

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, 2012

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:**

Common Stock, \$0.0001 par value

\_\_\_\_\_  
(Title of Each Class)

NASDAQ Capital Market

\_\_\_\_\_  
(Name of Each Exchange on Which Registered)

**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 (§232.405 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 (§229.405 of this chapter) 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  (Do not check if a smaller reporting company)

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, 2011 was approximately \$34,221,000 based on a total of 22,663,050 shares of the registrant's common stock held by non-affiliates on September 30, 2011, at the closing price of \$1.51 per share as reported on the NASDAQ Capital Market.

There were 32,479,015 shares of the registrant's common stock issued and outstanding on June 6, 2012.

**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 will 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 2012 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 annual report.

#### Our Business

We are a commercial healthcare company that designs, produces, and markets innovative, safe and effective drugs, devices, and nutritional products. We are pioneering innovative products for the dermatology, surgical, wound care, and animal healthcare markets. Our primary focus is on our proprietary technology platform called Microcyn® Technology. This technology is based on electrically charged oxychlorine small molecules designed to target 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. Several Microcyn® Technology tissue care products are designed to treat infections and 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.

We do not have the necessary regulatory approvals to market Microcyn® as a drug or as a medical device with an antimicrobial or wound healing indication in the United States. In the future, we expect to apply with the U.S. Food and Drug Administration, or FDA, for clearance as an antimicrobial in a liquid and a hydrogel form.

Outside the United States, our Microcyn® Technology products have 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 we do not have the necessary regulatory clearance for an antimicrobial or wound healing indication in the United States, several factors including global product experience, clinical and laboratory testing, physician-led clinical studies based on our technology, and scientific papers authored on our technology, 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® Technology 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® Technology platform in other markets outside of wound and skin care, including the respiratory, ophthalmology, dental, dermatology, animal healthcare and industrial markets.

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 and we believe Microcyn® Technology can fill a niche in the chronic and acute wound care markets.

We believe Microcyn® Technology is a stable, anti-infective therapeutic that treats infections and enhances wound healing through increased blood flow to the wound bed and reduction of chronic inflammation. Also, we believe Microcyn® Technology 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® Technology is a stable wound care solution that is as safe as saline, and also treats infection while simultaneously accelerating wound healing. Also, unlike most antibiotics, we believe Microcyn® Technology 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 use as an antiseptic, disinfectant and sterilant. Since then, physicians and scientists in the United States, Europe, India, Pakistan, China and Mexico have conducted more than 40 clinical and scientific studies of Microcyn® Technology, 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. 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 Practice (GCP) requirements. We used the data generated from some of these studies to support our application for the CE Mark, the 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. To date, our Microcyn-based products have received seven FDA 510(k) clearances. Many of these clearances 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 December 2011, we initiated a voluntary recall of select lot numbers of certain of our Microcyn-based products due to product labeling. The voluntary recall was prompted after notification by the FDA that a limited number of our products were improperly labeled. The recall has been classified by the FDA as a Class II recall, which means the probability of serious health consequences is remote. Customer safety and product quality are critically important to us and to date, we have received no complaints regarding customer safety or product quality issues. The costs of the voluntary recall were nominal and there were no restrictions on our future sales of Microcyn-based products, other than revising our product labeling for certain products. The voluntary recall did not materially impact revenues.

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, has 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 can also cause serious side effects; and
- growth regulators, skin substitutes and vacuum-assisted closure treatment accelerate wound healing but do not cure infection.

## **Our Solution**

We believe Microcyn® Technology has potential significant advantages over current methods of care in the treatment of chronic and acute wounds, such as the following:

- *Treats Infections.* Our Phase II results and several physician-based studies suggest that our Microcyn® tissue care products may be effective in treating 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 treating the infection.
- *Wound Care Solution.* In the United States, our products have received approval from the FDA for seven 510(k) clearances in wound care management (cleaning, debridement, lubricating, moistening and dressing). Laboratory testing and physician clinical studies further suggest that our 510(k) Microcyn-based products are effective against a wide range of bacteria that cause 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 products have 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 state that our 510(k) products, which are based on Microcyn® Technology, are 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 state 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 treat infection, enhance healing 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® Technology Platform**

### ***Mechanism of Action***

We believe Microcyn®'s ability to reduce the need for 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 functions 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 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 to 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:

**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 C, 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). 2005; 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, but do not, however, include pending product approvals including Scar HydroGel. 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 requiring a prescription.
	510(k)	2005	Moistening and debriding acute and chronic dermal lesions requiring a prescription.
	510(k)	2006	Moistening absorbent wound dressings and cleaning minor cuts as an over-the-counter product.
	510(k)	2009	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.
	510(k)	2009	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 preservative, which can kill listed bacteria such as MRSA & VRE and required as a prescription.
	510(k)	2010	As a hydrogel, for management of dermal irritation, sores, injuries and ulcers of dermal tissue 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.
	510(k)	2011	As a hydrogel, for management and relief of 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	Reducing the propagation of microbes in wounds and creating a moist environment for wound healing.

(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 United States, 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 oral antibiotic 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) 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% while the 95.0% confidence interval for the oral antibiotic 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 the oral antibiotic 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 oral antibiotic 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® Technology 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, or held at one time, 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.

Leading Physician	Country	Number of Patients	Publication
David E. Allie, MD (1)	U.S.	40	Allie D. Super-Oxidized Dermacyn in Lower-Extremity Wounds. <i>Wounds</i> . 2006; 18(Suppl):3-6.
Tom Wolvos, MD (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, PhD (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, MD (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; 18: 262-270.  Dalla Paola L. Treating diabetic foot ulcers with super-oxidized water. <i>Wounds</i> . 2006; 18(Suppl):14-16.
Alberto Piaggesi, MD (5)	Italy	33	Goretti C, Mazzurco S, Ambrosini Nobili L, Macchiarini S, Tedeschi A, Palumbo F, Scatena A, Rizzo L, Piaggesi A. Clinical Outcomes of Wide Postsurgical Lesions in the Infected Diabetic Foot Managed With 2 Different Local Treatment Tegimes Compared Using a Quasi-Experimental Study Design: A Preliminary Communication. <i>Int. J. Lower Extremity Wounds</i> . 2007; 6:22-27.
	Italy	40	Piaggesi A et al. A Randomized Controlled Trial to Examine the Efficacy and Safety of Microcyn® Technology on wide post-surgical lesions in the infected diabetic foot. <i>Int. J. Lower Extremity Wounds</i> . March 9, 2010.

Ariel Miranda, MD (5)	Mexico	64	Miranda-Altamirano A. Reducing Bacterial Infectious Complications from Burn Wounds. A look at the use of Oculus Microcyn60 to treat wounds in Mexico. <i>Wounds</i> . 2006; 18(Suppl):17-19.
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Lenka Veverkova, MD (3)	Czech Republic	27	Veverkova L, Jedlicka V, Vesely M, Tejkalova R, Zabranska S, Capov I, Votava M. Methicilin-resistant Staphylococcus aureus — problem in health care. <i>J Wound Healing</i> . 2005; 2:201-202.
Elia Ricci, MD (6)	Italy	40	Ricci E, Astolfi S, Cassino R. Clinical results about an antimicrobial solution (Dermacyn Wound Care) in the treatment of infected chronic wounds. Poster presented at: 17th Conference of the European Wound Management Association (EWMA); 2007 May 2-4; Glasgow, UK.
Alfredo Barrera, MD (5)	Mexico	40	Barrera-Zavala A, Guillen-Rojas M, Escobedo-Anzures J, Rendon J, Ayala O, Gutiérrez AA. A pilot study on source control of peritonitis with a neutral pH — super oxidized solution. Poster presented at: 16th World Congress of the International Association of Surgeons and Gastroenterologists (IASG); 2006 25-27 May; Madrid, Spain.
D. Peterson, MD	U.S.	5	Peterson D, Hermann K, Niezgoda J. Dermacyn Effective in Treatment of Chronic Wounds with Extensive Bioburden While Reducing Local Pain Levels. Presented at: Symposium on Advanced Wound Care and Wound Healing Society; 2007 April 28-May 1; Tampa, FL.
P. Steenvoorde, MD; L.P. Van Doorn, MA; C.E. Jacobi, PhD; and J. Oskam, MD, PhD (3)	Netherlands	10	An unexpected effect of Dermacyn on infected leg ulcers. <i>J Wound Care</i> . 2007; 16:60-61.
Fermin Martinez, MD	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.
SF Hadi, MD (3)	Pakistan	100	Hadi SF, Khaliq T, Bilal N, Sikandar I, Saaq M, Zubair M, Aurangzeb S. Treating infected diabetic wounds with superoxidized water as anti-septic agent: a preliminary experience. <i>J Coll Physicians Surg Pak</i> . 2007; 17:740-743.
BT Monaghan, DPM (3)	Ireland	10	Monaghan BT, Cundell JH. Dermacyn as the Local Treatment for Infected Diabetic Foot Wounds. A case series. Presented at: 5th International Symposium on the Diabetic Foot. 2007 May 9-12; Noordwijkerhout, The Netherlands.
Fernando Uribe, MD (6)	Mexico	80	Uribe F. Effect of neutral pH Superoxidized solution in the healing of diabetic foot ulcers. Poster presented at: 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Poster L-1144. 2007 Sept 17-20; Chicago, IL.
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. Presented at: Diabetic Foot Global Conference. 2008 March 13-15; Hollywood, CA.
Robert G. Frykberg, DPM, MPH (6)	U.S.	23	Frykberg RG, Tallis A, Tierney E. Wound Healing in Chronic Lower Extremity Wounds Comparing Super-Oxidized Solution (SOS) vs. Saline. Presented at: Diabetic Foot Global Conference. 2008 March 13-15; Hollywood, CA.
Matthew Regulski, DPM (5)	U.S.	18	Regulski M, Floros R, Petranto R, Migliori V, Alster H, Pfeiffer D. Efficacy and Compatibility of Combination Therapy with Super-Oxidized Solution and a Skin Substitute for Lower Extremity Wounds. Presented at: Symposium on Advanced Wound Care and Wound Healing Society. 2008 April 24-28; San Diego, CA.
Adam Landsman, DPM, PhD (5); Andres A. Gutierrez, MD, PhD(1); and Oculus Collaborative Group	U.S.	48	Landsman A, Blume P, Palladino M, Jordan D, Vayser DJ, Halperin G, Gutierrez AA and Oculus Collaborative Group. An Open Label, Three Arm Study of the Safety and Clinical Efficacy of Topical Wound Care vs. Oral Levofloxacin vs. Combined Therapy for Mild Diabetic Foot Infections. Presented at: Diabetic Foot Global Conference. 2008 March 13-15; Hollywood, CA.
Christopher J. Gauland, DPM. (3)	U.S.	5	Gauland C. Sickle Cell Disease. Presented at: Symposium on Advanced Wound Care and Wound Healing Society. 2008 April 24-28; San Diego, CA.
	U.S.	16	Gauland C. Comparison of Microcyn and Amerigel in the Podiatric Clinical Setting.
R.K. Chittoria	India	20	Chittoria RK, Yootla M, Sampatrao LM, Raman SV. The role of super oxidized solution in the management of diabetic foot ulcer: our experience. Nepal Med Coll J. 2007; 9:125-128.
A.R. Anand	India	50	Anand AR. Comparative Efficacy and Tolerability of Oxum against Povidone Iodine Topical Application in the Post-caesarean Section Wound Management. Indian Medical Gazette. December 2007: 498-505.
S.B. Dharap	India	30	Dharap SB, Ghag GS, Kulkarni KP, Venkatesh V. Efficacy and safety of Oxum in the treatment of the venous ulcer. J Indian Med Assoc. 2008; 106:326-330.
H. Dhusia	India	41	Dhusia H, Comparative Efficacy and Tolerability of Microcyn Superoxidized Solution (Oxum) against Povidone Iodine Application in Oro-dental Infections. Indian Medical Gazette. February 2008; 68-75.
M.G. Khairulasri	Malaysia	178	Khairulasri MG, Ramzisham ARM, Ooi JSM, Zamrin DM. Dermacyn irrigation in reducing sternotomy wound infection following coronary artery bypass graft surgery. Presented at: 11th Scientific Conference. 2008. Kota Bharu, Malaysia.
Andres Tirado-Sanchez and RosaMaria Ponce-Olivera	Mexico	89	Tirado-Sanchez A, Ponce-Olivera R. 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. Journal of Dermatological Treatment. 2009; 20:289-292.

