signature page sent by fax or pdf may be introduced into evidence in any proceeding arising out of or related to this Amendment as if it were an original signature page.

**9. Binding Effect** . This Amendment shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective legal representatives, successors and assigns.

**10. Further Assurances** . Landlord and Tenant hereby agree to execute such further documents or instruments as may be necessary or appropriate to carry out the intention of this Amendment.

**11. Voluntary Agreement** . The parties have read this Amendment, and on the advice of counsel they have freely and voluntarily entered into this Amendment. This Amendment is the product of negotiation between the parties and their respective counsel, and the parties agree that it shall be interpreted in accordance with its fair and apparent meaning and not for or against either party.

**12. Merger; Amendment** . This Amendment sets forth the entire agreement between the parties with respect to the subject matter hereto and all prior negotiations or agreements, whether oral or written, are superseded and merged herein. This Amendment may not be altered or amended except by a writing duly authorized and executed by the party against whom enforcement is sought. To the extent inconsistent with the Lease, this Amendment shall modify and amend the Lease.

**SIGNATURES ON FOLLOWING PAGE**

IN WITNESS WHEREOF, the parties executed this Amendment No. 6 to Lease as of the date first written above.

**LANDLORD:**

**RNM LAKEVILLE, L.P.**,  
a California limited partnership

By: **RNM PETALUMA, INC.**,  
a California corporation,  
its General Partner

Name: /s/ Paul B. Elmore  
Paul B. Elmore, President

Date: May 31, 2011

**TENANT:**

**OCULUS INNOVATIVE SCIENCES, INC.**,  
a Delaware corporation

By: /s/ Jim Schutz  
Jim Schutz

Its: Chief Operating Officer

Date: May 26, 2011

**EXHIBIT A**

**PREMISES**



INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Oculus Innovative Sciences, Inc. on Form S-3 (File No. 333-171411), Form S-8 (File No. 333-171412), Form S-8 (File No. 333-141017) and Form S-8 (File No. 333-163988) of our report dated June 3, 2011, with respect to our audits of the consolidated financial statements of Oculus Innovative Sciences, Inc. and Subsidiaries as of March 31, 2011 and 2010 and for the years then ended, which report is included in this Annual Report on Form 10-K of Oculus Innovative Sciences, Inc. for the year ended March 31, 2011.

/s/ Marcum LLP

New York, NY  
June 3, 2011

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Hojabr Alimi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oculus Innovative Sciences, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
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(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 3, 2011

By: /s/ Hojabr Alimi  
Hojabr Alimi  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Robert E. Miller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oculus Innovative Sciences, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
-

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 3, 2011

By: /s/ Robert E. Miller

Robert E. Miller

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Oculus Innovative Sciences, Inc., a California corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The annual report on Form 10-K for the year ended March 31, 2011 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 3, 2011

/s/ Hojabr Alimi

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Hojabr Alimi

Chief Executive Officer and Principal Executive Officer

/s/ Robert E. Miller

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Robert E. Miller

Chief Financial Officer, Principal Financial Officer and  
Principal Accounting Officer

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