- (1) Indicates that the physician is, or at one time was, a stockholder of our Company. The physician was also a member of our Medical and Business Advisory Board, which we dissolved in April 2007, and served as 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, or at one time was, a holder of warrants to purchase common stock of our Company.
- (3) Indicates that the physician received Microcyn to complete the study.
- (4) Indicates that the physician was a paid consultant, was a member of our Medical and Business Advisory Board, 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 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 C, González-Espinosa D, Guzman B, Snyder M, Reyes-Terán G, Torres K, Gutiérrez AA (1)	Mexico	Microcyn™: a novel super-oxidized water with neutral pH and disinfectant activity. <i>J Hosp Infect (UK)</i> . 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 (2), Faglia E	Italy	Treatment of diabetic foot ulcer: an overview. Strategies for clinical approach. <i>Current Diabetes Reviews</i> . 2006; 2:431-447.
González-Espinosa D, Pérez-Romano L, Guzman Soriano B, Arias E, Bongiovanni, CM (3), Gutiérrez AA (1)	Mexico, U.S.	Effects of neutral super-oxidized water on human dermal fibroblasts in vitro. <i>Int Wound J</i> . 2007; 4:241-250.
Medina-Tamayo J, Balleza-Tapia H, López X, Cid ME, González-Espinosa D, Gutiérrez AA (1), González-Espinosa C	Mexico, U.S.	Super-oxidized water inhibits IgE-antigen- induced degranulation and cytokine release in mast cells. <i>International Immunopharmacology</i> . 2007; 7:1013-1024.
Le Duc Q	UK	A cytotoxic analysis of antiseptic medication on skin substitutes and autograft. <i>Br J Dermatology</i> . 2007; 157:33-40.
McCurdy B	U.S.	Emerging Innovations in Treatment. <i>Podiatry Today</i> . 2006; 1940-48.
Zahumensky E	Czech Republic	Infections and diabetic foot syndrome in field practice. <i>Vnitr Lek</i> . 2006; 52:411-416.
Rose R, Setlow B, Monroe A, Mallozzi M, Driks A, Setlow P (5)	U.S.	Comparison of the properties of <i>Bacillus subtilis</i> spores made in liquid or on agar plates. Submitted 2008.
Paul M, Setlow B, 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), Gutierrez AA (1)	U.S.	The Anti-Bacterial Efficacy of a New Super-Oxidized Solution. Paper presented at: 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). 2007 Sept 17-20; Chicago, IL.
Taketa-Graham M (5), Gutierrez AA (1), Thatcher E (4)	U.S.	The Anti-Viral Efficacy of a New Super-Oxidized Solution. Poster presented at: 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Poster L-1144. 2007 Sept 17-20; Chicago, IL.
Dardine J, Martinez C, Thatcher E (4)	U.S.	Activity of a pH Neutral Super-Oxidized Solution Against Bacteria Selected for Sodium Hypochlorite Resistance. Poster presented at: 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Poster L-1144. 2007 Sept 17-20; Chicago, IL.
Sauer K, Vazquez G, Thatcher E (4), Northey R (5), Gutierrez AA (1)	U.S.	Neutral super-oxidized solution is effective in killing <i>P. aeruginosa</i> biofilms. <i>Biofouling</i> . 2009 January; 25(1): 45-54.

- (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 stockholder of our Company, 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 efforts to include wound care centers, hospitals, nursing homes, urgent care clinics and home healthcare, utilizing a contract sales organization to aid our sales force. 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-based human wound and skin care products available, both as prescription and over-the-counter products, under our seven 510(k) clearances in the United States, primarily through a combination of partnerships with Advocos LLC, a specialty U.S. contract sales organization, and with such partners as Amneal Enterprises, PreCision Dermatology and Eloquest Healthcare, Inc., a subsidiary of Ferndale Pharma, Inc., described in greater detail below. Specifically, we have announced the commercialization of a Microcyn® product for wound care sold through a combination of contract and commissioned sales forces and Eloquest Healthcare, and the commercialization of Microcyn® products 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, Inc., we currently make available Microcyn® Technology-based animal healthcare products branded as Vetericyn in the United States and Europe, and, in the future, we plan to expand the sale of Innovacyn products into other countries.

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

### *Animal Healthcare*

On January 26, 2009, we entered into a commercial agreement with VetCure, Inc., a California corporation, to market and sell our Vetericyn products. VetCure, Inc. later changed its name to Vetericyn, Inc., which, at the time, was wholly owned by Mr. Robert Burlingame. This agreement was amended on February 24, 2009, July 24, 2009, June 1, 2010, and November 1, 2010. Pursuant to the agreement, we provide Vetericyn, Inc. with bulk product and Vetericyn, Inc. bottles, packages, and sells Vetericyn products. We receive a fixed amount for each bottle of Vetericyn sold by Vetericyn, Inc. At the time of each of these 2009 transactions, Vetericyn was wholly owned by Mr. Burlingame, who was also our Director at that time. Mr. Burlingame resigned from our Board on February 10, 2010. After his resignation, Mr. Burlingame continued to own a significant portion of our stock from a transaction with us in 2009. To our knowledge, he ceased being a holder of more than 5% of our common stock in 2010.

On September 15, 2009, we entered a commercial agreement with V&M Industries, Inc., a California corporation, to market and sell our Microcyn over-the-counter liquid and gel products. V&M Industries, Inc. subsequently changed their name to Innovacyn, Inc. On June 1, 2010, September 1, 2010, and November 1, 2010, we amended this agreement granting Innovacyn, Inc. the exclusive right to sell certain of our over-the-counter products. 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. At the time of the 2009 transaction, V&M Industries, Inc. was wholly owned by Robert Burlingame, who was also our Director at that time. Mr. Burlingame resigned from our Board on February 10, 2010. After his resignation, Mr. Burlingame continued to own a significant portion of our stock from a transaction with us in 2009. To our knowledge, he ceased being a holder of more than 5% of our common stock in 2010.

Additionally, beginning on July 1, 2011, Vetericyn, Inc. and Innovacyn, Inc. share profits with us related to the Vetericyn and Microcyn over-the-counter sales, resulting in about a 30% royalty of net revenue.

### *Acute Care in U.S. Hospitals*

On August 1, 2011, we entered into a multi-year licensing agreement with Eloquest Healthcare, Inc., a subsidiary of Ferndale Pharma Group, Inc. Under this agreement, we granted Eloquest Healthcare an exclusive license to market certain Microcyn-based wound care products under the Eloquest Healthcare brand to hospitals, ambulatory surgical and acute care centers in the United States. In March 2012, Ferndale/ Eloquest launched a family of Microcyn-based wound care products.

### *Critical Care*

On August 22, 2011, we entered into an agreement to license the exclusive global rights to a unique endotracheal tube, or ETT, from the National Institutes of Health. We believe the ETT represents a potential breakthrough technology in mitigating ventilator-associated pneumonia. Under the licensing agreement, we agreed to pay a nonrefundable royalty of \$20,000 within sixty days of the effective date of the agreement, minimum annual royalties of \$5,000, and additional royalties based off of net sales from use of the license. The patent term of the ETT expires on March 15, 2025. The ETT requires a device clearance in the United States and we expect to obtain such clearance in the near future.



## *Dermatology*

On November 8, 2010, we announced a definitive agreement with Onset Therapeutics, now called PreCision Dermatology, Inc. Under this agreement, PreCision Dermatology combined our Microcyn® hydrogel with its new skin barrier product into a prescription convenience kit. The kit was launched in the first quarter of 2011 and sales are targeted toward patients with atopic dermatitis and related conditions. PreCision Dermatology has a sales force of about 35 people whom market a complete line of dermatology products throughout the United States.

On February 14, 2011, we announced 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., 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 in February 2011. Future prescription dermatology products can also be licensed for undisclosed upfront payments. In addition, Quinnova agreed to 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. In addition, Quinnova launched the Atrapro™ family of products formulated from Microcyn® Technology platform in late February 2012.

Additionally, we sold the option to exclusively sell and distribute our proprietary Microcyn-based acne drug candidate to AmDerma Pharmaceuticals, LLC, an Amneal alliance member, for a one-time non-refundable payment of \$500,000. On June 23, 2011, AmDerma exercised its option to license rights to the drug candidate. We expect to finalize a license agreement, outlining AmDerma's U.S. and European rights to the product, in the near future. We expect to 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, including in Italy, the Netherlands, Germany, Czech Republic, Sweden, Finland and Denmark.

In Mexico, we market our products through our established distribution network and a 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 dedicated sales force, comprised of over 30 people based in Mexico, 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 liquid products, which are currently sold under the product name "Microcyn" in the United States, 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 liquid 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 is cancellable if certain conditions are not met.

On June 26, 2011, we entered into an agreement with Shanghai Sunvic Technology Co. Ltd., a distributor in China, to sell certain of our gel products, which are currently sold under the product name "Microcyn" in the United States, into the People's Republic of China. The initial term of the contract is for five years and is 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.

## *Contract Testing*

We also operate a microbiology contract testing laboratory division that provides consulting and laboratory services to medical companies that design and manufacture biomedical devices and drugs, as well as testing on our products and potential products. Our testing laboratory complies with U.S. Current Good Manufacturing Practices (CGMPs) and Quality Systems Regulations.

## **Manufacturing and Packaging**

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 healthcare 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 Practices, Quality Systems Regulations for medical devices, 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 Practices, 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.

## **Nutritional Products**

We established a nutritional products division under the name Napa Valley Nutritionals, in the beginning of 2012 to expand our product pipeline. Under this division based out of Sacramento, California, we aim to develop and manufacture medical foods that combine the best of science and nature to create products which provide patients with natural healthcare therapies with a particular focus on the development of products to assist diabetics.

We launched our first nutritional product in April 2012, Glucorein™ Green Tea with chlorogenic acid, a medical food intended for the dietary management of glucose levels in both pre-diabetics and type 2 diabetics under the supervision of a medical professional. Our product is currently being test-marketed in the United States and by medical professionals. Primary marketing efforts for our nutritional products are directed toward securing the recommendation of our Napa Valley Nutritional brand of products by physicians or other health care professionals.

Competition for nutritional products in the segment is generally from other consumer and healthcare manufacturers. Competitive factors include consumer advertising, formulation, packaging, scientific innovation, intellectual property, price, and availability of product forms. A significant aspect of competition is the search for ingredient innovations. The introduction of new products by competitors, changes in medical practices and procedures, and regulatory changes can result in product obsolescence. In addition, private label and local manufacturers' products may increase competitive pressure.

## **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 June 4, 2012, we own four issued U.S. patents, two issued European patents, one issued Canadian patent, one issued Japanese patent, 16 pending U.S. patent applications and 101 pending foreign patent applications generally relating to electrolyzed water. The issued U.S. and foreign patents expire in 2022 with the exception of one U.S. patent that expires in 2027. Our portfolio of issued and pending applications can be divided into two groups.

The first group includes three issued U.S. patents, two issued European patents, one issued Canadian patent, one issued Japanese patent, one pending U.S. patent application, and two pending 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 one issued U.S. patent, 15 pending U.S. patent applications and 99 foreign patent 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.

We have further licensed the exclusive global rights to a unique endotracheal tube (ETT) from the National Institutes of Health. The patented ETT technology is potentially useful in mitigating ventilator-associated pneumonia.

Although we work diligently 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 following countries: 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 are related to improved patient outcomes, such as shortened time in the hospital, accelerated healing time, lack of 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. 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 and can be used 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 or use very large ranges of effectiveness to improve their shelf lives. Additionally, we believe Microcyn® Technology is a stable anti-infective therapeutic available throughout many parts of the world that treats infection while also enhancing 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, and 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 devices 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:

- imposing fines, injunctions and civil penalties;
- requiring a recall or seizure of products;
- implementing operating restrictions, which can include a 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 a company to repair, replace, or refund 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 potential or current 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.

## ***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.

### *Fraud and Abuse Laws*

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 Claims 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 false claims actions, 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 is currently under Class III consideration by the European Notified Body.

*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 to file 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 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, 2012 and 2011, research and development expense amounted to \$1,981,000 and \$2,046,000, respectively. None of this expense was borne by our customers.

### **Significant Customers**

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 revenues. During the year ended March 31, 2012, one customer represented 26% of net revenues. During the year ended March 31, 2011, one customer represented 17% of net revenues.

### **Our Employees**

As of May 25, 2012, we employed a total of 38 employees in the United States and the Netherlands. Additionally, we had 83 employees in Mexico, all of which were contracted through an employment agency. 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 on our website, free of charge, copies of 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 \$7,329,000 and \$7,948,000 for the years ended March 31, 2012 and 2011, respectively. At March 31, 2012, our accumulated deficit amounted to \$132,314,000. During the year ended March 31, 2012, net cash used in operating activities amounted to \$4,032,000. At March 31, 2012, our working capital amounted to \$2,211,000. We expect to continue incurring losses for the foreseeable future and may need to raise additional capital to pursue product development initiatives and to 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 United States, which are critical to the realization of our business plan and to future operations.

***If we are unable to regain compliance with the continued listing standards as set forth in the NASDAQ Listing Rules, our common stock could be delisted from the NASDAQ Capital Market, and if this were to occur, then the price of our common stock, the liquidity of our common stock, and our ability to raise additional capital may be adversely affected.***

Our common stock is currently quoted on the NASDAQ Capital Market. Continued listing of a security on the NASDAQ Capital Market is conditioned upon compliance with the continued listing standards set forth in the NASDAQ Listing Rules for NASDAQ Capital Market companies. There can be no assurance we will continue to satisfy the requirements for maintaining a NASDAQ Capital Market listing.

On May 21, 2012, we received a letter from the Listing Qualifications staff of The NASDAQ Stock Market LLC, notifying us that, for the previous 30 consecutive business days, we failed to comply with NASDAQ Listing Rule 5550(b)(2), which requires us to maintain a minimum Market Value of Listed Securities of \$35 million for continued listing on the NASDAQ Capital Market. In accordance with Listing Rule 5810(c)(3)(C), NASDAQ has granted us a period of 180 calendar days, or until November 19, 2012, to regain compliance with the Rule. We may regain compliance with the Listing Rule at any time during this compliance period if our Market Value of Listed Securities closes at \$35 million or more for a minimum of ten consecutive business days.

The letter has no effect on the listing or trading of our common stock at this time. However, there can be no assurance that we will be able to regain compliance with Listing Rule 5550(b)(2) or the other compliance alternatives under Listing Rule 5550(b). In the event we do not regain compliance with the Listing Rule prior to the expiration of the compliance period, we will receive written notification that our securities are subject to delisting, at which time we may appeal the delisting determination to a Hearings Panel.

If we are not able to comply with the continued listing standards as set forth in the NASDAQ Listing Rules for NASDAQ Capital Market companies, our common stock will be delisted from the NASDAQ Capital Market and an associated decrease in liquidity in the market for our common stock will occur. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets, and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from the NASDAQ Capital Market could also result in other negative implications, including the potential loss of confidence by our business partners and suppliers, the loss of institutional investor interest and fewer business development opportunities.

***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 United States 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 United States 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 such inability 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;
- finance capital expenditures and our general and administrative expenses; and
- develop new products.

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 or 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 could 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;
- delay in obtaining or failure to obtain FDA or other regulatory authority approval of a clinical trial protocol;

- patients 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 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 are 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 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 their underlying product formulations 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 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 product formulation(s) 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.

***We have recently created a new division, Napa Valley Nutritionals(TM), and if the products we create in our new division are not accepted by the marketplace, we may cease operations in this division.***

We recently created a new division, Napa Valley Nutritionals. We intend for this division to focus on green, healthy medical food products for diabetics. Additionally, our division has launched a new product, Glucorein™ Green Tea. Our Company does not have experience in the medical food products industry. Furthermore, we have only begun to test market our first product, Glucorein and we do not yet know whether it will be accepted by the market. It is possible we may not succeed in marketing Glucorein or other similar products we may develop. If we cannot generate sufficient revenues from the medical food products we develop, we may cease operations in this division.

***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 products 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.

***If we are unable to expand our direct domestic sales force, we may not be able to successfully sell our products in the United States.***

We have very limited commercialization capability in the United States and make Microcyn-based products available primarily through our website and several regional distributors. We plan for a more aggressive commercialization and product launch in the event we obtain drug approval from the FDA or obtain other clearance or approval with wound healing claims. Developing a sales force is expensive and time consuming, and the lack of qualified sales personnel could delay or limit the success of our product launch. Our domestic sales force, if established, will be competing with the sales operations of our competitors, which are better funded and more experienced. We may not be able to develop domestic sales capacity on a timely basis or at all.

***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 warning letters, injunctions, seizures, civil fines 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 our 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 certain intellectual property under specific 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 several U.S. and foreign patent applications related to our Microcyn-based products, the manufacturing technology for making the products, and their uses, only four 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, and could divert management's attention from our business and 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, lowering the cost of prescription pharmaceuticals and Medicare and Medicaid payment systems reform. 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, 2012 and 2011, approximately 56% and 62% 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 geographic area 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 the 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 using 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 revenues. During the year ended March 31, 2012, one customer represented 26% of our revenues. During the year ended March 31, 2011, one customer represented 17%, of our revenues. 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. The 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, 2012, one customer represented 13%, and two customers each represented 12% of our net accounts receivable balance. At March 31, 2011, one customer represented 11% 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 might 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. 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. 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.

***We will incur substantial research and development costs as a result of our attempts to obtain regulatory approval to market our Microcyn-based products under the proposed "Scar Reduction" indication, and our efforts may not be successful in obtaining FDA approval for our Microcyn-based products for a new indication.***

We are currently funding clinical and regulatory programs for a potential "Scar Reduction" indication of our Microcyn-based products. We cannot state with certainty when or whether any of our attempts to obtain a new indication will be approved or; whether any indication, if approved by the FDA, will be commercially successful. Even if we obtain regulatory approval for the potential "Scar Reduction" indication, our products may not gain market acceptance among physicians, patients, or the medical community for such indication. Additionally, the indication may be limited to a subset of the population or we may implement a distribution system and patient access program that is limited. We must maintain a continuous flow of successful new indications or brand extensions for our existing products sufficient both to cover our substantial research and development costs. Failure to do so in the short term or long term would have a material adverse effect on our business, results of operations, cash flow, financial position and prospects.

### **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 by 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, without stockholder approval, the rights of 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, without stockholder approval, the rights of 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 expires on September 30, 2014.

We currently lease approximately 1,800 square feet of office and manufacturing space in Sacramento, California, under a lease that is set to expire on December 31, 2012.

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, 2015 and October 31, 2014, 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, 2013.

**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.

On July 25, 2011, we received notice of a lawsuit filed in Mexico by Cesar Mangotich Pacheco and Prodinnv, S.A. de C.V. represented by Cesar Mangotich Pacheco. The lawsuit appears to allege conversion of assets, tortious interference and defamation, among other claims. We are currently evaluating the lawsuit, conferring with local counsel and translating the documents we have received. Our preliminary assessment is that the lawsuit is completely without merit and intend to vigorously defend our position. We have not accrued a loss reserve for this matter.

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. *Mine Safety Disclosures.***

Not applicable.



## 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. On May 21, 2012, we received a letter from the Listing Qualifications staff of The NASDAQ Stock Market LLC, notifying us that, for the previous 30 consecutive business days, we failed to comply with NASDAQ Listing Rule 5550(b)(2), which requires us to maintain a minimum Market Value of Listed Securities of \$35 million for continued listing on the NASDAQ Capital Market. In accordance with Listing Rule 5810(c)(3)(C), NASDAQ has granted us a period of 180 calendar days, or until November 19, 2012, to regain compliance with the Rule. We may regain compliance with the Listing Rule at any time during this compliance period if our Market Value of Listed Securities closes at \$35 million or more for a minimum of ten consecutive business days. The letter has no effect on the listing or trading of our common stock at this time. However, there can be no assurance that we will be able to regain compliance with Listing Rule 5550(b)(2) or the other compliance alternatives under Listing Rule 5550(b).

The following table sets forth the range of high and low sales prices for our common stock for each quarter during the last two fiscal years, based on the last daily sale in each of the quarters:

	Year Ended March 31, 2012			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Stock price-high	\$ 2.15	\$ 1.78	\$ 1.67	\$ 1.40
Stock price-low	\$ 1.59	\$ 1.18	\$ 0.98	\$ 0.89

  

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

#### Holdings

As of May 25, 2012, we had approximately 561 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.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is incorporated herein by reference. Refer to Item 12 of Part III of this annual report on Form 10-K for additional information.

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

We did not sell any unregistered equity securities during the quarter ended March 31, 2012.

#### 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 healthcare company that designs, produces, and markets innovative, safe and effective drugs, devices, and nutritional products. We are pioneering innovative products for the dermatology, surgical, wound care, and animal healthcare markets. Our primary focus is on our proprietary technology platform called Microcyn® Technology. This technology is based on electrically charged oxychlorine small molecules designed to target 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. Several Microcyn® Technology tissue care products are designed to treat infections and 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.

### **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, the 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 based on the estimated fair value of the award on the grant date. 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 revenue from sales of our products to hospitals, medical centers, doctors, pharmacies, and distributors. We sell our products directly to third parties and to distributors through various cancelable distribution agreements. We also entered into agreements to license our technology and products.

We also provide regulatory compliance testing and quality assurance services to medical device and pharmaceutical companies.

We record 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.

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 it customarily accepts orders by telephone in lieu of purchase orders.

We recognize revenue at the time in which we receive 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 are fixed, and agreed to with the customer, prior to shipment. Selling prices are generally based on established list prices. We do not customarily permit our customers to return any products for monetary refunds or credit against completed or future sales. We may, from time to time, replace expired goods on a discretionary basis. We record these types of adjustments, when made, as a reduction of revenue. Sales adjustments were insignificant during the years ended March 31, 2012 and 2011.

We evaluate 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, we either require the customer to remit payment prior to shipment or defer recognition of the revenue until payment is received. We maintain a reserve for amounts which may not be collectible due to risk of credit losses.

Additionally, we defer recognition of revenue related to distributors' that are unable to provide inventory or product sell-through reports on a timely basis, until 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.

When we receive 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. We analyze 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, we defer recognition of non-refundable upfront fees. If we have continuing performance obligations then such up-front fees are deferred and recognized over the period of continuing involvement.

We recognize 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.

### ***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 record 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 May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-04, "Fair Value Measurement (Topic 820) - Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs." This ASU addresses fair value measurement and disclosure requirements within Accounting Standards Codification ("ASC") Topic 820 for the purpose of providing consistency and common meaning between U.S. GAAP and International Financial Reporting Standards ("IFRSs"). Generally, this ASU is not intended to change the application of the requirements in Topic 820. Rather, this ASU primarily changes the wording to describe many of the requirements in U.S. GAAP for measuring fair value or for disclosing information about fair value measurements. This ASU is effective for periods beginning after December 15, 2011. It did not have any impact on our consolidated financial statements or disclosures.

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (Topic 220): Presentation of Comprehensive Income." This ASU increases the prominence of other comprehensive income ("OCI") in the financial statements and provides companies two options for presenting OCI, which until now has typically been placed within the statement of equity. One option allows an OCI statement to be included with the net income statement, and together the two will make a statement of total comprehensive income. Alternately, companies may present an OCI statement separate from the net income statement; however, the two statements will have to appear consecutively within a financial report. This ASU does not affect the types of items that are reported in OCI, nor does it affect the calculation or presentation of earnings per share. For public companies, this ASU is effective for periods beginning after December 15, 2011. We are evaluating the impact this standard will have on our consolidated financial position and results of operations.

Accounting standards that have been issued or proposed by the FASB, 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 consolidated financial statements upon adoption.

## **Comparison of Fiscal Years Ended March 31, 2012 and 2011**

### ***Revenues***

Total revenues were \$12,744,000 for the year ended March 31, 2012 compared to \$9,754,000 in the prior year. Product revenues increased \$3,027,000, or 34%, with increases in the United States, Mexico, Europe, China and India, offset by a slight decline in the Middle East.

Product revenue in the United States increased \$1,932,000, or 69%, primarily due to increased unit growth and increased royalty fees received from our partner Innovacyn, Inc. Effective July 1, 2011, the royalty rate we receive from Innovacyn increased from approximately 19% to approximately 30%. Additionally, revenue growth in the United States was driven by increased demand for our products in the professional human wound care and dermatology markets, partially offset by a decline in sales by our partner, Union Springs Pharmaceuticals.

Revenue in Mexico increased \$883,000, or 21%, from the prior year with a 20% increase in sales of our 120 ml, 240 ml and gel presentations, and a 22% increase in sales of our 5 liter presentation. The growth in our 120 ml, 240 ml and gel presentations occurred as a result of strong unit growth in the 120 ml and gel categories and the increase in the 5 liter presentation was the result of unit growth and favorable channel mix.

Revenue in Europe and Rest of World increased \$212,000, up 12% over the prior year period, primarily the result of increases in sales in Europe, India, China and Singapore, partially offset by a slight decline in Middle East.

The following table shows our product revenues by geographic region:

	Year ended Ended March 31,		\$ Change	% Change
	2012	2011		
United States	\$ 4,716,000	\$ 2,784,000	\$ 1,932,000	69%
Mexico	5,190,000	4,307,000	883,000	21%
Europe and Rest of World	1,947,000	1,735,000	212,000	12%
Total	<u>\$ 11,853,000</u>	<u>\$ 8,826,000</u>	<u>\$ 3,027,000</u>	<u>34%</u>

Service revenue decreased \$37,000 when compared to the prior year due to a decrease in the number of tests provided by our services business.

### ***Gross Profit***

We reported gross profit related to our Microcyn® products of \$8,599,000, or 73%, of product revenues, during the year ended March 31, 2012, compared to a gross profit of \$5,950,000, or 67%, for the same period in the prior year. Our improved gross profit is primarily the result of higher gross profit margins in all business segments as a result of higher revenues. Our margins in Mexico were 78% during the year ended March 31, 2012, compared to 72% for the same period in the prior year.

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

Research and development expense decreased \$65,000, or 3%, to \$1,981,000 for the year ended March 31, 2012, compared to \$2,046,000 for the same period in the prior year due to fewer tests and studies conducted during the year ended March 31, 2012.

We expect that our research and development expense will increase slightly 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 \$1,600,000, or 14%, to \$13,200,000 during the year ended March 31, 2012, from \$11,600,000 during the same period of the prior year. The increase for the year ended March 31, 2012 was primarily due to the occurrence of higher stock compensation charges of \$305,000 and higher sales-related costs in Mexico and the United States.

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

### ***Interest Expense and Interest Income***

Interest expense increased \$525,000 during the year ended March 31, 2012 as compared to the same period of the prior year. This increase for the year ended March 31, 2012 relates to an additional \$236,000 of cash interest incurred and an additional \$289,000 of non-cash interest incurred during the year ended March 31, 2012. The cash and non-cash interest is related to borrowings from Venture Lending & Leasing V, Inc. and Venture Lending & Leasing VI, Inc. Interest income for the year ended March 31, 2012 showed no material change from the same period of the prior year.

### ***Other Expense, Net***

Other expense, net increased \$42,000 to other expense, net of \$217,000 expense for the year ended March 31, 2012, compared to \$175,000 for the same period in the prior year. The change in other expense, net for the year ended March 31, 2012 was primarily related to the unrealized foreign exchange gains and losses on intercompany transactions, and taxes accrued in Mexico.

### ***Derivative Liability***

During the year ended March 31, 2012, we recorded a decrease in the fair value of our derivative liability of \$282,000 and as a result we recorded this amount as a non-cash gain. For the year ended March 31, 2011, we recorded non-cash income of \$135,000. The change in the fair value of our derivative liability for the year ended March 31, 2012 was primarily the result of decreases in our stock price and a decrease in the remaining life of the underlying warrants.

### ***Net Loss***

Net loss for the year ended March 31, 2012 was \$7,329,000, a decrease of \$619,000, as compared to \$7,948,000 for the same period in the prior year. Our stock compensation charges were \$2,799,000 and \$2,366,000 for the years ended March 31, 2012 and 2011, respectively.

### **Liquidity and Capital Resources**

We incurred a net loss of \$7,329,000 for the year ended March 31, 2012. At March 31, 2012, our accumulated deficit amounted to \$132,314,000. We had working capital of \$2,211,000 as of March 31, 2012. 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 need to raise additional capital to pursue our product development initiatives, to penetrate markets for the sale of our products and continue as a going concern. We cannot provide any assurances that we will be able to 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, if needed; however, we have not secured any commitment for new financing at this time, nor can we provide any assurance that new financing will be available on commercially acceptable terms, if needed.

### **Sources of Liquidity**

As of March 31, 2012, we had cash and cash equivalents of \$3,351,000. 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 April 1, 2010, substantially all of our operations have been financed through the following transactions:

- proceeds of \$313,000 received from the exercise of common stock purchase warrants and options;
- proceeds of \$3,000,000 received from the issuance of a debt instrument in the year ended March 31, 2011;
- proceeds of \$2,500,000 received from the issuance of a debt instrument in the year ended March 31, 2012;
- net proceeds of \$1,894,000 received from a registered direct offering of common stock on December 28, 2011; and
- net proceeds of \$2,833,350 received from a registered direct offering of common stock on April 25, 2012.

On June 29, 2011, we entered into a loan and security agreement and a supplement to the loan and security agreement with Venture Lending & Leasing VI, Inc. to borrow up to an aggregate of up to \$2,500,000 (collectively, the "VLL6 Agreements"). The VLL6 Agreements provide for a first tranche of \$1,500,000 and, upon meeting certain financial milestones, a second tranche of \$1,000,000. The loan is secured by the assets of our Company including intellectual property. On June 29, 2011, we borrowed \$1,500,000 on the first tranche. On September 30, 2011, we met the financial milestones to borrow the second tranche. On November 10, 2011, we borrowed the second tranche. The cash interest or "streaming" rate on the loan is 10%. In connection with the first tranche, for the first nine months, we made monthly interest-only payments set at \$12,500 through March 1, 2012. Going forth, we make principal and interest payments of \$56,250 per month through September 1, 2014. Additionally, we will make a final balloon payment of \$116,505 on September 29, 2014. In connection with the second tranche, for the first nine months, we make monthly interest-only payments set at \$8,333 through August 31, 2012. Thereafter, we will make principal and interest payments of \$37,500 per month through February 1, 2015. Additionally, we will make a final balloon payment of \$77,670 on February 1, 2015, resulting in an effective interest rate of 13%.

In connection with the VLL6 Agreements, we issued a warrant to Venture Lending & Leasing VI, LLC for the purchase of 226,325 shares of our common stock at a purchase price per share equal to \$1.657. Once we became eligible to draw the second tranche of the loan, we were required to issue a second warrant to Venture Lending & Leasing VI, LLC with coverage equal to \$62,500 for the purchase of additional shares of our common stock at a strike price equal to the 10-day volume-weighted average price (“VWAP”) ending on the trading day prior to the date we satisfied the second tranche milestones. On September 30, 2011, we met the second tranche milestones and we issued the second warrant for the purchase of 39,100 shares of our common stock at a purchase price per share equal to \$1.5985. On November 10, 2011, we borrowed the second tranche and therefore we became obligated to issue a third warrant to Venture Lending & Leasing VI, LLC with coverage equal to \$62,500 for the purchase of additional shares of our common stock at a strike price equal to the 10-day VWAP ending on the trading day prior to the borrowing date of the second tranche. In connection with borrowing the second tranche, we issued the third warrant for the purchase of 41,187 shares of our common stock at a purchase price per share equal to \$1.5175. The three warrants issued to Venture Lending & Leasing VI, LLC are hereinafter collectively referred to as the “Warrants”. The Warrants have a cashless exercise feature. The Warrants expire on November 30, 2018. Additionally, the Warrants include a put option. The warrant related to the first tranche may be put back to us for \$937,500 cash. On September 30, 2011, when we became eligible to draw the second tranche and issued the second warrant, the second warrant included a put option in an amount equal to \$156,250, which increased the total cash payment to \$1,093,750. On November 10, 2011, when we borrowed the additional \$1,000,000 on the second tranche and issued the third and final warrant, the third warrant included a put option in an amount equal to \$156,250, which increased the total cash payment under the Warrants to \$1,250,000. The put feature is available to the holder of the Warrants for 60 days after the first of the following to occur: (i) a change in control of our Company, (ii) the closing of at least \$20,000,000 of a round of additional equity financing, or (iii) July 31, 2015.

On April 25, 2012, we entered into agreements with institutional and accredited investors to issue up to: a) 2,360,001 shares of common stock b) 1,000 shares of Series A 0% Convertible Preferred Stock (the “Series A Preferred Stock”); and c) warrants to purchase up to 3,471,112 shares of common stock (the “Warrants”). We also offered up to 1,111,111 shares of common stock issuable upon conversion of the Series A Preferred Stock and 3,471,112 shares of common stock in the event the Warrants are exercised. The Warrants have an initial exercise price of \$1.18 per share, are not exercisable for six months from the date of issuance, and have an exercise term of 2.5 years from the date of issuance. We received approximately \$3,124,000 in gross proceeds from the sale of these securities. Net proceeds after deducting the placement agent commissions, legal expenses and other offering expenses, and assuming no exercise of the Warrants, was \$2,833,350. We retained Rodman & Renshaw, LLC as the exclusive placement agent for this offering, and paid them \$218,680 in placement agent commissions. On May 4, 2012, the investors converted 1,000 shares of the Series A Preferred Stock purchased in the transaction into 1,111,111 shares of common stock.

## Cash Flows

As of March 31, 2012, we had unrestricted cash and cash equivalents of \$3,351,000 compared to \$4,371,000 at March 31, 2011.

Net cash used in operating activities during the year ended March 31, 2012 was \$4,032,000, primarily due to the \$7,329,000 net loss for the period. These increases were offset in part by non-cash charges including \$2,799,000 of stock-based compensation and \$448,000 of non-cash interest expense.

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 investing activities was \$360,000 and \$164,000 for the years ended March 31, 2012 and 2011, respectively, primarily related to the purchase of equipment.

Net cash provided by financing activities was \$3,449,000 for the year ended March 31, 2012. We received net proceeds from the issuance of a debt instrument of \$2,500,000 during this period, offset by principal payments on the debt in the amount of \$1,164,000. Additionally, we received proceeds of \$219,000 related to the exercise of common stock options and common stock purchase warrants, and net proceeds of \$1,894,000 related to a registered direct common stock offering.

Net cash provided by financing activities was \$2,684,000 for the year ended March 31, 2011. We received net proceeds from the issuance of a debt instrument of \$3,000,000 during this period, offset by principal payments on the debt in the amount of \$410,000. Additionally, we received proceeds of \$94,000 related to the exercise of common stock options.

## Contractual Obligations

As of March 31, 2012, 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	\$ 4,632	\$ 2,039	\$ 2,593	\$ —
Operating leases	911	341	570	—
Total	<u>\$ 5,543</u>	<u>\$ 2,380</u>	<u>\$ 3,163</u>	<u>\$ —</u>

## Operating Capital and Capital Expenditure Requirements

We incurred a net loss of \$7,329,000 for the year ended March 31, 2012. At March 31, 2012 and 2011, our accumulated deficit amounted to \$132,314,000 and \$124,985,000, respectively. At March 31, 2012, our working capital amounted to \$2,211,000.

We may need to 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 need to raise additional capital to pursue our product development initiatives and to penetrate markets for the sale of our products.

In order for us to potentially commercialize Microcyn® as a drug product in the United States, we must conduct clinical trials, which can be costly. Therefore, commencement of such pivotal clinical trials will be delayed until we find a strategic partner to assist with funding. 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. Consolidated 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, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' (deficiency) 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 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 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 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, 2012 and 2011, and the 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 21, 2012

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

	March 31,	
	2012	2011
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,351	\$ 4,371
Accounts receivable, net	2,151	2,094
Inventory, net	953	733
Prepaid expenses and other current assets	505	611
Total current assets	6,960	7,809
Property and equipment, net	806	802
Other assets	72	53
Total assets	\$ 7,838	\$ 8,664
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 816	\$ 669
Accrued expenses and other current liabilities	844	694
Deferred revenue	1,619	1,808
Current portion of long-term debt, net of debt discount of \$624 and \$237 at March 31, 2012 and March 31, 2011, respectively	1,415	907
Derivative liability	55	337
Total current liabilities	4,749	4,415
Deferred revenue	133	160
Long-term debt, net of debt discount of \$769 and \$354 at March 31, 2012 and March 31, 2011, respectively, less current portion	1,824	1,638
Put warrant liability	2,000	750
Total liabilities	8,706	6,963
Commitments and Contingencies		
Stockholders' (Deficiency) Equity		
Convertible preferred stock, \$0.0001 par value; 5,000,000 shares authorized, none issued and outstanding at March 31, 2012 and 2011	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 29,007,903 and 26,576,302 shares issued and outstanding at March 31, 2012 and 2011, respectively	3	3
Additional paid-in capital	134,496	129,584
Accumulated other comprehensive loss	(3,053)	(2,901)
Accumulated deficit	(132,314)	(124,985)
Total stockholders' (deficiency) equity	(868)	1,701
Total liabilities and stockholders' (deficiency) equity	\$ 7,838	\$ 8,664

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,	
	2012	2011
	(In thousands, except per share amounts)	
Revenues		
Product	\$ 11,853	\$ 8,826
Service	891	928
Total revenues	12,744	9,754
Cost of revenues		
Product	3,254	2,876
Service	776	737
Total cost of revenues	4,030	3,613
Gross profit	8,714	6,141
Operating expenses		
Research and development	1,981	2,046
Selling, general and administrative	13,200	11,600
Total operating expenses	15,181	13,646
Loss from operations	(6,467)	(7,505)
Interest expense	(931)	(406)
Interest income	4	3
Gain due to change in fair value of derivative instruments	282	135
Other expense, net	(217)	(175)
Net loss	\$ (7,329)	\$ (7,948)
Net loss per common share: basic and diluted	\$ (0.27)	\$ (0.30)
Weighted-average number of shares used in per common share calculations:		
Basic and diluted	27,387	26,374
Other comprehensive loss		
Net loss	\$ (7,329)	\$ (7,948)
Foreign currency translation adjustments	(152)	87
Comprehensive loss	\$ (7,481)	\$ (7,861)

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

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

	Common Stock (\$0.0001 par Value)		Additional Paid in Capital	Accumulated Other	Accumulated Deficit	Total
	Shares	Amount		Comprehensive Loss		
(In thousands, except share and per share amounts)						
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	26,576,302	\$ 3	\$ 129,584	\$ (2,901)	\$ (124,985)	\$ 1,701
Issuance of common stock in connection with December 28, 2011 closing of offering, net of commissions, expenses and other offering costs	1,809,653	—	1,894	—	—	1,894
Issuance of common stock in connection with exercise of stock options	134,821	—	55	—	—	55
Issuance of common stock in connection with exercise of stock purchase warrants	144,724	—	164	—	—	164
Issuance of common stock for services	342,403	—	586	—	—	586
Fair value of common stock purchase warrants issued to service providers	—	—	42	—	—	42
Employee stock-based compensation expense, net of forfeitures	—	—	2,171	—	—	2,171
Foreign currency translation adjustment	—	—	—	(152)	—	(152)
Net loss	—	—	—	—	(7,329)	(7,329)
Balance, March 31, 2012	29,007,903	\$ 3	\$ 134,496	\$ (3,053)	\$ (132,314)	\$ (868)

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>2012</b>	<b>2011</b>
	<b>(In thousands)</b>	
<b>Cash flows from operating activities</b>		
Net loss	\$ (7,329)	\$ (7,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	326	395
Provision for doubtful accounts	2	17
Provision for obsolete inventory	61	98
Stock-based compensation	2,799	2,366
Change in fair value of derivative liability	(282)	(135)
Non-cash interest expense	448	159
Foreign currency transaction losses (gains)	26	(2)
Loss on disposal of assets	—	157
Changes in operating assets and liabilities:		
Accounts receivable	(164)	(626)
Inventories	(309)	(245)
Prepaid expenses and other current assets	251	375
Accounts payable	158	(266)
Accrued expenses and other liabilities	(19)	1,226
Net cash used in operating activities	<u>(4,032)</u>	<u>(4,429)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(336)	(174)
Long-term deposits	(24)	10
Net cash used in investing activities	<u>(360)</u>	<u>(164)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net of offering costs	1,894	—
Proceeds from issuance of common stock upon exercise of stock options and warrants	219	94
Proceeds from issuance of long-term debt	2,500	3,000
Principal payments on long-term debt	(1,164)	(410)
Net cash provided by financing activities	<u>3,449</u>	<u>2,684</u>
Effect of exchange rate on cash and cash equivalents	(77)	22
Net decrease cash and cash equivalents	(1,020)	(1,887)
Cash and cash equivalents, beginning of year	4,371	6,258
Cash and cash equivalents, end of year	<u>\$ 3,351</u>	<u>\$ 4,371</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 483</u>	<u>\$ 247</u>
Issuance of common stock for accounts payable obligations	<u>\$ —</u>	<u>\$ 57</u>
<b>Non-cash operating and financing activities:</b>		
Insurance premiums financed	<u>\$ 160</u>	<u>\$ 165</u>
<b>Non-cash investing and financing activities:</b>		
Equipment financed	<u>\$ —</u>	<u>\$ 68</u>
Debt discount in connection with long-term debt	<u>\$ 1,250</u>	<u>\$ 750</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 is a commercial healthcare company that designs, produces, and markets innovative, safe and effective drugs, devices, and nutritional products. It is pioneering innovative products for the dermatology, surgical, wound care, and animal healthcare markets. The Company’s primary focus is on its proprietary technology platform called Microcyn® Technology. This technology is based on electrically charged oxychlorine small molecules designed to target a wide range of organisms that cause disease (pathogens). Several Microcyn® Technology tissue care products are designed to treat infections and enhance healing while reducing the need for antibiotics.

**NOTE 2 — Liquidity and Financial Condition**

The Company incurred a net loss of \$7,329,000 for the year ended March 31, 2012. At March 31, 2012, the Company’s accumulated deficit amounted to \$132,314,000. The Company had working capital of \$2,211,000 as of March 31, 2012. The Company may need to 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 need to raise additional capital to pursue its product development initiatives, to penetrate markets for the sale of its products, and to continue as a going concern.

On April 25, 2012, the Company entered into agreements with various investors to issue up to: a) 2,360,001 shares of common stock b) 1,000 shares of Series A 0% Convertible Preferred Stock (the “Series A Preferred Stock”); and c) warrants to purchase up to 3,471,112 shares of common stock (the “Warrants”). The Company also offered up to 1,111,111 shares of common stock issuable upon conversion of the Series A Preferred Stock and 3,471,112 shares of common stock in the event the Warrants are exercised. The Warrants have an initial exercise price of \$1.18 per share, are not exercisable for six months from the date of issuance, and have an exercise term of 2.5 years from the date of issuance. The Company received approximately \$3,124,000 in gross proceeds from the sale of these securities. Net proceeds after deducting the placement agent commissions, legal expenses and other offering expenses, and assuming no exercise of the Warrants, was \$2,833,350. The Company retained Rodman & Renshaw, LLC as the exclusive placement agent for this offering, and paid them \$218,680 in placement agent commissions. On May 4, 2012, the investors converted 1,000 shares of the Series A Preferred Stock purchased in the transaction into 1,111,111 shares of common stock (Note 17).

On December 22, 2011, the Company entered into agreements with institutional and accredited investors to issue 1,809,653 shares of its common stock at \$1.15 per share, yielding gross proceeds of \$2,081,000 and net proceeds of \$1,894,000 after deducting placement agent commissions of \$145,000 and other offering costs of \$42,000. The offering closed on December 28, 2011 (Note 12).

On June 29, 2011, the Company entered into a loan and security agreement and a supplement to the loan and security agreement with Venture Lending & Leasing VI, Inc. to borrow up to an aggregate of up to \$2,500,000 (collectively, the “VLL6 Agreements”). The VLL6 Agreements provided for a first tranche of \$1,500,000 and, upon meeting certain financial milestones, the Company was permitted to borrow a second tranche of \$1,000,000. On June 29, 2011, the Company borrowed \$1,500,000 on the first tranche. On September 30, 2011, the Company met the financial milestones and became eligible to draw the second tranche of the loan. On November 10, 2011, the Company borrowed the second tranche of \$1,000,000 (Note 9).

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, 2013. 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.

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 and its products.

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, 2012 and 2011.

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 are unable 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 up-front 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, 2012, one customer represented 13% and two customers each represented 12% of the net accounts receivable balance. At March 31, 2011, one customer represented 11% of the net accounts receivable balance. During the year ended March 31, 2012, one customer represented 26% of net revenues. During the year ended March 31, 2011, one customer represented 17% of net revenues.

#### ***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, 2012 and 2011 represents probable credit losses in the amounts of \$52,000 and \$62,000, 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 \$105,000 and \$158,000 at March 31, 2012 and 2011, 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, 2012 Using</b>			
	<b>Total March 31, 2012</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>
Liabilities:				
Derivative liability - warrants	\$ 55	\$ —	\$ —	\$ 55

	<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>
Liabilities:				
Derivative liability - warrants	\$ 337	\$ —	\$ —	\$ 337

### ***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 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, 2012 and 2011, 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, 2012 and 2011, research and development expense amounted to \$1,981,000 and \$2,046,000, respectively.

### ***Advertising Costs***

Advertising costs are expensed as incurred. Advertising costs amounted to \$177,000 and \$304,000, for the years ended March 31, 2012 and 2011, 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 product revenues. Shipping and handling costs incurred are recorded in cost of product revenues. For the years ended March 31, 2012 and 2011, the Company recorded revenue related to shipping and handling costs of \$70,000 and \$63,000, 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, 2012 and March 31, 2011.

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 gains of \$26,000 and foreign currency transaction losses of \$2,000 for the years ended March 31, 2012 and 2011, respectively. The related net gains were recorded in other 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.

### ***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 changes in stockholders' (deficiency) equity. To date, other comprehensive loss consists of changes in accumulated foreign currency translation adjustments. Accumulated other comprehensive losses at March 31, 2012 and 2011 were \$3,053,000 and \$2,901,000, 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, 2012 and 2011 excludes potentially dilutive securities because their inclusion would be anti-dilutive.

	<u>Year Ended March 31,</u>	
	<u>2012</u>	<u>2011</u>
	(In thousands)	
<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	6,266	4,396
Warrants to purchase common stock	8,493	9,366
	<u>14,759</u>	<u>13,762</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) 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, 2012, other than certain warrants that contain reset provisions that the Company classified as derivative liabilities as more fully described in Note 10.

#### *Subsequent Events*

Management has evaluated subsequent events or transactions occurring through the date these consolidated financial statements were issued (Note 17).

#### *Recent Accounting Pronouncements*

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-04, "Fair Value Measurement (Topic 820) - Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs." This ASU addresses fair value measurement and disclosure requirements within Accounting Standards Codification ("ASC") Topic 820 for the purpose of providing consistency and common meaning between U.S. GAAP and International Financial Reporting Standards ("IFRSs"). Generally, this ASU is not intended to change the application of the requirements in Topic 820. Rather, this ASU primarily changes the wording to describe many of the requirements in U.S. GAAP for measuring fair value or for disclosing information about fair value measurements. This ASU is effective for periods beginning after December 15, 2011. It is not expected to have any impact on the Company's consolidated financial statements or disclosures.

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (Topic 220): Presentation of Comprehensive Income." This ASU increases the prominence of other comprehensive income ("OCI") in the financial statements and provides companies two options for presenting OCI, which until now has typically been placed within the statement of equity. One option allows an OCI statement to be included with the net income statement, and together the two will make a statement of total comprehensive income. Alternately, companies may present an OCI statement separate from the net income statement; however, the two statements will have to appear consecutively within a financial report. This ASU does not affect the types of items that are reported in OCI, nor does it affect the calculation or presentation of earnings per share. For public companies, this ASU is effective for periods beginning after December 15, 2011. The Company is evaluating the impact this standard will have on the Company's consolidated financial position and results of operations.

Accounting standards that have been issued or proposed by the FASB, 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 consolidated financial statements upon adoption.

**NOTE 4 — Accounts Receivable**

Accounts receivable consists of the following (in thousands):

	March 31,	
	2012	2011
Accounts receivable	\$ 2,203	\$ 2,156
Less: allowance for doubtful accounts	(52)	(62)
	<u>\$ 2,151</u>	<u>\$ 2,094</u>

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

Year Ended March 31	Balance at Beginning of Year	Additions Charged to Operations	Deductions Write-Offs	Balance at End of Year
2011	\$ 96	\$ 17	\$ (51)	\$ 62
2012	\$ 62	\$ 2	\$ (12)	\$ 52

**NOTE 5 — Inventories**

Inventories consist of the following (in thousands):

	March 31,	
	2012	2011
Raw materials	\$ 558	\$ 482
Finished goods	500	409
	1,058	891
Less: inventory allowances	(105)	(158)
	<u>\$ 953</u>	<u>\$ 733</u>

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

Year Ended March 31	Balance at Beginning of Year	Additions Charged to Cost of Product Revenues	Deductions Write-Offs	Balance at End of Year
2011	\$ 143	\$ 98	\$ (83)	\$ 158
2012	\$ 158	\$ 61	\$ (114)	\$ 105

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

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

	March 31,	
	2012	2011
Prepaid expenses	\$ 431	\$ 403
Value Added Tax receivable	8	24
Other current assets	66	184
	<u>\$ 505</u>	<u>\$ 611</u>

## NOTE 7 — Property and Equipment

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

	March 31,	
	2012	2011
Manufacturing, lab, and other equipment	\$ 2,666	\$ 2,375
Office equipment	334	333
Furniture and fixtures	55	53
Leasehold improvements	269	284
	3,324	3,045
Less: accumulated depreciation and amortization	(2,518)	(2,243)
	\$ 806	\$ 802

Depreciation and amortization expense amounted to \$326,000 and \$395,000 for the years ended March 31, 2012 and 2011, respectively.

During the year ended March 31, 2011, the Company incurred losses on the disposal of assets in the amount of \$157,000. This amount was recorded within operating expenses in the accompanying consolidated statements of operations for the year ended March 31, 2011. During the year ended March 31, 2012, the Company did not incur losses related to the disposal of assets.

## NOTE 8 — Accrued Expenses and Other Current Liabilities

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

	March 31,	
	2012	2011
Salaries and related costs	\$ 547	\$ 472
Professional fees	155	36
Value Added Tax payable	121	143
Other	21	43
	\$ 844	\$ 694

## NOTE 9 — Long-Term Debt

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, 2012 and 2011, the Company made principal payments on this note in the amount of \$20,000 and \$19,000, respectively. During the years ended March 31, 2012 and 2011, the Company made interest payments related to this note in the amounts of \$2,000. The remaining balance of this note amounted to \$50,000 at March 31, 2012, 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 years ended March 31, 2012 and 2011, the Company made principal payments on this note in the amount \$11,000, respectively. During the years ended March 31, 2012 and 2011, the Company made interest payments related to this note in the amounts of \$300 and \$400, respectively. The remaining balance of this note amounted to \$29,000 at March 31, 2012, of which \$11,000 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

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 all assets of the Company excluding intellectual property under certain circumstances. Related to the first tranche, the Company made eight monthly interest-only payments of \$16,660 through December 1, 2010. Thereafter, the Company began making interest and principal payments of \$75,000 per month through June 1, 2013. Related to the second tranche, the Company paid monthly interest only payments of \$8,330 through May 1, 2011. Thereafter, the Company began making 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 years ended March 31, 2012 and 2011, the Company made interest payments of \$317,000 and \$160,000, respectively. During the years ended March 31, 2012 and 2011, the Company made principal payments of \$974,000 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 Warrants 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 years ended March 31, 2012 and 2011, the Company recorded \$237,000 and \$159,000, respectively, of non-cash interest expense related to these notes. The remaining balance of the discount on the note amounted to \$354,000 at March 31, 2012. The remaining balance of the notes amounted to \$1,864,000 at March 31, 2012, of which \$1,171,000 is included in the current portion of long-term debt, net of debt discount in the accompanying consolidated balance sheet.

On August 12, 2010, the Company entered into a note agreement for \$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 years ended March 31, 2012 and 2011, the Company made interest payments related to this note in the amounts of \$3,500 and \$3,000, respectively. During the years ended March 31, 2012 and 2011, the Company made principal payments related to this note in the amounts of \$6,000 and \$8,000, respectively. The remaining balance of this note amounted to \$26,000 at March 31, 2012, of which \$7,000 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 \$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 years ended March 31, 2012 and 2011, the Company made interest payments related to this note in the amount of \$2,000 and \$700, respectively. During the years ended March 31, 2012 and 2011, the Company made principal and interest payments related to this note in the amount of \$5,000 and \$1,000, respectively. The remaining balance of this note amounted to \$22,000 at March 31, 2012, of which \$5,000 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 was payable in monthly installments of \$18,700 with the final payment on October 25, 2011. During the years ended March 31, 2012 and 2011, the Company made interest payments of \$2,000, respectively, on this note. During the years ended March 31, 2012 and 2011, the Company made principal payments of \$129,000 and \$36,000, respectively. The final payment on this note was made in October 2011.

On June 29, 2011, the Company entered into a loan and security agreement and a supplement to the loan and security agreement with Venture Lending & Leasing VI, Inc. to borrow up to an aggregate of \$2,500,000 (collectively, the "VLL6 Agreements"). The VLL6 Agreements provided for a first tranche of \$1,500,000 and, upon meeting certain milestones, the Company would become eligible to borrow an additional \$1,000,000. The loan is secured by all assets of the Company. On June 29, 2011, the Company borrowed \$1,500,000 on the first tranche. On November 10, 2011, the Company borrowed \$1,000,000 on the second tranche. The cash interest or "streaming" rate on the loan is 10%. In connection with the first tranche, for the first nine months, the Company made monthly interest-only payments of \$12,500 through March 1, 2012. Going forth, the Company began making principal and interest payments of \$56,250 per month for thirty months. Additionally, the Company will make a final balloon payment of \$116,505 on September 1, 2014. In connection with the second tranche, for the first nine months, the Company makes monthly interest-only payments of \$8,333 through August 1, 2012. Thereafter, the Company will make principal and interest payments of \$37,500 per month for thirty months. Additionally, the Company will make a final balloon payment of \$77,670 on February 1, 2015, resulting in an effective interest rate of 13%. During the year ended March 31, 2012, the Company made interest payments of \$155,000.

In connection with the VLL6 Agreements, the Company issued a warrant to Venture Lending & Leasing VI, LLC for the purchase of 226,325 shares of the Company's common stock at a purchase price per share equal to \$1.657. Once the Company became eligible to draw the second tranche of the loan, it was required to issue a second warrant to Venture Lending & Leasing VI, LLC with coverage equal to \$62,500 for the purchase of additional shares of the Company's common stock at a strike price equal to the 10-day volume-weighted average price ("VWAP") ending on the trading day prior to the date the Company satisfied the second tranche milestones. On September 30, 2011, the Company met the second tranche milestones and it issued the second warrant for the purchase of 39,100 shares of the Company's common stock at a purchase price per share equal to \$1.5985. On November 10, 2011, the Company borrowed the second tranche and therefore the Company became obligated to issue a third warrant to Venture Lending & Leasing VI, LLC with coverage equal to \$62,500 for the purchase of additional shares of the Company's common stock at a strike price equal to the 10-day VWAP ending on the trading day prior to the borrowing date of the second tranche. In connection with borrowing the second tranche, the Company issued the third warrant for the purchase of 41,187 shares of the Company's common stock at a purchase price per share equal to \$1.5175. The three warrants issued to Venture Lending & Leasing VI, LLC are hereinafter collectively referred to as the "Warrants". The Warrants have a cashless exercise feature. The Warrants expire on November 30, 2018. Additionally, the Warrants include a put option. The warrant related to the first tranche may be put back to the Company for \$937,500 cash. On September 30, 2011, when the Company became eligible to draw the second tranche and issued the second warrant, the second warrant included a put option in an amount equal to \$156,250, which increased the total cash payment to \$1,093,750. On November 10, 2011, when the Company borrowed the additional \$1,000,000 on the second tranche and issued the third and final warrant, the third warrant included a put option in an amount equal to \$156,250, which increased the total cash payment under the Warrants to \$1,250,000. The put feature is available to the holder of the Warrants for 60 days after the first of the following to occur: (i) a change in control of the Company, (ii) the closing of at least \$20,000,000 of a round of additional equity financing, or (iii) July 31, 2015.





The Company recorded the \$1,250,000 cash value of the Warrants as a put warrant liability and a corresponding amount of \$1,250,000 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. For the year ended March 31, 2012, the Company recorded \$211,000 of non-cash interest related to the note. The remaining balance of the discount on the note amounted to \$1,039,000 at March 31, 2012. The remaining balance of the note amounted to \$2,500,000 at March 31, 2012, of which \$684,000 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

On February 25, 2012, the Company entered into a note agreement for \$160,000 with an interest rate of 4.76% per annum. This instrument was issued in connection with financing insurance premiums. The note is payable in monthly installments of \$20,400 with the final payment on October 25, 2012. During the year ended March 31, 2012, the Company made principal and interest payments of \$19,000 and \$1,000, respectively. The remaining balance of this note amounted to \$141,000 at March 31, 2012 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, 2012 is as follows (in thousands):

**For Years Ending March 31,**

2013	\$	2,039
2014		1,669
2015		916
2016		8
Total principal payments		<u>4,632</u>
Less: current portion		<u>(2,039)</u>
Long-term portion	\$	<u><u>2,593</u></u>

**NOTE 10 — 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 between the two models 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 derivative liability for changes in fair value until the earlier of the exercise, at which time the liability will be reclassified to stockholders' (deficiency) equity, or expiration of the warrants.

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

	<b>March 31, 2012</b>	<b>March 31, 2011</b>
Expected Term	0.87 yrs	1.87 yrs
Risk-free interest rate	0.18%	0.61%
Dividend yield	0.00%	0.00%
Volatility	89.0%	83.0%
Warrants outstanding	762,876	725,866
Fair value of warrants	\$ 55,000	\$ 337,000

The fair value of the derivative liability decreased to \$55,000 at March 31, 2012 from \$337,000 at March 31, 2011. Accordingly, the Company decreased the derivative liability by \$282,000 to reflect the change in fair value at March 31, 2012. This amount is included as a gain due to the change in the fair value of derivative instruments in the accompanying consolidated statement of operations for the year ended March 31, 2012. 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>2012</u>	<u>2011</u>
Beginning balance	\$ (337)	\$ (472)
Net unrealized gain	282	135
Ending balance	<u>\$ (55)</u>	<u>\$ (337)</u>

#### **NOTE 11 — Commitments and Contingencies**

##### ***Lease Commitments***

On May 31, 2011, the Company entered into Amendment No. 6 to its property lease agreement in Petaluma, California, extending the lease expiration to September 30, 2014.

On October 31, 2011, the Company leased approximately 1,800 square feet of office and manufacturing space in Sacramento, California, under a lease that is set to expire on December 31, 2012.

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

##### **For Years Ending March 31,**

2013	\$ 341
2014	324
2015	235
2016	11
Total minimum lease payments	<u>\$ 911</u>

Rental expense amounted to \$431,000 and \$486,000 for the years ended March 31, 2012 and 2011, respectively and is recorded in the accompanying consolidated statement of operations.

##### ***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 its 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 its 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 its financial position or results of operations.

On July 25, 2011, the Company received notice of a lawsuit filed in Mexico by Cesar Mangotich Pacheco and Prodinnv, S.A. de C.V. represented by Cesar Mangotich Pacheco. The lawsuit appears to allege conversion of assets, tortious interference and defamation, among other claims. The Company is currently evaluating the lawsuit, conferring with local counsel and translating the documents it has received. The Company's preliminary assessment is that the lawsuit is completely without merit and intends to vigorously defend its position. The Company has not accrued a loss reserve for this matter.

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.

##### ***Employment Agreements***

As of March 31, 2012, 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, 2012, potential severance amounted to \$1,918,000 and aggregated annual salaries amounted to \$1,360,000.

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

On January 26, 2009, the Company entered into a commercial agreement with VetCure, Inc., a California corporation, to market and sell its Vetericyn products. VetCure, Inc. later changed its name to Vetericyn, Inc., which, at the time, was wholly-owned by Mr. Robert Burlingame. This agreement was amended on February 24, 2009, July 24, 2009, June 1, 2010, and November 1, 2010. Pursuant to the agreement, the Company provides Vetericyn, Inc. with bulk product and Vetericyn, Inc. bottles, packages, and sells Vetericyn products. The Company receives a fixed amount for each bottle of Vetericyn sold by Vetericyn, Inc. At the time of these 2009 transactions, Vetericyn was wholly-owned by Mr. Burlingame, who was also a director of the Company at that time. Mr. Burlingame resigned from the Company's board of directors on February 10, 2010. After his resignation, Mr. Burlingame continued to own a significant portion of the Company's stock from a transaction in 2009. To the Company's knowledge, he ceased being a holder of more than 5% of its common stock in 2010.

On September 15, 2009, the Company entered a commercial agreement with V&M Industries, Inc., a California corporation, to market and sell its Microcyn over-the-counter liquid and gel products. V&M Industries, Inc. subsequently changed its name to Innovacyn, Inc. On June 1, 2010, September 1, 2010, and November 1, 2010, the Company amended this agreement granting Innovacyn, Inc. the exclusive right to sell certain of its over-the-counter products. At the time of the 2009 transaction, V&M Industries, Inc. was wholly-owned by Robert Burlingame, who was also a director of the Company at that time. Mr. Burlingame resigned from the Company's board of directors on February 10, 2010. After his resignation, Mr. Burlingame continued to own a significant portion of the Company's common stock from a transaction in 2009. To the Company's knowledge, he ceased being a holder of more than 5% of its common stock in 2010.

Additionally, beginning on July 1, 2011, the Company shares profits related to Vetericyn and Microcyn over-the-counter sales. During the years ended March 31, 2012 and 2011, the Company recorded revenue related to these agreements in the amounts of \$3,367,000 and \$1,810,000, respectively. The revenue is recorded in product revenues in the accompanying consolidated statements of operations. At March 31, 2012, the Company had outstanding accounts receivable of \$290,000 and \$118,000, respectively, related to Innovacyn, Inc.

### ***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 years ended March 31, 2012 and 2011, the Company recorded revenues of \$28,000 and \$238,000, 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, 2012, 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 was amortized on a straight line basis over the first contract year. During the years ended March 31, 2012 and 2011, the Company recorded revenue of \$291,000 and \$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, and the contract is cancellable if certain conditions are not met.

On June 26, 2011, the Company entered into an agreement with Shanghai Sunvic Technology Co. Ltd., a distributor in China, to sell certain of its gel products, which are currently sold under the product name "Microcyn" in the United States, into the People's Republic of China. The initial term of the contract is for five years and is 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. The Company 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. At March 31, 2012 and 2011, the remaining prepayment balance amounted to \$309,000 and \$500,000, respectively, and is recorded as deferred revenue in the accompanying consolidated balance sheets.

On February 14, 2011, the Company entered into a Product Option Agreement with an Amneal affiliate, AmDerma Pharmaceuticals, LLC (“AmDerma”). 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. On June 23, 2011, AmDerma exercised its option to license rights to the drug candidate. The Company expects to finalize a license agreement, outlining AmDerma’s U.S. and European rights to the product, in the near future. The Company will retain rights to the “rest of world,” including undisclosed upfront, milestone and royalty payments. Upon execution of a separate license and supply agreement for the future Acne Product, the option payment of \$500,000 will be credited against payments in the transaction. This amount is recorded in deferred revenue in the March 31, 2012 accompanying consolidated balance sheet.

## **NOTE 12 — Stockholders’ (Deficiency) 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.

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

On December 22, 2011, the Company entered into agreements with institutional and accredited investors to issue 1,809,653 shares of its common stock at \$1.15 per share, with no warrant coverage, yielding gross proceeds of \$2,081,000 and net proceeds of \$1,894,000 after deducting placement agent commissions of \$145,000 and other offering costs of \$42,000. The offering closed on December 28, 2011.

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

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 the Company’s 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 years ended March 31, 2012 and 2011, the Company issued 99,257 and 44,400 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 years ended March 31, 2012 and 2011, the Company recorded \$167,000 and \$82,000 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 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 years ended March 31, 2012 and 2011, the Company issued 83,146 and 84,354 shares of common stock, respectively. During the years ended March 31, 2012 and 2011, the Company recorded \$135,000 and \$156,000, respectively, of stock compensation 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 entered into an agreement with Vista Partners LLC, for providing financial advisory services. Pursuant to the agreement, the Company agreed to pay Vista Partners, LLC 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 years ended March 31, 2012 and 2011, the Company issued 85,000 and 55,000 shares of common stock, respectively, in connection with this agreement. During years ended March 31, 2012 and 2011, the Company recorded \$151,000 and \$90,000, respectively, of stock compensation expense related to this agreement. The expense was recorded as selling, general and administrative expense in the accompanying condensed consolidated statements of operations.

On April 1, 2011, the Company entered into an agreement with NetGain Financial, Inc., for providing financial advisory services. Pursuant to the agreement, the Company agreed to pay NetGain Financial, Inc. 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, 2012, the Company issued 75,000 shares of common stock in connection with this agreement. During the year ended March 31, 2012, the Company recorded \$133,000 of stock compensation expense related to this agreement. The expense was recorded as selling, general and administrative expense in the accompanying condensed consolidated statements of operations.

#### ***Common Stock Purchase Warrants Issued to Service Providers***

During the year ended March 31, 2012, the Company issued 90,000 common stock purchase warrants with service conditions. The recorded \$42,000 of expense related to the warrants is included as stock compensation expense in the accompanying consolidated statements of operations. The warrants were adjusted to the fair value using the Black Scholes pricing model and the following weighted average assumptions: fair value of the underlying stock of \$1.36; risk-free interest rate of 0.94% percent; contractual life of 4.61 years; dividend yield of 0.00%; and vitality of 85.0%.

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

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 anti-dilution provisions contained in the August 13, 2007 private placement and in the placement agent warrant agreement, for various financing transactions and common stock issuances the Company is required to adjust the exercise price and the number of warrants held by each warrant holder under these agreements. Over-time, the exercise price for the warrants has been adjusted from the original exercise price of \$9.50 to \$4.12. At March 31, 2012 and 2011, there were 762,876 and 725,866 warrants outstanding that contain this anti-dilution provision, respectively. The warrants were classified as derivative liabilities in the March 31, 2012 consolidated balance sheet (Note 10).

#### **NOTE 13 — 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 Company's reincorporation in Delaware 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 a subsequent 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 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). The number of shares authorized for issuance will be subject to adjustment on April 1, 2012 (Note 17).

### ***2011 Stock Plan***

On September 12, 2011, upon recommendation of the board, the stockholders approved the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The 2011 Plan shall be effective as of the date of the initial offering of common stock to the public pursuant to a registration statement filed by the Company with the Securities and Exchange Commission. As of March 31, 2012, the Company has not filed such registration statement for the 2011 Plan.

The 2011 Plan provides for the grant of incentive stock options as defined in Section 422 of the Internal Revenue Code to employees, and the grant of non-statutory stock options and stock purchase rights to employees, non-employee directors, advisors and consultants. The 2011 Plan also permits the grant of stock appreciation rights, stock units and restricted stock.

The board has authorized 3,000,000 of the Company's common stock for issuance under the 2011 Plan, in addition to automatic increases provided for in the 2011 Plan through April 1, 2021. The number of shares of the Company's common stock reserved for issuance under the 2011 Plan will automatically increase, with no further action by the stockholders, at the beginning of each fiscal year by an amount equal to the lesser of (i) 15% of the outstanding shares of the Company's common stock on the last day of the immediately preceding year, or (ii) an amount approved by the board (Note 17).

Options issued under the 2011 Plan will generally have a ten-year term.

In accordance with the 2011 Plan, the stated exercise price of an employee incentive stock option shall not be less than 100% of the estimated fair market value of a share of common stock on the date of grant, and the stated exercise price of a nonstatutory option shall not be less than 85% of the estimated fair market value of a share of common stock on the date of grant, as determined by the board of directors. An employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company shall not be eligible for the grant of an employee incentive stock option unless such grant satisfies the requirements of Section 422(c)(5) of the Internal Revenue Code.

Shares subject to awards that expire unexercised or are forfeited or terminated for any other reason will again become available for issuance under the 2011 Plan. No participant in the 2011 Plan can receive option grants, stock appreciation rights, restricted shares, or stock units for more than 750,000 shares in the aggregate in any calendar year. As provided under the 2011 Plan, the aggregate number of shares authorized for issuance as awards under the 2011 Plan automatically increases on April 1 of each year by in an amount equal to the lesser of (i) 15% of the outstanding shares on the last day of the immediately preceding year, or (ii) an amount determined by the board (Note 17).

Options and restricted stock units outstanding at March 31, 2012 under the various plans is as follows (in thousands):

<b>Plan</b>	<b>Total Number of Options and Restricted Stock Units Outstanding in Plan</b>
1999 Plan	4
2000 Plan	—
2003 Plan	147
2004 Plan	486
2006 Plan	5,629
2011 Plan	—
	<u>6,266</u>

A summary of activity under all option plans for the years ended March 31, 2012 and 2011 is presented below (in thousands, except per share data):

	<u>Number of Shares</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
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	<u>4,396</u>	2.96		
Options granted	2,173	1.60		
Options exercised	(135)	0.41		
Options forfeited or expired	(168)	4.61		
Outstanding at March 31, 2012	<u>6,266</u>	\$ 2.36	7.47	\$ 653
Exercisable at March 31, 2012	<u>4,759</u>	\$ 2.54	7.02	\$ 629
Options available for grant as of March 31, 2012	<u>2,833</u>			

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 (\$1.33) 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, 2012</b>	<b>Employee Stock-based Compensation for the Year Ended March 31, 2011</b>
Cost of revenues	\$ 113	\$ 58
Research and development	278	206
Selling, general and administrative	1,780	1,620
Total stock-based compensation	<u>\$ 2,171</u>	<u>\$ 1,884</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>2012</b>	<b>2011</b>
Fair value of common stock on date of grant	\$ 1.60	\$ 1.95
Expected Term	5.75 yrs	5.60 yrs
Risk-free interest rate	1.27%	2.03%
Dividend yield	0.00%	0.00%
Volatility	83.5%	83.5%

The weighted-average fair values of options granted during the years ended March 31, 2012 and 2011 were \$1.11 and \$1.35, respectively.

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 the Securities and Exchange Commission's Staff Accounting Bulletin No. 110 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. 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 become 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, 2012 ranged from 0.53% to 2.53%.

At March 31, 2012, there were unrecognized compensation costs of \$1,871,000 related to stock options which are expected to be recognized over a weighted-average amortization period of 1.95 years.

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 14 — Income Taxes**

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

	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 34,966	\$ 34,532
Research and development tax credit carryforwards	1,470	1,187
Stock-based compensation	3,319	2,451
Reserves and accruals	1,511	2,044
Other deferred tax assets	27	23
Basis difference in assets	24	—
Total deferred tax assets	<u>\$ 41,317</u>	<u>\$ 40,237</u>
Deferred tax liabilities:		
Basis difference in assets	—	(19)
Net deferred tax asset	<u>41,317</u>	<u>40,218</u>
Valuation allowance	<u>(41,317)</u>	<u>(40,218)</u>
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>2012</b>	<b>2011</b>
Income tax benefit	\$ (1,099)	\$ (442)
Change in valuation allowance	1,099	442
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>2012</b>	<b>2011</b>
Expected federal statutory rate	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(4.8)%	(2.8)%
Research and development credit	(0.1)%	(1.1)%
Foreign earnings taxed at different rates	1.3%	1.7%
Recognition of change in estimate of state and foreign NOL carryforward benefits	0.0%	0.0%
Effect of permanent differences	5.9%	13.2%
Impact of change in foreign rate on deferred and true-ups	17.5%	9.0%
Cancellation of stock options and true-ups	0.5%	8.4%
Other	(0.5)%	0.0%
	<u>(14.2)%</u>	<u>(5.6)%</u>
Change in valuation allowance	14.2%	5.6%
Totals	<u>0.0%</u>	<u>0.0%</u>

The impact of change in foreign rate and true-ups is approximately 17% representing a reduction in foreign deferred tax assets. The Company's net loss is comprised of a net loss of approximately \$5,383,000 from domestic operations and approximately \$1,946,000 from foreign operations.

At March 31, 2012, the Company had net operating loss carryforwards for federal, state and foreign income tax purposes of approximately \$79,150,000, \$65,850,000 and \$16,940,000, respectively. The carryforwards expire at various time beginning March 31, 2012. The Company also had, at March 31, 2012, federal and state research credit carryforwards of approximately \$727,500 and \$742,900, respectively. The federal credits expire beginning in March 31, 2024 and the state credits do not expire.

The Company is not aware of any changes in ownership that would result in a change in control under Internal Revenue Code section 382. The Company, after considering all available evidence, fully reserved for these and its other deferred tax assets since it is more likely than not 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, 2012. 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, 2012 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 \$533,000 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 such tax benefits in its financial statements.

The Company has identified its federal tax return and its state tax return in California as major tax jurisdictions. The Company also filed tax returns in foreign jurisdictions, principally Mexico and The Netherlands. The Company's evaluation of uncertain tax matters was performed for tax years ended through March 31, 2012. Generally, the Company is subject to audit for the years ended March 31, 2011, 2010 and 2009 and may be subject to audit for amounts relating to net operating loss carryforwards generated in periods prior to March 31, 2009. 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 provision or benefit as well as its outstanding income tax assets and liabilities. 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 12 months of March 31, 2012. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business.

**NOTE 15 — 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 401(k) plan. Under the 401(k) plan, the Company matches employee contributions to the plan up to 4% of the employee's salary. Company contributions to the plans amounted to an aggregate of \$103,000 and \$81,000 for the years ended March 31, 2012 and 2011, respectively.

**NOTE 16 — Segment and Geographic Information**

The Company generates product revenues from wound care products which are sold into the human and animal healthcare markets, and the Company generates service revenues from laboratory testing services which are provided to medical device manufacturers.

The Company operates a single segment business for product sales which consists of three geographical sales territories as follows (in thousands):

	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
U.S.	\$ 4,716	\$ 2,784
Mexico	5,190	4,307
Europe and other	1,947	1,735
	<u>\$ 11,853</u>	<u>\$ 8,826</u>

The Company's service revenues amounted to \$891,000 and \$928,000 for the years ended March 31, 2012 and 2011.

## **NOTE 17 — 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, 2012 by 1,450,395 shares (which number constitutes 5% of the outstanding shares on the last day of the year ended March 31, 2012). Total shares authorized for issuance from the 2006 Plan subsequent to the increase is 4,283,405.

As provided under the 2011 Plan, the Company may increase the aggregate number of shares authorized for issuance on the first day of each fiscal year during the term of the 2011 Plan in an amount equal to the lesser of (i) 15% of the outstanding shares of common stock of the Company on the last day of the immediately preceding year, or (ii) an amount determined by the Company's board of the directors.

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

On April 25, 2012, the Company entered into agreements with various investors to issue up to: a) 2,360,001 shares of common stock b) 1,000 shares of Series A 0% Convertible Preferred Stock (the "Series A Preferred Stock"); and c) warrants to purchase up to 3,471,112 shares of common stock (the "Warrants"). The Company also offered up to 1,111,111 shares of common stock issuable upon conversion of the Series A Preferred Stock and 3,471,112 shares of common stock in the event the Warrants are exercised. The Warrants have an initial exercise price of \$1.18 per share, are not exercisable for six months from the date of issuance, and have an exercise term of 2.5 years from the date of issuance. The Company received approximately \$3,124,000 in gross proceeds from the sale of these securities. Net proceeds after deducting the placement agent commissions, legal expenses and other offering expenses, and assuming no exercise of the Warrants, was \$2,833,350. The Company retained Rodman & Renshaw, LLC as the exclusive placement agent for this offering, and paid them \$218,680 in placement agent commissions. On May 4, 2012, the investors converted 1,000 shares of the Series A Preferred Stock purchased in the transaction into 1,111,111 shares of common stock.

## **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, 2012.

#### **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 such term is defined in the Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we 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 our evaluation under the framework set forth in *Internal Control — Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of March 31, 2012. 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, 2012 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 2012 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, 2012 (the "2012 Proxy Statement").

Item 405 of Regulation S-K requires the disclosure of, based upon our review of the forms submitted to us during and with respect to our most recent fiscal year, any known failure by any director, officer, beneficial owner of more than ten percent of any class of equity securities of the registrant registered pursuant to section 12 of the Exchange Act, or any other person subject to section 16 of the Exchange Act ("reporting person") to file timely 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 2012 Proxy Statement.

### **Code of Business Conduct and Senior Financial Officers' Code of Ethics**

We have adopted a Code of Business Conduct that applies to all of our officers and employees, including our Chief Executive Officer, 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, Chief Operating Officer, Chief Financial Officer, and other key management employees. We will provide any person, without charge, copies of our Code of Business Conduct and Ethics and our Senior Financial Officers' Code of Ethics upon request. Such requests should be in writing and addressed to: 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 or Senior Financial Officers' Code of Ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct or Senior Officers' Code of Ethics or any waivers, if and when granted, of our Code of Business Conduct 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.

### **Procedures for Nominating Directors**

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors. The Board of Directors will consider candidates for director positions that are recommended by any of our stockholders. Any such recommendation for a director nomination should be provided to our Secretary. The recommended candidate should be submitted to us in writing and addressed to Oculus Innovative Sciences, Inc., Attention: Secretary, 1129 N. McDowell Blvd., Petaluma, California 94954. The recommendation should include the following information: name of candidate; address, phone and fax number of candidate; a statement signed by the candidate certifying that the candidate wishes to be considered for nomination to our Board of Directors and stating why the candidate believes that he or she would be a valuable addition to our Board of Directors; a summary of the candidate's work experience for the prior five years and the number of shares of our stock beneficially owned by the candidate. The Board will evaluate the recommended candidate and shall determine whether or not to proceed with the candidate in accordance with our procedures. We reserve the right to change our procedures at any time to comply with the requirements of applicable laws.

## **ITEM 11. Executive Compensation**

The information required by this Item is incorporated by reference to the 2012 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 2012 Proxy Statement.

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," appears under the caption "Equity Compensation Plan Information" in the 2012 Proxy Statement and such information 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 2012 Proxy Statement.

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

The information required by this Item is incorporated by reference to the 2012 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 No.</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc. (included as Exhibit 3.1 of the Company's Annual Report on Form 10-K filed June 20, 2007, and incorporated herein by reference).
3.2	Certificate of Amendment of Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc. (included as Exhibit A in the Company's Definitive Proxy Statement on Schedule 14A filed July 21, 2008, and incorporated herein by reference).
3.3	Amended and Restated Bylaws, as Amended of Oculus Innovative Sciences, Inc., effective November 3, 2010 (included as Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010, and incorporated herein by reference).
4.1	Specimen Common Stock Certificate (included as Exhibit 4.1 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).
4.2	Warrant to Purchase Series A Preferred Stock of Oculus Innovative Sciences, Inc. by and between the Company and Venture Lending & Leasing III, Inc., dated April 21, 2004 (included as Exhibit 4.2 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).
4.3	Warrant to Purchase Series B Preferred Stock of Oculus Innovative Sciences, Inc. by and between the Company and Venture Lending & Leasing IV, Inc., dated June 14, 2006 (included as Exhibit 4.3 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).
4.4	Form of Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. (included as Exhibit 4.4 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).
4.5	Form of Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. (included as Exhibit 4.5 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).
4.6	Form of Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. (included as Exhibit 4.11 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).
4.7	Form of Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. (included as Exhibit 4.12 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).
4.8	Form of Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 13, 2007, and incorporated herein by reference).
4.9	Form of Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. (included as Exhibit 4.1 to the Company's Current Report on Form 8-K filed March 28, 2008, and incorporated herein by reference).
4.10	Form of Common Stock Purchase Warrant for April 2009 offering (included as 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).

- 4.11 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).
- 4.12 Form of Common Stock Purchase Warrant for July 2009 offering (included as Exhibit 4.15 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)
- 4.13 Warrant to Purchase Shares of Common Stock of Oculus Innovative Sciences, Inc. issued to Venture Lending & Leasing V, LLC (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 6, 2010, and incorporated herein by reference).
- 4.14 Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. issued to Venture Lending & Leasing VI, LLC (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 6, 2011 and incorporated herein by reference).
- 4.15 Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. issued to Venture Lending & Leasing VI, LLC (included as Exhibit 4.15 to the Company's Quarterly Report on Form 10-Q filed November 3, 2011, and incorporated herein by reference).
- 4.16 Warrant to Purchase Common Stock of Oculus Innovative Sciences, Inc. issued to Venture Lending & Leasing VI, LLC (included as Exhibit 4.16 to the Company's Quarterly Report on Form 10-Q, filed February 10, 2012, and incorporated herein by reference).
- 4.17 Form of Common Stock Purchase Warrant for April 2012 offering (included as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed April 25, 2012, and incorporated herein by reference).
- 4.18 Certificate of Designation of Preferences, Rights and Limitations of Series A 0% Convertible Preferred Stock, filed with the Delaware Secretary of State on April 24, 2012 (included as Exhibit 4.2 to the Company's Current Report on Form 8-K, filed April 25, 2012, and incorporated herein by reference).
- 10.1 Form of Indemnification Agreement between Oculus Innovative Sciences, Inc. 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 Amended and Restated Oculus Innovative Sciences, Inc. 2006 Stock Incentive Plan and related form stock option plan agreements (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 2, 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 (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).
- 10.5 Office Lease Agreement, dated October 26, 1999, between Oculus Innovative Sciences, Inc. 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).
- 10.6 Amendment No. 1 to Office Lease Agreement, dated September 15, 2000, between Oculus Innovative Sciences, Inc. 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).
- 10.7 Amendment No. 2 to Office Lease Agreement, dated July 29, 2005, between Oculus Innovative Sciences, Inc. 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).
- 10.8 Amendment No. 3 to Office Lease Agreement, dated August 23, 2006, between Oculus Innovative Sciences, Inc. 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).
- 10.9 Amendment No. 4 to Office Lease Agreement, dated September 13, 2007, by and between Oculus Innovative Sciences, Inc. 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).
- 10.10 Office Lease Agreement, dated May 18, 2006, 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).
- 10.11 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).
- 10.12 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).



- 10.13 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).
- 10.14 Framework Agreement, dated June 16, 2005, by and among Javier Orozco Gutierrez, Quimica Pasteur, S de R.L., Jorge Paulino Hermosillo Martin, Oculus Innovative Sciences, Inc. 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).
- 10.15 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).
- 10.16 Partnership Interest Purchase Option Agreement, dated June 16, 2005, by and between Oculus Innovative Sciences, Inc. 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).
- 10.17 Termination of Oculus Innovative Sciences, Inc. and Oculus Technologies de Mexico, S.A. de C.V.'s 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).
- 10.18 Termination of Oculus Innovative Sciences, Inc. and Oculus Technologies de Mexico, S.A. de C.V.'s 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).
- 10.19 Form of Securities Purchase Agreement, dated March 27, 2008, by and between Oculus Innovative Sciences, Inc. 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).
- 10.20 Purchase Agreement by and between Oculus Innovative Sciences, Inc. 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).
- 10.21 Purchase Agreement by and between Oculus Innovative Sciences, Inc. 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).
- 10.22 Revenue Sharing Distribution Agreement by and between Oculus Innovative Sciences, Inc. 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).
- 10.23 Purchase Agreement by and between Oculus Innovative Sciences, Inc. and accredited investors, dated February 6, 2009 (refiled as Exhibit 10.32 to the Company's Quarterly Report on Form 10-Q filed November 4, 2010, and incorporated herein by reference).
- 10.24 Purchase Agreement by and between Oculus Innovative Sciences, Inc., 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).
- 10.25 Amendment No. 1 to Revenue Sharing Distribution Agreement by and between Oculus Innovative Sciences, Inc. and VetCure, 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).
- 10.26 Consultant Agreement by and between Oculus Innovative Sciences, Inc. 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).
- 10.27 Microcyn U.S. Commercial Launch Agreement by and between Oculus Innovative Sciences, Inc. and Advocos, dated April 24, 2009 (included as Exhibit 10.53 to the Company's Annual Report on Form 10-K filed June 11, 2009, and incorporated herein by reference).
- 10.28 Amendment No. 5 to Office Lease Agreement by and between Oculus Innovative Sciences, Inc. and RNM Lakeville, LLC, dated May 18, 2009 (included as Exhibit 10.54 to the Company's Annual Report on Form 10-K filed June 11, 2009, and incorporated herein by reference).
- 10.29 Engagement Agreement by and between Oculus Innovative Sciences, Inc. 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).
- 10.30 Amendment and Clarification of Engagement Letter by and between Oculus Innovative Sciences, Inc. 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).
- 10.31 Second Amendment and Clarification of Engagement Letter by and between Oculus Innovative Sciences, Inc. 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).
- 10.32 Warrant Purchase Agreement by and between Oculus Innovative Sciences, Inc. 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).
- 10.33 Loan and Security Agreement between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing V, Inc., dated May 1, 2010 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 6, 2010, and incorporated herein by reference).

- 10.34 Supplement to the Loan and Security Agreement between Oculus Innovative Sciences, Inc., and Venture Lending & Leasing V, Inc., dated May 1, 2010 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 6, 2010, and incorporated herein by reference).

10.35†	Amendment No. 2 to Revenue Sharing, Partnership and Distribution Agreement between Oculus Innovative Sciences, Inc. 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).
10.36†	Amendment No. 3 to Revenue Sharing, Partnership and Distribution Agreement between Oculus Innovative Sciences, Inc. 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).
10.37†	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).
10.38	Continuous Offering Program Agreement between Oculus Innovative Sciences, Inc. and Rodman & Renshaw, LLC, dated September 3, 2010 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 17, 2010, and incorporated herein by reference).
10.39†	Distribution Agreement between Oculus Innovative Sciences, Inc. and Tianjin 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).
10.40†	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).
10.41†	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).
10.42	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).
10.43	Amendment No. 6 to Office Lease Agreement by and between Oculus Innovative Sciences, Inc. and RNM Lakeville, L.P., dated April 26, 2011 (included as Exhibit 10.52 to the Company's Annual Report on Form 10-K filed June 3, 2011, and incorporated herein by reference).
10.44	Loan and Security Agreement between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing VI, Inc., dated June 29, 2011 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 6, 2011, and incorporated herein by reference).
10.45	Supplement to the Loan and Security Agreement between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing VI, Inc., dated June 29, 2011 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 6, 2011, and incorporated herein by reference).
10.46	Amendment No. 1 to the Loan and Security Agreement and Supplement to the Loan and Security Agreement between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing V, Inc., dated June 29, 2011 (included as Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 6, 2011, and incorporated herein by reference).
10.47	Intellectual Property Security Agreement between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing VI, Inc., dated June 29, 2011 (included as Exhibit 10.5 to the Company's Current Report on Form 8-K filed July 6, 2011, and incorporated herein by reference).
10.48	Intellectual Property Security Agreement between Oculus Innovative Sciences, Inc. and Venture Lending & Leasing V, Inc., dated June 29, 2011 (included as Exhibit 10.6 to the Company's Current Report on Form 8-K filed July 6, 2011, and incorporated herein by reference).
10.49†	Distribution Agreement between Oculus Innovative Sciences, Inc. and Shanghai Sunvic Technology Co. Ltd., dated June 26, 2011 (included as Exhibit 10.58 to the Company's Quarterly Report on Form 10-Q filed August 4, 2011 and incorporated herein by reference).
10.50	Oculus Innovative Sciences, Inc. 2011 Stock Incentive Plan (included as Exhibit A in the Company's Definitive Proxy Statement on Schedule 14A filed July 29, 2011, and incorporated herein by reference).
10.51	Securities Purchase Agreement by and between the Company and the Purchasers, dated April 22, 2012 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed April 25, 2012, and incorporated herein by reference).
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 Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Officers pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	XBRL Taxonomy Extension Label Linkbase.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase.

\* Filed herewith.

† 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.



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. 333-177642); 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 20, 2012, with respect to our audits of the consolidated financial statements of Oculus Innovative Sciences, Inc. and Subsidiaries as of March 31, 2012 and 2011 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, 2012.

/s/ Marcum LLP

New York, NY  
June 21, 2012

**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
  - (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 21, 2012

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

**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 21, 2012

By: /s/ Robert E. Miller  
Robert E. Miller  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)



**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, 2012 (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 21, 2012

/s/ Hojabr Alimi

\_\_\_\_\_  
Hojabr Alimi

Chief Executive Officer

(Principal Executive Officer)

/s/ Robert E. Miller

\_\_\_\_\_  
Robert E. Miller

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)